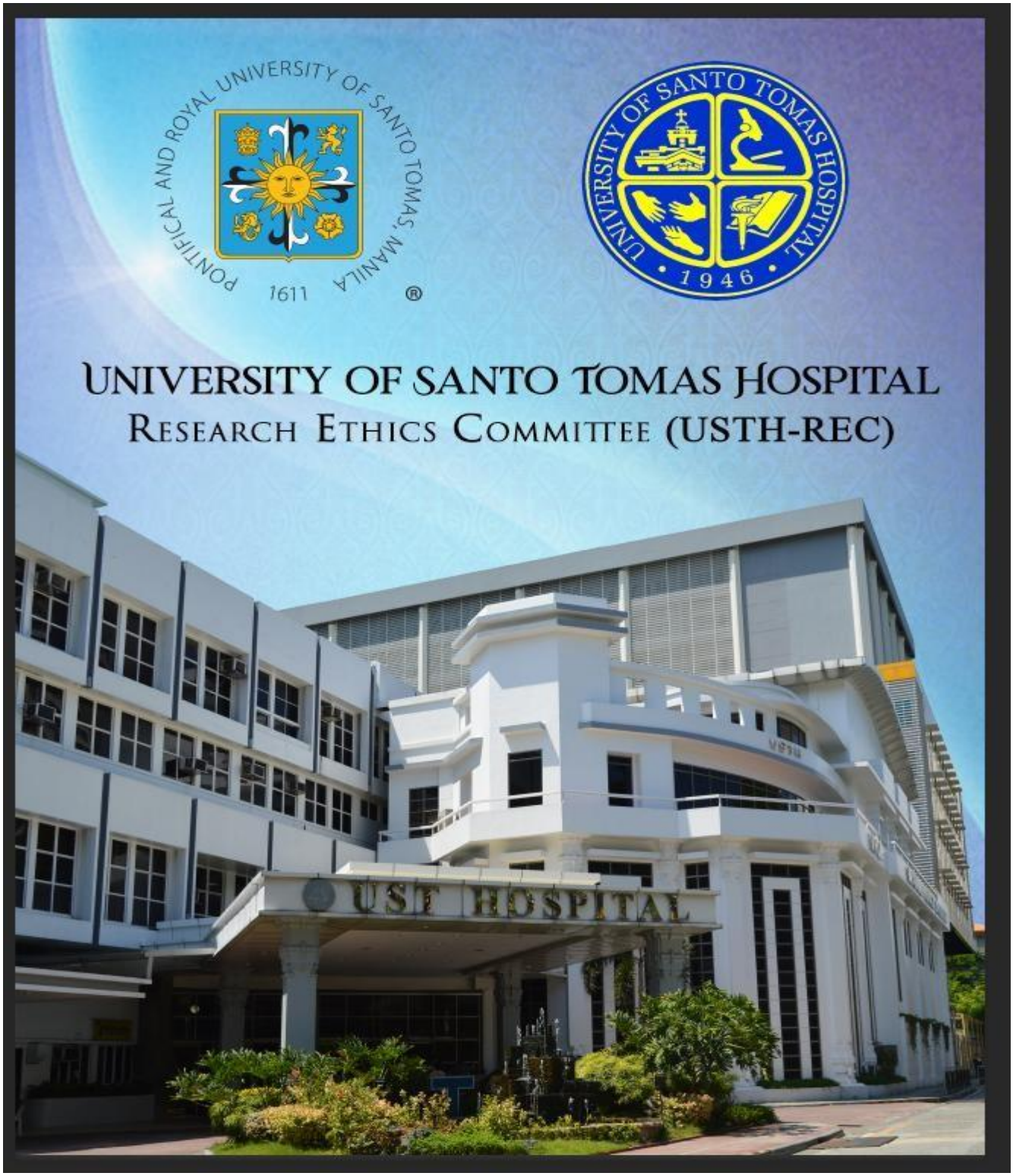


# STANDARD OPERATING PROCEDURES

## Revision 7
## 23 June 2025

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## INTRODUCTION

### PURPOSE OF THE SOP

The **USTH-REC Standard Operating Procedure (SOP) Manual** defines the functional process of the conduct of review of research protocols involving humans and their data at the UST Hospital. This aims to ensure consistency and efficiency in the review of the scientific and ethical soundness of scientific research done within the jurisdiction of the UST Hospital.

The Standard Operating Procedures are aligned with *WHO Operating Guidelines for Ethical Review Committees that Review Biomedical Research (2011), National Guidelines for Ethics Committees* and *ICH (International Conferences on Harmonization) Good Clinical Practice Standards (GCP), Council for International Organizations of Medical Sciences (CIOMS)* and the *National Ethical Guidelines for Research Involving Human Participants, 2022*.

The USTH-REC coordinates closely with other committees and departments in the hospital but is independent in its conduct of review and decision making.

The USTH-REC SOP may not comprehensively contain all procedures relevant to the function of the committee and in such circumstances, a decision from a majority vote may be derived from the members. This may be considered to be included in the revision of the SOP.

The USTH-REC SOP is revisited regularly and may be revised to meet the committee's purpose in ensuring the ethical conduct of research.

### HOSPITAL VISION

The University of Santo Tomas Hospital envisions itself as a premier teaching hospital in Asia, upholding its tradition of excellence in medical education, training, research, and compassionate healthcare services, guided by Catholic principles and teachings.

## HOSPITAL MISSION

The University of Santo Tomas Hospital commits itself to:

- Education, training and clinical research, as well as to the professional growth and development of future health professionals

- Delivery of cost-effective, reliable and holistic healthcare services to all, with preferential option for the poor, by competent, ethical, and compassionate healthcare professionals

- Provision of up-to-date equipment, facilities and infrastructure with patient-friendly systems and processes

- Practice of good planning and management of resources

## USTH CORE VALUES

The University of Santo Tomas Hospital holds in highest esteem the core values of COMPETENCE, COMMITMENT and COMPASSION in the healthcare profession and service, nourished and tempered by truth and justice, understood and taught within the Catholic and Dominican tradition.

## TERMS OF REFERENCE AND INSTITUTIONAL ISSUANCE

The USTH-REC is a committee created to:

1. protect the rights and safety of human participants in research by upholding the principles of international and national guidelines for Health Research Ethics, Good Clinical Practice, statutory and regulatory requirements, institutional policies as well as standards to ensure the integrity of the scientific material and data;

2. review research protocols of the trainees (fellows, residents, interns, clerks), medical consultants, hospital employees, for social value, scientific, technical, and ethical soundness.
3. review clinical trials for social value, scientific, technical, and ethical soundness;
4. review research protocols which involve trainees, consultants, and hospital personnel as research participants; and protocols utilizing the hospital facilities, human data & samples from biobanks, registries, databases of the hospital for social value, scientific, technical, and ethical soundness; and
5. on a case-to-case basis, it may review research proposals from academic and research units within and outside of the University, other hospitals and research units for social value, scientific, technical, and ethical soundness.

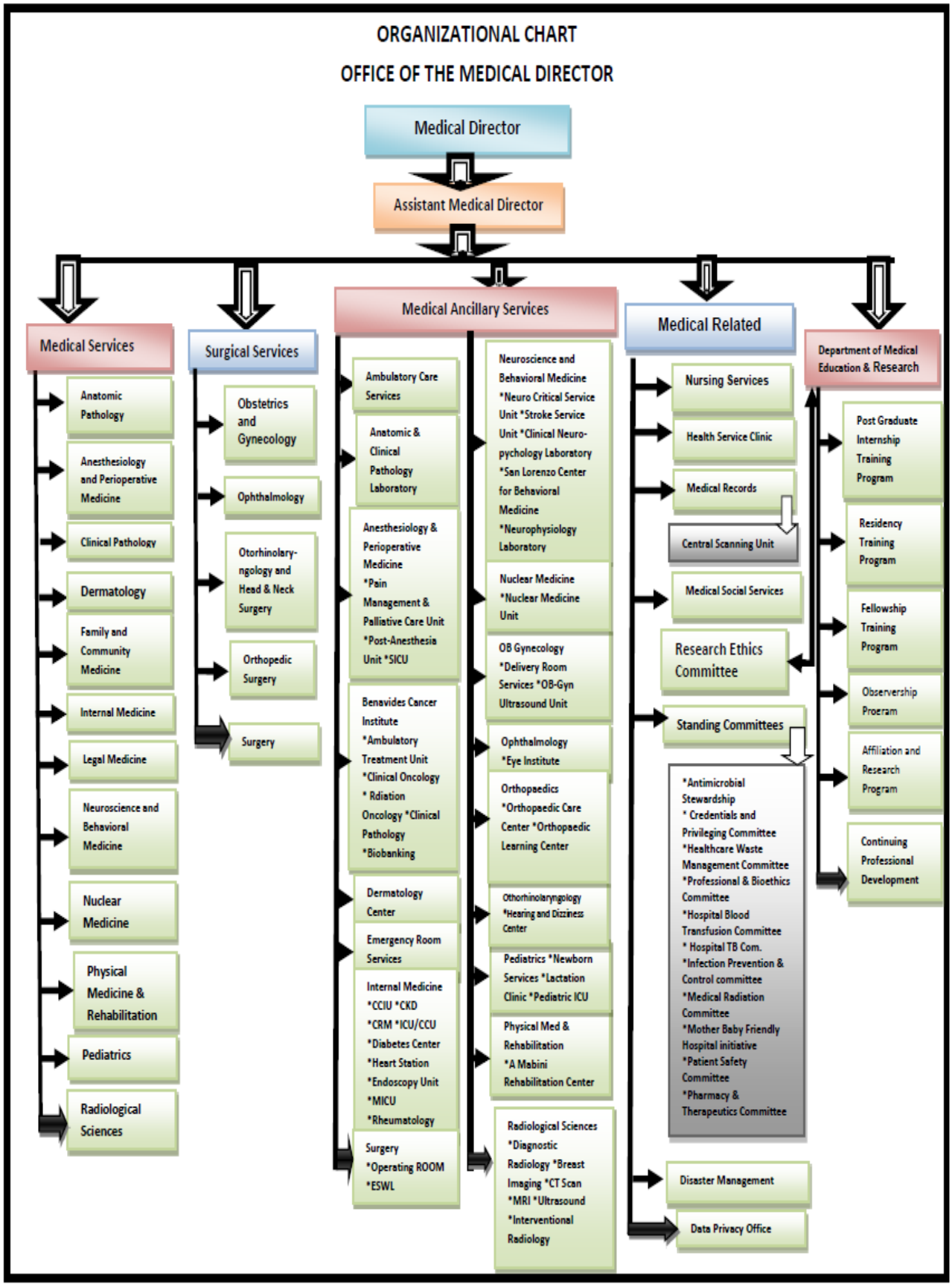
**STRUCTURE:**

The USTH-REC is under the direct supervision of the Office of the Chief Executive Officer (CEO) of the University of Santo Tomas Hospital. The CEO, upon the recommendation of the Medical Director, appoints the USTH-REC officers and members to facilitate the discharge of functions of the USTH-REC along the line of authority indicated in the organizational chart.

The USTH-REC, however, is independent in its reflection, advice, and decision in matters pertaining to ethical review of research proposals.

The USTH-REC coordinates closely with the Department of Medical Education & Research (DMER), Clinical Departments, and all hospital committees but is independent in its conduct of review and decision making.

## ORGANIZATIONAL CHART



**ORGANIZATIONAL CHART**

**MEMBERSHIP COMPOSITION:**

1. The USTH-REC is composed of nine (9) Regular Members inclusive of the Head, Vice-Head, and Member Secretary. Nine (9) Alternate Members and a roster of Independent Consultants also form part of the membership. It also includes an Office Secretary and an Office Clerk.

2. The USTH - REC shall be composed of highly qualified, competent, multidisciplinary, gender and age-balanced, medical/scientific, and non-medical/non-scientific members duly appointed by the Chief Executive Officer (CEO), upon the recommendation of the Medical Director for a specified period.

3. Because of the extensive time commitment and expertise required for REC service, the REC Members shall be entitled to an honorarium for reviewing assigned protocols, participating in committee meetings, and other tasks related to the functions of the REC. The REC Members shall likewise be provided support for REC-related training, seminars, and workshops.

4. The USTH-REC shall ensure that all members have the updated required trainings on Basic Research Ethics (BRET), Good Research Practice (GRP), and basic and advanced Good Clinical Practice (GCP), Standard Operating Procedures (SOPs), research methodologies and other research ethics-related trainings.

5. USTH-REC Members must have good interpersonal relationship skills, excellent work and professional ethics and must uphold the highest standard of research ethics.

## HISTORY OF THE COMMITTEE

The ethics review process in the University of the Santo Tomas Hospital was implemented as early as 1980 as part of the UST Hospital Pharmacy and Therapeutics and the Hospital Research Committee established under the directorship of Dr. Gregorio Moral. In 1998, this committee was split into two: the Pharmacy and Therapeutics Committee and the Institutional Review Board (IRB). At this time, the IRB was affiliated with both the UST Faculty of Medicine & Surgery (UST FMS) and the UST Hospital.

In 2004, the USTH-IRB registered with the Philippine Health Research Ethics Board (PHREB), which is the national policy making body in health research ethics in the country. The PHREB was created under *DOST Special Order No. 091 s. 2006*, to ensure adherence to the universal ethical principles for the protection and promotion of the dignity of health research participants.

On July 4, 2005, Dr. Rolando Cabatu, the UST Hospital Medical Director, issued a memorandum that all research papers involving patients in both Clinical Division (CD) and Private Division (PD) must be approved by the **UST Hospital - Institutional Review Board**.

In March 2006, the UST Hospital separated its functions from the UST FMS making the USTH-IRB an independent unit at the UST Hospital under the leadership of Dr. Ma. Graciela G. Gonzaga. In addition, it also registered with the Office of Human Research Protection (OHRP) of the United States Department of Health and Human Services. The UST Hospital upholds the OHRP's Federal-Wide Assurance (FWA**),** a document which acts as a guide for its human subjects' research protections.

In 2010, Dr. Wilson L. Tan De Guzman was appointed as Head of the USTH-IRB. Under his leadership, FERCAP recognition was granted in November 2015 to 2018 and PHREB granted a three-year Level III accreditation from February 2016 to 2019. Dr. Wilson L. Tan De Guzman served as IRB Head from 2010 until August 2018.

In September 2018, Dr. Josephine Lumitao was appointed as the Head of the IRB. In February 2019, a memorandum from the Medical Director's Office was issued to revise the name of the USTH-IRB to UST Hospital Research Ethics Committee (USTH-REC).

Under Dr. Lumitao's leadership, the REC was granted another 3-year PHREB re-accreditation from September 2019 to 2022 and FERCAP recognition from November 2019 to 2022.

# STANDARD OPERATING PROCEDURES

## 1. Policy Statement

The selection of REC Members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists, medical and non-medical, affiliated, lay and non-affiliated), and should have adequate representation of various age groups (below 40 years old, 40-60 years old, above 60 years old) as well as gender. Members shall be classified as Regular or Alternate Members. Initial appointment of REC Members is for a period of one (1) year and re-appointment may extend to a period of two (2) years. Appointments may be renewed upon the recommendation of the REC Head, endorsement of the USTH Medical Director, and approval of the Chief Executive Officer. The Alternate Members shall serve on a yearly basis and shall attend meetings whenever called to ensure that meetings are conducted with a quorum. A lay person and non-affiliated member whose presence is needed for quorum is necessary for a meeting to proceed.

## 2. Objective of the Activity

Selection and Appointment of REC Members aims to ensure that the composition of the REC complies with the international, national, and institutional guidelines and that appropriate expertise is taken into consideration.

## 3. Scope

This SOP applies specifically to the selection of members of the REC.

It begins with the call for nominations and ends with the filing of appointment documents and CVs of REC members in the Membership File.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY |
|---|---|
| **Step 1:** Calling for a special meeting *(See SOP 18 - Preparing for a Meeting)* for nomination of Regular and Alternate Members | REC Head |
| **Step 2:** Recommending the REC Regular and Alternate Members to the USTH Medical Director for appointment by the USTH CEO | REC Head |
| **Step 3:** Receiving Appointment documents of Regular and Alternate Members | REC Head and REC Staff |
| **Step 4:** Forwarding Appointment documents to the Regular and Alternate members | REC Staff |
| **Step 5:** Accepting and signing the conforme, *Conflict of Interest Disclosure Agreement & Confidentiality Agreement (F02)* | REC Regular and Alternate Members |
| **Step 6:** Filing of duplicate copies of appointment documents and CVs in the Membership File (*See SOP 24 - Management of Active Files*) | REC Staff |

## 5. Description of Procedures

**Step 1 - Calling for a special meeting:** The REC Head calls for a special meeting for the nomination of new members who may be added to the current membership or replace vacant positions.

**Step 2 – Recommending for appointment:** The REC Head recommends the elected officers to the Medical Director who in turn endorses them to the USTH Chief Executive Officer. The CEO appoints the Regular and Alternate Members. The REC Head makes the recommendations based on qualifications, work performance and requirements stated in the international, national, and institutional policies. It shall require accomplishment of a *REC Nomination Form (F32)* and submission of other related, essential documents.
The appointment letters include the roles and responsibilities of the Regular and Alternate Members.

### 2.1. Roles and responsibilities of the REC Regular Member

2.1.1. Is required to review all assigned research protocols (Protocol and informed consent) and ensure adherence to the highest ethical standards of research.

2.1.2. The Layperson is a Regular Member who reviews all assigned Informed consent forms and ensures adherence to the highest ethical standards of research.

2.1.3. Is allowed to vote during the deliberation of protocols and other REC related matters.

2.1.4. Attends REC meetings on a regular basis. If he/she cannot attend the meeting, he/she notifies the Office Secretary in advance to facilitate the preparation and attendance of an appropriate alternate REC member.

2.1.5. During full review, participates actively in the discussion, deliberation, and decision making.

2.1.6. During expedited review, may discuss and deliberate with other Primary Reviewers prior to his decision-making process and promptly submits to the Office Secretary his recommendations.

2.1.7. Accomplishes the forms relevant to the review process completely and in a timely manner.

**2.2. Roles and Responsibilities of the REC Alternate Member**

2.2.1. Serves as a substitute for an absent Regular Member during meetings

2.2.2 Assumes the role of a Regular Member when called upon to perform such role.

2.2.3. Reviews protocols when the scientific expertise is beyond the competence of the Regular Members

2.2.4 Performs other functions as member of committee assigned by the REC Head

**Step 3 – Receiving appointment documents:** The REC Staff receives and informs the REC Head about the appointment documents from the office of the Chief Executive Officer of the USTH.

**Step 4 – Forwarding appointment documents to Regular and Alternate Members:** The REC Staff forwards the appointment documents to the Regular and Alternate Members. The appointment letters include the roles and responsibilities of the Regular and Alternate Members.

**Step 5 - Accepting and signing the conforme, Conflict of Interest Disclosure Agreement & Confidentiality Agreement Receipt of Appointment papers of new members**: The new REC member/s sign the *Confidentiality Agreement &* and *Conflict of Interest Disclosure Agreement (F02).*

**Step 6- Filing of the duplicate copy of appointment documents and CVs and signed Agreements in the Membership File**: The REC Staff files the duplicate copy of the appointment documents, CVs and signed Agreements in the Membership File. (See *SOP 24 - Management of Active Files).*

## 6. Forms

*F01: CV & Training Record Form*
*F02: Confidentiality & COI Disclosure Agreement Form*
*F04: Appointment of Member Letter Template*
*F32: Nomination Form*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary:

*Scientists – are individuals whose formal education is at least a master's degree in a scientific discipline, e.g., biology, physics, social science, etc.*

*Non-Scientists – are individuals whose primary interest may not be in any of the natural, physical, and social sciences or whose highest formal education is a bachelor's degree.*

*Medical Members – are individuals with academic degrees and training in the medical sciences (Physicians, dentists, etc.)*

*Non-medical Members- are individuals without academic degrees in the medical sciences.*

*Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution, nor do they receive regular salary or stipend from the institution.*

*Regular Members – are members constituting the research ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.*

*Alternate Members – individuals who possess the qualifications of specified regular members and provide expertise outside that of the regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting. They may be assigned to review protocols and to be member of committees depending on their expertise. They are allowed to vote during meetings.*

*Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.*

*Confidentiality – is the duty to not freely disclose private/research information entrusted to an individual or organization.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The UST Hospital - Research Ethics Committee shall have a REC Head, Vice Head & Member Secretary who shall be appointed by the USTH Chief Executive Officer upon the recommendation of the Medical Director to facilitate the efficient function of the REC.

## 2. Objective of the Activity

This activity aims to ensure that the REC Officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

## 3. Scope

The scope of this SOP includes the selection of REC Head, Vice Head and Member Secretary.

It starts with the nomination of the concerned officers and ends with the filing of appointment documents of the officers.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY |
|---|---|
| **Step 1:** Calling for a special meeting *(See SOP 18 - Preparing for a Meeting)* for the nomination and election of REC officers | Incumbent REC Head |
| **Step 2:** Nominating and electing REC officers | REC Members |
| **Step 3:** Recommending the REC Officers to the USTH Medical Director for appointment by the USTH CEO | REC Head |
| **Step 4:** Receiving Appointment documents of new officers | REC Staff and REC Head |
| **Step 5:** Forwarding Appointment documents to the new officers | REC Staff |

| | |
|---|---|
| **Step 6:** Accepting and signing the conforme, *Conflict of Interest Disclosure Agreement & Confidentiality Agreement (F02)* | Elected REC Officers |
| **Step 7:** Filing of duplicate copies of appointment documents (See *SOP 24 - on Management of Active Files)* | REC Staff |

## 5. Description of Procedures

**Step 1 - Calling for a special meeting**: See *SOP 18 - Preparing for a Meeting*. The REC Staff upon instruction of the incumbent REC Head sends a Notice of Meeting to all members of the REC.

**Step 2 – Nominating and electing REC Officers:** The incumbent REC Head presides over the nomination process for the next REC Head. In case the incumbent REC Head may be nominated for another term, a REC member may be asked to preside over the process. After which the newly elected REC Head leads the nomination process for the Vice Head and Member Secretary who must also have been members of the REC for at least one (1) year. Election of officers shall be based on the majority rule.

**Step 3 - Recommending the REC Officers to the USTH Medical Director for appointment by the USTH CEO:** The REC Head recommends the elected officers to the Medical Director who in turn endorses them to the USTH Chief Executive Officer. The Chief Executive Officer issues the appointment papers that includes the roles and responsibilities of the specific officers and the corresponding terms of office. To ensure continuity of functions, officers are appointed on a two-year term.

### 3.1 REC Head

The REC Head provides leadership, oversees and directs the whole operations and management of the REC within applicable regulatory requirements and ensuring that all clinical trials and research protocols are in adherence to the highest ethical standards of research. He/she serves as a regular voting member of the REC.

3.1.1. Represents the USTH-REC in the organizational structure of UST Hospital.

3.1.2. Oversees the operations of the REC and supervises the management of the Office.

3.1.3 Recommends policy amendments and changes.

3.1.4. Recommends appointment or reappointment of REC Members to the Medical Director.

3.1.5. Appoints the REC Vice Head or any REC Member to assume his responsibilities during his absence.

3.1.6. Invites and recommends Independent Reviewers to provide special expertise on relevant proposed research protocols.

3.1.7. Classifies research protocols/clinical trial protocols as expedited or full board review and assigns appropriate reviewers. He may designate any regular REC Member to perform this task.

3.1.8. Reviews all assigned research protocols/clinical trials and ensure adherence to the highest ethical standards of research. He is authorized to vote during the decision-making process.

3.1.9. Calls and presides over meetings with the members, assigns specific duties and responsibilities and serves as a voting member.

3.1.10. Acts on suggestions, complaints, and queries from stakeholders.

3.1.11. Represents UST Hospital in national and international ethics seminars.

3.1.12. Submits annual report to Medical Director, Philippine Health Research Ethics Board (PHREB) and UST Institutional Research Ethics Board (IREB).

3.1.13. Prepares the annual budget proposal.

### 3.2 REC Vice Head

The REC Vice Head assists the REC Head in managing the operations of REC within the applicable regulatory requirements and the highest ethical standards of research. He/she provides leadership in the absence of the REC Head. He or she serves as a regular voting member of the REC.

3.2.1. Assumes the responsibility of the REC Head in his absence.

3.2.2. Heads the REC Standard Operating Procedure (SOP) Team which prepares, reviews, revises and amends guidelines and forms.

3.2.3. As designated by the REC Head, classifies research protocols/clinical trial protocols as expedited or full board review and assigns appropriate Primary Reviewers.

3.2.4 Reviews all assigned research protocols/clinical trials and ensure adherence to the highest ethical standards of research. S/he is authorized to vote during the decision-making process.

3.2.5 Perform other functions as assigned by the REC Head.

### 3.3 REC Member Secretary

The REC Member Secretary coordinates all the activities among the members and the research stakeholders. He assumes the leadership in the absence of the REC Head and REC Vice Head. He serves as a regular voting member of the REC.

3.3.1. Assumes the responsibilities of the REC Head and REC Vice Head in their absence.

3.3.2. As designated by the REC Head, classifies research protocols/clinical trials as expedited or full board review and assigns appropriate primary reviewers.

3.3.3. Reviews all assigned research protocols/clinical trials and ensure adherence to the highest ethical standards of research. He is authorized to vote during the decision-making process.

3.3.4. Takes part in the review and revision of the Manual as a member of the SOP Sub-Committee Team. Maintains and updates the REC Manual of Standard Operating Procedures.

3.3.5. Supervises the Office Secretary in documentation of protocols and office management.

3.3.6. Perform other functions as assigned by the REC Head.

**Step 4: Receiving Appointment documents of officers:** The REC Staff receives and informs the REC Head about the appointment papers of the elected officers that contain the roles and responsibilities of the specific officers and the corresponding terms of office.

**Step 5 - Forwarding Appointment documents to the new officers:** The REC Staff forwards the appointment documents to the REC Officers.

**Step 6 - Accepting and signing the conforme, Conflict of Interest Disclosure Agreement & Confidentiality Agreement (F02).** The concerned officers sign the conforme documents.

**Step 7 - Filing of appointment documents**: The REC Staff files the duplicate copy of the appointment papers accordingly (see S*OP 24 - Management of Active Files*).

## 6. Forms

*F28: Notice of Meeting*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
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| 7 | 2025 June 23 | Dr. JM Lumitao; Dr. ALL Enriquez; Dr. SIO Cortez; Ms. CC Morota; Ms. LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.*

*Majority rule - is a policy based on the principle that the decision made by the greater number should be carried/accepted.*

*Term of office – the specified length of time that a person serves in a particular designation /role.*

*Appointing authority - the institutional official that has the power to designate or appoint individuals to specific offices or roles.*

*Conforme - acceptance of or agreement to an assignment or designation.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC Officer/s shall invite an Independent Consultant whose expertise is not represented in the current membership but is needed in a study under review for scientific or technical opinions. The Independent Consultant is not considered as a primary reviewer, and he/she need not be affiliated with the institution. He/she shall not possess any conflict of interest on the protocol to be reviewed.

## 2. Objective of the Activity

This activity aims to ensure that the appointment of Independent Consultants conforms to institutional procedures and complements the pool of expertise in the REC.

## 3. Scope

This SOP specifically pertains to the selection and designation of Independent Consultants in the review of research protocols of the REC.

It begins with the identification of the Independent Consultant for a study that requires a scientific or technical assessment within his area of expertise and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY |
|---|---|
| **Step 1:** Identifying the Independent Consultant for a study that requires a scientific or technical assessment | REC Head / Vice Head or Member Secretary, |
| **Step 2:** Inviting and appointing the Independent Consultant | REC Head |

| | |
|---|---|
| **Step 3:** Accepting the appointment and signing the Appointment document, conflict of interest, disclosure and confidentiality agreement | Independent Consultant |
| **Step 4:** Receiving of the signed appointment, conflict of interest disclosure and confidentiality agreement | REC Staff and<br>REC Head |
| **Step 5:** Including the Independent Consultant in the pool of Independent Consultants | REC Staff |

## 5. Description of Procedures

**Step 1 - Identifying the Independent Consultant for a study that requires a scientific or technical assessment**: Either the REC Head, the Vice Head or the Member-Secretary, identifies the independent consultant for a study that requires a scientific or technical assessment within his area of expertise which may not be provided by the current members of the REC.

**Step 2: Inviting and appointing the Independent Consultant.** The REC Head instructs the REC Staff to prepare and send a letter of invitation (*Invitation/Appointment of Independent Consultant - F05*) containing the Terms of Reference to the identified expert. The letter of invitation contains a section for acceptance of the invitation.

**Step 3: Accepting the appointment and signing the Appointment document, conflict of interest disclosure, and confidentiality agreement.** The Independent Consultant agrees and signs the *Invitation/Appointment of Independent Consultant (F05), and Confidentiality Agreement & Disclosure of Conflict of Interest (F02).*

**Step 4: Receiving of the signed appointment, conflict of interest disclosure and confidentiality agreement.** The REC Staff receives and informs the REC Head about the signed *Invitation/Appointment of Independent Consultant* document *(F05), and Confidentiality Agreement & Disclosure of Conflict of Interest (F02).*

**Step 5: Including the Independent Consultant in the pool of Independent Consultants.** The REC Staff files the documents and includes the Independent Consultant in the Pool of Independent Consultants including the date of appointment, expertise, and institutional affiliation.

## 6. Forms

*F02: Confidentiality Agreement & Disclosure of Conflict of Interest Form*
*F05: Appointment of Independent Consultants*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
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| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Independent consultants - Resource persons who are not members of the Research Ethics Committee, whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

*Expertise - a proficiency, skill or know-how possessed by experts in a certain academic or professional field.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Protocols that neither involve human participants nor identifiable human tissue, biological samples and data may be considered by the REC for exemption from review. Protocols that involve institutional quality assurance, public health surveillance, educational evaluation activities, consumer acceptability tests and protocols that use publicly available information are also exempt from review. The results of the initial review shall be released to the Principal Investigator within seven to ten (7-10) working days after the submission of all the required documents.

The study protocol that was exempted from review shall be reported in the subsequent regular committee meeting and included in the Annual Report to PHREB. Additionally, all protocols exempt from review shall undergo internal audit of turn-around time to be reported in January of the next year.

The following may also be considered exempt from review provided they do not involve more than minimal risks or harm:

- Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities and consumer acceptability tests
- Protocols that involve the use of publicly available data and information
- Research that includes interactions by survey procedures, interview procedures or observations of public behavior provided: that there will be no disclosure of human participants' responses outside the research that could place them at risk for civil, criminal liability and damaging to their financial standing, employability and reputation; and that identity of participants cannot be ascertained through information and identifiers linked to participant.

## 2. Objective of the Activity

Exemption from Review aims to demonstrate due diligence and training to facilitate approval for exemption of protocols that neither involve human participants nor identifiable human tissue, biological samples and data and do not involve more than minimal risks or harms.

## 3. Scope

This SOP applies to study protocols submitted to the REC that qualifies for Exemption from Review which does not entail more than minimal risk to study participants and neither involve human participants nor identifiable human tissue, biological samples and data.

It begins with the determination of the proposal's exemption from review and ends with the inclusion of the review in the agenda of the next meeting.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Determining the exempt status of the proposal | REC Head and Vice Head or REC Head and Member Secretary or the Vice Head and Member Secretary | 4 days |
| **Step 2:** Consolidating and finalizing the review result for exemption or re-classifying for expedited review if needed. (See SOP 5 Expedited Review) | REC Head | 2 days |
| **Step 3:** Communicating review results to the researcher with instructions to submit Amendment and Final Report (See *SOP 22 - Communicating REC Decisions)* | REC Head and REC Staff | 1 day |
| **Step 4:** Filing of documents in the Protocol File (See *SOP 24 - Management of Active Files)*<br>Appending of the Exempt from Review protocol in the agenda of the next meeting (See *SOP 19 - Preparing the Meeting Agen*da) | REC Staff | |
| **Step 5:** Append the Protocols Exempt from Review in the Agenda of the next REC regular meeting | REC Staff | 1 working day |
| **Step 6:** Filing of documents in the Protocol File and update of Protocol Database | REC Staff | 1 working day |

## 5. Description of Procedures

**Step 1 – Determining of the exempt status of the proposal**: The REC Head and Vice Head or the REC Head and Member Secretary or the Vice Head and Member Secretary determine whether the protocol neither involves human participants nor identifiable human tissue, biological samples and data and fulfills the criteria for protocols exempt from review cited from NEGRIHP 2022. The REC Head and or the designated REC Member evaluates the study protocol using the *Exemption Review Application Form (F24)*.

**Step 2 – Consolidating and finalizing the exemption status of the protocol**:
The REC Head consolidates and finalizes the decision regarding the exempt status of the protocol based on the assessment of Head and Vice Head or Vice Head and Member Secretary or the Head and Member Secretary. The REC Head evaluates the recommendation and makes the final decision to uphold the exempt status of the protocol or to re-classify the protocol for Expedited review. If the protocol is for expedited review, the REC Head assigns the reviewers and the REC Staff will send the protocol to the assigned reviewers. (*See SOP on Expedited Review).*

**Step 3 – Communicating review results to the researcher**: The REC Head reviews and signs the *Exemption Certificate Form (F25)* for issuance by the Office Secretary to the Principal Investigator. The *Exemption Certificate Form (F25)* issued to the PI reminds him/her to **ensure continuous compliance** with the exemption criteria stated in the *NEGRIHP 2022;* If there are changes to the approved protocol, PI is required to submit an application for protocol amendment which is subject to ethics review and may affect the status of the study or will invalidate the exemption. Additionally, submission of Final Report is required not later than eight (8) weeks after the end of the study. The Office Secretary sends by e-mail the certification letter to the Principal Investigator. *(See SOP 22 - Communicating REC Decisions)*

**Step 4 - Filing of documents in the Protocol File**: The Office Secretary records the recommendations in the Protocol Submission Logbook and Database. (See *SOP 24 - Management of Active Files)*

**Appending the protocol Exempted from review in the agenda of the next REC regular meeting**: The REC Staff append the protocol and recommendations in the Meeting Agenda of the next regular meeting. (See *SOP 19 - Preparing the Meeting Agend*a)

**Step 5 - Append the protocols Exempt from Review in the Agenda of the next REC regular meeting:** The REC Staff appends the protocol and recommendations in the Meeting Agenda of the next regular meeting. (See *SOP 19 - Preparing the Meeting Agend*a)

**Step 6 - Filing of documents in the Protocol File:** The Office Secretary records the recommendations in the Protocol Submission Logbook and Database. (See *SOP 24 – Management of Active Files)*

## 6. Forms

*F25 Certificate of Exemption from Review Template*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.*

*Exempt from Review - a decision made by the REC Head and another officer of the committee regarding a submitted study proposal based on criteria in the NEGRIHP 2022 The Research Ethics Review Process Guideline 46-50. This means that the protocol will not undergo an expedited nor a full review.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Reviewer- a regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to the principal investigator within three to four (3-4) weeks after the submission of all the required documents. The study protocol that underwent expedited review shall be reported in the subsequent regular committee meeting.

The study protocol that underwent expedited review shall be reported in the regular committee meeting and included in the Annual Report to PHREB. Additionally, all protocols that underwent expedited review shall undergo internal audit of turn-around time to be reported in January of the next year.

## 2. Objective of the Activity

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants.

## 3. Scope

This SOP applies to initial review of protocols and post-approval submissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise.

It begins with the assignment of reviewers or Independent Consultant/s and ends with the inclusion of the review in the agenda of the next meeting.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Assigning of Primary Reviewers or Independent Consultant/s (See *SOP 03 - Appointment of Independent Consultants)* | REC Head/<br>Vice Head/<br>Member Secretary | 1 working day |
| **Step 2:** Notifying Primary Reviewers or Independent Consultant/s and Provision of study documents and *Protocol & Consent Assessment Form (F08)* | REC Staff | 2-3 working days |
| **Step 3:** Accomplishing and submitting the *Protocol & Consent Assessment Form (F08)* | REC Primary Reviewers | 10-14 working days |
| **Step 4:** Consolidating review results Recommending to elevate to full board review by the Primary Reviewer to the REC Head for approval *See SOP 6* | REC Primary Reviewers<br>REC Head | 4-6 working days |
| **Step 5:** Communicating review results to the researcher (See *SOP 22 - Communicating REC Decisions)* | REC Head and<br>REC Staff | 2-3<br>working days |
| **Step 6:**<br>Appending the Review in the Agenda of the next meeting (See *SOP 19 - Preparing the Meeting Agen*da) | REC Staff | 1 working day |
| **Step 7:** Filing of documents in the Protocol File (See *SOP 24 - Management of Active Files)* and updating the Protocol Database | REC Staff | 1 working day |

## 5. Description of Procedures

**Step 1 - Assigning Reviewers or Independent Consultant/s**: The REC Head/ Vice Head/ Member Secretary assigns one (1) Primary Reviewer for protocols not requiring informed consent. The Primary Reviewer may be a Regular member, Alternate member or an Independent Consultant. A non-medical and/or non-scientific member is added as a second reviewer for protocols requiring an informed consent. Primary Reviewers are selected on the basis of their expertise.

The medical and scientific reviewers are tasked to review scientific soundness, technical soundness, related ethical issues and the informed consent process and forms while the non-medical and/or non-scientific reviewer is tasked to review the informed consent process and Form. If the protocol requires a reviewer outside the expertise of current REC members, an Independent Consultant will be appointed by the REC Head. (See *SOP 03 - Appointment of Independent Consultants)*

**Step 2 – Notifying Primary Reviewers or Independent Consultant/s and Provision of Protocol and Protocol-related documents:** The REC Staff distributes protocols for expedited review to the Primary Reviewers by e-mail, together with the relevant documents pertinent to the required review (for initial submissions: the complete submission package; for post-approval submissions: the pertinent information from the retrieved protocol and the report itself).

**Step 3 - Accomplishing and Submitting Assessment Forms:** Primary Reviewers and Independent Consultant evaluate and make recommendations, accomplish the *Protocol & Consent Assessment Form (F08)* completely and comprehensively, and submits to the Office Clerk all documents. Recommendations may be:

- Approved
- Disapproved
- Major modifications
- Minor modifications
- Recommended for Full Review

**Step 4 - Consolidating and finalizing the review results:** A Primary Reviewer collates, consolidates and finalizes the decision regarding the protocol and informed consent based on the comments and recommendations of the reviewers. If there is a considerable difference in opinion between the review points of the reviewers, the reviewers are required to discuss and come up with a common decision. If no common decision is reached, the protocol is elevated for a Full Board Review and the REC Staff will include it in the agenda of the next regular meeting. The REC Staff prepares the action letter.

**Step 5 – Communicating review results to the researcher:** The REC Head reviews and signs the Action Letter/ Approval Letter for issuance by the Office Secretary to the Principal Investigator. The Office Secretary sends by email the action letter to the Principal Investigator. If necessary, she informs and schedules the Principal Investigator for a clarificatory interview as needed. (See *SOP 22 - Communicating REC Decisions)*

**Step 6 - Append the Expedited Review in the Agenda of the next REC regular meeting:** The REC Staff appends the protocol and recommendations in the Meeting Agenda of the next regular meeting. (See *SOP 19 - Preparing the Meeting Agend*a)

**Step 7 - Filing of documents in the Protocol File: The Office Secretary records the recommendations in the Protocol Submission Logbook and update the Protocol Database**. (See *SOP 24 – Management of Active Files)*

## 6. Forms

*F08: Protocol & Consent Assessment Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.*

*Exempt from Review - a decision made by two REC officers regarding a submitted study proposal based on criteria in the NEGRIHP 2022 The Research Ethics Review Process Guideline 46-50. This means that the protocol will not undergo an expedited nor a full review.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Full Review- is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage of.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Independent Consultant - Resource persons who are not members of the Research Ethics Committee, whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

*Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.*

*Minor Modification - is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g., incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*Clarificatory Interview/meeting – is a meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

A Full Review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Studies that involve collection of stigmatizing information, do not use anonymized data, continuing review of Clinical trials, previous studies reviewed under full board and protocols reviewed under expedited process but elevated for full board review will also require Full Review.

Protocols for Full Review will be scheduled on a first-come first-served basis in the agenda of the full board meeting. Full Review shall be conducted through a primary reviewer system. If necessary, Independent Consultants and/or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within six to seven (6-7) weeks after submission of required documents.

The study protocol that underwent full board review shall be included in the Annual Report to PHREB. Additionally, all protocols that underwent full board review shall undergo internal audit of turn-around time to be reported in January of the next year.

## 2. Objective of the Activity

A Full Review aims to ensure compliance with technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.

## 3. Scope

This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups.

It begins with the assignment of Primary Reviewers or Independent Consultant/s and ends with the filing of protocol-related documents.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Assignment of Primary Reviewers or Independent Consultant/s (See *SOP 03 - Appointment of Independent Consultants)* | REC Head/ Vice Head/ Member Secretary | 1-2 working days |
| **Step 2:** Notification of Primary Reviewers for availability to do the review and distribution of protocol, protocol-related documents and *Protocol & Consent Assessment Form (F08) (See SOP 18 Preparing for a Meeting)*<br>Notification of PI for clarificatory interview if recommended by the Primary Reviewer | REC Staff | 1-2 working days |
| **Step 3:** Review, accomplishment and submission of *Protocol & Consent Assessment Form (F08)* to the Office Secretary | REC Primary Reviewers | 10-14 days |
| **Step 4:** Scheduling of protocol for discussion in Full review meeting | REC Office Secretary | 14-21 days |
| **Step 5:** Presentation of review findings and recommendations during a committee meeting (See *SOP 20 - Conduct of Meetings)* | REC Primary Reviewers | 1 day |
| **Step 6:** Discussion of technical and ethical issues | REC Members | |
| **Step 7:** Summary of issues and resolutions | REC Head | |
| **Step 8:** Committee action | REC Members and Head | |
| **Step 9:** Documentation of Committee deliberation and action (See *SOP 21 - Preparing the Meeting Minutes)* | REC Staff | |
| **Step 9:** Communication of Committee Action to the researcher (See *SOP 22 - Communicating REC Decisions*) | REC Head and REC Staff | 3-5 working days |
| **Step 11:** Filing of protocol-related documents in the Protocol File and updating the Protocol Database | REC Staff | 1 working day |

## 5. Description of Procedures

**Step 1 - Assigning Primary Reviewers or Independent Consultant/s:** The REC Head/ Vice Head/Member Secretary assigns at least three members (1-2 medical or 1 scientific and 1 non-scientific member) who have the necessary expertise as Primary Reviewers and designates an Independent Consultant in case such technical expertise is not present among the members. The non-scientific member will review the Informed Consent Process and Form.

**Step 2 - Notifying Primary Reviewers and Distributing Protocol, protocol-related documents and *assessment forms:*** The REC Staff notifies the assigned Primary Reviewers and/or Independent Consultants about their assignment by e-mail with a request that they confirm their acceptance and availability. The protocol, protocol-related documents and *Protocol & Consent Assessment Form (F08)* are sent by e-mail to Primary Reviewers. The PI for clarificatory interview is also notified by e-mail.

**Step 3 - Reviewing, accomplishing and submitting the *Protocol & Consent Assessment Form (F08)* to the Office Secretary:** The Primary Reviewers assess, accomplish and submit their *Protocol & Consent Assessment Form (F08)* to the Office Secretary.

**Step 4 - Scheduling of protocol for discussion in Full review meeting:** The Office Secretary schedules the protocol on a first-come first-served basis in the agenda of the review meeting. The Office Secretary also sends protocol-related materials and protocol summary to other members before the meeting.

**Step 5 - Presenting the review findings and recommendations during a committee meeting:** The Primary Reviewers present their findings and recommendations (*Protocol & Consent Assessment Form (F08)*) during the actual meeting. If a Primary Reviewer cannot attend the meeting, he/she submits comments/review points to the REC Head who takes the role of the Primary Reviewer so that the meeting can proceed.

**Step 6 - Discussing the technical and ethical issues:** If a PI is for Clarificatory interview, the Primary reviewers and REC members ask questions to clarify certain issues, after which the PI is asked to leave the meeting before the discussion. The REC Head and the Primary Reviewers facilitate the discussion of the technical and ethical issues using the *Protocol & Consent Assessment Form (F08)* and the assessment of the Primary Reviewers as guides for an orderly exchange of ideas.

**Step 7 - Summary of issues and resolutions:** The REC Head summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved

**Step 8 - Deciding the committee action**: The REC decides by voting and the majority decision is adopted. In case of a tie, the REC Members will discuss the relevant issues that justify their recommendations after which the Members will vote again. The decision may be:

- Approved
- Minor Modifications
- Major Modifications
- Clarificatory Interview
- Disapproved

**Step 9 - Documenting the committee deliberation and action:** All the committee deliberations are recorded by the Office Secretary in the Minutes of the meeting in real time. (See S*OP 21 - Preparing the Meeting Minutes*)

**Step 10 - Communicating the committee action to the researcher:** The REC Head reviews and signs the action letters/approval letters for issuance by the Office Secretary to the Principal Investigator. (See *SOP 22 - Communicating REC Decisions)*

**Step 11 - Filing of protocol-related documents and updating the Protocol Database:** The Office Secretary records the recommendations in the *Protocol Database* and annexes the protocol and recommendations in the *Meeting Agenda*. (See *SOP 24 – Management of Active Files*)

## 6. Forms

*F08: Protocol & Consent Assessment Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |

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|---|---|---|---|
| 5 | 2023<br>June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024<br>January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025<br>June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Full Board Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Independent Consultant - Resource persons who are not members of the Research Ethics Committee, whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of*

*vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.*

*Minor Modification – is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*Resubmissions - revised study proposals that are submitted after the initial review.*

*Protocol-related Documents - consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,*

*Clarificatory Interview/meeting – is a meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC. The PI will be asked to leave the meeting during the discussion and decision process by the REC*

*Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall require the submission of a set of pertinent documents through the UST Hospital REC website **(usthrec.online)** for an application for ethical review to be accepted. A hard copy of the complete study protocol package will likewise be submitted for the Protocol File. Protocols will be evaluated and classified as either exempt from review, expedited review, or full review based on The Research Ethics Review Process guidelines of the National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022.

## 2. Objective of the Activity

Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

## 3. Scope

The USTH-REC reviews clinical trial and research protocols conducted by members of the hospital staff, residents, fellows and other trainees, and employees of the University of Santo Tomas Hospital (USTH). It also reviews research protocols conducted by non-USTH Principal Investigators (PIs) who plan to conduct their research involving hospital patients, hospital employees, staff and trainees as subjects; the use of specimen, hospital facilities, records, databases; and, the use of the hospital as a research site. Under special circumstances, the REC may accept other research protocols outside of the aforementioned jurisdiction.

Initial submission processes for the Single Joint Research Ethics Board (SJREB) are found in the *SOP 30 – Review of SJREB Protocols* and for the initial submission for special circumstances are found in SOP 29.

It begins with the receipt of study documents for initial review via online submission through the USTH REC website (**usthrec.online**) and ends with entry of protocol information in the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving study documents for initial review and determination of completeness of submission | REC Secretariat | 1-2 working days |
| **Step 2:** Coding and assigning a protocol code to complete study protocol package | REC Secretariat | |
| **Step 3:** Accomplishing the Submission *Protocol Tracking Form (F27)* and entering the protocol into the Protocol Submission Logbook | REC Secretariat | |
| **Step 4:** Forwarding submissions to REC Officers | REC Secretariat | |
| **Step 5:** Determining the type of Review and assigning Primary Reviewers<br>a. Exempt from Review *(SOP 04 Exempt from Review)*<br>b. Expedited Review *(SOP 05 Expedited Review)*<br>a. Full Review *(SOP 06 Full Review)* | REC Head, REC Vice Head or REC Member Secretary | 1-2 working days |
| **Step 6:** Filing of Protocol File/Folder in the Protocol Database | REC Staff | 1 working day |

## 5. Description of Procedures

**Step 1 – Receiving study documents for initial review and determining completeness of submission**: The REC Secretariat will accept and process online protocol submissions, through the USTH REC website (**usthrec.online**) from 9:00AM to 3:00PM every Wednesday and Friday except for government- and hospital-sanctioned, non-working holiday. The REC Secretariat will check the correctness and completeness of the submitted study protocol package for initial review which must be received together with duly signed and accomplished forms, including *F07- Application Form for Ethics Review of a New Protocol; F08- Protocol & Consent Assessment Form; F24- Exemption Review Application Form,* if applicable; and, other pertinent protocol documents, as enumerated in the F06: Requirements Checklist Form (basic documents and study-specific documents). Incorrect and/or incomplete documents will not be accepted. However, the REC Secretariat will notify the submitting investigator and request to submit the correct and complete documents. The investigators must also submit one (1) set of the complete study protocol package in print at the USTH-REC Office for filing purposes.

**Step 2 - Coding and assigning a protocol code to complete study protocol package**:
The REC Secretariat will assign a Protocol Reference Number to complete study protocol package. The Protocol Reference Number is assigned as follows:

**< REC-YYYY-MM-NNN-LL-short name >**

| | | |
|---|---|---|
| **YYYY** | Represents the year submitted (i.e., 2022) | |
| **MM** | Represents the month submitted (i.e., 01 - January; 02 – February) | |
| **NNN** | Represents sequential number as issued by Office Clerk (e.g., 001) | |
| **LL** | Represents the letters based on the following: | |
| | **TI** | Trainee Intern |
| | **TR** | Trainee Resident |
| | **TF** | Trainee Fellow |
| | **MD** | Medical Consultant |
| | **CT** | Clinical Trial |
| | **IS** | Internal Students (students from UST) |
| | **ES** | External Students (Non-UST students) |
| | **OO** | Others |
| | **Short name** | represents short title of the protocol |

This Protocol Reference Number is the ID number of the protocol and cannot be assigned to other protocols. When referring to the protocol in communications or presentations, the Protocol Reference Number is lengthened to include a short title of the protocol to be more informative (e.g., 2022-01-12-TR COVID).

**Step 3 – Accomplishing the *Protocol Tracking Form* and entering the protocol in the Protocol Database and Logbook**: The REC Secretariat will accomplish the *Protocol Tracking Form (F27)* for complete and coded study protocol packages. The REC Secretariat will also enter the protocol into the Protocol Submission Logbook and Database upon receipt of the printed complete study protocol package.

**Step 4 – Forwarding submissions to REC Officers**: The REC Secretariat shall forward the online submissions to the REC Officers through e-mail for the determination of the type of Review or Action.

**Step 5 – Determining the type of Action and/or Type of Review and assigning Primary Reviewers:** The REC Head/Vice Head/Member Secretary conducts a preliminary review of the protocol to determine the type of Review.

If the REC Head/Vice Head/Member Secretary decides that the protocol is exempt from review, the policies and procedures for an Exempt for Review, as indicated in *SOP 04 Exempt for Review*, will be observed.

If the REC Head/Vice Head/Member Secretary determines that the protocol should undergo either Expedited or Full Review, the policies and procedures for an Expedited Review, as indicated in *SOP 05 Expedited Review,* or for a Full Review, as stipulated in *SOP 06 Full Review*, will be observed. The REC Head/Vice Head/Member Secretary will also assign the Primary Reviewers for the protocol.

**Step 6 – Preparing and filing the Protocol File/Folder:** The REC Staff files the printed study protocol documents in a Protocol File/Folder and labels it accordingly, including the assigned Protocol Reference Number. The REC Staff shall file the Protocol File Folder in the Active File and enter the protocol details in the Protocol Database. *(See SOP 24 - Managing Active Files).*

## 6. Forms:

*F27: Protocol Tracking Form*
*F06: Requirements Checklist Form*
*F07: Application Form for Ethics Review of a New Protocol*
*F08: Protocol & Consent Assessment Form*
*F24: Exemption Review Assessment Form*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |

| | | | |
|---|---|---|---|
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Full Review – The ethical evaluation of a research protocol and other protocol-related documents, a resubmission, and post-approval submissions, conducted by the Research Ethics Committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Initial Submission – A set of documents consisting of the full protocol and other study-related documents needed to be submitted so that review can be conducted.*

*Study Documents – This includes all documents (study protocol; research instruments or tools; informed consent forms; accomplished REC forms; certificates; etc.) which are pertinent to a research protocol and that must be submitted to the REC for review.*

*Initial Review – The ethical and technical review conducted on initially-submitted study documents. It may be expedited or full.*

*Amendment – A change in or revision of the protocol made after its approval.*

*Coding – A unique number assigned to a protocol indicating the year and series it was received.*

*Protocol Logbook – A real-time, chronological record of incoming protocols that includes the Title of the Protocol, Name of Proponent, Date and Time of Receipt, Title of Submitted Document(s), Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person, and Action done. It is usually in a physical form used for tracking the entry of submitted protocols.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

*Exempt from Review – A decision made by two REC Officers regarding a submitted study protocol based on the criteria in the NEGRIHP 2022 in The Research Ethics Review Process Guideline (pp. 46 to 50). This decision means that the protocol will not undergo an expedited nor a full review.*

*Expedited Review – A of a research protocol and other protocol-related documents, a resubmission, and post-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Full Review –The ethical evaluation of a research protocol and other protocol-related documents, a resubmission, and post-approval submissions, conducted by the Research Ethics Committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*REC Secretariat – This will be composed of the REC Member Secretary, select REC Members, and REC Staff.*

*Tracking Form - a document used to record important details and monitor the progress of a research protocol. It includes information such as protocol title, investigator name, type of study, version dates, review dates, approval dates, and document submissions. It helps the IRB/REC keep track of all actions and communications related to a protocol.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall require a resubmission of a revised protocol which required either minor or major modification/s not later than 6 weeks, equivalent to thirty (30) working, after receipt of the Decision Letter. Resubmitted protocols will maintain their original classification (expedited or full review) unless otherwise reclassified by the REC.

## 2. Objective of the Activity

Management of resubmission ensures that the researcher addressed the required modifications before approval of the protocol.

## 3. Scope

This SOP pertains to the resubmission of revised or modified protocols, via the USTH-REC website (**usthrec.online**), which have undergone initial review process by the REC. The procedure begins with the receipt of the revised protocol documents and ends with filing of the documents in the Protocol File and the updating the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and assessing completeness of resubmission ensuring the correctness of revised protocol version number and date. | REC Secretariat | 1 working day |
| **Step 2:** Coding of resubmitted protocol documents | REC Secretariat | |

| | | |
|---|---|---|
| **Step 3:** Logging resubmission in the Protocol Submission Logbook, Database, and *Protocol Tracking Form (F27)* | REC Secretariat | |
| **Step 4:** Notify and distribute revised documents to original Primary Reviewers | REC Secretariat | |
| **Step 5:** Review of the Resubmission<br>a. Expedited Review (SOP 04 Expedited Review)<br>b. Full Review (SOP 05 Full Review) | REC Primary Reviewers | 5-7 working days (Expedited)<br>14-21 working days (Full Review) |
| **Step 6:** Collate assessment points and comments of Primary Reviewers | REC Secretariat | 3 working days |
| **Step 7:** Communicate Decision | REC Head & Secretariat | 1 working day |
| **Step 8:** File the documents in the Protocol File/Folder and update the Protocol Database and *Protocol Tracking Form (F27)* | REC Secretariat | 1 working day |

## 5. Description of Procedures

**Step 1 - Receiving and assessing completeness of resubmission:** The REC Secretariat shall receive the study documents through the USTH-REC Website, assesses completeness of the resubmission documents, and ensures that the submission is properly logged. The resubmitted documents must include a cover letter, an accomplished *Resubmission Form (F11)*, the revised protocol/ICFs with correct version number and date, and other pertinent documents of the protocol. The investigators must also submit one (1) set of the resubmitted documents in print at the USTH-REC Office for filing purposes.

**Step 2 - Coding of resubmitted protocol documents**: The REC Secretariat stamps or indicates the code assigned to the protocol and the date of receipt on all the documents.

**Step 3 - Logging resubmission in the Protocol Submission Logbook, Database, and Tracking Form:** The REC Secretariat shall enter the information of the resubmitted protocol, such as date of resubmission, in the Protocol Submission Logbook and Database. The REC Secretariat shall check from the Protocol Database the names of the original Primary Reviewers who initially reviewed the protocol. In addition, the REC Secretariat shall record the pertinent information of the resubmitted protocol in *Protocol Tracking Form (F27).*

**Step 4 - Notifying and distributing revised documents to original Primary Reviewers:** The REC Secretariat retrieves the Decision Letter that pertains to the original protocol and

shall inform the originally assigned Primary Reviewers through e-mail. The REC Secretariat shall also distribute via e-mail the resubmitted protocol and other pertinent forms and documents to the originally assigned Primary Reviewers.

**Step 5 - Reviewing the Resubmission:** The resubmitted protocols will be reviewed either via Expedited or Full Review which will depend on the REC decision during the initial review. If the resubmitted protocol is for Expedited Review, the policies and procedures indicated in *SOP 05: Expedited Review* will be adhered to. However, if the resubmitted protocol is for Full Review, *SOP 06: Full Review* will be observed.

The assigned Primary Reviewers will evaluate the resubmitted protocol by referring to the accomplished *Resubmission Form (F11)* which should contain the REC recommendations vis-à-vis the actions and responses of the investigators. The Primary Reviewers will evaluate whether the actions and responses of the investigators satisfactorily addressed the REC recommendations in the resubmitted protocol. The Primary Reviewers will submit the accomplished *Resubmission Form (F11)* to the REC Staff and will be included in the next regular meeting.

To ensure efficient and timely review, the Reviewers may recommend a Clarificatory Interview of the PI during the full board meeting to discuss the issues that were not complied with to expedite the review process.

**Step 6 – Collating assessment points and comments of Primary Reviewers:** The REC Secretariat will collect all accomplished *Resubmission Form (F11)* from the Primary Reviewers and collate their assessment points, recommendations, and recommended action. For resubmitted protocols which have undergone Expedited Review, the Decision Letter will then be prepared. If the resubmitted protocol underwent Full Review, the REC Secretariat will collate the assessments and recommendations and include the protocol in the agenda of the next regular meeting. Decisions for protocols which underwent full bord review and require Minor Modifications shall be re-classified for expedited review if resubmissions are needed.

**Step 7 – Communicating Decision:** The draft Decision Letter shall be sent to the REC Head for review, correction, and finalization. The REC Head will take note of the protocols with more than two (2) resubmissions and take action to expedite the approval of the protocols. Once finalized and signed, the REC Secretariat will communicate the REC Decision to the investigator. For resubmissions which underwent Full Review, refer to *SOP 22: Communicating Committee Decisions*.

**Step 8 – Filing the documents in the Protocol File/Folder and Updating the Protocol Database and *Protocol Tracking Form*:** The REC Secretariat gathers all the pertinent documents related to the resubmission (e.g., accomplished *Resubmission Form (F11)*, revised protocol, excerpts of minutes, approval letter, etc.) and files these documents in the appropriate Protocol File Folder. The Protocol Database and *Protocol Tracking Form (F27)* of the protocol will also be updated for pertinent details of the resubmission (e.g., date of review, etc.).

## 6. Forms

*F11: Resubmission Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula, LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Initial Submission – refers to the first (initial) package of study documents forwarded to the REC for review.*

*Resubmission – the revised study proposal that is re-forwarded to the REC following the recommendations from the initial review.*

*Study Documents – include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for a comprehensive review.*

*Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC so that review can be conducted*

*Coding- a unique number assigned to a protocol indicating the year and series it was received.*

*Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall require the submission of progress reports at a frequency based on the level of risk of the study as determined by the REC during a full board meeting. This requirement shall be explicitly stated in the Approval Letter.

## 2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

## 3. Scope

This SOP applies to the management and review of progress reports submitted by the proponent while the study is on-going or is applying for continuing review.

It begins with the receipt and entry to *Protocol Submission Logbook* of incoming documents and the Protocol Database and ends with filing of progress report and committee decision in the Protocol File and Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and entering the Progress Report into Protocol Submission Logbook (See *SOP 24 - Management of Active Files) and in Protocol Database* | REC Staff | 1 day |
| **Step 2:** Retrieving of pertinent Protocol File | REC Staff | 1-2 days |

| | | |
|---|---|---|
| Notifying the REC Head and determining the type of review based on the initial classification: expedited *(See SOP 05 - Expedited Review)* or full review *(See SOP 06 - Full Review). Notification of initial Primary Reviewers and sending protocol-related documents* | REC Head and REC Secretariat | |
| **Step 3:** Reviewing, assessing and deciding on the progress report | Primary Reviewers | 7-10 days |
| **Step 4:** Consolidating of review points for expedited review | Primary Reviewer for expedited review | 2-3 days |
| Presenting, discussing and deciding in the full review meeting | Primary Reviewers & REC Members for full Review | 10-14 days |
| **Step 5:** Communicating of committee action *(See SOP 22 on Communicating REC Decisions)* | REC Head | 1-2 days |
| **Step 6:** Filing of Progress Report and decision letter in the Protocol File and update of the Protocol Database. *(See SOP 24 - Management of Active Files)* | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving and entering the Progress Report into Protocol Submission Logbook:** The REC Staff receives the progress report written in the *REC Progress Report Form (F19)* and enters the date and pertinent information in the *Protocol Submission Logbook (L1)* of incoming documents (*See SOP 24 – Management of Active Files) and in the Protocol Database.*

**Step 2 - Retrieving of pertinent Protocol File:** The REC Staff retrieves the corresponding Protocol File for reference and guidance of the REC Head and Primary Reviewers.

**Notifying the REC Head and determining the type of review based on the initial classification:** Determination of type of Review: The REC Staff notifies and sends the pertinent Protocol File to the REC Head and the previously assigned Primary Reviewers. The REC Head decides the type of review based on the initial review of the protocol concerned and proceeds accordingly. For Expedited review, see *SOP 05*: and for Full Review, see *SOP 06.*

**Step 3 - Reviewing, assessing and deciding on the progress report:** The previously assigned Primary Reviewers review, assess and decide on the submitted progress report.

**Step 4 - Consolidating review points: Presentation, discussion and decision in the full board meeting:** The assigned Primary Reviewer consolidates the review points. The Primary Reviewers present, discuss and decide together with the other REC members in a full board meeting the decision regarding the progress report.

**Step 5 - Communicating of committee action:** The REC communicates the committee action, see *SOP 22 on Communicating REC Decisions)*. For progress reports, the committee action may be:

- Approved
- Request additional information
- Require further action

The REC Staff prepares a draft of the committee decision based on the minutes of a full board meeting. The REC Head signs the decision letter and the REC Staff sends it to the Principal Investigator by email.

**Step 6 - Filing of Progress Report and decision letter in the Protocol File and updating the Protocol Database:** The REC Staff files the progress report and a copy of the committee decision in the appropriate Protocol File. He/she proceeds to update the pertinent Protocol Database.

## 6. Forms

*F19: Progress Report Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*
*L1: Protocol Submission Logbook*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |

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|---|---|---|---|
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

**8. Glossary**:

*Progress Report - description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form (F19). The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Full Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Protocol Submission Logbook - a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.

## 2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol so that any change does not impact safety and welfare of study participants.

## 3. Scope

This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is ongoing.

It begins with the receipt and entry of the submission of amendment to *Protocol Submission Logbook (L1)* and the *Protocol Database* and ends with filing of the amendments and committee decision in the Protocol File and Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and entering into the Protocol *Submission Logbook* the submission of amendments *(See SOP 24 - Management of Active Files*). | REC Staff | 1 day |
| **Step 2:** Retrieving of pertinent Protocol File | REC Staff | 1 day |

| | | |
|---|---|---|
| **Step 3:** Determining the type of review: expedited *(See SOP 04 - Expedited Review)* or full review *(See SOP 05 on Full Review) and* | REC Head and Primary Reviewer | 1-2 days |
| **Step 4:** Notifying the Primary Reviewer/s | REC Staff | |
| **Step 5:** Consolidating of review points for expedited review<br><br>Presenting, discussing and deciding in the full board meeting for full review | Primary Reviewers | 2-3 days<br><br>10-14 days |
| **Step 6:** Communicating the committee action (S*OP 22 - Communicating REC Decisions)* | Primary Reviewer for expedited review<br><br>Primary Reviewers for full review | 2-3 days |
| **Step 7:** Filing of Amendments and decision letter and updating the Protocol Database. *(SOP 24 - Management of Active Files)* | REC Head and REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 – Receiving and entering to Protocol Submission Logbook**: The REC Staff receives *Application for Review of Protocol Amendments (REC F14)* and enters the date and pertinent information in the *Protocol Submission Logbook (L1)* of incoming documents *(See SOP 24: Management of Active Files).*

**Step 2 - Retrieving pertinent protocol file**: The REC Staff retrieves the corresponding protocol file for reference and guidance of the Head and Reviewers.

**Step 3 - Determining type of review: expedited or full review**: The REC Head decides the type of review based on the type of amendment and proceeds accordingly. For Expedited review, see *SOP 05*: and for Full review, see *SOP 06.*

A Full Review will be done for major amendments that involve any of the following:

- Change in study design
- Change in methodology
- Additional treatments or the deletion of treatments
- Any changes in inclusion/exclusion criteria
- Change in dosage formulation, route of administration (e.g., oral changed to intravenous)
- Significant change in the number of subjects
- Significant decrease or increase in dosage amounts

- As determined by the REC Head/Vice Head/Member Secretary depending on the specificities of the protocol

An expedited review will be done for minor amendments which:

- Do not involve changes in study populations
- Do not involve the collection of stigmatizing information
- Do not change approved use of anonymized or archived samples
- Do not involve further recruitment of participants
- Are administrative in nature (such as contact details of study
- personnel)
- Do not materially affect the risk-benefit ratio of the approved protocol or the increase risks to study participants

**Step 4 - Notifying Primary Reviewer/s**: After receipt of the Application for Review of Amendments, the REC Staff notifies and sends the pertinent protocol file to the Head and previously assigned REC Primary Reviewer/s.

**Step 5: Consolidating review points for expedited review. Presenting, discussing and deciding in the full board meeting for full review**: For expedited review, the assigned Primary Reviewer consolidates the review points. If the concerns involve major amendments as stated above, the primary reviewers will recommend that the amendment will be presented in a full board meeting.

For full board review: the Primary Reviewers present, discuss and decide together with the other REC members in a full board meeting for the Amendment report.

**Step 6 - Communicating committee decision**: The REC communicates the committee action, see *SOP 22 Communicating REC Decisions*. REC Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The REC Head signs the decision letter as follows: Approval, request for additional justification/information or specific action/s e.g., reconsent required or disapproved.

For amendments, the committee action may be any of the following:

- Approved
- Additional information required
- Additional action (e.g. Re-consent required)
- Disapproved.

**Step 7 – Filing of Amendment documents and committee decision and updating the Protocol Database:** The REC Staff files the Amendment and a copy of the committee decision in the appropriate Protocol File. S/he proceeds to update the pertinent Protocol Database.

## 6. Forms

*F14: Protocol Amendment Form*

*F12: Action Letter Template*

*F13: Approval Letter Template*

*L1: Protocol Submission Logbook*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Amendment – Any change or revision in the protocol made after its approval.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted*

*by only 2-3 members of the committee without involvement of the whole committee.*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Protocol Submission Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

## 9. References:


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants NEGHRIP 2022*

## 1. Policy Statement

Researchers shall report protocol deviations and violations in the conduct of approved researches within seven (7) days from the detection of the protocol violation/deviation. Protocol violations undergo full review while protocol deviations undergo expedited review.

## 2. Objective of the Activity

Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

## 3. Scope

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the Protocol Submission Logbook and ends with the filing of all related documents and update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and documenting reports of protocol violations and deviations in the Protocol Logbook. | REC Staff | 1 day |
| **Step 2:** Retrieving of pertinent protocol file | REC Staff | 1 day |

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| **Step 3:** Determining type of review based on initial classification and degree of risk to participants and integrity of data. Expedited review *(SOP 05 - Expedited Review)*, full review (*SOP 06 - Full Review*) | REC Head/<br>Vice Head/<br>Member Secretary | 1 day |
| **Step 4:** Notifying of initial Primary Reviewers and sending protocol and protocol-related documents | REC Secretariat | 1-2 days |
| **Step 5:** Including the Protocol violation/ protocol deviation in the agenda of the next REC regular meeting *(SOP 19 - Preparing the Meeting Agenda); SOP 20 - Conduct of Meetings)* | REC Head and<br>REC Staff | 7-10 days |
| **Step 6:** Communicating of decision to the Principal Investigator/researcher (*SOP 22 - Communicating REC Decisions*) | REC Secretariat and REC Head | 1 day |
| **Step 7:** Filing of all related documents and updating the Protocol Database *(Management of Active Files)* | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving and documenting of report of protocol violations and deviations in the Protocol Submission Logbook and Database:** The REC Staff receives the report on protocol deviation or violation in the appropriate *REC Protocol Violation/ Deviation Report Form (F16)* and records this in the *Protocol Submission Logbook.*

**Step 2 - Retrieving pertinent protocol file.** The REC Staff retrieves the approved protocol and checks the identity of the Primary Reviewers for reference and guidance of the REC Head in the selection/ designation of reviewers.

**Step 3 - Determining type of review - expedited or full review:** The REC Head/Vice Head/ Member Secretary determines the type of review such that protocol violations undergo full review. Protocol deviation undergoes expedited review. *See SOP 05: Expedited Review and SOP 06: Full Review.*

**Step 4 - Notifying Primary Reviewers.** The REC Staff notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the primary reviewers of original protocol

**Step 5 - Including the report in the agenda of the next REC regular meeting.** The REC Head includes the report on protocol violation in the agenda of the next meeting.

**Deciding on the Protocol Deviation/Violation:** For expedited review, the Primary Reviewer decides on the protocol deviation depending on its impact on participants safety and credibility of data. For full board review, the REC committee members make the decision.

**Step 6 – Communicating the Decision to the Principal Investigator/researcher:** The REC Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following:

- Require additional information
- Require corrective and preventive action
- Invitation to a clarificatory interview
- Requirement for an amendment
- Site visit
- Suspension of recruitment
- Withdrawal of ethical clearance

**Step 7 - Filing of all related documents and updating the Protocol Database.** The REC Staff collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the Protocol Database with the relevant information.

## 6. Forms

*F16: Protocol Deviation/Violation Report Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |

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|---|---|---|---|
| 5 | 2023<br>June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024<br>January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025<br>June 23 | Dr. JM Lumitao, Dr. ALL Enriquez; Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Protocol Deviation – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.*

*Major Protocol Violation - non-compliance with the approved protocol that increases risk to health and well-being or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.*

*Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.*

*Researcher - is the individual primarily responsible for the conceptualization, planning and implementation of a study.*

*Sponsored Clinical Trials – are clinical studies on investigational drugs.*

*Clinical Monitor - an individual who oversees the progress of a clinical trial.*

*Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period.*

*Regular Meeting – a periodically scheduled assembly of the REC.*

*Drug or device – health product used for diagnosis or treatment.*

*Protocol File – is an organized physical or electronic compilation of all documents related to a Protocol*

*Full Review - the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Expedited Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Site Visit – is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes.*

*Clarificatory Interview/meeting – is a meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Reportable Negative Events (RNE) are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and/or the study team and the integrity of data. These events need to be reported to the REC as essential to the continuing concern for a favorable balance of risks and benefits from the study.

The REC shall require the submission of RNE reports, at the latest five (5) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved or it may be included in a regular meeting.

## 2. Objective of the Activity

Review of RNE reports aims to ensure that the safety and welfare of human participants, research team and the integrity of data are safeguarded and that information on RNEs are properly documented and evaluated.

## 3. Scope

This SOP applies to the review of RNE reports.

It begins with the receipt and documentation of submission of RNE report in the Protocol Submission Logbook and ends with the filing of all related documents and update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and documenting the submission of RNE report in the Protocol Submission Logbook. Retrieving protocol file and notifying the REC Head | REC Staff | 1-2 days |
| **Step 2:** Calling for a Meeting | REC Head | 3-5 days |
| **Step 3:** Deliberating on the RNE | REC Members | 1 day |
| **Step 4:** Communicating of REC action to the researcher *(SOP 22 - Communicating REC Decisions*) and to the Institutional authority | REC Head | 1 day |
| **Step 5:** Filing of all related documents (*SOP 24 - Management of Active Files*) and updating the Protocol Database | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving and documenting submission of the RNE report in the Protocol Submission Logbook and Database. Retrieving the Protocol file and Notifying the REC Head**: The REC Staff receives the accomplished *RNE Report Form (F23)* and enters the submission into the *Protocol Submission Logbook (L1).* The REC Staff notes whether the submission is within the required timeline. The REC Staff notifies and sends the report and the retrieved documents to the REC Head who may decide to call for a special meeting or include it in an upcoming meeting. The REC Staff retrieves the approved Protocol File, checks the identity of the Primary Reviewers and sends the protocol documents to them.

**Step 2 - Calling for a Meeting:** The REC Staff prepares for a special meeting or includes the RNE report in a regular meeting. *(See SOP 18 – Preparing for a Meeting).* The Researcher and other members of the Study Team may be invited for a clarificatory meeting.

**Step 3 – Deliberating on the RNE:** The REC Head leads the discussion of the meeting, summarizes the RNE report and informs the REC Members regarding the presence of the Research Team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The Research Team is excused and the REC Members deliberate on possible options, as follows:

- Suspension of the study until risk is resolved.
- Withdrawal of ethical clearance
- Submission of a plan to mitigate risk/harm

- Require an amendment to the protocol
- Uphold original ethical clearance

**Step 4 – Communicating REC recommendation to the researcher**: The REC Staff prepares the draft decision based on the minutes of the meeting in the full review. The REC Head checks and signs the decision letter which is e-mailed to the Researcher/Principal Investigator. (*See SOP 22 - Communicating REC Decisions)*

**Step 5 - Filing of all related documents and updating the Protocol Database**: The REC Staff collates and files the retrieved protocol documents, the report on Reportable Negative Events and the decision letter in the appropriate Protocol File and updates the Protocol Database with the relevant information. (*See SOP 24 - Management of Active Files).*

## 6. Forms

*F23: RNE Report Form*
*F28 Notice of Meeting*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |

| | | | |
|---|---|---|---|
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.*

*Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,*

*Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action*

*Clarificatory Meeting/ Interview – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGHRIP) 2022*

## 1. Policy Statement

Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) are important issues in sponsored clinical trials. Reporting SAEs and SUSARs is the responsibility of the sponsor who collects such reports from all its study sites. Monitoring procedures by the Principal Investigator are required especially on the protection of the safety of study participants. This requirement shall be explicitly stated in the Approval Letter.

For on-site SAEs and SUSARs, the REC shall require the submission of reports within seven (7) days after the event has come to the attention of the researcher. The evaluation of the SAEs and SUSARs shall be conducted by the Subcommittee on SAEs and SUSARs whose recommendation shall be submitted to the REC for final action during the Full Review.

For off-site SAEs and SUSARs, the *SAE Subcommittee* is notified and reports the findings in a full board meeting. Trends in SAEs in local or foreign sites shall be submitted to the REC on a periodic basis (every 6 months).

The *SAE Subcommittee* Team is composed of one (1) Team Head and at least two (2) members including the original Primary Reviewer. A Clinical Pharmacologist is necessary when the study is a Clinical Trial or involves a drug-related SAE or SUSARs. The SAE Sub-committee Team is appointed by the REC Head for a period of one (1) year for the following purposes:

1.1. Receives and assesses submitted serious adverse events package, SUSARs related to ongoing studies

1.2. Recommends actions regarding participant safety and risk mitigation and monitors the same.

1.3. For full board review, presents SAE reports to the committee and secure full board recommendations.

1.4. For expedited reviews, evaluates and recommends actions. These are annexed to the Meeting Agenda.

## 2. Objective of the Activity

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

## 3. Scope

This SOP applies to the review of reports of SAEs and SUSARS in clinical trials and various studies

It begins with the receipt and documentation of submission of reports of SAEs and SUSARs in the Protocol Submission Logbook and ends with the filing of all related documents and update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and documenting the submission of reports of SAEs and SUSARs in the Protocol Submission Logbook. Retrieving of pertinent Protocol File. Notifying of REC Head | REC Staff | 1 day |
| **Step 2:** Submitting of report to the *SAE Subcommittee* | REC Staff | 1 day |
| **Step 3:** The *SAE Subcommittee* reviews the SAE report | SAE Subcommittee Team | 2-3 days |
| **Step 4:** Including of report of *SAE Subcommittee* in the agenda of the next regular REC meeting | REC Staff and REC Head | 10-14 days |
| **Step 5:** Communicating of REC action to the Principal Investigator/researcher *(SOP 22 - Communicating REC Decisions)* | REC Staff and REC Head | 2-3 days |
| **Step 6:** Filing of all related documents (*SOP 24 – Management of Active Files*) and updating the Protocol Database | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving and documenting the submission of reports of SAEs and SUSARs in the Protocol Submission Logbook and Database. Retrieving of pertinent Protocol File. Notifying of REC Head:**

The REC Staff receives the accomplished *SAE/SUSARs Report Forms (F15)* and enters the submission into the Protocol Submission Logbook. The REC Staff notes whether the submission is within the required timeline. The REC Staff retrieves the identity of the Primary Reviewers and a tabulation of earlier SAE/SUSAR reports. The REC Staff notifies and sends the report and the retrieved documents to the REC Head by email.

**Step 2 - Submitting of report to SAE Subcommittee:** The REC Head forwards the report and pertinent documents to the primary reviewers and to the SAE/SUSAR Subcommittee for action and decision.

**Step 3 The SAE Subcommittee Team reviews the SAE report:** The SAE Subcommittee Team calls a separate meeting to discuss the causal relationship between the SAE/SUSAR to the investigational product. This should be done within three (3) days from receipt of the SAE and SUSAR report.

**Step 4 - Including of report of SAE Subcommittee Team in meeting agenda:** The suggested action/decision of the SAE/SUSAR Subcommittee is included in the agenda of the next meeting *(see SOP 19 - Preparing the Meeting Agenda)* for ratification or discussion and final decision. Possible actions include:

- Notation with no further action required
- Require further information
- Require further action
- Site visit
- Suspension of recruitment

**Step 5- Communicating of REC recommendation to the Principal Investigator/researcher**: *See SOP 22 - Communicating REC Decisions*.

**Step 6 - Filing of all related documents and updating the Protocol Database**: *See SOP 24 - Management of Active Files.*

## 6. Forms

*F15: SAE/SUSAR Report Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*SAE (Serious Adverse Events) - is an event observed during the implementation of a study where the outcome is any of the following*

- Death
- Life threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/ birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events *whether or not it is related to the study intervention.*

*A Serious Adverse Event (SAE) - is one that leads to a serious harm to the participants such as life-threatening incidents leading to prolonged hospitalization, significant disability, incapacity, a congenital anomaly or even death. The event is associated with the intervention or circumstances in the study protocol.*

*A SUSAR (Suspected Unexpected Serious Adverse Reaction) is any serious adverse event which may or may not be dose or parameter related but are not expected or anticipated since the reaction is not consistent with the current information about the intervention in question. It may also be a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.*

*An Unexpected Adverse Event (UAE) is any non-serious adverse reaction in a research participant who was provided with an intervention which may or may not be dose or parameter related but are not expected or anticipated since the reaction is not consistent with the current information about the intervention in question.*

*SAE Subcommittee - a group of individuals with the necessary expertise, assigned by the REC to review SAEs and SUSARs and provide the pertinent recommendation for action of the REC.*

*Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.*

*Sponsor - an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.*

*Researcher-Initiated Studies - are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.*

*Sponsored-Clinical Trials - are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall require the submission of an Application for Continuing Review not later than thirty (30) days before the expiration of the ethical clearance of the protocol. Protocols that underwent Full Review in its initial submission shall undergo Full Review in its Application for Continuing Review. Similarly, protocols that underwent Expedited Review shall undergo Expedited Review in its Application.

## 2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

## 3. Scope

This SOP applies to the management of an Application for Continuing Review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. It begins with the receipt of an Application for Continuing Review and ends with entry to REC Protocol Submission Logbook and Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Reminding the Primary Investigator to apply for Continuing Review not later than 30 days prior to expiration of ethical clearance | REC Staff | Not later than 30 days before expiration of ethical clearance |

| | | |
|---|---|---|
| **Step 2:** Receiving and entry of the Application for Continuing Review to Protocol Submission Logbook *(SOP 24- Management of Active Files)* | REC Staff | 1 day |
| **Step 3:** Retrieval of pertinent Protocol Files | REC Staff | 2-3 days |
| **Step 4:** Determining the type of review: Expedited *(SOP 05- Expedited review) or Full review (SOP 06- Full review)* | REC Head/Vice Head/Secretary | 1 day |
| **Step 5:** Notifying the initial Primary Reviewers and sending protocol and protocol-related documents | REC Secretariat | 1-2 days |
| **Step 6:** Reviewing, assessing and deciding of Primary Reviewers. | Primary Reviewers | 7-10 days |
| **Step 7:** Consolidating of review points for expedited review<br><br>Presenting, discussing and deciding in the full board meeting for full review | Primary Reviewer for expedited review<br><br>Primary Reviewers & REC Members for full Review | 2-3 days<br><br>10-14 days |
| **Step 8:** Communicating the decision to the Principal Investigator/researcher (*SOP 22 - Communicating REC Decisions*) | REC Secretariat & REC Head | 1 day |
| **Step 9:** Filing of all related documents and updating the Protocol Database *(SOP 24- Management of Active Files)* | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Reminding the Primary Investigator to apply for Continuing Review:** The Approval Letter contains a reminder to apply for a Continuing Review not later than 30 days prior to its expiration. The REC Staff reminds Primary Investigator whose research protocol ethical clearance is about to expire in 45 days to apply for Continuing Review not later than thirty (30) days prior to expiration of his/her research protocol ethical clearance.

**Step 2 - Receiving and entering of the Application for Continuing Review to Protocol Submission Logbook:** The REC Staff receives, logs and enter in the Protocol Database the information included in the *Application for Continuing Review (F19).*

**Step 3 - Retrieving the pertinent Protocol Files**: The REC Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

**Step 4 - Determining the type of review: Expedited or Full Review:** The REC Head/Vice Head/Secretary determines the type of review in accordance with the policy that protocols which underwent Full review in its initial submission shall undergo Full review in the Application for Continuing Review while protocols which underwent Expedited review shall undergo Expedited review in the *Application for Continuing Review (SOP 05 - Expedited Review and SOP 06- Full Review).*

**Step 5 - Notifying the REC Head and Primary Reviewers:** The REC Staff notifies the REC Head and Primary Reviewers relevant matters about the research protocol for continuing review like the date of submission, summary of reports submitted and decisions made during the period of effectivity of the initial ethical clearance.

**Step 6 - Reviewing, assessing and deciding on the Progress Report and Continuing Review:** The previously assigned Primary Reviewers review, assess and decide on the submitted Continuing Review Application.

**Step 7** – **Consolidating review points for expedited review and full review.**

**Presentation, discussion and decision in the full board meeting for full review:** For expedited review, the assigned Primary Reviewer consolidates the review points. For full review, the Primary Reviewers present, discuss and decide together with the other REC members in a full review meeting on the Application for Continuing Review.

**Step 8 - Communicating committee action:** The REC Staff prepares the draft of the decision/s based on the report/s of the primary reviewer/s of the research protocols under Expedited review or the decisions made for research protocols under Full Review as stated in the minutes of the meeting. The REC Head finalizes and signs the Action/Decision Letter (F31). Decisions include the following:

- Approval
- Additional information required
- Submission of an explanation for failure to submit required reports
- Disapproval

**Step 9 - Filing of Documents in the appropriate Protocol File and updating the Protocol Database:** The REC Staff files the Application for Continuing Review (F19), the recommendation of the Primary Reviewer, the decision made during Full Board review, as well as the signed action/ decision letter in the corresponding Protocol File and Protocol Database.

## 6. Forms

*F19: Continuing Review Application Form*
*L1: Protocol Submission Logbook*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Continuing Review - is the decision of the REC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.*

*Progress Report - A description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form (F19). The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.*

*Amendment - a change in/revision of the protocol made after it has been approved.*

*Protocol Deviation - non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.*

*Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.*

*SAE- Serious Adverse Event - is an event where the outcome observed in a study is any of the following, whether or not it is related to the study intervention:*

- *Death*
- *Life-threatening*
- *Hospitalization (initial or prolonged)*
- *Disability or permanent damage*
- *Congenital anomaly/birth defect*
- *Required intervention to prevent permanent impairment or damage (devices)*
- *Other serious (important medical) events*

*A Serious Adverse Event (SAE) is one that leads to a serious harm to the participants such as life-threatening incidents leading to prolonged hospitalization, significant disability, incapacity, a congenital anomaly or even death. The event is associated with the intervention or circumstances in the study protocol.*

*A SUSAR (Suspected Unexpected Serious Adverse Reaction) is any serious adverse event which may or may not be dose or parameter related but are not expected or anticipated since the reaction is not consistent with the current information about the intervention in question. It may also be a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.*

*An Unexpected Adverse Event (UAE) is any non-serious adverse reaction in a research participant who was provided with an intervention which may or may not be dose or parameter related but are not expected or anticipated since the reaction is not consistent with the current information about the intervention in question.*

*Reportable Negative Event (RNE) - an occurrence in the study site that indicates risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Expedited Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Full Board Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval conducted by the*

*research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Logbook - a real-time chronological record of incoming protocols that includes Date/Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entry, Name and Signature of the Receiving Person and Action done.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Submission and review of final reports signal the completion of the study and its acceptance by the research ethics committee. The Final Report Form is useful in checking the consistency of study implementation with the approved protocol and the knowledge gained from the endeavor

The REC shall require the submission of the final report not later than eight (8) weeks after the end of the study. Final reports shall undergo either expedited or full review based on the original classification and shall follow the same process of review.

## 2. Objective of the Activity

This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

## 3. Scope

This SOP applies to the management and review of final reports submitted by proponents at the end of the study.

It begins with the receipt and entry of the final report into the Protocol Submission Logbook and ends with an update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving of final report and entry into Protocol Submission Logbook *(SOP 24 - Management of Active Files)* Retrieving of pertinent Protocol File. Notifying of Primary Reviewer/s | REC Staff | 1 day |
| **Step 2:** Reviewing the Final Report Expedited Review (SOP 05) or *Full Review (SOP 06)* | REC Head,<br>Primary Reviewer,<br>REC Members | 2-5 days<br><br>10-14 days |
| **Step 3:** Communicating of committee action *(SOP 22 - Communication REC Decisions)* | REC Head,<br>REC Staff | 2-3 days |
| **Step 4:** Filing of the Final Report and related documents and updating the Protocol Files. | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 – Receiving and entering the final report into the Protocol Submission Logbook. Retrieving of pertinent Protocol File. Notifying of REC Head and Primary Reviewer/s:** The REC Staff receives and enters the date of receipt of the final report into the *Protocol Submission Logbook (L1).* The REC Staff retrieves the corresponding Protocol File as reference in the review of the Final Report. The REC Staff notifies the REC Head and the Primary Reviewers of the receipt of the Final Report and awaits further instructions.

**Step 2 – Reviewing the Final Report Expedited review or Full review**: Final reports include the status of the research participants and the results of the study. If the protocol underwent an expedited review, the Primary Reviewers assess the Final Report on the consistency of study implementation with the approved protocol and the knowledge gained from the endeavor.

If the protocol underwent full review, the REC Head instructs the Staff to include the report in the agenda of the next meeting and to ensure that the Primary Reviewer is given the necessary documents so that s/he can prepare the presentation during the next meeting (See *SOP 06 - Full Review*).

**Step 3 - Communicating committee action** (*SOP 22 - Communicating REC Decisions*): The REC Staff prepares the Action/Decision Letter based on the recommendation of the Primary Reviewer or from the minutes of meeting. The REC Head signs the Action/Decision Letter which may have any of the following decisions:

- Approval
- Request information
- Recommend further action

**Step 4 - Filing of the Final Report and related documents and updating the Protocol Database:** The REC Staff files the Final Report and related documents in the appropriate Protocol File/Folder and updates the Protocol Database. If the Final report is approved, the Protocol File will now be placed in the Archive.

## 6. Forms

*F18: Final Report Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Final Report - is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The REC requires the accomplishment of the Final Report Form not later than 8 weeks after the completion of the study.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Risks - summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.*

*Benefits - summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value.*

*Status of participants - summary of what happened to or the condition of participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol.*

*Full Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Expedited Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".*

*Logbook - a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Early termination may be a decision of the researcher/investigator or the sponsor for reasons that make the continuation of the research untenable, e.g., poor recruitment, high number of SUSARs, or lack of funding. On some occasions, the REC may recommend early termination of the study when, based on its assessment, the participants and/or the study team may be at high risk of harm that cannot be mitigated.

When a decision for early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

## 2. Objective of the Activity

Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have already been recruited and that there is adherence to the principle of fairness for all concerned.

## 3. Scope

This SOP applies to the review of early termination reports.

It begins with the receipt and entry to the *Protocol Submission Logbook (L1)* of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|

| | | |
|---|---|---|
| **Step 1:** Receiving of the Early Termination Report and entering into the *Protocol Submission Logbook* (*SOP 24 - Management of Active Files*) Retrieving of pertinent Protocol File Notifying of REC Head and sending the report and relevant protocol documents to the Primary Reviewers | REC Staff | 1 day |
| **Step 2:** Reviewing, assessing and deciding on the Early Termination Report. Scheduling in Agenda of next meeting | REC Primary Reviewers | 10-14 days |
| **Step 3:** Discussing and deciding of the Report in a Full review *(SOP 06 - Full Review)* | REC Head, Primary Reviewers and Members | 1 day |
| **Step 4:** Communicating of committee action and update of the Protocol Database (*SOP 24 - Management of Active Files*) | REC Head, REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 – Receiving and entering to the Protocol Submission Logbook and Database of early termination reports for review. Retrieving of pertinent Protocol File notifying of REC Head and sending the Early Termination Report and relevant protocol documents to the Primary Reviewers:** The REC Staff receives the *Early Termination Report Form (F17)* and enters the appropriate information into the *Protocol Submission Logbook (L1)*. *(See SOP 24 Management of Active Files)*

The REC Staff retrieves the Protocol File and summarizes the documents that have been submitted. The REC Staff notifies the REC Head and informs the Primary Reviewers by email about the report and the summary of documents that have been submitted.

**Step 2 - Reviewing, assessing and deciding on the Early Termination Report. Scheduling in Agenda of next meeting:** The review of the early termination report should ensure the rights, safety, and welfare of the study participants, in the form of a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants. The REC Head instructs the Staff to include the report in the agenda of the next meeting and to ensure that the Primary Reviewers are given the necessary documents so that s/he can prepare the presentation during the next meeting (See *SOP 06 - Full Review)*

**Step 3 - Discussing and deciding of the Report in a Full review** *(See SOP 06 - Full Review)* The REC Head and Members discuss the implication of the Early Termination to subjects already recruited and ensure mechanism for continued care and monitoring of research participants as needed. The REC considers the following possible decisions in the review of an Early Termination Report:

- Approval of the Decision

- Request for additional information
- Requirement for further action

**Step 4** - **Communicating of committee action and updating the Protocol Database**: The REC Staff prepares a draft of the committee decision based on the minutes of the meeting (See *SOP 22 - Communicating REC Decisions*) for signature of the REC Head. S/he updates the Protocol Database accordingly.

## 6. Forms

*F17: Early Termination Report Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*
*L1: Protocol Submission Logbook*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Early Termination -* refers *to the decision of the researcher, principal investigator, the institution, sponsor or REC to end the implementation of a study before its completion*.

*Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGHRIP) 2022*

## 1. Policy Statement

Appeals are requests from researchers (sometimes, from sponsors or funding agencies) for reconsideration of a decision or action of the research ethics committee with regard to the protocol or related documents. Consideration of appeals is a reflection of the open-mindedness of REC members and their adherence to the principles of transparency and fairness.

The REC shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within six (6) weeks upon receipt of the fully documented appeal.

## 2. Objective of the Activity

Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

## 3. Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee's action to the researcher and updating the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving of an appeal; | REC Staff | 1 day |

| | | |
|---|---|---|
| **Step 2:** Retrieving of pertinent Protocol File; | REC Staff | 3-4 weeks |
| **Step 3:** Notifying of REC Head and Primary Reviewer/s and including in Agenda of the next regular meeting | REC Staff | 1-2 days |
| **Step 4:** Discussing and deliberating on the appeal in a full board meeting | REC Head<br>REC Members<br>Primary Reviewers | 1 day |
| **Step 5:** Communication of REC action (SOP 22 - Communicating REC Decisions) and updating the Protocol Database | REC Head<br>REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 – Receiving of an appeal:** The REC Staff receives the Letter of Appeal and enters the pertinent information into the *Protocol Submission Logbook (L1).*

**Step 2: Retrieving of pertinent Protocol File:** The REC Staff retrieves the pertinent files for reference in the review. The file includes the initially submitted protocol, informed consent form, research tools and other related documents.

**Step 3: Notifying of REC Head and Primary Reviewer/s and including in Agenda of the next regular meeting.** The REC Staff notifies the REC Head and the Primary Reviewers about the Letter of Appeal. The REC Head instructs the Staff to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

**Step 4: Discussing and deliberating on the appeal in a full board meeting:** The REC Primary Reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The REC Head presents the contents of the appeal and leads the discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides by majority voting whether to accept any or all of the points raised in the appeal.

**Step 5: Communicating of committee action and filing of documents and updating the Protocol Database:** Based on the deliberation, the REC Head summarizes the decision points and instructs the REC Staff to prepare the draft decision letter (*F12 - Action Letter Template)* for his/her finalization and signature before forwarding to the researcher. (*SOP 22 - Communicating REC Decisions).*

The REC Staff files all the documents into the appropriate Protocol File/Folder and updates the Protocol Database accordingly. (*SOP 24 - Management of Active Files).*

## 6. Forms

*L1: Protocol Submission Logbook*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Appeal – a request of a researcher/ investigator for a reconsideration of the REC recommendation.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Protocol File/Folder – is an organized compilation of all documents (in physical or electronic form) related to a study.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Site visits are important REC action that can be done in the performance of their oversight and monitoring responsibilities.

The REC Site Visit Team shall conduct this action for a cause on selected sites of approved protocols that fall within the following established criteria for such: (a) high-risk studies, (b) significant violation reports (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports and (e) multiple studies conducted by a researcher, (f) or for other reasons upon recommendation of the members.

## 2. Objective of the Activity

Site visits are mechanisms with which the REC monitors compliance with approved protocols, ICF process and continuing protection and promotion of participant's dignity, rights and well-being.

## 3. Scope

This SOP includes the steps in conducting visits to study sites for reasons set by the REC.

It begins with the selection of the site to be visited and ends with filing of Site-Visit Reports in the Protocol File and updating the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Selecting site to visit, notifying the researcher and notifying the Site Visit Team | REC Members and<br>REC Staff | 1 day |
| **Step 2:** Notifying the PI of intended date of site visit and preparing of PI for site visit | REC Head<br>REC Staff<br>Site Principal Investigator | 10-14 days |
| **Step 3:** Conducting site visit and drafting of report | REC Site Visit Team | 1-2 days |
| **Step 4:** Presenting Site Visit Report during meeting and discussing for recommendations | REC Site Visit Team<br>REC Members | 1-2 days |
| **Step 5:** Communicating recommendation of Site Visit Report to the Researcher/Investigator; Filing of Site-Visit Report in the Protocol File & update of Protocol Database | REC Head<br>REC Staff | 1-2 days |

## 5. Description of Procedures

**Step 1 - Selecting site to visit and notifying the Site Visit Team:** The REC decides which sites to visit based on high- risk studies, significant violation reports (receipt of significant number of protocol violations, receipt of complaints from participants and families, non-receipt of required after-approval reports and (e) multiple studies conducted by a researcher. The decision for a site visit is made during a full board meeting. The REC Staff notifies the researcher about the proposed site visit by letter sent through e-mail. The investigator is given 7-10 days to prepare the relevant documents for the site visit. The Site Visit Team is notified by the REC Staff.

**Step 2 - Notifying the PI of the site visit:** Preparing of Primary Investigator for site visit: The REC Staff notifies the researcher about the proposed site visit by letter sent through e-mail. The investigator is given not less than 14 days to prepare the relevant documents for the site visit.

**Step 3 - Conducting site visit:** The REC Site Visit Team examines the following documents:

- Study protocol version,
- Informed consent documents whether the most recently approved version is used,
- Post-approval documents: whether submitted and approved by the REC,

- Security, privacy, and confidentiality of the documents at the study site,
- Facilities in the study site and if possible, interview of study participants
- Determination of the protection of the rights, safety, and welfare of human participants in the study

**Step 3 – Conducting the site visit and drafting of report and presenting during meeting and discussion for recommendations:** The Site Visit Team completes the Site Visit Report Form (F20) focusing on the documents in step 2. The Site Visit report is included in the agenda of next Full Board meeting where the Site Visit Team Head will make the presentation. The REC will make recommendation/s to the PI based on the report of the Site Visit Team.

The Site Visit Team completes the Site Visit Report Form (F20) focusing on the ethical merits of the documents above. The Site Visit report is included in the agenda of the next Full Board meeting.

**Step 4: Presenting during meeting and discussion for recommendations:** The Site Visit Team Head presents the findings of the report during the REC Full Board Meeting. The REC members will discuss and make recommendation/s to the PI based on the report of the Site Visit Team.

The following recommendations may be issued by the REC:

- Uphold original approval
- Request further action
- Request further information

**Step 5 - Communicating recommendation of Site Visit Report to the Researcher/ Investigator; Filing of Site Visit Reports in the Protocol File and update of Protocol Database:** The REC Staff prepares the recommendations of the REC based on the deliberations during the meeting and prepares for signature of the REC Head *(See SOP 22 - Communicating REC Decisions).*

The REC Staff files the Site Visit Report and the recommendations in the appropriate Protocol File/Folder and updates the Protocol Database accordingly. (*See SOP 24 - Management of Active Files*)

## 6. Forms

*F20: Site Visit Report Form*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Site Visit - is an action of the REC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.*

*Site Visit Team - consists of the Site Visit Team Head appointed by the REC Head on a yearly basis. The members consist of the Head of the SAE Subcommittee Team, a clinical pharmacologist, and a primary reviewer of the protocol.*

*Post-approval reports – are reports, e.g., progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.*

*Protocol Violation- non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.*

*High Risk Studies – research where harm or danger resulting from the study intervention is very likely for participants.*

*Primary Reviewer – a member of the Research Ethics assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Decision - the result of the deliberations of the REC in the review of a protocol or other submissions.*

*Protocol File/Folder – is an organized compilation of all documents (physical or electronic form) related to a study.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall have a regular schedule of meetings, once a month, every 3rd or 4th Thursday of the month, except in the month of December, unless there are urgent protocols for full board review. All meetings shall be held through teleconferencing via Zoom or Google Meet or in the boardroom of the REC office. Special meetings shall be held as the need arises to resolve issues that require immediate attention (e.g., safety of participants, protocol violation that impact research integrity, administrative concerns, SOP revision).

## 2. Objective of the Activity

Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings.

## 3. Scope

This SOP covers all activities prior to the conduct of an REC meeting.

It begins with the preparation of the agenda and ends with the notification of REC Members and confirmation of attendance.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Preparing the Agenda *(See SOP 19 - Preparing the Meeting Agenda)* | REC Staff and Member Secretary | 10 days |
| **Step 2:** Collating of materials and documents needed for the meeting | REC Staff | 7 days |

| | | |
|---|---|---|
| **Step 3:** Preparing the boardroom of REC office or sending of Zoom or Google Meet link for teleconferencing. | REC Staff | 1 day |
| **Step 4:** Preparing the presentation and record equipment, food arrangements for the meeting | REC Staff | 1 day |
| **Step 5:** Notifying the REC Members, including the minutes of the previous meeting and the provisional agenda.<br>Independent Consultants and PI for clarificatory interview and confirmation of attendance | REC Staff | At least 5 days before the scheduled meeting |

## 5. Description of Procedures

**Step 1 - Preparing the agenda**: The REC Office Secretary prepares the agenda of the meeting by including all submission information in the Protocol Database and review comments and the previous Minutes of the meeting. *(See SOP 19 - Preparing the Meeting Agenda)*

**Step 2 - Collating of materials and documents needed for the meeting**: The REC Staff collates the documents and materials for the meeting based on the provisional agenda, (e.g. copies of the provisional agenda, provisional minutes of the previous meeting, protocols and related documents submitted, post-approval reports, expedited review reports, administrative memos) **at least two (2) weeks before** the meeting.

**Step 3 - Preparing the boardroom of REC office or sending of Zoom or Google Meet link for the teleconferencing:** The REC Staff sends to the members the Google Meet or Zoom link for the teleconferencing or prepares its own boardroom for the meeting one (1) week before the schedule.

**Step 4 - Preparing the presentation, recording equipment, and food arrangements for the face to face meeting:** The REC Staff ensures that the following are prepared and available for the meeting: laptop, projector, and screen, microphones, adequate food and drinks/water depending on the expected duration of the meeting.

**Step 5 - Notifying the REC Members including the minutes of the previous meeting and the Provisional Agenda.**

**Notifying Independent Consultants and PI for clarificatory interview and confirmation of attendance:** The REC Staff sends the notice of meeting, including the Minutes of the previous meeting, provisional agenda and protocol summary to the Members of the committee at least five (5) day before the schedule and follows-up the confirmation of attendance to ensure quorum. Investigators who are scheduled for Clarificatory Interview must confirm their attendance.

The Independent Consultants may not be required to attend a meeting provided they have submitted their comments. If Clarificatory Interview is scheduled for the specified protocol, the Independent Consultant must also be present.

In case, quorum cannot be met, the REC Staff informs the Head and the Member Secretary so that Alternate Members may be called in.

## 6. Forms

*F28: Notice of Meeting*
*F09: Meeting Agenda Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Quorum – For RECs with nine members, a quorum requires at least 5 members, otherwise a quorum shall follow the 50% + 1 rule. A quorum also requires the presence of at least one non-medical or non-scientist and one non-affiliated member to make decisions about the proposed research. (WHO 2011)*

*Support Staff – institutional personnel assigned by administration to assist in the operations of the REC.*

*Regular Meeting - a periodically scheduled assembly of the REC*

*Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action*

*Administrative Documents – documents that pertain to the operations of the REC and are not directly related to a study or protocol.*

*Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".*

*Alternate Members – individuals who possess qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The meeting agenda shall be based on the submissions received, at the latest, **ten (10) days** before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

## 2. Objective of the Activity

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

## 3. Scope

This SOP describes how the REC determines what items are to be included in the agenda of regular and special meetings.

It begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELIINE |
|---|---|---|
| **Step 1:** Preparing the draft meeting agenda | REC Staff and Member Secretary | Not less than 10 days before the meeting |
| **Step 2:** Preparing the provisional meeting agenda | REC Head<br>REC Staff | 2 days |

| | | |
|---|---|---|
| **Step 3:** Distributing the Provisional Meeting Agenda and Minutes of the previous meeting (*SOP 18 - Preparing for a Meeting*) | REC Staff | At least 5 days before the scheduled meeting |
| **Step 4:** Approving the Provisional Meeting Agenda | REC Members | 1 day |
| **Step 5:** Filing of the final Meeting Agenda (*SOP 24 on Management of Active Files*) | REC Staff | 1 day |

## 5. Detailed Procedures

**Step 1 – Preparing the draft meeting agenda**: The REC Staff under the supervision of the Member Secretary prepares the draft agenda using the *Meeting Agenda Template (F09)*. The agenda (with date, time, and venue of the meeting) includes the following:

1. Call to Order
2. Declaration of Quorum
3. Presentation and Approval of Provisional Agenda
4. Disclosure of Conflict of Interest
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes
7. New Business:
    - 7.1. Initial Review of Protocols
    - 7.2. Review of Resubmissions
    - 7.3. Review of Post-Approval Submissions
    - 7.4. Report on Exempt Review Protocols
    - 7.5 Report on Expedited Review of New Protocols
    - 7.6. Report on Expedited Review of Post-Approval Submissions
    - 7.7 Report of Site Visits
8. Other Matters

**Step 2 – Preparing the provisional meeting agenda**: The REC Head reviews the draft agenda as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting.

**Step 3 - Distributing the provisional meeting agenda**: The provisional agenda is included in the Notice of Meeting sent by e-mail to the members before the meeting. (*See SOP 18 - Preparing for a Meeting*).

**Step 4 - Approving the provisional meeting agenda**: The REC Members approve the provisional agenda during the meeting. (*See SOP 20 - Conduct of Meetings*).

**Step 5 - Filing of the final meeting agenda**: The REC Staff files the final (approved) meeting agenda in a special folder that contains all meeting agenda in a chronological order. (*See SOP 24 - Management of Active Files*).

## 6. Forms:

*F09: Provisional Agenda Template*
*F28: Notice of Meeting*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the REC Head for his/her approval.*

*Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Head.*

*Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Members in a regular or special meeting.*

*Quorum – For RECs with nine members, a quorum requires at least 5 members, otherwise a quorum shall follow the 50% + 1 rule. A quorum also requires the presence of at least one non-medical or non-scientist and one non-affiliated member to make decisions about the proposed research. (WHO 2011)*

*Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different roles or duties are not compatible such that decisions may adversely affect the official/primary duty.*

*Protocols for Full Review – Study proposals that require an en banc ethical assessment because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.*

*Exemption Report – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.*

*Expedited Review Reports – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review for information of the REC members and for record viewers.*

*Post-approval reports – are reports, e.g., progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.*

*Administrative Issuance – official communications or announcements from institutional authorities.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Meetings shall be presided by the REC Head or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review.

## 2. Objective of the Activity

Meetings are conducted to provide an opportunity for the REC to arrive at collegial decisions regarding study protocols and REC operations and to be informed of pertinent administrative matters.

## 3. Scope

This SOP describes the manner by which the REC conducts all its meetings. It covers REC actions and activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned.

It begins with the declaration of quorum and ends with the collection, storage, and disposal of meeting materials.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Declaring quorum (call to order) | REC Head | |

| | | |
|---|---|---|
| **Step 2:** Presenting and approving the Provisional Agenda | REC Head<br>REC Members | 1 day |
| **Step 3:** Declaring of conflict of interest (COI) | REC Members (with COI) | |
| **Step 4:** Approving of minutes of the previous meeting | REC Members | |
| **Step 5:** Discussing "Business arising from the minutes" | REC Head and<br>REC Members | |
| **Step 6:** Reviewing of protocols and protocol-related submissions *(SOP 05 - Full Review)* | REC Head and Members<br>Independent Consultant | |
| **Step 7:** Reporting of results of expedited review *(SOP 04 - Expedited Review*) | REC Vice Head | |
| **Step 8:** Discussing operations-related and other matters | REC Head and Members<br>REC Staff | |
| **Step 9:** Adjourning the meeting | REC Head | |
| **Step 11:** Collecting, storing and disposing of meeting materials | REC Staff | |

## 5. Description of Procedures

**Step 1 - Declaring of quorum**: The quorum includes the majority of the members, at least 5 members with sex and age distribution and the presence of the medical/scientific, non-scientific and non-institutional members. The Members and the Secretariat are reminded by the REC Head that quorum will be determined anytime a member leaves the room.

**Step 2 - Presenting and approving of the Provisional Agenda**: The REC Head invites the members to examine the provisional agenda and inquires any addition or deletion of protocols to be reviewed and other matters to be discussed.

**Step 3 - Declaring of Conflict of Interest**: Prior to the REC meeting, each member (including Primary Reviewers, Independent Consultants, and any invited guests) is required to disclose any potential conflicts of interest related to the protocols under review. This includes financial, professional, or personal relationships that could influence their impartiality. The REC Head will review these disclosures and determine if any member has a COI with respect to the specific protocol being discussed. If a member is identified as having a COI with a protocol under discussion, they must recuse themselves from the review process for that specific protocol. The affected member must step out of the room or online meeting during the protocol

deliberation and voting. This ensures that they do not influence the discussion or decision-making process.
The REC Head will ensure that the member with COI does not participate in the review of the protocol in any capacity during the deliberation period.

**Step 4 - Approving the minutes of previous meeting**: The Minutes of the previous meeting is sent at least five (5) days before the meeting so that the members can read it beforehand. The REC Head inquires about revisions and if there are none, asks for Approval of Minutes from the Members.

**Step 5 - Discussing "Business arising from the minutes"**: The REC Head and Members discuss the pertinent matters that transpired regarding important issues arising from the Minutes of the previous meeting.

**Step 6 - Reviewing protocols and protocol-related submissions**: The REC Head starts the review of protocols by requesting the Primary Reviewer to provide a short summary of the protocol and to provide his/her review points as to the scientific validity, technical issues, ethical issues, qualifications of the researchers and suitability of the study sites, and informed consent process/form issues. The Primary Reviewers are guided by the *Protocol & Consent Assessment Form (F08*) in their presentations. The Independent Consultant can present the review points if his/her expertise is required by the protocol. (*See SOP 05 - Full Review*). The researcher/principal investigator may be called for a clarificatory interview as deemed necessary by the Primary Reviewer or the committee, after which, they are asked to leave the meeting. If the protocol requires an Informed Consent, the non-scientific member will present his/her assessment of the informed Consent process and form.

The REC Head summarizes the pertinent review points of the protocol. The REC arrives at a decision by majority voting, indicated verbally.

- Approved
- Minor revisions
- Major revisions
- Disapproved (with reasons stated)

The REC Member Secretary and REC Staff takes note of voting results, records and includes them in the Minutes of the Meeting.

- Review of the following, if any:
- Review of Amendments
- Review of Progress Reports
- Protocol Violations/Deviations
- Early Termination Reports
- SAE, SUSAR Reports
- Site Visit Reports

**Step 7 - Reporting of results of expedited review**: The REC Vice Head presents the results of expedited review to the members.

**Step 8 - Discussing of operations-related and other matters**: The REC Head informs the Members about operational and other matters like administrative policies pertinent to REC function or requests for GRP/GCP workshop by hospital trainees.

**Step 9 – Adjourning the meeting**: The REC Head declares adjournment of the Meeting after all items in the agenda have been discussed and/or resolved.

**Step 10 - Collecting, storing, and disposing of meeting materials:** The REC Staff sort the documents distributed during the meeting and returned to the shelves. The extra copies are disposed of by shredding. *(See SOP 24 - Management of Active Files and SOP 19 – Preparing the Meeting Agenda*

## 6. Forms

*F30: Attendance Sheet*
*F08: Protocol & Consent Assessment Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |

| | | | |
|---|---|---|---|
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Quorum - For RECs with nine members, a quorum requires at least 5 members, otherwise a quorum shall follow the 50% + 1 rule. A quorum also requires the presence of at least one non-medical or non-scientist and one non-affiliated member to make decisions about the proposed research. (WHO 2011)*

*Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.*

*Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".*

*Adjournment - Formal closure of the meeting. Motion for adjournment and record of the time are minuted.*

*Voting – act of formally manifesting a choice in a meeting.*

*Consensus – the process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no stronger objection is registered.*

*Collegial Decision - a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any one member.*

*Meeting Minutes - the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.*

*REC Operations - the overall activities of the REC that reflect performance of its functions and responsibilities.*

*Protocol – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.*

*Protocol-related submissions– other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.*

*Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.*

*Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.*

*Clarificatory Interview/meeting – is a face-to-face consultation between the REC and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC to make these issues less confusing or more comprehensible.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

## 2. Objective of the Activity

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an REC meeting.

## 3. Scope

This SOP includes REC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting.

It begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Entering preliminary information on the Minutes template | REC Staff | 1 day |
| **Step 2:** Preparing the draft Minutes | REC Staff and Member Secretary | 1-2 days from meeting |
| **Step 3:** Notating the draft Minutes | REC Head | 7 days from the meeting |

| | | |
|---|---|---|
| **Step 4:** Approving the Minutes in the next REC meeting | REC Head and Members | 1 day |
| **Step 5:** Filing of the approved Minutes *(SOP 24 - Management of Active Files)* | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Entering of preliminary information on the minutes template**: The REC Staff uses the *Meeting Minutes Template (F10)* and enters preliminary information under the supervision of the Member Secretary.

**Step 2 - Preparing the draft minutes**: During the meeting, the REC Staff documents the proceedings in accordance with the agenda. The REC Staff documents all board opinions and actions by real-time note-taking in all specific sections of the agenda or projecting the template on screen during face-to-face meetings. The REC Staff documents the discussion as the agenda is developed and discussed, with respective reasons for protocol-related actions. Information included are comments and recommendations on the scientific issues, ethical issues, and informed consent form issues. The opinions and actions included in the minutes are collective and not attributed to specific members. The Presiding Officer moderates the discussion to ensure efficient time management.

The Member Secretary and REC Staff shall prepare and verify the draft of the minutes within two (2) days.

**Step 3 - Notating the draft minutes**: Notations are done in real time with immediate corrections made by the REC Members. The final draft minutes must be completed in 1 week, reviewed and corrected by the Member Secretary and noted by the REC Head. The draft minutes is sent to the Members at least five (5) days prior to the next full board meeting where it will be presented and approved.

The following items are included in the minutes of the meeting:

- Date and venue of meeting
- Members attendance (members present and absent)
- Presence of Independent consultants, primary investigators, guests, and observer's attendance (if any)
- Time when the meeting was called to order
- Declaration of Quorum at the beginning of the meeting and before every protocol discussion
- Name of Presiding officer
- Conflict of Interest (COI) declaration
- Items discussed, issues raised, and resolutions
- REC decisions and recommendations
- Name and signature of REC Staff who prepared the minutes

- Name and signature of Member Secretary who verified the draft
- Name and signature of the REC Head and date of notation

**Step 4 - Approving the minutes in the next REC meeting**: Approval of the provisional meeting minutes is done through a formal motion from any member of the committee and seconded accordingly.

**Step 5 - Storing the approved minutes**: The REC Staff will store the final meeting minutes in a central file by year to facilitate retrieval. *(See SOP 24 - Management of Active Files).*

## 6. Forms

*F10: Meeting Minutes Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Meeting Agenda- the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".*

*Draft Meeting Minutes – Proceedings of the meeting prepared by the Secretariat under the supervision of the Member-Secretary.*

*Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer.*

*Final Meeting Minutes – Proceedings of the meeting that have been approved by the REC members.*

*Real-time Recording – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.*

*Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The REC shall communicate its decisions to the researcher within **seven (7) days** after the decision has been made by the REC. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the REC and signed by the REC Head.

## 2. Objective of the Activity

The management of communicating REC decisions ensures that all stakeholders are appropriately, accurately, and promptly informed of the results of deliberations of the REC.

## 3. Scope

This SOP covers REC actions related to the communicating REC decisions (e.g., actions to applications submitted to the REC).

It begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the Protocol File.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Finalizing the recommendations of the committee (in case of full review) (See *SOP 05 - Full Review)* or finalizing the recommendations of reviewers (in case of expedited review) *(See SOP 04 - Expedited Review)* | REC Head | 1 day |

| | | |
|---|---|---|
| **Step 2:** Transferring of information from meeting minutes or reports to REC Action Letter/Approval Letter template | REC Staff<br>Member Secretary | 7 days |
| **Step 3:** Approving of the REC decision document | REC Head | 1 day |
| **Step 4:** Transmitting of REC decision to Researcher | REC Staff | 1 day |
| **Step 5:** Filing of the decision document in the Protocol File *(SOP 24 - Management of Active Files)* and Update of *Protocol Tracking Form (F27)* and Protocol Database | REC Staff | |

## 5. Description of Procedures

**Step 1** – Finalizing of recommendations of the committee (in case of full review) or reviewers (in case of expedited review): For protocols assessed through full board review, the REC Head approves the recommendations of full board meeting after the notation of the Member Secretary. For protocols which underwent expedited review, the REC Head reviews and approves the review points of the Primary Reviewers.

**Step 2 -** Transferring of information from meeting minutes to Action Letter/Approval Letter Template.
Upon approval of the draft minutes, or finalization of the reviewers' recommendations, the Office Secretary, supervised by the REC Member Secretary, collates the comments and recommendations and prepares the Action Letters/Approval Letters.

**Step 3** - Approving of the Action Letters/Approval Letters: The REC Head reviews and signs the *Decision Letters* for issuance to the Primary Investigator.

**Step 4 -** Transmitting of REC decision to researcher: The Office Secretary sends an e-mail of the *Action Letter* to the Principal Investigator. All Action Letters/Approval Letters shall be communicated to the Principal Investigator within 7 days after the decision has been made by the REC.

**Step 5 –** Filing the decision document in the Protocol File and Update of the Protocol Database: The REC Staff files all protocol related decisions or actions in the Protocol File to facilitate retrieval. The Office Secretary updates the *Protocol Tracking Form (F27)* and actions in the Protocol Database. (*See SOP 24 - Management of Active Files*).

## 6. Forms

*F12: Action Letter Template*

*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Action Letter - an official written communication issued by the Research Ethics Committee (REC) to the Principal Investigator (PI) or research team that conveys the REC's decision on a submitted research protocol or related documents. The Action Letter outlines the outcome of the IRB review, including approval status, required modifications, conditions for approval, or reasons for disapproval. It also provides instructions on the necessary next steps and deadlines for compliance, serving as a formal record of the IRB's correspondence and decisions.*

*Approval Letter - a specific type of Action Letter issued by the Research Ethics Committee (REC) that officially grants approval for a research protocol to proceed. The letter outlines the conditions of approval, duration of the approval period, and any continuing review or reporting requirements.*

*Expedited Review - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Protocol Tracking Form – is a chronological record of the document's activity in the protocol file. The tracking form is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The tracking form is included in the protocol file/folder for easy reference and checking.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

*Active Files – are documents pertaining to protocols which are currently being assessed, managed or monitored by the REC.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

All communications shall be recorded accurately and appropriately in a physical log book and electronic Protocol Database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

## 2. Objective of the Activity

The management of REC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

## 3. Scope

This SOP covers REC actions related to organizing incoming and outgoing documents and ensuring an appropriate REC response.

It begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Sorting of incoming/outgoing communications | REC Staff | 1 day |
| **Step 2:** Recording of incoming/outgoing communications | REC Staff | 1 day |

| | | |
|---|---|---|
| **Step 3:** Acting on incoming communications | REC Head/ Vice Head/ Member Secretary | 2-3 days |
| **Step 4:** Filing of incoming/outgoing communications and update of the Protocol Database | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Sorting of incoming/outgoing communications:** The REC Staff is responsible for receiving, recording, coding, and filing of received protocols and protocol-related forms. Under the supervision of the Member Secretary, the REC Staff is also responsible for separating protocol-related from process-related communication.

**Step 2 - Recording of incoming/outgoing communications:** The REC Staff records the incoming/outgoing records in the *Protocol Tracking Form (F27)* and *Protocol Submission Logbook (L1)*. This logbook is updated as each submission is received. The REC has a recording system that documents the following: date received, source (person who sent communication, department, contact details), type and content (protocol or non-protocol submission), person who received communication, action taken.

**Step 3 - Acting on communications:** The REC Head/Vice Head/Member Secretary are responsible for classifying protocol submissions and assignment of Primary Reviewers. The REC Staff refers to the REC Head for all incoming administrative communications recorded in the *Incoming Communications Logbook (L2)*.

The REC Head is the usual signatory for outgoing communications documented in the *Outgoing Communications Logbook (L3)*. The REC Vice Head or Member Secretary may sign the outgoing communications on behalf of the REC Head when he/she is not available.

**Step 4 - Storing or filing of incoming/outgoing communication:** The REC Staff files protocol-related communications in the study Protocol File and the Protocol Submission Logbook while non-protocol-related documents are filed in the appropriate administrative files.

## 6. Forms

*L1: Protocol Submission Logbook*
*L2: Incoming Communications Logbook*
*L3: Outgoing Communications Logbook*
*F27: Protocol Tracking Form*

## 7. History of the SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Incoming Communications – are documents which are directed to and received at the REC office.*

*Outgoing Communications – are documents generated within the REC office intended for individuals or offices related to the operations of the REC.*

*Administrative Documents - documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.*

*Protocol-related File/ Documents - consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions Indexing System.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by *SOP 26 - Managing Access to Confidential Files*

## 2. Objective of the Activity

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

## 3. Scope

This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the REC.

It begins with the classification and coding of active files and ends with the periodic updating of the file.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Classification and coding of Active Files | REC Member Secretary and REC Staff | 1 day |
| **Step 2:** Preparation of the Protocol File/Folder | REC Staff | 1 day |
| **Step 3:** Periodic updating of the Protocol File | REC Member Secretary and REC Staff | After every post-approval submission |

## 5. Description of Procedure

**Step 1**. **Classification and coding of active files**: The REC Staff under the supervision of the member secretary classifies active files as follows:

- Initial Submission
- Resubmission
- Progress Report
- Amendment
- Protocol Deviation
- Protocol Violation
- SAE - Serious Adverse Event
- SUSAR - Suspected Unexpected Serious Adverse Reaction –
- Early Termination
- Continuing Review
- Final Report Report

The REC Staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The Protocol Reference Number is assigned as follows:

**< REC-YYYY-MM-NNN-LL-short name >**

**e.g., 2022-01-001-CT TRIAL**

| | | |
|---|---|---|
| **YYYY** | Represents the year submitted (i.e., 2022) | |
| **MM** | Represents the month submitted (i.e., 01 - January; 02 – February) | |
| **NNN** | Represents sequential number as issued by Office Clerk (e.g 001) | |
| **LL** | Represents the letters based from the following: | |
| | **TI** | Trainee Intern |
| | **TR** | Trainee Resident |
| | **TF** | Trainee Fellow |
| | **MD** | Medical Consultant |
| | **CT** | Clinical Trial |
| | **IS** | Internal Students (students from UST) |
| | **ES** | External Students (Non-UST students) |
| | **OO** | Others |
| | **Short name** | represents short title of the protocol |

**Step 2. Preparation of the Protocol File/Folder**: The REC Staff files all documents pertaining to a study in a vertical folder that is labeled on the side label with: Protocol Reference Number. The REC Staff attaches a *Protocol Tracking Form (F27)* on the first page that indicates the contents of the Protocol File/Folder.

**Step 3. Periodic Updating of the Protocol File**: The REC Staff ensures that the documents are filed in chronological order such that the **most recent documents are topmost**. These documents include the following:

- Protocol (Original and Revised) versions
- Informed consent (Original and Revised) versions
- Post-approval Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports
- Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
- Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
- Decision and Approval Letters
- Communications

The REC Staff updates the *Protocol Tracking Form (F27)* each time a new document is added to the file. The Protocol File/Folder is periodically checked for orderliness and completeness.

## 6. Forms:

*F27: Protocol Tracking Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |

| | | | |
|---|---|---|---|
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Initial Submission - a set of documents consisting of the full proposal and other study-related documents that is received by the REC so that ethical review can be done.*

*Resubmission - the revised study proposal that is forwarded to the REC in response to the recommendations given during the initial review.*

*Progress Reports - a systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form. The frequency of submission (e.g. quarterly, semi-annually or annually) is determined by the REC based on the level of risk.*

*Amendments - a change in or revision of the protocol made after it has been approved.*

*Protocol Deviation - non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.*

*Protocol Violation - non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.*

*Serious Adverse Event (SAE) - is an event observed during the implementation of a study where the outcome is any of the following:*

- *Death*
- *Life Threatening*
- *Hospitalization (initial or prolonged)*
- *Disability or permanent damage*

- *Congenital anomaly/birth defect*
- *Required intervention to prevent permanent impairment or damage (devices)*
- *Other serious (important medical) events whether or not it is related to the study intervention*

*Suspected Unexpected Serious Adverse Reaction (SUSAR) - is a noxious response to a drug that is not described in the Investigator's Brochure not in the drug insert.*

*Early Termination - is ending the implementation of a study before its completion. This is a decision made by the sponsor or a regulatory authority and/or recommended by the Data Safety Monitoring Board, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.*

*Continuing Review - is the decision of the REC to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.*

*Protocol Index – is a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking,*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

*Active Files – are documents pertaining to protocols which are currently being assessed, managed or monitored by the REC.*

*Final Reports - is a summary of the outputs and outcomes of the study upon its completion. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.*

*Assessment Form - evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGHRIP) 2022*

## 1. Policy Statement

Protocols for archiving include those (a) with approved/ accepted Final Reports, (b) with approved Early Termination reports and (c) whose proponent/researcher/investigator has not submitted a response to the REC recommendation after six (6) weeks/30 working days (cancelled protocols).

Files of studies which have been completed, terminated, or canceled shall be kept in a separate and secured storage room for three (3) years. For clinical trials, the files are kept for a period of fifteen (15) years. Administrative files are, likewise, kept in the storage room for three years.

## 2. Objective of the Activity

Archiving cancelled, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

## 3. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as completed, terminated or inactive.

It begins with the acceptance of final report or early termination reports or identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Filing of REC-approved Final Report or Early Termination Reports. *See SOP 14 - Review of Final Reports, SOP 15 - Review of Early Termination Reports,* and Identifying of a Protocol as Inactive. | REC Staff | 1 day |
| **Step 2:** Updating of corresponding Protocol File/Folder | REC Staff | 1 day |
| **Step 3:** Transferring of the Protocol File/Folder in the archives, Coding of Archived files and update of the Protocol Database | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 – Filing of Final or Early Termination Reports and identifying an Inactive File:** After approval of a final report/early termination report in a REC meeting, the REC Staff files the Protocol File/Folder in the Archive.

**Step 2 - Updating the corresponding active file**: The REC Staff files the Final or Early Termination Report in the corresponding Protocol File/Folder. For inactive files, excerpts of the minutes that declared the protocol as inactive are included in the Protocol File/Folder.

**Step 3 - Transferring the Protocol File/Folder in the Archives and updating the Protocol Database:** The REC Staff checks whether the documents listed in the *Protocol Tracking Form (F27)* are complete and removes extraneous documents. Then, the REC Staff transfers the folder to the archive section and codes the archived files by writing the month and year it was archived followed by the original protocol code on the side of Protocol File/Folder. The REC Staff updates the Protocol Database.

## 6. Forms

*L6: Borrower's Logbook*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Final Report – is a summary of the outputs and outcomes of the study upon its completion. The REC requires the accomplishment of the Final Report Form within eight weeks after the end of the study.*

*Early Termination - ending the implementation of a study before its completion*.

*Cancelled Protocol - a study whose proponent has not communicated with the REC with regard to issues pertaining to the approval or implementation of the study within six weeks / 30 working days .*

*Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.*

*Inactive study - is a completed study with an approved Final report*

*Archiving - is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.*

*Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the REC must not be freely shared or disclosed.*

*Controlled document – pertains to the document that have been entrusted or submitted to the REC that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGHRIP) 2022*

## 1. Policy Statement

It is the responsibility of the REC to keep particular documents in its custody confidential. This is to protect the intellectual property rights of research proponents and to protect REC members from unnecessary scrutiny and pressure from non-authorized individuals. In the Philippines, personally identifiable documents entered into a database system are subject to protections under the *Data Privacy Act of 2012*, emphasizing the need to lay down policies authorizing access to such documents. Confidential files include study protocol-related documents (e.g. protocols, case report forms, informed consent documents, scientific documents, expert opinions or reviews), meeting minutes, decisions, action letters/notification of committee decision, approval letters, and study protocol-related communications.

The UST Hospital has a Data Privacy Officer (DPO) whose office issues policies or standards to promote confidentiality of institutional files.

Access to the REC confidential files shall be regulated and limited to REC Members and Staff. Other persons with legitimate interest in these files (e.g., institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own Protocol Files upon a written request.

Photocopying of documents may be allowed, however, photographs are not permitted. Photocopying costs will be charged to the requesting individual.

## 2. Objectives of the Activity

Management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the REC.

## 3. Scope

This SOP consists of procedures for accessing confidential files including document handling and distribution.

It begins with the receipt of the request to access and ends with the return of the documents to the Protocol File/Folder.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving and logging of request for access to confidential files | REC Staff | 1 -2 days |
| Approving of requests for access and retrieval of documents | REC Head or<br>REC Member Secretary | |
| **Step 2:** Supervising use of retrieved document<br>Returning of document to the files | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving and logging of request for access to confidential files approval of requests for access and retrieval of documents:** The REC Staff receives the Request Letter to access specific files and refers this to the REC Head or Member Secretary. The REC Head or Member Secretary considers the indicated reason for the request and when found satisfactory approves it. The REC Staff asks the individual requesting to sign the *Confidentiality Agreement (F02)* and proceeds to retrieve the pertinent document.

**Step 2 - Supervision of use of retrieved document return of document to the files** The REC Staff asks the user to sign the *Borrowers Logbook (L6*), enforces the restriction to room-use of documents and limits photocopying to concerned researchers/principal investigators. The REC Staff is responsible for returning the retrieved files to the Protocol File.

## 6. Forms

*L6: Borrowers Logbook*
*F02: Confidentiality Agreement Form*

## 7. History of SOP

**8.**

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
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| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 9. Glossary

*Confidentiality - is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.*

*Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REC and the researcher.*

*Sponsor - an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.*

*Intellectual property – refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce), that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.*

*Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.*

*Meeting Minutes – narration of the proceedings of the assembly of REC members.*

*Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research Institutions.*

*Room-use Restriction – the rule that limits the use of a document within the designated premises.*

## 10. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Queries and complaints from research participants, families, researchers, and concerned parties shall be attended to promptly and appropriately while exercising due diligence. The nature of queries and complaints shall determine whether they can be addressed by the REC Staff or referred to the REC Head.

All complaints shall be referred to the REC Head who shall determine the level of risk involved. Minor complaints or complaints involving minimal risk to the participants shall be referred to the primary reviewers for resolution and submitted to the REC Head for approval. Major complaints or complaints involving more than minimal risk to the participants shall be taken up in a special meeting within forty-eight (48) hours for deliberation by the committee en banc with the Primary Reviewers leading the discussion.

## 2. Objective of the Activity

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the REC and to ensure that the rights and well-being of participants are attended to.

## 3. Scope

This SOP applies to all queries and complaints of research participants, their families, researchers and concerned parties involving studies that have been submitted to the REC or have been issued an ethical approval.

It begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the meeting.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving, logging, and acknowledging of written queries and complaints *(Management of Incoming and Outgoing Communications)* | REC Staff | 1 day |
| **Step 2:** Addressing the query or complaint<br>2.1 Addressing the query<br>2.2 Referring of complaints to REC Head for action to be taken | REC Staff | 1 day |
| **Step 3:** Formulating of response<br>3.1. Queries<br>3.2. Minimal-risk complaints<br>3.3. More than minimal risk complaints: full board meeting (SOP on meetings) | 3.1 REC Staff<br>3.2 Primary Reviewers and REC Head<br>3.3 REC Head and REC Members | 2 days |
| **Step 4:** Communicating of response *(SOP 22 - Communicating REC Decisions)*<br>Logging of the response *(SOP 23 – Management of Incoming and Outgoing Communications)* | REC Staff | 1 day |

## 5. Description of Procedures

**Step 1 - Receiving, logging, and acknowledging queries and complaints:** The REC Staff receives and enters the written queries and complaints in a logbook dedicated to these communications. The REC Staff records the date, time, name of concerned party, specific study and nature of query or complaint in the *Incoming Communications Logbook (L2)*.

**Step 2 - Addressing the query or complaint**

2.1 Addressing the query: The REC Staff determines whether the query may be addressed at their level or referred to the REC Head for consultation.

2.2 Referring of complaints to REC Head for action to be taken: The REC Head determines whether the complaint is of minimal risk or more than minimal risk in relation to the research participants, their families, researchers or concerned parties.

**Step 3 - Formulating of response**

3.1. Queries

3.2. Minimal-risk complaints

3.3. More than minimal risk complaints: en-banc committee

3.3.1. For queries addressed at the level of the REC Staff, these are properly documented in the *Incoming Communications Logbook (L2)*. For queries consulted at the level of the REC Head, the Query Reply is accomplished.

3.3.2. For minimal risk complaints, the REC Primary Reviewers accomplish the Complaints Resolution.

3.3.3. For more than minimal risk, a special meeting is held to address the complaint and come up with any but not limited to the following actions:

3.3.3.1. Constitute a Site Visit Team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

3.3.3.2. Designate the REC Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.

3.3.3.3. Formulate recommendation if satisfied with the adequacy of information:

- request for explanation/justification from researcher
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- others

**Step 4 - Communicating of response Logging of the response and inclusion in the agenda of the REC meeting**: The REC Staff prepares the response to queries and complaints from the recommendation of the Primary Reviewer or from the Minutes of the Special meeting where the query/complaint was discussed. The response is reviewed and signed by the REC Head. *(See SOP 22 - Communicating REC Decisions).*

The REC Staff logs the response in the concerned Protocol File *See Management of Incoming and Outgoing Communications)*

## 6. Forms

*F21: Queries and Complaints Form*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |

| | | | |
|---|---|---|---|
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Query – the act of asking for information or clarification about a study or any relevant REC process or procedures.*

*Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.*

*Regular Meeting– a periodically scheduled assembly of the REC.*

*Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for specific purpose.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Site Visit Team – members/staff of the REC (2-4 members) assigned by the REC Head to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

Protocols that involve the use of a new device entail more than minimal risks or harms to human participants and are therefore reviewed during full board meetings. A *Certificate of Medical Device Notification (CMDN)* for class A devices (low risk) and a *Certificate of Medical Device Registration (CMDR)* for class B, C and D devices (low-moderate, moderate-high and high risk) from the Philippine Food & Drug Administration (PFDA) are requirements for review and approval since the risks in their use may have impact on health and safety of research participants. A *Certificate of Medical Device Listing (CMDL)* is also needed for a medical device that is intended for research, clinical trial, exhibit, or donation and not intended for sale.

## 2. Objective of the Activity

Protocol Using New Device aims to demonstrate due diligence and compliance with technical and ethical standards in the conduct of research involving human participants using a new device in order to protect their safety and well-being.

## 3. Scope

This SOP applies to initial, resubmissions and post-approval submissions of protocols that involve the use of a new device either for diagnostic or treatment purposes.

It begins with the assignment of Primary Reviewers or Independent Consultant/s and ends with the filing of protocol-related documents.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Assigning of Primary Reviewers or Independent Consultant/s (See *SOP 03 - Appointment of Independent Consultants)*<br>Notifying of Primary Reviewers or Independent Consultants for availability to do the review and providing of protocol, protocol-related documents (CMDN or CMDR) depending on the risk of protocol and *Assessment Forms (F08)* | REC Head/ Vice Head/ Member Secretary<br><br>REC Secretariat | 1-2 days |
| **Step 2:** Reviewing, assessing and deciding on the protocol. The assigned Primary Reviewers present review findings and recommendations including the use of the new device in a full board meeting and the Members make the decision. (See *SOP 06 - Full Board Review* and *SOP 20 - Conduct of Meetings)* | REC Primary Reviewers and REC Members | 4-5 weeks |
| **Step 3:** Documenting of Committee deliberation and action (See S*OP 21 - Preparing the Meeting Minutes)* | REC Secretariat | 1 day |
| **Step 4:** Communicating of Committee action to the Investigator (See *SOP 22 - Communicating REC Decisions*)<br>Filing of protocol-related documents and updating the Protocol Database | REC Head and Secretariat | 1 day |

## 5. Description of Procedures

**Step 1 - Assigning of Primary Reviewers or Independent Consultant/s. Notifying of Primary Reviewers or Independent Consultants for availability to do the review and providing of protocol, protocol-related documents and *Protocol & Consent Assessment Form (F08)***. The REC Head/ Vice Head/Member Secretary assigns at least three (3) members (1-2 medical or 1 scientific and 1 non-scientific member) who have the necessary expertise as Primary Reviewers or designates an Independent Consultant in case such technical expertise is not present among the members. He will be assigned to review the protocol and (CMDN or CMDR) The non-scientist member will review the Informed Consent Process and Form. The REC Staff notifies the assigned Primary Reviewers and/or Independent Consultants about their assignment by e-mail with a request that they confirm their acceptance and availability. The protocol, protocol-related documents and *Protocol & Consent Assessment Form (F08)* are sent to Primary Reviewers and/or Independent Consultant.

**Step 2 - Reviewing, assessing and deciding on the protocol.** The assigned Primary reviewers and/or Independent Consultant present review findings and recommendations including the use of the new device in a full board meeting and the Members make the decision**.** The impact of the use of a new device on the health and safety of the participants is essential to decision-making. The REC decides by voting and the majority decision is adopted. In case of a tie, the REC Members will discuss the relevant issues that justify their recommendations after which the Members will vote again. The decision may be:

- Approved
- Minor Modifications
- Major Modifications
- Clarificatory Interview

**Step 3 - Documenting of Committee deliberation and action.** All the committee deliberations are recorded by the Office Secretary in the Minutes of the meeting in real time. The need for a Certificate of Medical Device Notification (CMDN), a Certificate of Medical Device Registration (CMDR) and a Certificate of Medical Device Listing (CMDL) from the Philippine FDA before approval of the protocol is emphasized in the decision. (See S*OP 21 - Preparing the Meeting Minutes*)

**Step 4 - Communicating of Committee Action to the researcher. Filing of protocol-related documents and updating the Protocol Database**: The REC Head reviews and signs the Action Letters/Approval Letters for issuance by the Office Secretary to the Principal Investigator. (See *SOP 22 - Communicating REC Decisions)***.** The Office Secretary records the recommendations in the *Protocol Reference Logbook* and *Database.*

## 6. Forms

*F08: Protocol & Consent Assessment Form*
*F12: Action Letter Template*
*F13: Approval Letter Template*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |

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|---|---|---|---|
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*New device - a device which is not part of the standard of care provided for the clinical condition being studied in a protocol. This device needs to be registered with the FDA if it is to be used for research purposes.*

*Full Board Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Independent Consultant - Resource persons who are not members of the Research Ethics Committee, whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.*

*Minor Modification – is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g., incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*Resubmissions - revised study proposals that are submitted after the initial review.*

*Protocol-related Documents - consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,*

*Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.*

*Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.*

## 9. References


*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

*DOH AO 2018-0002: Guidelines Governing the Issuance of an Authorization for a Medical Device based on ASEAN Harmonized Technical Requirements*

## 1. Policy Statement

The REC shall conduct review of pandemic related protocols and other emergency situations taking into consideration the need for an efficient and timely process.

## 2. Objective of the Activity

This SOP is created to ensure the continuity of functions of the REC and to prioritize review for pandemic related protocols and other emergency situations relevant for the common good and ensure the safety of the research participants, REC members and secretariat staff and research investigators.

## 3. Scope

This SOP begins with the receipt of pandemic related protocols and other emergency situations and ends with the filing of all related documents and update of the Protocol Database.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving, classifying, assigning protocols and notifying Primary Reviewers, and providing protocol related documents and assessment forms | REC Head/<br>Vice Head<br>Member Secretary<br>Secretariat Staff | 1-2 days |
| **Step 2:** Reviewing, assessing, and deciding on the protocol | **Expedited review:** Primary Reviewers<br>**Full review:** Primary Reviewers and REC Members | 1-2 weeks |
| **Step 3:** Collating and documenting committee deliberation and action | REC Head and Secretariat | 1 day |

| | | |
|---|---|---|
| **Step 4:** Communicating committee action to the researcher, filing of protocol related documents, and update of the Protocol Database | REC Head and Secretariat | 1 day |

**5. Description of Procedures**

**Step 1 - Receiving, classifying, assigning protocols and notifying Primary Reviewers, and providing protocol-related documents and assessment forms.** The Head/Vice Head or Member Secretary classify and assign the protocol to the Primary Reviewer. The REC Staff notify the Primary Reviewers and send the protocol-related documents and Assessment Forms.

**Step 2 - Reviewing, assessing, and deciding on the protocol.**

Expedited review: 5-7 days *See SOP 05*

Full review: 7-10 days See *SOP 06*

**Step 3 – Collating the review points for expedited review. Documenting committee deliberation and action from the Minutes of the meeting for full board review:** The REC Head approve the recommendation of the Primary Reviewer for expedited review. The REC Head review the committee decision made during the full board meeting.

**Step 4 - Communicating of committee action to the researcher, filing of protocol related documents, and updating Protocol Database**

**6. Forms**

*F08: Protocol & Consent Assessment Form*

**7. History of SOP**

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |

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|---|---|---|---|
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Epidemic - epidemic outbreaks an occurrence of more cases of diseases than normally expected within a specific place or groups of people over a given period (Republic Act 11332: Mandatory reporting of notifiable diseases and health events of public health concern)*

*Pandemic - a widespread occurrence of an infectious disease over a whole country or the world at a particular time*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

## 1. Policy Statement

The USTH REC participates in a joint review with the Single Joint Research Ethics Board (SJREB) for multi-site protocols to be conducted in at least 3 government hospitals, of which UST Hospital is a participating research site.

## 2. Objective of the Activity

Joint review with SJREB aims to demonstrate due diligence in review and to facilitate evaluation for multi-site protocols without prejudice to the national and international guidelines and to the institutional policies and values of UST Hospital.

## 3. Scope

This SOP applies to initial review of multi-site protocols and post-approval submissions which were submitted to the USTH REC and the SJREB.

It begins with the invitation from the SJREB for the joint review and ends with the inclusion of the review in the agenda of the next meeting.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY | TIMELINE |
|---|---|---|
| **Step 1:** Receiving the invitation for a joint review from SJREB with the relevant protocol documents. Entering the protocol into the Protocol Submission Logbook and Protocol Database | REC Secretariat | 1 day |
| **Step 2:** Notifying the REC Head and determination of the Primary Reviewers and | REC Secretariat and REC Head | 1 day |

| | | |
|---|---|---|
| Appointing the Reviewer to attend the SJREB meeting | | |
| **Step 3:** Sending the Protocol documents to Primary Reviewers and sending the COI & CA and the date of the meeting to the appointed Reviewer joining the SJREB meeting. | REC Secretariat | 2-3 days |
| Step 4a: Expedited Review: Reviewing, assessing and deciding on the protocol. *(See SOP 05 - Expedited Review)* | Primary Reviewers | 10-14 days |
| Step 4b: Full Board Review: Reviewing, assessing and deciding on the protocol. *See SOP 06 - Full Review* | REC Members | 10-14 days |
| **Step 5:** Attending the SJREB meeting by the assigned Primary Reviewer | Primary Reviewer | 1 day |
| **Step 6:** Reporting the review decision from SJREB in the REC meeting. Collating the comments for a final decision. | Primary Reviewer | 1-2 days |
| **Step 7:** Communicating decision to the PI from the minutes of meeting. Updating the Protocol File and Protocol Database. | REC Head and REC Secretariat | 1-2 days |

## 5. Description of Procedures

**Step 1 –. Receiving the invitation for a joint review from SJREB with the relevant protocol documents. Entering the protocol into the Protocol Submission Logbook and Protocol Database.** The REC Secretariat receives the invitation for a Joint Review from SJREB for multi-center protocols which includes UST Hospital as a research site. The REC Staff checks the completeness of the protocol documents and enters it into the Protocol Submission Logbook and Protocol Database. The SJREB Protocol Number in parenthesis appears after the USTH Protocol Reference Number in all Protocol Files and Database.

**Step 2 - Notifying the REC Head and determination of the Primary Reviewers and appointing the Reviewer to attend the SJREB meeting.** The REC Secretariat notifies the REC Head who will determine the type of review and assign the Primary Reviewers. Depending on the reviewer invited by SJREB, scientific or non-scientific, the REC Head assigns the Reviewer who will attend the SJREB meeting.

**Step 3 - Sending the Protocol documents to Primary Reviewers and sending the COI & CA and the date of the meeting to the appointed Reviewer joining the SJREB meeting.** The REC Secretariat sends the protocol documents to the Primary Reviewers and notifies the assigned Reviewer the date of SJREB meeting. The SJREB *B2 Confidentiality and Conflict of Interest Agreement for Participants, SJREB Form 2 Protocol Assessment Form* and *SJREB Form 3 Informed Consent Assessment Form* are also sent to the Reviewer attending the SJREB meeting.

**Step 4 - Step 4a: Expedited Review: Reviewing, assessing and deciding on the protocol.** The assigned Primary Reviewers review, assess and decide on the protocol.

**Step 4b: Full Board Review: Reviewing, assessing and deciding on the protocol.** The assigned Primary Reviewers present the protocol and the REC Members make decision on the protocol. In both type of reviews, the Primary Reviewers will determine the site-specific modifications required in UST Hospital site.

**Step 5 - Attending the SJREB meeting by the assigned Primary Reviewer.** The assigned Primary Reviewer attends the SJREB meeting, presents the review points on the protocol and takes note of the final decision on the protocol after discussion.

**Step 6 - Reporting/appending the review decision from SJREB.** The SJREB decision is reported to the REC Head and the REC Head decides whether the decision may be released and appended in the next meeting or included in the agenda for discussion.

**Step 7 - Communicating decision to the PI from the minutes of meeting. Updating the Protocol File and Protocol Database.** The REC Head signs the Action Letter prepared by the REC Staff from the minutes of the meeting and sends it to the Principal Investigator by e-mail. The REC Secretariat files the relevant documents into the Protocol File and updates the Protocol Database.

## 6. Forms

*F12: Action Letter Template*
*F13: Approval Letter Template*
*SJREB Form B2 Confidentiality and Conflict of Interest Agreement for Participants*
*SJREB Form 2 Protocol Assessment Form*
*SJREB Form 3 Informed Consent Assessment Form*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |

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|---|---|---|---|
| 5 | 2023<br>June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template;<br>Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024<br>January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |
| 7 | 2025<br>June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*SJREB - Single Joint Research Ethics Board is an ethics board that conducts joint review for multi-site protocols done in at least three government hospitals and USTH to facilitate decision-making*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Full Review - the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Protocol Submission Logbook - a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.*

*Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different roles or duties are not compatible such that decisions may adversely affect the official/primary duty.*

*Confidentiality – is the duty to not freely disclose private/research information entrusted to an individual or organization.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGHRIP) 2022*

| UNIVERSITY OF SANTO TOMAS HOSPITAL<br>España Blvd., Manila | Document Code: MD-ST-IR | Issue No 1 | Revision No 7 |
|---|---|---|---|
| Name of Manual:<br>**RESEARCH ETHICS COMMITTEE STANDARD OPERATING PROCEDURES** | **Effective Date:** June 23, 2025 | Page No. 161 of 375 | |
| | **Document Title:**<br>**SOP No. 31<br>Writing & Revising SOPs** | | |
| **Prepared by:**<br>**Josephine M. Lumitao, MD, MHPEd, FPOGS<br>REC Head** | **Approved by:**<br>CHARITO P. MALONG CONSOLACION, MD,MHA<br>Medical Director | | |

## 1. Policy Statement

SOPs ensure efficiency, transparency, and consistency of REC operations. The SOP manual needs to be periodically reviewed to determine the need for revision or creation of new SOPs to respond to emerging operational issues of the REC.

The REC Head shall designate the Vice Head who creates an SOP Sub-Committee Team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations. The SOP Sub-Committee Team shall consist of the Vice Head and two (2) Regular Members.

## 2. Objective of the Activity

Writing and revising SOPs ensures continuing quality assurance and relevance of REC functions.

## 3. Scope

This SOP applies to all REC activities involved in the development of its SOPs and their revisions as published and distributed by the institution.

It begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

## 4. Workflow

| ACTIVITY | RESPONSIBILITY |
|---|---|
| **Step 1:** Proposing for a revision or writing of a new SOP and the members of the SOP Sub-Committee Team | REC Vice Head |
| **Step 2:** Approving proposal and the SOP Sub-Committee Team | REC Head |

| | |
|---|---|
| **Step 3:** Drafting of the revision or new SOP | SOP Sub-Committee Team |
| **Step 4:** Reviewing and finalizing the SOP | REC Members |
| Step 5. Submitting the finalized SOP to the institutional authority | REC Head |
| **Step 6:** Including the new or revised SOP in the SOP Manual and its dissemination | REC Staff |

## 5. Description of Procedures

**Step 1 - Proposing for a revision or writing of a new SOP**: The REC Vice Head is responsible for ascertaining the need for new SOP and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including REC Members. He/she is likewise responsible for recommending two (2) Regular Members as part of the SOP Sub-Committee Team.

**Step 2 - Approving the proposal and the SOP Sub-Committee Team**: The REC Head will approve the proposal and the recommended members of the SOP Sub-Committee Team.

**Step 3 - Drafting of the revision or new SOP**: The SOP Sub-Committee Team is responsible for proposing design and format as well as the substantial contents of the SOP.

In designing this template, the following contents are included:

(a) Title, which is descriptive of contents
(b) Policy statement
(c) Objective/s of the activity, which defines the purpose and intended outcome
(d) Scope, which defines the extent of coverage of the SOP and its limitations
(e) Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step
(f) Detailed instructions, which elaborates the steps listed in workflow
(g) Forms, documents to be accomplished by different parties as required by the SOP
(h) Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
(i) Glossary – acronyms and terms which need to be defined
(j) References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

The REC Staff codes the SOP, using SOP Version Number, the date (month and year) it was created, and its effectivity date.

**Step 4 - Reviewing and finalizing the SOP**: The SOP Sub-Committee Team presents the revised SOP to the REC Members through a meeting where discussion, determination of favorable action, decisions are made by a majority vote and documentation of action is done**.**

The draft of the new SOP is submitted to the Quality Management Office (QMO) for review and approval to ensure alignment with the quality standards of the hospital. Once approved, the QMO returns the manual to the REC for the signature of the REC Head.

**Step 5 – Submitting the SOP to the institutional authority**: The REC Head submits the signed SOP to the UST Hospital Medical Director for final approval.

**Step 6 - Including the new or revised SOP in the SOP Manual and its dissemination**: The REC Staff will distribute copies of the approved SOP to the members by e-mail within 3-5 days. Additionally, an electronic copy is provided to the office of the CEO, Medical Director, Department of Medical Education & Research (DMER), and in the REC website. A hard copy of the approved SOP is filed by the REC Staff under the supervision of the Member Secretary. The custodian of the official approved copy is the REC Vice Head. The approved SOP may only be reproduced with permission from the REC and the Head of the Quality Management Office. In case of amended or revised SOP, the old version is superseded and stored in the Archive. The updated SOP is filed together with the REC Administrative Files.

## 6. Forms

*F31 Request for Creation/Revision of an SOP*

## 7. History of SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 1 | 2014 September 01 | Dr. ALL Enriquez, TF Artuz, LS Blanco | First draft for 1st PHREB accreditation |
| 2 | 2019 January 15 | Dr. JM Lumitao, Dr. ALL Enriquez, TF Artuz, LS Blanco | Revision in preparation for 2nd PHREB reaccreditation |
| 3 | 2019 April 15 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco | Revision in conformance to PHREB reaccreditation |
| 4 | 2020 August 01 | Dr. JM Lumitao, Dr. ALL Enriquez, LS Blanco, MJ Aquino | Pandemic hospital wide SOP revisions |
| 5 | 2023 June 15 | Dr. ALL Enriquez, Dr. JM Lumitao, Dr. ER Advincula; Dr. MO Mateo, Dr. CMG Trinidad, Dr. SIO Cortez, Dr. JD Ngo, Sr. MVC Cordero, JRB Macindo, LS Blanco | Followed the PHREB SOP Workbook Template; Revision in preparation for 3rd PHREB reaccreditation |
| 6 | 2024 January 26 | Dr. JM Lumitao, Dr. ER Advincula; LS Blanco | Revision following the PHREB audit findings |

| | | | |
|---|---|---|---|
| 7 | 2025 June 23 | Dr. JM Lumitao, Dr. ALL Enriquez, Dr. SIO Cortez, Ms. CC Morota, LS Blanco | Revision following the PHREB audit findings; Deletion of Scholastica |

## 8. Glossary

*Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.*

*Coding – unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.*

*Format - general style or layout of the document*

*Date of Effectivity – date when the guidelines shall be enforced.*

## 9. References

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*

# GLOSSARY

***Glossary***

*Action Letter - an official written communication issued by the Research Ethics Committee (REC) to the Principal Investigator (PI) or research team that conveys the REC's decision on a submitted research protocol or related documents. The Action Letter outlines the outcome of the IRB review, including approval status, required modifications, conditions for approval, or reasons for disapproval. It also provides instructions on the necessary next steps and deadlines for compliance, serving as a formal record of the IRB's correspondence and decisions.*

*Active Files – are documents pertaining to protocols which are currently being assessed, managed or monitored by the REC.*

*Active Study – is an ongoing study, implementation of which is within the period covered by ethics clearance.*

*Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.*

*Administrative Documents/File – documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.*

*Administrative Issuance – official communications or announcements from institutional authorities*

*After-approval reports – are reports, e.g., progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.*

*Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".*

*Alternate Members – individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.*

*Amendment – a change in or revision of the protocol made after it has been approved.*

*Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.*

*Appeal – a request of a researcher/ investigator for a reconsideration of REC recommendation.*

*Appointing authority - the institutional official that has the power to designate or appoint individuals to specific offices or roles.*

*Approval Letter - a specific type of Action Letter issued by the Research Ethics Committee (REC) that officially grants approval for a research protocol to proceed. The letter outlines the conditions of approval, duration of the approval period, and any continuing review or reporting requirements.*

*Archiving- is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.*

*Assessment Form– evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.*

*Benefits – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value*

*Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.*

*Clarificatory Interview/meeting – is a face-to-face consultation between the REC and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.*

*Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period as a significant step in quality control.*

*Clinical Monitor - an individual who oversees the progress of a clinical trial.*

*Clinical Trial – a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers in order to discover or verify the effects of and/or identify and adverse reactions to investigational products with the object of ascertaining their efficacy and safety.*

*Coding - a unique number assigned to a document. A protocol code indicates the year and order of receipt. The SOP code indicates its serial position among the other SOPs and its version number.*

*Collegial Decision – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered as a group action and is not ascribed to any one member.*

*Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.*

*Confidentiality – is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.*

*Confidentiality of Documents – pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the REC must not be freely shared or disclosed.*

*Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.*

*Conforme - an indication of acceptance of or agreement to an assignment or designation*

*Consensus – a collective agreement. The process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objections are registered.*

*Continuing Review - is the decision of the REC to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.*

*Controlled document – pertains to the document that have been entrusted or submitted to the REC that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded. .*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary*

*Date of Effectivity – date when the guidelines shall be enforced.*

*Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.*

*Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the REC Head for his/her approval.*

*Draft Meeting Minutes – Proceedings of the meeting prepared by the Secretariat.*

*Drug or device – health product used for diagnosis or treatment.*

*Early Termination - is ending the implementation of a study before its completion. This is a decision made by the sponsor or a regulatory authority and/or recommended by the Data Safety Monitoring Board, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.*

*Exempt from Review – a decision made by the REC Head or designated member of the committee regarding a submitted study proposal based on criteria in the NEGRIHP 2022 The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.*

*Exemption Report – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.*

*Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.*

*Expedited Review Reports – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review presented during a regular REC meeting for information of the REC members and for record purposes.*

*Final Meeting Agenda - is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Members in a regular or special meeting.*

*Final Meeting Minutes – Proceedings of the meeting that have been approved by the REC members.*

*Final Reports/ Close Out Reports – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.*

*Format- general style or layout of the document*

*Full Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.*

*Honorarium- monetary payment for a specific professional service.*

*Inactive Study – a study whose proponent has not communicated with the REC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the REC.*

*Incoming Communications – are documents which are directed to and received at the REC office.*

*Independent Consultant - Resource persons who are not members of the Research Ethics Committee, whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

*Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC for assessment that can be expedited or full review*

*Initial Submission – a set of documents consisting of the full proposal and other study-related documents that is received by the REC so that ethical review can be done.*

*Intellectual property – refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.*

*Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.*

*Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.*

*Major Modification – is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.*

*Majority rule - is a policy based on the principle that the decision made by the greater number should be carried/accepted.*

*Meeting Minutes – the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.*

*Medical Members – are individuals with academic degrees in the medical profession and a master's in the nursing profession.*

*Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Minor Modification - is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g., incomplete documentation, incomplete IC elements, unsatisfactory IC format)*

*More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution since they do not receive regular salary or stipend from the institution.*

*Non-medical members - are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.*

*Non-Scientists – are individuals whose primary interest is not in any of the natural, physical and social sciences and whose highest formal education is a bachelor's degree.*

*Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.*

*Outgoing Communications – are documents generated within the REC office intended for individuals or offices related to the operations of the REC.*

*Physical Plant Division – unit within the institution that is in charge of the maintenance and use of physical facilities.*

*Post-approval reports – are reports, e.g., progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the REC for submission by the researcher/investigator after the study has been approved for implementation.*

*Primary Reviewer - a regular or an alternate member of the Research Ethics Committee or an Independent Consultant who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee. However, an Independent Consultant is not required to review the ethical criteria of a protocol.*

*Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial*

*Progress Report – A systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form (F19). The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.*

*Protocol – the documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.*

*Protocol Database - is an organized record of information which includes the assigned protocol number, Protocol Title, authors, submission date, review classification, assigned reviewers, date of release of action letters, and post-approval information including but not limited to amendments, deviations, progress report, early termination, protocol deviation, protocol violation, SAEs/SUSARs, site visits, final report, archiving, and disposal dates. It is updated in real time and is managed by the office secretary under the supervision of the member secretary.*

*Protocol Deviation – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.*

*Protocol File/Folder – is an organized compilation of all documents (physical or electronic form) related to a study.*

*Protocols for Full Review – Study proposals that require an en banc ethical because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.*

*Protocol Index – is a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.*

*Protocol-related Documents - consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions.*

*Protocol Tracking Form – is a chronological record of the document's activity in the protocol file. The tracking form is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The tracking form is included in the protocol file/folder for easy reference and checking.*

*Protocol Violation - non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.*

*Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Head.*

*Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer.*

*Query – the act of asking for information or clarification about a study.*

*Quorum – For RECs with nine members, a quorum requires at least 5 members, otherwise a quorum shall follow the 50% + 1 rule. A quorum also requires the presence of at least one non-medical or non-scientist and one non-affiliated member to make decisions about the proposed research. (WHO 2011)*

*Real-time Recording – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.*

*REC Operations - the overall activities of the REC that reflect performance of its functions and responsibilities.*

*Regular Meeting – a periodically scheduled assembly of the REC.*

*Regular Members – are members constituting the research to ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.*

*Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research*
*Institutions*

*Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,*

*Researcher - is the individual primarily responsible for the conceptualization, planning and implementation of a study.*

*Researcher-Initiated Studies – are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.*

*Resubmissions - the revised study proposals that are forwarded to the REC in response to the recommendations given during the initial review.*

*Reviewer - a regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.*

*Risks – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.*

*Room-use Restriction – the rule that limits the use of a document within the designated premises.*

*Scientists – are individuals whose formal education is at least a master's degree in a scientific discipline, e.g. biology, physics, social science, etc.*

*Serious Adverse Event (SAE) – is an event observed during the implementation of a study where the outcome is any of the following:*

- *Death*
- *Life threatening*
- *Hospitalization (initial or prolonged)*
- *Disability or permanent damage*
- *Congenital anomaly/ birth defect*
- *Required intervention to prevent permanent impairment or damage (devices)*
- *Other serious (important medical) events whether or not it is related to the study intervention.*

*Site Visit – is an action of the REC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.*

*Site Visiting Team – members/staff of the REC (2-4 members) assigned by the REC Head to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.*

*Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.*

*Sponsor - an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.*

*Sponsored Clinical Trials – are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization,*

*protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.*

*Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an activity.*

*Status of participants – summary of what happened to (condition of) participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol.*

*Study Documents – include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for review.*

*Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REC and the researcher.*

*Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.*

*SUSAR – Suspected Unexpected Serious Adverse Reaction – is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.*

*SAE Subcommittee – a group of experts designated to analyze SAE/SUSAR reports and make the necessary recommendations to the REC. The experts may or may not be members of the REC.*

*Termination package - refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned.*

*Term of office – the specified length of time that a person serves in a particular designation /role.*

*Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.*

*Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.*

# REC
# FORMS

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St. Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


## CURRICULUM VITAE AND TRAINING RECORD FORM

| Last Name: | First Name: | Middle Name: |
|---|---|---|
| Position in the REC: | Address: | |
| Date of 1st Appointment: | Contact No.: | |
| Term of Office: | E-mail: | |
| 1. Education Background | | |
| 1.1. Post-graduate degree | | |
| 1.2. Graduate degree | | |
| 1.3. Bachelor's degree | | |
| 1.4. Other qualifications and specializations | | |
| 2. Work Experience | | |
| 2.1. Occupation | | |
| 2.2. Present Work Experience | | |
| 2.3. Previous Work Experience | | |
| 3. Publications and patents (as applicable) | | |
| *add fields as needed | | |

## TRAINING RECORD

| BASIC COURSES | | Training Provider | Venue | Date | USTH Funded (Y/N) | |
|---|---|---|---|---|---|---|
| 1 | GCP Training | | | | ☐ | ☐ |
| 2 | Research Ethics | | | | ☐ | ☐ |
| 3 | Standard Operating Procedures (SOP) | | | | ☐ | ☐ |

| CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures | | Training Provider | Venue | Date | USTH Funded (Y/N) | |
|---|---|---|---|---|---|---|
| 1 | | | | | ☐ | ☐ |
| 2 | | | | | ☐ | ☐ |
| 3 | | | | | ☐ | ☐ |
| 4 | | | | | ☐ | ☐ |
| 5 | | | | | ☐ | ☐ |

| AS A SPEAKER OR RESOURCE PERSON | | Training Provider | Venue | Date | USTH Funded (Y/N) | |
|---|---|---|---|---|---|---|
| 1 | | | | | ☐ | ☐ |
| 2 | | | | | ☐ | ☐ |
| 3 | | | | | ☐ | ☐ |

| Certified Correct: | | | |
|---|---|---|---|
| REC Member | Signature over<br>Printed Name: | | Date: |
| REC Head | Signature over<br>Printed Name: | | Date: |

**UNIVERSITY OF SANTO TOMAS HOSPITAL**
**RESEARCH ETHICS COMMITTEE**
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


## CONFIDENTIALITY AGREEMENT FORM

I sign this document as _____ of the **University of Santo Tomas Hospital – Research Ethics Committee (USTH-REC)** and voluntarily agree not to disclose or reproduce any confidential information and/or research protocols under consideration during the course of my activities with the Committee, or anytime afterwards.

Confidentiality covers information or materials prepared by the investigators, and/or sponsors for the ethics committee review either in written or verbal forms. This information includes technical and scientific data, financial and personal information concerning wages, remunerations, salaries and benefits. I agree to return the related data or document to the office of REC after the completion of the activity.

In case I have to disclose the confidential information by court order, I will so inform the committee within two (2) days after notification.

| | |
|---|---|
| Signature: | |
| Name: | |
| Institutional Affiliation: | |
| Date: | |

| | |
|---|---|
| **Noted by:** | |
| Signature: | |
| Name of REC Head: | |
| Date: | |

## DISCLOSURE OF CONFLICT OF INTEREST FORM

In general, *Conflict of Interest* occurs when there is conflict (actual, potential or perceived) between an individual's duties and his/her personal or private interest. *Conflict of Interest* impairs one's abilities to exercise objectivity in the performance of official duties.

The Members (including the REC Head) of the University of Santo Tomas Hospital – Research Ethics Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of research protocols and other related documents.

The following can be used as a guide to determining whether he/she has *Conflict of Interest*.

***INSTRUCTIONS TO USTH-REC MEMBERS OR INDEPENDENT CONSULTANTS***

*Before affixing your signature below, please consider each of the following statements in relation to: 1) all your past and current official positions; and 2) all your immediate family members, especially spouse and children. Then, TICK your answer in the 'yes' or the 'no' column.*

| STATEMENTS | YES | NO |
|---|---|---|
| • I/My family have owned stocks and shares in the proponent organization(s). | ☐ | ☐ |
| • I/My family have received a salary, an honorarium, a compensation, concessions and gifts from the proponent organization(s). | ☐ | ☐ |
| • I/My family have served as an officer, director, advisor, trustee, consultant or an active participant in the activities of the proponent organization(s). | ☐ | ☐ |
| • I/My family/my other organizations have had research work experience with the principal investigator(s). | ☐ | ☐ |
| • I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency. | ☐ | ☐ |
| • I/My family have regular social activities, such as parties, home visits and sports events, with the principal investigator(s). | ☐ | ☐ |
| • I/my family/my other organizations have an interest in or an ownership issue against the proposed topic. | ☐ | ☐ |

*As a Member/Independent Consultant of the USTH-REC, I shall disclose any conflict of interest that I may have in connection with the review of specific research protocols and related documents. I shall do this before or during any deliberations so that I may not participate in the decision regarding the said protocol.*

| | |
|---|---|
| Signature: | |
| Name: | |
| Institutional Affiliation: | |
| Date: | |

**UNIVERSITY OF SANTO TOMAS HOSPITAL**
**RESEARCH ETHICS COMMITTEE**
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


Date

**NAME**
Department and Position
Institutional Affiliation

**Subject:** Appointment as REC Officer

Dear **Name:**

You are hereby appointed as _____ of the **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** effective Date_Month_Year to Date_Month_Year.

**(As REC Head)**
Over and above duties as a Member, the Head shall have the following responsibilities:

1. Represent the REC in internal and external meetings and conferences.
2. Preside over REC Meeting.
3. Oversee review of protocols.
4. Assign Primary Reviewers of protocols based on expertise and experience.
5. Supervise development and revisions of SOPs.
6. Prepare and submit annual budget of the REC.
7. Prepare and submit annual report of the REC to the office of the Institutional Authority and to PHREB.
8. Ensure initial and continuing research ethics trainings of members and staff.

**(As REC Vice Head)**
Over and above duties as a Member, the Vice Head shall have the following responsibilities:

1. Perform duties of Head in his/her absence.
2. Perform tasks assigned by Head Participate in the review of research proposals and other related reports when requested.

**(As REC Member Secretary)**
Over and above duties as a Member, the Member Secretary shall have the following responsibilities:

1. Supervise the Secretariat Staff in the daily operations of the REC.
   a. Receipt of protocol documents
   b. Preparation of protocol files and folders
   c. Preparation of draft of communications
   d. Preparation of draft Agenda and Minutes
   e. Updating of records

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


2. Assist the REC Head in assigning Primary Reviewers.
3. Assist the REC Head in the preparation of the Agenda, Annual Report, and budget.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the **REC Head/ Vice Head/ Member Secretary** of the USTH-REC. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

**INSTITUTIONAL AUTHORITY**

**Conforme:**

_____
Name and Signature of Appointee
Date:

**UNIVERSITY OF SANTO TOMAS HOSPITAL**
**RESEARCH ETHICS COMMITTEE**
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Date

**NAME**
Department and Position
Institutional Affiliation

**Subject:** Appointment as REC Regular Member

Dear **Name:**

You are hereby appointed as _____ of the **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** effective Date_Month_Year to Date_Month_Year.

As REC **< Regular Member/Alternate Member >**, your responsibilities are as follows:

1. Attend REC meetings consistently.
2. Participate in the ethical review of research proposals and other related reports. The non-scientific member shall give special attention to the Informed Consent Form and process to ensure that these are comprehensible by ordinary persons and are considerate of community values.
3. Participate in the after-review activities, e.g., continuing review, site visits, etc.
4. Declare any conflict of interest (COI) in the review of research proposals.
5. Maintain confidentiality of the documents and deliberations of the REC meetings.
6. Attend continuing ethics education and other related activities.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be **< Regular Member/Alternate Member >** of the USTH-REC. Kindly signify your acceptance by signing the conforme below.

For the USTH Research Ethics Committee:

**INSTITUTIONAL AUTHORITY**

**Conforme:**

_____
Name and Signature of Appointee
Date:

**UNIVERSITY OF SANTO TOMAS HOSPITAL**
**RESEARCH ETHICS COMMITTEE**
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Date

**NAME**
Department and Position
Institutional Affiliation

**Subject:** Appointment as REC Independent Consultant

Dear **Name:**

You are hereby appointed as _____ of the **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** effective Date_Month_Year to Date_Month_Year.

Based on **USTH-REC Standard Operating Procedures**, *Independent Consultants are resource persons who are not members of the REC but whose scientific and technical expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.*

As **< REC Independent Consultant >**, your responsibilities are as follows:

1. Attend REC meeting when requested.
2. Participate in the review of research proposals and other related reports when requested.
3. Declare any conflict of interest (COI) in the review of research proposals.
4. Maintain confidentiality of the documents and deliberations of the REC meetings.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be **< Independent Consultant >** of the USTH-REC. Kindly signify your acceptance by signing the conforme below.

For the USTH – Research Ethics Committee:

**REC Head**

**Conforme:**

_____
Name and signature of Appointee
Date:

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## REQUIREMENTS CHECKLIST FORM

**Instructions to the Researcher:** All submissions must be made online in PDF format (except F08 - MS word) through the usthrec.online portal. After receiving acknowledgment from the REC Secretariat, a printed complete set must also be submitted to the REC Office. Submissions are accepted only on Wednesdays and Fridays from 9AM to 3PM. **Incomplete requirements will not be accepted.** The review process follows a first-come, first-served basis, and the cut-off for submissions is the last Wednesday/Friday of the month to be considered for review at the **3rd Thursday full review meeting.**

**Receiving Stamp/ Date of Submission:**

CLICK TO ENTER TEXT.

| | |
|---|---|
| **REC Protocol Ref. No.** | **CLICK TO ENTER TEXT.** |
| **Protocol No./Title:** | Click to enter text. |
| **Name of Investigator:** | Click to enter text. |
| **Department/Section:** | Click to enter text. |
| **Sponsor/CRO:** | Click to enter text. |

| Tick box | BASIC DOCUMENTS:<br>*all documents must be arranged in the following order:* | Must submit<br>*in pdf form except REC F08* |
|---|---|---|
| ☐ | 1. Request Letter | A formal letter requesting review, addressed to the REC Head, signed by **ALL** Principal Investigators. |
| ☐ | 2. Endorsement Letter or certification of technical review and approval. *For Investigator-Initiated Research Protocols, include/attach a Plagiarism Certificate confirming that the similarity index is 20% or lower. | A certification stating that the protocol has been technically reviewed, approved, and endorsed. *For USTH Trainees, this certification must be signed & issued by their Department Research Committee and noted by DMER.* |
| ☐ | 3. Requirements Checklist *(REC F06)* | Ensure all required documents are included. |
| ☐ | 4. Application Form *(REC F07)* | Must contain **relevant data and contact information** about the Principal Investigators, study team, and sponsors. |
| ☐ | 5. Research Protocol & Informed Consent Assessment Form *(REC F08)* | Must be **completely filled out**, including page and paragraph numbers. Submit in MS Word format |
| ☐ | 6. Certificate of Agreement & Compliance *(REC Form 22)* | Must be signed by ALL Principal Investigators |
| ☐ | 7. Clinical Trial Protocol/ Research Protocol | Provide the following:<br>▪ Protocol abstract/project summary<br>▪ Process flow chart of the protocol (not applicable for case report/series)<br>▪ Ethical considerations as a separate section in the protocol |
| ☐ | 8. Informed Consent Forms<br>In English and Filipino or dialect spoken & understood by research participants. | For research that poses **no more than minimal risk,** the REC may approve a request to waive some or all elements of informed consent under specific circumstances. Refer to *NEGRIHP 2022 Edition.* |
| ☐ | 9. Curriculum Vitae | An updated short resume of Principal Investigator and research team signed and dated. |
| ☐ | 10. Basic Research Ethics Training (BRET), Good Research Practice (GRP) or Good Clinical Practice (GCP) Training Certificate (as appropriate) | Training is mandatory for all staff involved in clinical research to ensure an understanding of ethical research principles. BRET, updated GRP or GCP certificates of the Principal Investigator and research team (valid for 3 years) must be issued by a certified local GCP provider. |
| ☐ | 11. Photocopy of REC Review Fee payment | Proof of payment (charge slip & official receipt) |
| ☐ | 12. Study Budget | Line-item budget of operational expenses & number of subjects for recruitment including honoraria for investigators, compensation for subjects, other research-related expenses etc. |

| Tick box | STUDY-SPECIFIC DOCUMENTS: | Submit as needed *in pdf form |
|---|---|---|
| ☐ | 1. Informed Consent Forms:<br>0 to < 7 — Parental Consent<br>7 to < 12 — Parental Consent + Verbal Assent Script<br>12 to < 15 — Parental Consent + Simplified Assent Form<br>15 to < 18 — Co-Sign ICF to be signed by the Participant & Parent<br>18 & above — Informed Consent Form for Adults | Must be provided in English and Filipino or a dialect spoken and understood by research participants.<br>For research that poses no more than minimal risk, the REC may approve a request to waive some or all elements of informed consent under specific circumstances.<br>(Refer to the *National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022 Edition.* |
| ☐ | • Investigator's Brochure or<br>• Basic Product Information document;<br>• Published literature/ medical device information | A - For phase I, II, III studies (for pharmaceutically sponsored clinical trial)<br>B - For phase IV studies |
| ☐ | 2. Case Report Form & Data Collection Forms | Only the specified data as required by the objectives of the clinical study should be taken. All personal identifiers are removed or replaced with codes. |
| ☐ | 3. Questionnaires / Survey Forms | Study instruments (e.g. surveys, questionnaires, interview guides, etc. & other tools that will be used in the study. |
| ☐ | 4. Recruitment Materials / Advertisements | Recruiting documents for participants (e.g. advertisements, posters, flyers, scripts, emails, social media posts, letters, identification cards, videos, etc.) |
| ☐ | 5. List of other sites (local and international) & assigned Principal Investigators | For multicenter local and global clinical trials<br>(with contact numbers and address) |
| ☐ | 6. Philippine FDA Protocol Approval/<br>FDA Proof of submission (for clinical trials) | Certification letter that protocol (including amendments) has been approved by the Philippine Food & Drug Administration (PFDA);<br>Required prior to the issuance of REC approval |
| ☐ | 7. Certificate of Medical Device Notification (CMDN) or Certificate of Medical Device Registration (CMDR) | For protocols using New Device: CMDN for class A devices (low risk) or CMDR for class B, C & D devices (low-moderate, moderate-high & high-risk) |
| ☐ | 8. **Others:**<br>Permission Letters, Memorandum of Agreement/ Understanding (MOA/MOU), Material Transfer Agreement (MTA), Insurance Coverage for trial/participants etc. | Letters to Medical Director, Data Privacy Officer (DPO), Dept Chairs or Unit Head requesting permission to conduct study & to access confidential records, facility use; MOA/MOU on collaboration terms, data ownership, publication rights; MTA for transfer of biological materials or data between institutions; Coverage insurance for trial participants, if applicable. |
| **Tick box below** | **REC PAYMENT FEES** | All REC payments are fixed fees and are net of all applicable taxes. |
| ☐ | **1. Company Sponsored Clinical Trials/ Agency/society-funded clinical trial** | Applicable to studies funded by pharmaceutical companies, funding agencies or approved grants |
| ☐ | • Initial Review Fee | **Php 60,000.** Must be paid prior to the initial review.<br>Non-refundable. |
| ☐ | • Continuing Review Fee | **Php 15,000.** Must be paid upon application for renewal of approval thirty (30) days before expiration date of REC approval; Non-refundable |
| ☐ | • Amendment Review Fee | **Php 7,500.** Must be paid upon application of any protocol amendment; Non-refundable. |
| ☐ | • Institutional Fee | 10% of the study budget for UST Hospital. Separate payment from the review fee. Must be paid after issuance of REC initial approval; Non-refundable. |
| ☐ | • Administrative & Research Fee<br>• Procedural fees (if applicable) | **Php 150,000** per annum or 10% of the total budget whichever is higher (storage room, rental utilities (excluding additional refrigerators) maintenance of area |
| ☐ | **2. Investigator-Initiated Research Protocols:** | Applicable to locally-developed protocols |
| ☐ | • USTH Consultants & Employees | **Php 20,000.** For agency funded protocols;<br>10% of the administrative cost of the grant or Php 5,000 whichever is higher. |
| ☐ | • USTH Trainees<br>(Fellows/Residents, Post Graduate Interns) | **Php 2,500** per protocol or 10% of administrative cost of the grant or Php 5,000 whichever is higher. |
| ☐ | • UST Undergraduate Students<br>(currently enrolled under Bachelor's Degree) | 10% of administrative cost of the grant or Php 3,500 whichever is higher. |
| ☐ | • UST Faculty Members (except USTFMS)<br>• UST Post-Graduate Students<br>(currently enrolled under Medicine, Law, Master's Degree) | 10% of the administrative cost of the grant or Php 7,500 whichever is higher |
| ☐ | • UST Doctorate Degree | 10% of administrative cost of the grant or Php 15,000 whichever is higher. |
| ☐ | • Continuing Review Fee<br>– For Consultants & Faculty Members | **Php 2,000.** Must be paid upon application for renewal of approval thirty (30) days before the REC approval expiration date. |

| | | |
|---|---|---|
| ☐ | **3. Non-UST Research Protocols** | 15% of the administrative cost of the grant or as follows whichever is higher.<br>▪ Students/Trainees – Php 10,000<br>▪ Professionals/ Masteral/ Doctorate) – Php 20,000 |
| | **REC PAYMENT INSTRUCTIONS** | |
| | **For ONLINE & CHEQUE payments:**<br>• See UST Hospital bank details | **Payee Name/Beneficiary**: UNIVERSITY OF SANTO TOMAS HOSPITAL<br>**Bank Name**: SECURITY BANK CORPORATION<br>**Bank Address**: Q. Pavillion UST España Blvd. Sampaloc Manila 1008 Philippines UST Branch<br>**Bank Account No**. 0171-008-008-011<br>**Swift Code**: SETCPHMM |
| | **For CASH & CHEQUE payments:** | ▪ Secure an electronic **Service Invoice** to be issued by the USTH-REC Secretariat Staff to be presented at the Cashier upon payment. |
| | **For Issuance of OFFICIAL RECEIPT:** | ▪ Submit a photocopy or scanned copy of the proof of cheque payment or online payment with the **Service Invoice** to the USTH Cashier for issuance of **Official Receipt.** |
| | **For submission of NEW Research Protocol/Clinical Trial:** | ▪ Include a photocopy or scanned copy of the proof of CHEQUE or ONLINE payment &/or OFFICIAL RECEIPT as proof of payment.<br>▪ Submit together with the REC Initial Submission Application Requirements through the USTH-REC portal: **usthrec.online** |

**GENERAL FORMATTING GUIDELINES:**

**Paper size:** A4 size
**Font:** Arial, size 11
**Folder:** 1.5 inch 2-hole black arch file
**Document Requirements: For New Protocols:**

1. Use double-spacing throughout, except for the title page.
2. Include supplementary documents (e.g., Informed Consent Forms (ICFs), Data Collection Form, Questionnaires, CV, GCP certificates, etc.). Ensure each document is **separately paginated** and placed in the appropriate order.
3. Properly accomplish, sign and date all required REC Forms. Submit in REC F08 MS Word format.
4. Number all pages **consecutively**, beginning with the title page.
5. Indicate the type of document with version no. and creation date in the footer, at the lower left corner of each document.
   - *Protocol Version No._ dated dd_month_ yyyy*
   - *ICF English/Filipino Version No._ dated dd_month_yyyy*
6. Paginate the documents separately indicating the page number followed by the total number of pages in the lower right corner.

**Paper size:** A4 size
**Font:** Arial, size 11
**Folder:** ordinary folder
**Document Requirements: For Resubmissions, Amendments & Final Reports:**

1. **Do not resubmit** CV and GCP certificates unless they have been updated.
2. Integrate revisions into the revised/amended research protocol, consent forms and any related documents. Highlight all changes made by **writing modified parts in bold text**.
3. Properly accomplish, sign and date all required REC Forms and submit in MS Word format.
4. Attach a copy of the previously issued REC Action Letter for REC Reviiewer's reference.
5. Indicate the type of protocol in the footer at the lower left corner along with the version number and creation date.
   **For Resubmissions:**
   - *Revised Protocol Version No. 2 dated dd_month_yyyy*
   - *ICF Version No. 2 dated dd_month_yyyy*

   **For Amendments:**
   *Protocol Amendment No. 1 dated dd_month_yyyy*
   **For Final Reports:**
   *Final Report Protocol Version No. 1 dated dd_month_yyyy*
6. Paginate the documents separately indicating the page number followed by the total number of pages in the lower right corner.

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## APPLICATION FORM FOR ETHICS REVIEW OF A NEW PROTOCOL

| Instructions to the Researcher:<br>Please complete this form accurately. Submit it along with a cover letter addressed to the REC Head. Attach the basic requirements as listed in the REC F06 Requirements Checklist. Submit this F07 Form as PDF files via usthrec.online | Receiving Stamp/<br>Date of Submission:<br><br>CLICK TO ENTER TEXT. |
|---|---|

| | | | |
|---|---|---|---|
| REC Protocol Reference No.:<br>*to be assigned by USTH-REC | CLICK TO ENTER TEXT. | | |
| Protocol No./Title: | Click to enter text. | | |
| Principal Investigator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Co-Investigator:<br>*add fields as needed | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Study Coordinator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Research/<br>Faculty Adviser : | Click to enter text. | | |
| Sponsor: | Click to enter text. | | |
| Office Address: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Contract Research Organization (CRO): | Click to enter text. | | |
| Office Address: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Category of Investigator:** | USTH Consultant ☐ | USTH Trainee Fellow ☐ | USTH Trainee Resident ☐ | USTH Trainee Graduated ☐ | USTH Employee ☐ | | | | | | |
| | UST Faculty ☐ | UST Graduate Student ☐ | UST Undergraduate Student ☐ | | Others: ☐ | | | | | | |
| | Investigator initiated research: ☐ | | Non-investigator-initiated research: ☐ | | | | | | | | |
| **Type of Study** | **Clinical trial (sponsored):** | ☐ | **Social/behavioral research:** | ☐ | **Biomedical research:** | ☐ | | | | | |
| | - *Phase 1* | ☐ | - *KAP* | ☒ | - *diagnostics* | ☐ | | | | | |
| | - *Phase 2* | ☐ | - *public health intervention* | ☐ | - *prospective* | ☐ | | | | | |
| | - *Phase 3* | ☐ | **Public health/ epidemiologic research:** | ☐ | - *Retrospective/ review of medical records* | ☐ | | | | | |
| | - *Phase 4/ PMS* | ☐ | - *prevalence* | ☐ | **Health operations:** | ☐ | | | | | |
| | **Clinical trial (researcher-initiated):** | ☐ | - *incidence* | ☐ | - *Health programs & policies* | ☐ | | | | | |
| | *Multicenter (international)* | ☐ | - *survey study* | ☐ | **Herbal research** | ☐ | | | | | |
| | *Multicenter (national)* | ☐ | **Internet research** | ☐ | **Complementary Alternative Medicine** | ☐ | | | | | |
| | **Case reports/ Case series** | ☐ | **Meta-analysis/ systematic review** | ☐ | **Stem cell research** | ☐ | | | | | |
| **Source of funding** | Self-funded | ☐ | Scholarship/ Research grant | ☐ | Institution- funded | ☐ | | | | | |
| | Government funded | ☐ | Sponsored by pharma company | ☐ | Others: | ☐ | | | | | |
| **Duration of the study:** Click to enter text. | | | **Start date:** Click to enter text. | | **End date:** Click to enter text. | | | | | | |
| **Study Budget For USTH:** Click to enter text. | | | **Study Site:** **specify assigned location/office* Click to enter text. | | **No. of Target Participants:** Click to enter text. | | | | | | |
| **Initial Review Fee** | **Service Invoice No.** | | **Date Issued** | | **Official Receipt No.** | | **Payment Date** | | | | |
| | Click to enter text. | | | | Click to enter text. | | | | | | |
| **Institutional Fee** | **Service Invoice No.** | | **Date Issued** | | **Official Receipt No.** | | **Payment Date** | | | | |
| | Click to enter text. | | | | Click to enter text. | | | | | | |
| **Has the research undergone technical review?** *If yes, attach technical review results | Yes ☐ | No ☐ | Click to enter text. | | | | | | | | |
| **Has the research been submitted to another REC?** (e.g. SJREB) *If yes, please indicate | Yes ☐ | No ☐ | Click to enter text. | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature: CLICK TO ENTER TEXT. | | | | Date: | | | | | | |

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## RESEARCH PROTOCOL & INFORMED CONSENT ASSESSMENT FORM

**Instructions:**
**To the Principal Investigator:** Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. Submit this F08 form in Word file format.

**To the Reviewer:** Kindly evaluate how the assessment points outlined below have been addressed by the clinical trial/research protocol & Informed Consent Form (ICF). Confirm the submitted information by putting your comments in the space provided under "Reviewers Comments". Summarize your comments in the space provided and finalize your review by indicating your conclusions under "Recommendation". Sign and date the space provided for the reviewers.

**Receiving Stamp/ Date of Submission:**

CLICK TO ENTER TEXT.

| | |
|---|---|
| **REC Protocol Reference No.:** **to be assigned by USTH-REC* | CLICK TO ENTER TEXT. |
| **Protocol No./Title:** | Click to enter text. |
| **Principal Investigator:** | Click to enter text. |
| **Sponsor/CRO:** | Click to enter text. |

| **PART I: RESEARCH PROTOCOL CHECKLIST**<br>**Guide questions for reviewing the proposal/ protocol** | **TO BE FILLED-UP BY THE PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | **TO BE FILLED-UP BY THE REC REVIEWER** |
|---|---|---|---|---|---|
| | **Clear** | **Not clear** | **Unable to assess** | **Put page & paragraph where it is found** | **Reviewer's Comments & Recommendations** |
| **I. Title Page**<br>Includes Study Title, Principal Investigator Name, contact information, and affiliation; Co-Investigator – Name and affiliation; Study Duration – start & end dates of the study & Protocol Version No. & Date (footer) | ☐ | ☐ | ☐ | | Click to enter text. |
| **II. Abstract** | | | | | |
| • **Overview of Study**<br>Brief description of study objectives, methodology, and expected outcomes. | ☐ | ☐ | ☐ | | Click to enter text. |
| **III. Introduction** | | | | | |
| • **Background Information**<br>Context of the research, literature review, and theoretical foundation | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Study Objectives**<br>General & specific objectives. Ensure objectives are SMART (Specific, Measurable, Attainable, Relevant, Time-bound). | ☐ | ☐ | ☐ | | Click to enter text. |
| **IV. Definition of Terms**<br>Operational definitions of key terms to clarify terminology for readers. | ☐ | ☐ | ☐ | | Click to enter text. |
| **V. Study Design and Methodology** | | | | | Click to enter text. |
| • **Study Design** – Type of study (e.g., RCT, cohort, observational, etc.). | ☐ | ☐ | ☐ | | Click to enter text. |

| | | | | | |
|---|---|---|---|---|---|
| • **Methodology**<br>• Detailed step-by-step description of study procedures & interventions. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Primary & Secondary Outcomes**<br>Clearly defined outcomes and how they will be measured. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Sample Size**<br>Statistical justification for the number of participants. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Control Groups/Placebo**<br>Justification for any use of control groups or placebos. (if applicable) | ☐ | ☐ | ☐ | | Click to enter text. |
| **VI. Participant Information** | | | | | |
| • **Inclusion criteria**<br>Criteria for selecting participants. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Exclusion criteria**<br>Criteria for excluding participants | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Withdrawal criteria**<br>Circumstances under which participants can be withdrawn from the study. | ☐ | ☐ | ☐ | | Click to enter text. |
| **VII. Data Analysis Plan** | | | | | |
| • **Statistical Methods**<br>Outline of the analysis plan, including the type of statistical tests to be used, handling of missing data, and any software to be employed (e.g., SPSS, SAS, R). | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Analysis of Primary & Secondary Outcomes**<br>How the study's outcomes will be analyzed | ☐ | ☐ | ☐ | | Click to enter text. |
| **VIII. Ethical Considerations** section in the protocol | | | | | |
| • **Compliance:**<br>Statement that research will comply with both international & local ethical regulations. (Declaration of Helsinki, ICH-GCP guidelines, & the NEGRIHP 2022 Edition). | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Ethical Review**<br>Statement that the protocol will be reviewed & approved by USTH-REC. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Informed Consent Process**<br>How participants will be informed about the study, the nature of their participation, and the voluntary nature of their involvement. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Confidentiality and Data Protection**<br>a. Data Anonymization - Participants' personal data is anonymized<br>b. Data Security - Procedures for secure data storage & handling.<br>c. Data Sharing & Retention - How data will be shared & retained, ensuring confidentiality.<br>d. Data Disposal - Procedures for securely destroying data after the study ends. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Risk Assessment and Minimization**<br>a. Risk Identification - Identify & assess potential risks to participants.<br>b. Risk Minimization – Strategies to reduce or manage risks.<br>c. Adverse Event Reporting - Procedures for monitoring, documenting, & reporting any adverse events. | ☐ | ☐ | ☐ | | Click to enter text. |

| | | | | | |
|---|---|---|---|---|---|
| • **Risk Assessment and Minimization**<br>a. **Risk Identification** – Identify & assess potential risks to participants.<br>b. **Risk Minimization** – Strategies to reduce or manage risks.<br>c. **Adverse Event Reporting** – Procedures for monitoring, documenting, & reporting any adverse events. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Participant Safety and Monitoring**<br>a. **Safety Monitoring** – Procedures for monitoring participant safety throughout the study.<br>b. **Adverse Event Monitoring** – Specific protocols for managing adverse events. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Special Considerations for Vulnerable Participants**<br>Identification & protection of vulnerable population (e.g., minors, pregnant women, cognitively impaired individuals) | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Investigator/s & Research Team**<br>PI qualifications, experience, roles & responsibilities of the team; Institutional support, facilities & resources for conducting the study. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Recruitment Process**<br>a. Recruitment Methods - non-coercive, voluntary<br>b. Participant Remuneration (if applicable) - Appropriate payment & does not unduly influence participation.<br>c. Informed Recruitment - Methods to ensure participants are fully informed about the study before consenting. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Conflict of Interest**<br>Investigators & Study Team should disclose any financial or personal COI & strategies for managing conflicts to maintain the integrity of the study. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Community Impact and Local Considerations**<br>Local communities are consulted, assess how the study benefits them (e.g., healthcare improvements or capacity building), & outline plans for sharing study results with participants & the community. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Specimen/Sample Handling & External Collaborations**<br>a. Standards for the collection, use, & storage of biological samples.<br>b. MTAs – agreements when transferring biological materials between institutions. | ☐ | ☐ | ☐ | | Click to enter text. |
| c. **Budget and Funding**<br>Detailed breakdown of study costs and how the funds will be used & source of funding | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Dissemination of Study Results**<br>Plans to publish study results in peer-reviewed journals. | ☐ | ☐ | ☐ | | Click to enter text. |
| • **Study Timeline and Gantt Chart**<br>Detailed timeline of protocol submission, approval, recruitment, data collection, data analysis, final report, & publication submission | ☐ | ☐ | ☐ | | Click to enter text. |
| **PART II: INFORMED CONSENT CHECKLIST** | **TO BE FILLED-UP BY THE PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | **TO BE FILLED-UP BY THE REC REVIEWER** |

| Guide questions for reviewing the informed consent process and form | Indicate If the protocol contains the specified point | | | Page & paragraph where it is found | Reviewer's Comments & Recommendations |
|---|---|---|---|---|---|
| | Clear | Not clear | Unable to assess | | |
| Is it necessary to seek the informed consent of the participants? | ☐ | ☐ | ☐ | | Click to enter text. |
| **If NO, please explain.** | | | | | |
| **If YES, are the participants provided with sufficient information regarding:** | | | | | |
| 1. Informed Consent Form has 2 parts:<br>a. Participant Information Sheet<br>b. Consent Form | ☐ | ☐ | ☐ | | Click to enter text. |
| 2. Does the Informed Consent document state that the procedures are primarily intended for research? | ☐ | ☐ | ☐ | | Click to enter text. |
| 3. Are procedures for obtaining Informed Consent appropriate? | ☐ | ☐ | ☐ | | Click to enter text. |
| 4. Does the Informed Consent document contain comprehensive and relevant information? | ☐ | ☐ | ☐ | | Click to enter text. |
| 5. Is the information provided in the protocol consistent with those in the consent form? | ☐ | ☐ | ☐ | | Click to enter text. |
| 6. Are study-related risks mentioned in the consent form? | ☐ | ☐ | ☐ | | Click to enter text. |
| 7. Is the language in the Informed Consent document understandable? | ☐ | ☐ | ☐ | | Click to enter text. |
| 8. Is the Informed Consent translated into the local language/dialect? | ☐ | ☐ | ☐ | | Click to enter text. |
| 9. Are there vulnerable participants? | ☐ | ☐ | ☐ | | Click to enter text. |
| 10. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? | ☐ | ☐ | ☐ | | Click to enter text. |
| 11. Are names and contact numbers from the research team and the REC in the informed consent? | ☐ | ☐ | ☐ | | Click to enter text. |
| 12. Does the ICF provide privacy & confidentiality protection? | ☐ | ☐ | ☐ | | Click to enter text. |
| 13. Is there any undue inducement for participation? | ☐ | ☐ | ☐ | | Click to enter text. |
| 14. Is there provision for medical/psychosocial support? | ☐ | ☐ | ☐ | | Click to enter text. |
| 15. Is there provision for treatment of study-related injuries | ☐ | ☐ | ☐ | | Click to enter text. |
| 16. Is the amount paid to participants stated? | ☐ | ☐ | ☐ | | Click to enter text. |

**TO BE FILLED-UP BY THE USTH- REC REVIEWER:**

*Summarize your assessment review comments in this space provided:*

| | | |
|---|---|---|
| RECOMMENDATIONS: | ☐ | FOR CLARIFICATORY INTERVIEW |
| | ☐ | APPROVED |
| | ☐ | MINOR REVISIONS |
| | ☐ | MAJOR MODIFICATIONS |
| | ☐ | DISAPPROVED<br>State Reasons for Disapproval: |

| | | |
|---|---|---|
| REC REVIEWER: | Name & Signature:<br>CLICK TO ENTER TEXT. | Date: |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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Email: usth_irb@yahoo.com.ph Website: usthrec.online

**PROVISIONAL AGENDA FORM**

**<ordinal> REGULAR MEETING**
**<DD/MM/YYYY>**
**Time, Venue**

**AGENDA OF THE MEETING:**

1. OPENING PRAYER
2. CALL TO ORDER
3. DECLARATION OF QUORUM
4. APPROVAL OF THE PROVISIONAL AGENDA
5. DISCLOSURE OF CONFLICT OF INTEREST
6. REVIEW & APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING (Date)
7. BUSINESS ARISING FROM THE MINUTES OF THE MEETING
8. NEW BUSINESS
9. FULL REVIEW OF PROPOSALS:

9.1. NEW PROTOCOLS FOR INITIAL FULL REVIEW:

**9.1.1.**

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Quorum Status | |
| Discussion | 1. In Protocol:<br>a. Scientific Soundness<br>b. Technical Soundness<br>c. Ethical Soundness<br>i. Social Value<br>ii. Vulnerability issue<br>iii. Measures to protect vulnerability population |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
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| | | |
|---|---|---|
| | iv. Risk/benefit ratio<br>v. Measures to mitigate risks<br>vi. Confidentiality and privacy<br>vii. Informed Consent process, form and content<br>2. **In Informed Consent Forms:** | |
| Recommendations: | | |
| Decision Points: | ☐ | Minor Modifications for expedited review on resubmission |
| | ☐ | Major Modifications |
| | ☐ | Approved |
| | ☐ | Disapproved |

9.2. **PROTOCOLS FOR CLARIFICATORY INTERVIEW:**

**9.2.1.**

| | | |
|---|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** | |
| Submission Date | < Date_Month_Year > | |
| Protocol No./Title | | |
| Principal Investigator | | |
| Department | | |
| Sponsor | | |
| Type of Research | | |
| Type of Review | | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> | |
| Documents Submitted | | |
| Quorum Status | | |
| Discussion | | |
| Recommendations: | | |
| Decision Points: | ☐ | Minor Modifications for expedited review on resubmission |
| | ☐ | Major Modifications |
| | ☐ | Approved |
| | ☐ | Disapproved |

9.3. **RESUBMITTED PROTOCOLS FOR FULL REVIEW:**

**9.3.1.**

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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| | | |
|---|---|---|
| Type of Review | | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> | |
| Documents Submitted | | |
| Quorum Status | | |
| Discussion | | |
| Recommendations: | | |
| Decision Points: | ☐ | Minor Modifications for expedited review on resubmission |
| | ☐ | Major Modifications |
| | ☐ | Approved |
| | ☐ | Disapproved |

9.4. PROTOCOL AMENDMENTS FOR FULL REVIEW:

9.4.1.

| | | |
|---|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL | |
| REC Initial Approval Date | | |
| Submission Date | < Date_Month_Year > | |
| Protocol No./Title | | |
| Principal Investigator | | |
| Department | | |
| Sponsor/CRO | | |
| Type of Research | | |
| Type of Review | | |
| Primary Reviewers | | |
| Documents Submitted: | | |
| Summary & Reasons for Amendment | Current REC Approved Protocol / Proposed Amendments: / Reason/Justification for the Amendments: | |
| Quorum Status | | |
| Discussion | | |
| Recommendations: | | |
| Decision Points: | ☐ | Approved |
| | ☐ | Disapproved |
| | ☐ | Reconsent required |
| | ☐ | Additional information required |

9.5. PROTOCOL DEVIATION & VIOLATION REPORTS FOR FULL REVIEW:

9.5.1.

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
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| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew: |
| Details of Protocol Deviation | 6. Description of Reported Deviation/Violation<br>7. Nature of Deviation/Violation<br>8. Impact of deviation/violation on participants' risks/harms and integrity of data<br>9. Investigator's assessment on impact of deviation on credibility of data:<br>10. Description of investigators corrective action and preventive action (CAPA):<br>11. Sponsor assessment of severity:<br>**12.** Description of Sponsor corrective action:<br>13. Actions taken to prevent future deviation/violation: |
| Quorum Status | |
| Discussion | |
| Recommendations: | |
| Decision Points: | ☐ Notation with no further action required<br>☐ Require additional information<br>☐ Require corrective and preventive action<br>☐ Invitation to a clarificatory interview<br>☐ Requirement for an amendment<br>☐ Site visit<br>☐ Suspension of recruitment<br>☐ Withdrawal of ethical clearance |

**9.6. CONTINUING REVIEW APPLICATIONS & PROGRESS REPORTS FOR FULL REVIEW:**

9.6.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |

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| | |
|---|---|
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| USTH-REC Approval Date | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew:<br>6. Deviations from the approved protocol:<br>7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:<br>8. Issues/problems encountered:<br>9. Progress Status (short description and indicate completion status, e.g., 50% complete, 75% complete):<br>10. Justification for application for Continuing Review: |
| Quorum Status | |
| Discussion | |
| Recommendations: | |
| Decision Points | ☐ Approved<br>☐ Disapproved<br>☐ Require additional information<br>☐ Submission of an explanation for failure to submit required reports |

9.7. **FINAL REPORTS FOR FULL REVIEW:**

9.7.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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| | |
|---|---|
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. End of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew:<br>6. Deviations from the approved protocol:<br>7. Issues/problems encountered: |
| Summary of Results & Conclusion | 8. Results:<br>9. Conclusions:<br>10. Actions for dissemination of study results: |
| Quorum Status | |
| Discussion | |
| Recommendations: | |
| Decision Points | ☐ Approved<br>☐ Request information<br>☐ Recommend further action |

9.8. **EARLY TERMINATION REPORTS FOR FULL REVIEW:**

9.8.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew: |
| Details of Early Termination | 6. Reason/s for cancellation/termination:<br>7. Support mechanisms/interventions for enrolled participants<br>8. Post-termination actions: |
| Quorum Status | |
| Discussion | |
| Recommendations: | |
| Decision Points | ☐ Approval of the decision |

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6th Floor St. John Macias O.P. Building
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| | |
|---|---|
| | ☐ Request for additional information<br>☐ Require further action |

9.9. **SAE & SUSARS SAFETY REPORTS FOR FULL REVIEW:**

9.9.1.

| | | |
|---|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL | |
| REC Initial Approval Date | | |
| Submission Date | < Date_Month_Year > | |
| Protocol No./Title | | |
| Principal Investigator | | |
| Department | | |
| Sponsor/CRO | | |
| Type of Research | | |
| Type of Review | | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> | |
| Documents Submitted: | | |
| ***Assessment of SAEs reported*** | | |
| SAE 1 | Submission Date | |
| | Date of SAE | |
| | Subject No. Age/Sex | |
| | Country | |
| | Nature of AE | |
| | Report No. | |
| Quorum Status | | |
| Discussion | | |
| Recommendations: | | |
| Decision Points | ☐ Notation with no further action required<br>☐ Require further information<br>☐ Require further action<br>☐ Suspension of recruitment | |

9.10. **SITE VISIT REPORTS FOR FULL BOARD REVIEW:**

9.10.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |

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6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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| | |
|---|---|
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew:<br>6. Deviations from the approved protocol:<br>7. Onsite SAE reports: |
| SAE/Pharmacovigilance Team Report: | 8. Date & Time of Visit:<br>9. Reasons for site visit:<br>10. Name of REC Representatives<br>11. Study Team present during visit:<br>12. Findings: |
| Quorum Status | |
| Discussion | |
| Decision Points | ☐ Continue study and post approval monitoring<br>☐ Amend Protocol &/or Informed Consent<br>☐ Stop Recruitment<br>☐ Terminate Study<br>☐ Blacklist Principal Investigator / Sponsor<br>☐ Recommend other corrective measures (specify)<br>☐ Others (specify) |

9.11. **QUERIES OR COMPLAINTS:**

9.11.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Details of queries/ complaints | |
| Discussion | |
| Decision: | |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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## 10. REPORT ON EXPEDITED REVIEW OF PROPOSALS:

### 10.1. NEW PROTOCOLS FOR EXPEDITED REVIEW:

10.1.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

### 10.2. RESUBMITTED PROTOCOLS FOR EXPEDITED REVIEW:

10.2.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

### 10.3. PROTOCOL AMENDMENT APPLICATION FOR EXPEDITED REVIEW:

10.3.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |

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| | |
|---|---|
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Summary & Reasons for Amendment | Current REC Approved Protocol / Proposed Amendments: / Reason/Justification for the Amendments: |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

10.4. PROTOCOL DEVIATION/ NON-COMPLIANCE & VIOLATION REPORTS FOR EXPEDITED REVIEW:

10.4.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew: |
| Details of Protocol Deviation | 6. Description of Reported Deviation/Violation<br>7. Nature of Deviation/Violation<br>8. Impact of deviation/violation on participants' risks/harms and integrity of data<br>9. Investigator's assessment on impact of deviation on credibility of data: |

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6th Floor St. John Macias O.P. Building
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| | |
|---|---|
| | 10. Description of investigators corrective action and preventive action (CAPA):<br>11. Sponsor assessment of severity:<br>12. Description of Sponsor corrective action:<br>13. Actions taken to prevent future deviation/violation: |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

10.5. CONTINUING REVIEW APPLICATION FOR EXPEDITED REVIEW:

10.5.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| USTH-REC Approval Date | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew:<br>6. Deviations from the approved protocol:<br>7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:<br>8. Issues/problems encountered:<br>9. Progress Status (short description and indicate completion status, e.g., 50% complete, 75% complete):<br>10. Justification for application for Continuing Review: |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

10.6. FINAL REPORTS FOR EXPEDITED REVIEW:

10.6.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |

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6th Floor St. John Macias O.P. Building
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| | |
|---|---|
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. End of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew:<br>6. Deviations from the approved protocol:<br>7. Issues/problems encountered: |
| Summary of Results & Conclusion | 8. Results:<br>9. Conclusions:<br>10. Actions for dissemination of study results: |
| Recommendations: | |
| Decision | ☐ Approved<br>☐ Request information<br>☐ Recommend further action |
| Decision Letter Date | |

**10.7. CANCELLED PROTOCOLS REPORT:**

10.7.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Research | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Study Updates | 1. Start of study:<br>2. Expected end of study:<br>3. Number of required participants:<br>4. Number of enrolled participants:<br>5. Number of participants who withdrew: |
| Details of Cancellation | 6. Reason/s for cancellation/termination: |

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6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
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Email: usth_irb@yahoo.com.ph Website: usthrec.online

| | |
|---|---|
| | 7. Support mechanisms/interventions for enrolled participants<br>8. Post-termination actions: |
| Recommendations: | |
| Decision | ☐ Approval of the decision<br>☐ Request for additional information<br>☐ Require further action |
| Decision Letter Date | |

**11. PROTOCOLS EXEMPT FROM REVIEW:**

11.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Research | |
| Type of review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Recommendations: | |
| Decision | |
| Decision Letter Date | |

**12. OTHER MATTERS:**

**13. ADJOURNMENT:**

**Agenda of the meeting prepared by:**

_____
**SIGNATURE OVER PRINTED NAME**
REC Office Secretary

**Reviewed by:**

_____
**SIGNATURE OVER PRINTED NAME**
REC Member Secretary

**Noted by:**

_____
**SIGNATURE OVER PRINTED NAME**
REC Head

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
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A.H. Lacson St. Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: *usth_irb@yahoo.com.ph*


## MINUTES OF THE MEETING FORM

<ordinal> REGULAR MEETING
<DD/MM/YYYY>
Time, Venue

**ATTENDANCE:**

**Present:**

| No. | Name of Member | Initials | Designation | Expertise |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |

**Also Present:**

| No. | Name of Member | Initials | Designation | Expertise |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |

**Absent:**

| No. | Name of Member | Initials | Designation | Expertise |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |

**AGENDA OF THE MEETING:**

1. OPENING PRAYER
2. CALL TO ORDER
3. DECLARATION OF QUORUM
4. APPROVAL OF THE PROVISIONAL AGENDA
5. DISCLOSURE OF CONFLICT OF INTEREST
6. REVIEW & APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING (Date)
7. BUSINESS ARISING FROM THE MINUTES OF THE MEETING
8. NEW BUSINESS
9. FULL REVIEW OF PROPOSALS:

9.1. NEW PROTOCOLS FOR INITIAL FULL REVIEW

**9.1.1.**

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Discussion/Comments: | **1. In Protocol:**<br>a. Scientific Soundness<br>b. Technical Soundness<br>c. Ethical Soundness<br>i. Social Value<br>ii. Vulnerability issue<br>iii. Measures to protect vulnerability population<br>iv. Risk/benefit ratio<br>v. Measures to mitigate risks<br>vi. Confidentiality and privacy<br>vii. Informed Consent process, form and content<br>**2. In Informed Consent Forms:** |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

9.2. PROTOCOLS FOR CLARIFICATORY INTERVIEW

**9.2.1.**

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

9.3. **RESUBMITTED PROTOCOLS FOR FULL REVIEW**

**9.3.1.**

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor | |
| Type of review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

8.3. **PROGRESS REPORTS FOR FULL REVIEW**

8.3.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| USTH-REC Approval Date | |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

8.4. **PROTOCOL AMENDMENT FOR FULL REVIEW**

8.4.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |

| | |
|---|---|
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| USTH-REC Approval Date | |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

8.5. **PROTOCOL DEVIATION & VIOLATIONS REPORT FOR FULL REVIEW**

8.5.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

8.6. **SAE and SUSAR REPORTS FOR FULL REVIEW**

8.6.1.

| | | |
|---|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** | |
| REC Initial Approval Date | | |
| Submission Date | < Date_Month_Year > | |
| Protocol No./Title | | |
| Principal Investigator | | |
| Department | | |
| Sponsor/CRO | | |
| Type of Review | | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> | |
| Documents Submitted: | | |
| ***Assessment of SAEs reported*** | | |
| SAE 1 | Submission Date | |
| | Date of SAE | |

| | | |
|---|---|---|
| | Subject No. Age/Sex | |
| | Country | |
| | Nature of AE | |
| | Report No. | |
| Recommendations: | | |
| Decision: | | |
| Decision letter date | | |

8.7. CONTINUING REVIEW APPLICATIONS FOR FULL REVIEW

8.7.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| USTH-REC Approval Date | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

8.8. FINAL REPORTS FOR FULL REVIEW

8.8.1.

| | | |
|---|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL | |
| REC Initial Approval Date | | |
| Submission Date | < Date_Month_Year > | |
| Protocol No./Title | | |
| Principal Investigator | | |
| Department | | |
| Sponsor/CRO | | |
| Type of Review | | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> | |
| Documents Submitted: | | |
| Summary of Results | No. of study participants in the beginning of the study: | |
| | No. of participants at the end of the study: | |
| | Duration of the study (inclusive dates: | |
| | Initial Recruitment Date: | |
| | End of Recruitment Date: | |
| Conclusion | | |
| Recommendations: | | |
| Decision: | | |
| Decision letter date | | |

8.9. EARLY TERMINATION REPORTS FOR FULL REVIEW

8.9.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

## 8.10. SITE VISIT REPORTS FOR FULL BOARD REVIEW

8.10.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| REC Initial Approval Date | |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

## 8.11. QUERIES OR COMPLAINTS

8.11.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | **YYYY/MM/NNN/LL** |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Sponsor/CRO | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Details of queries/ complaints | |
| Recommendations: | |
| Decision: | |
| Decision letter date | |

## 9. REPORT ON EXPEDITED REVIEW OF PROPOSALS

### 9.1. NEW PROTOCOLS FOR EXPEDITED REVIEW

| No. | USTH-REC Prot. Ref. No | Protocol No./Title | Principal Investigator | Primary Reviewers | Status |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |

### 9.2. RESUBMITTED PROTOCOLS FOR EXPEDITED REVIEW

| No. | USTH-REC Prot. Ref. No | Protocol No./Title | Principal Investigator | Primary Reviewers | Status |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |

### 9.3. PROTOCOL AMENDMENT APPLICATION FOR EXPEDITED REVIEW

| No. | USTH-REC Prot. Ref. No | Protocol No./Title | Principal Investigator | Primary Reviewers | Status |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |

### 9.4. CONTINUING REVIEW APPLICATION FOR EXPEDITED REVIEW

| No. | USTH-REC Prot. Ref. No | Protocol No./Title | Principal Investigator | Primary Reviewers | Status |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |

### 9.5. FINAL REPORTS FOR EXPEDITED REVIEW

| No. | USTH-REC Prot. Ref. No | Protocol No./Title | Principal Investigator | Primary Reviewers | Status |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |

## 10. PROTOCOLS FOR EXEMPT REVIEW

10.1.

| | |
|---|---|
| USTH-REC Prot. Ref. No. | YYYY/MM/NNN/LL |
| Submission Date | < Date_Month_Year > |
| Protocol No./Title | |
| Principal Investigator | |
| Department | |
| Type of Review | |
| Primary Reviewers | <Name of Primary Reviewer – Dept> |
| Documents Submitted: | |
| Comments and Recommendations | |
| Decision: | |
| Decision letter date | |

11. OTHER MATTERS

12. ADJOURNMENT

**Minutes of the meeting taken and prepared by:**

_____
**SIGNATURE OVER PRINTED NAME**
REC Office Secretary

**Reviewed, corrected and approved by:**

_____
**SIGNATURE OVER PRINTED NAME**
REC Head
Date:

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


## RESUBMISSION FORM

| Instructions to the Researcher: | Receiving Stamp/<br>Date of Submission: |
|---|---|
| Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach the Revised Protocol, ICFs, and any other relevant documents requiring revisions. Submit this F11 Form as a Word document and other documents as PDF files via usthrec.online | CLICK TO ENTER TEXT. |

| | | | |
|---|---|---|---|
| REC Protocol Reference No.: | CLICK TO ENTER TEXT. | | |
| Protocol No./Title: | Click to enter text. | | |
| Name of Investigator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Department: | Click to enter text. | Institution: | Click to enter text. |
| Sponsor/CRO: | Click to enter text. | | |
| Documents Submitted: | Click to enter text. | | |

| To be filled-out by the Principal Investigator | | To be filled-out by the REC |
|---|---|---|
| REC RECOMMENDATIONS FROM LAST REVIEW (paste below & add rows as needed) | REVISIONS MADE BY THE PRINCIPAL INVESTIGATOR<br>Were the recommendations met? (Yes/No) Explain and highlight changes in the protocol submitted. Indicate page number where changes are made, if applicable | REVIEWER COMMENTS |
| | | |
| | | |
| | | |
| | | |
| | | |

| | | |
|---|---|---|
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br><br>CLICK TO ENTER TEXT. | Date: |
| | **To be filled-out by the REC Primary Reviewer** | |
| **Additional comments:** | | |
| **RECOMMENDATION:** | ☐ **APPROVAL** | |
| | ☐ **MINOR MODIFICATION** | |
| | ☐ **MAJOR MODIFICATION** | |
| | ☐ **DISAPPROVED** | |
| **REC REVIEWER:** | Name & Signature:<br><br>CLICK TO ENTER TEXT. | Review Date: |

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RESEARCH ETHICS COMMITTEE
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Email: usth_irb@yahoo.com.ph Website: usthrec.online


Date

**NAME**
Designation
Department Affiliation
Institution

**Re:** Action Letter to the Review of **< New/Resubmitted/Amended >** Protocol
**REC Protocol Reference No.:**
**Protocol No./Title:**
**Sponsor/CRO:**

**Dear _____:**

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** acknowledges receipt of your **< Research Protocol Version No. >** and its related documents, submitted online on Date_Month_Year. These have been assessed through **< expedited/full > review.**

Below are the specific scientific, technical, and ethical issues that require clarification or modification prior to further consideration and approval:

1. **In Protocol:**
   a. **Scientific Soundness:**
   b. **Technical Soundness:**
   c. **Ethical Soundness:**

2. **In Informed Consent Forms:**

3. **Others:**

**For the USTH – Research Ethics Committee:**

**< SIGNATURE OVER PRINTED NAME >**
REC Head

# UNIVERSITY OF SANTO TOMAS HOSPITAL
## RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
**Email:** usth_irb@yahoo.com.ph **Website:** usthrec.online


Date

**NAME**
Designation
Department Affiliation
Institution

**Re: Approval Letter to the Review of < New/Resubmitted > Protocol**
**REC Protocol Reference No.:**
**Protocol No./Title:**
**Sponsor/CRO:**

**Dear _____:**

**The University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC) acknowledges receipt of your < Research Protocol Version No. > and its related documents, submitted online on Date_Month_Year. These have been assessed through < expedited/full > review.**

The REC grants ethical approval for your < nature of study >.

**Validity of Ethics Approval:** DATE_MONTH_YEAR to DATE_MONTH_YEAR

Please be reminded that the study team must always adhere to the principles of *Good Clinical Practice (GCP)* and the *National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022.*

**The following responsibilities must be observed by the investigator after approval:**

- Utilize USTH-REC stamped Informed Consent Forms (ICFs). Approved consent forms must include the USTH-REC stamp and the approval date in the document footer.
- Submit any amendments to the Protocol and/or Informed Consent Form (using ***REC F14***) for approval prior to implementation.
- Apply for Continuing Review (using ***REC F19***) for renewal of ethical clearance at least thirty (30) days before the expiration of the protocol approval; failure to do so will result in withdrawal of ethical clearance.
- Be advised that if a continuing review application is not submitted within one (1) year, the REC will implement standard procedures for non-compliance, which may lead to a recommendation for withdrawal of ethical clearance and subsequent inactivation and archiving of the study file.

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Email: usth_irb@yahoo.com.ph Website: usthrec.online

- Submit Related Non-Events (RNE), Serious Adverse Events (SAE), and Suspected Unexpected Serious Adverse Reactions (SUSAR) reports (using ***REC F15***) to the site REC within seven (7) days.
- Report any Protocol Deviations or Violations (using *REC F16*) within seven (7) days upon detection.
- **Submit the Final Report** (using ***REC F18***) **no later than eight (8) weeks after completing protocol procedures at the study site.**
- Submit an Early Termination Form (using ***REC F17***) if the approved study is terminated prior to completion.
- Ensure compliance with all relevant international and national guidelines and regulations regarding the safety and protection of study participants.

The following items have been received, reviewed, and approved in connection with the study to be conducted by the investigator:

| No. | Document Name | Version No. | Date |
|---|---|---|---|
| 1 | **Research Protocol** | | |
| 2 | **Informed Consent Forms** | | |
| 3 | **CV & GCP Training Certificate of Investigator** | | |
| 3.1 | | | |
| 3.2 | | | |

Furthermore, we would like to inform you that the Research Ethics Committee of the University of Santo Tomas Hospital is organized and operates according to Good Clinical Practice and applicable laws and regulations.

For requests regarding REC forms or any inquiries, please contact us at **+63 2 8731-3001 local 2610** or visit the USTH REC website at ***usthrec.online***.

**For the USTH – Research Ethics Committee:**

**JOSEPHINE M. LUMITAO, MD, MHPEd, FPOGS**
REC Head

# UNIVERSITY OF SANTO TOMAS HOSPITAL
## RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
**Email:** usth_irb@yahoo.com.ph *Website: usthrec.online*


## COMMITTEE COMPOSITION

Name of Institution: UNIVERSITY OF SANTO TOMAS HOSPITAL (USTH)

Address of Institution: España Blvd., Manila, Philippines, 1015

| No. | Name of Member | REC Designation/ Department/Expertise | Affiliation w/ the institution | |
|---|---|---|---|---|
| | | | Yes | No |
| 1 | | Head | ☐ | ☐ |
| 2 | | Vice Head | ☐ | ☐ |
| 3 | | Member Secretary | ☐ | ☐ |
| 4 | | Regular Member | ☐ | ☐ |
| 5 | | Regular Member | ☐ | ☐ |
| 6 | | Regular Member | ☐ | ☐ |
| 7 | | Regular Member | ☐ | ☐ |
| 8 | | Regular Member | ☐ | ☐ |
| 9 | | Regular Member<br>Non-medical/Layperson | ☐ | ☐ |

| Signed: | | |
|---|---|---|
| USTH - REC Head | Printed Name & Signature | Date of Approval |
| | REC Head | Date_Month_Year |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
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Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online

## PROTOCOL AMENDMENT FORM

| **Instructions to the Researcher:** Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach the amended Protocol, ICFs, and any other relevant documents requiring amendment. Submit this **F14 Form** as a Word document and other documents as PDF files via **usthrec.online** | **Receiving Stamp/ Date of Submission:** CLICK TO ENTER TEXT. |
|---|---|

| | | | |
|---|---|---|---|
| **REC Protocol Reference No.:** | CLICK TO ENTER TEXT. | | |
| **Protocol No./Title:** | Click to enter text. | | |
| **Name of Investigator:** | Click to enter text. | | |
| **Contact No.:** | Click to enter text. | **Email address:** | Click to enter text. |
| **Department:** | Click to enter text. | **Section:** | Click to enter text. |
| **Sponsor/CRO:** | Click to enter text. | | |
| **Current REC Approved Protocol/ICF:** (Protocol Version No. & Date) Click to enter text. | | **Proposed Amendments:** (Protocol/ICF Amendment Version No. & Date) Click to enter text. | |

**To be filled-out by the Principal Investigator**

| **Current REC Approved Protocol/ICF/Others** *List the document(s) and specific portions that are approved by the REC* | **Proposed Amendments:** *Explain & specify the exact document and section/portion that needs to be amended. Include page number/s.* | **Reason/Justification for the Amendments:** *Provide a clear and detailed explanation for why these amendments are necessary* |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

| | | |
|---|---|---|
| **Type of Amendments** (check all that apply):<br>☐ Revision to currently approved *Protocol*<br>☐ Revision to currently approved *Consent Forms* change<br>☐ Other (e.g., advertisement) | | ☐ Minor<br>☐ Major |
| **Effect on Risks** (check one):<br>☐ This amendment ***does not*** increase risks to participants enrolled in the study<br>☐ This amendment ***does*** increase risks to participants enrolled in the study | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>CLICK TO ENTER TEXT | Date: |
| **To be filled-out by the REC Primary Reviewer** | | |
| Does the amendment increase the risks to participants? | | ☐ Yes<br>☐ No |
| Does the amendment increase the benefits to participants? | | ☐ Yes<br>☐ No |
| Is there favorable benefit/risk ratio? | | ☐ Yes<br>☐ No |
| **Additional comments:** | | |

| | | |
|---|---|---|
| **RECOMMENDATION:** | ☐ | **APPROVAL** |
| | ☐ | **REQUEST FOR FURTHER INFORMATION/MODIFICATION** |
| | ☐ | **RECONSENT REQUIRED** |
| | ☐ | **DISAPPROVAL** |
| **REC REVIEWER:** | Name & Signature:<br>CLICK TO ENTER TEXT | Review Date: |

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RESEARCH ETHICS COMMITTEE
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Email: usth_irb@yahoo.com.ph Website: usthrec.online


## SERIOUS ADVERSE EVENT SAE & SUSARS FORM

| | |
|---|---|
| **Instructions to the Researcher:**<br>Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach other relevant documents in relation to the SAE/SUSARS. Submit the F15 Form as a Word document and other documents as PDF files via usthrec.online | **Receiving Stamp/ Date of Submission:**<br>CLICK TO ENTER TEXT. |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **REC Protocol Reference No.:** | CLICK TO ENTER TEXT. | | | | | | |
| **Protocol No./Title:** | Click to enter text. | | | | | | |
| **Name of Investigator:** | Click to enter text. | | | | | | |
| **Sponsor:** | Click to enter text. | **CRO:** | Click to enter text. | | | | |
| **Study Site:** | Click to enter text. | **On-site** | ☐ | **Off-site** | ☐ | | |
| Name of the study drug/device: | Date of first use: | | | | | | |
| Onset Date: | ☐ | Initial Report | ☐ | Follow-up Report | Report Date: | | |
| Patient's Code:<br>Click to enter text. | Age:<br>Click to enter text. | ☐ | Male | ☐ | Female | | |
| Patient's Date of Birth:<br>Click to enter text. | Weight: kg | Height: cm | | | | | |
| Relevant medical history and concurrent conditions:<br>Click to enter text. | | | | | | | |

**I. REACTION INFORMATION:**

| | |
|---|---|
| _____<br>(use CIOMS definition)<br>List all relevant tests/ lab data: | **Check all appropriate:** |
| | ☐ Resulting in death |
| | ☐ Required in-patient hospitalization/prolonged hospitalization |
| | ☐ Persistent or significant disability or incapacity |
| | ☐ Life threatening |
| | ☐ Pregnancy |

**II. SUSPECT DRUG/S INFORMATION:**

| | | | | | | |
|---|---|---|---|---|---|---|
| Suspect drug/s (include generic name):<br>Click to enter text. | | **Did reaction abate after stopping drug?** | | | | |
| | | ☐ | Yes | ☐ | No | ☐ NA |
| Daily dose/s:<br>Click to enter text. | Route of administration:<br>Click to enter text. | **Did reaction appear after reintroduction?** | | | | |
| | | ☐ | Yes | ☐ | No | ☐ NA |
| Indication/s for use:<br>Click to enter text. | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Therapy date/s: (from/to) | | | | Therapy duration: | | | | | | |
| Is this reaction | ☐ | Expected | ☐ | Unexpected | ☐ | Related | ☐ | Not related | | |
| Treatment Given for Adverse Event:<br>Click to enter text. | | | | | | | | | | |
| Causality Assessment by Investigator: | ☐ | Certain | ☒ | Probable | ☐ | Possible | ☐ | Unlikely | ☐ | Unclassifiable |
| Outcome of reaction/event at the time of last observation: | ☐ | Recovered | ☐ | Recovering | ☐ | Recovering with sequelae | | | | |
| | ☐ | Not recovering | ☐ | Death | ☐ | Unknown | | | | |

**III. NARRATIVE DESCRIPTION OF THE EVENT:**
Click to enter text.

**IV. CONCOMITANT DRUG/S AND HISTORY:**

Concomitant drug/s and dates of administration (exclude drug used to treat reaction)
Click to enter text.

Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
Click to enter text.

**V. MANUFACTURER'S INFORMATION:**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Name and address of manufacturer: | Click to enter text. | | | | | | | |
| Manufacturer control no.: | Click to enter text. | | | | | | | |
| Date received by manufacturer:<br>Click to enter text. | Report source: | ☐ | Study | ☐ | Literature | ☐ | Health professional | |
| Date of this report:<br>Click to enter text. | Report type: | ☐ | Initial | ☐ | Follow-Up | | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>CLICK TO ENTER TEXT. | | | | | | Date: | |

**VI. CURRENT STATUS OF PARTICIPANT:**

**TO BE FILLED-UP BY THE BY THE USTH-REC SAE SUBCOMMITTEE TEAM:**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **TYPE OF REVIEW** | **FULL REVIEW** | | | | ☐ | **EXPEDITED REVIEW** | | | | ☐ |
| Causality Assessment by SAE Subcommittee Team: | ☐ | Certain | ☐ | Probable | ☐ | Possible | ☐ | Unlikely | ☐ | Unclassifiable |

**REVIEWER'S COMMENTS:** *(Must determine causality of SAE independent of the PI's judgement)*

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online

## PROTOCOL DEVIATION & VIOLATION FORM

| Instructions to the Researcher: Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach other relevant documents in relation to the deviation/violation. Submit this F16 Form as a Word document and other documents as PDF files via usthrec.online | Receiving Stamp/ Date of Submission: CLICK TO ENTER TEXT. |
|---|---|

| | | | |
|---|---|---|---|
| REC Protocol Reference No.: | CLICK TO ENTER TEXT. | | |
| Protocol No./Title: | Click to enter text. | | |
| Name of Investigator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Department: | Click to enter text. | Institution: | Click to enter text. |
| Sponsor/CRO: | Click to enter text. | | |
| Ethical clearance effectivity period: Click to enter text. | | Study Site: Click to enter text. | |

**Protocol Deviation & Violation:**

| | |
|---|---|
| 1. Start of study: | Click to enter text. |
| 2. Expected end of study: | Click to enter text. |
| 3. Number of required participants: | Click to enter text. |
| 4. Number of enrolled participants: | Click to enter text. |
| 5. Number of participants who withdrew: | Click to enter text. |

6. **Description of Reported Deviation/Violation:** *(Describe/explain the reported deviation/ violation. Identify who committed the deviation - i.e. Patient, Investigator, Sponsor, Research Coordinator)*

**Click to enter text.**

| | | | | |
|---|---|---|---|---|
| 7. Nature of Deviation/Violation: | MAJOR | ☐ | MINOR | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| 8. Investigator's assessment on Impact of deviation/violation on participants' risks/harms and integrity of data:<br>**Click to enter text.** | | | | | |
| 9. Investigator's assessment on impact of deviation on credibility of data:<br>**Click to enter text.** | | | | | |
| 10. Description of Investigator's corrective action and preventive action (CAPA):<br>**Click to enter text.** | | | | | |
| 11. Sponsor assessment of severity: | **MAJOR** | ☐ | **MINOR** | ☐ | |
| 12. Description of Sponsor corrective action:<br>**Click to enter text.** | | | | | |
| 13. Actions taken to prevent future deviation/violation:<br>**Click to enter text.** | | | | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT.** | | Date: | | |
| **To be filled-out by the REC Primary Reviewer** | | | | | |
| **Reviewer's comments on the following:** | | | | | |
| Impact of Deviation on Participant's risks or harms: | Click to enter text. | | | | |
| Impact of deviation on integrity and credibility of data: | Click to enter text. | | | | |
| Corrective actions: | Click to enter text. | | | | |
| **RECOMMENDATION:** | ☐ | **REQUIRE ADDITIONAL INFORMATION** | | | |
| | ☐ | **REQUIRE CORRECTIVE & PREVENTIVE ACTION** | | | |
| | ☐ | **INVITATION TO A CLARIFICATORY INTERVIEW** | | | |
| | ☐ | **REQUIREMENT FOR AN AMENDMENT** | | | |
| | ☐ | **SITE VISIT** | | | |
| | ☐ | **SUSPENSION OF RECRUITMENT** | | | |
| | ☐ | **WITHDRAWAL OF ETHICAL CLEARANCE** | | | |
| **REC REVIEWER:** | Name & Signature:<br>**CLICK TO ENTER TEXT** | | Review Date: | | |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth irb@yahoo.com.ph Website: usthrec.online


## EARLY TERMINATION / CANCELLED PROTOCOL FORM

| Instructions to the Researcher: | Receiving Stamp/<br>Date of Submission: |
|---|---|
| Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach the amended Protocol, ICFs, and any other relevant documents requiring amendment. Submit this F17 form as a Word document and other documents as PDF files via usthrec.online | CLICK TO ENTER TEXT. |

| | | | |
|---|---|---|---|
| REC Protocol Reference No.: | CLICK TO ENTER TEXT. | | |
| Protocol No./Title: | Click to enter text. | | |
| Name of Investigator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Department: | Click to enter text. | Institution: | Click to enter text. |
| Sponsor/CRO: | Click to enter text. | | |
| Ethical clearance effectivity period:<br>Click to enter text. | | Study Site:<br>Click to enter text. | |
| Recommended by:<br>*(e.g. Sponsor, Funding Agency, Data Safety Monitoring Board, Researcher/Proponent)* | | Click to enter text. | |
| Tick the appropriate box: | For cancellation of study ☐ | | For early termination ☐ |
| 1. Start of study: | Click to enter text. | | |
| 2. Expected end of study: | Click to enter text. | | |
| 3. Number of required participants: | Click to enter text. | | |
| 4. Number of enrolled participants: | Click to enter text. | | |
| 5. Number of participants who withdrew: | Click to enter text. | | |
| 6. How many have completed the study? | Click to enter text. | | |
| 7. How many are still active? | Click to enter text. | | |
| 8. Reason/s for cancellation/termination: | | | |

| | | |
|---|---|---|
| Click to enter text. | | |
| 9. What are the plans for those who are still active in the study? Include support mechanisms/ interventions for enrolled participants<br>Click to enter text. | | |
| 10. Post-termination actions:<br>Click to enter text. | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>CLICK TO ENTER TEXT. | Date: |
| **To be filled-out by the REC Primary Reviewer** | | |
| **Additional comments:** | | |
| **RECOMMENDATION:** | ☐ **APPROVAL** | |
| | ☐ **REQUEST FOR ADDITIONAL INFORMATION** | |
| | ☐ **REQUEST FOR FURTHER ACTION** | |
| **REC REVIEWER:** | Name & Signature:<br>CLICK TO ENTER TEXT. | Review Date: |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
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Email: usth_irb@yahoo.com.ph Website: usthrec.online

## FINAL REPORT FORM

| Instructions to the Researcher: | Receiving Stamp/ Date of Submission: |
|---|---|
| Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach the Final Report Protocol, and permission letters secured during the conduct of the study. Submit this F18 form as a Word document and other documents as PDF files via usthrec.online | CLICK TO ENTER TEXT. |

| | | | |
|---|---|---|---|
| **REC Protocol Reference No.:** | CLICK TO ENTER TEXT. | | |
| **Protocol No./Title:** | Click to enter text. | | |
| **Name of Investigator:** | Click to enter text. | | |
| **Department:** | Click to enter text. | **Institution:** | Click to enter text. |
| **Sponsor:** | Click to enter text. | **CRO:** | Click to enter text. |
| **Duration of study: (months):** Click to enter text. | | **Study Site:** Click to enter text. | |

**Final Report Form:**

| | |
|---|---|
| 1. Date of Initial REC Approval: | Click to enter text. |
| 2. Start of study: | Click to enter text. |
| 3. End of study: | Click to enter text. |
| 4. Number of required participants: | Click to enter text. |
| 5. Number of enrolled participants: | Click to enter text. |
| 6. Number of randomized participants: | Click to enter text. |
| 7. Number of participants who completed the study: | Click to enter text. |
| 8. Number of participants withdrawn from the study: | Click to enter text. |
| 9. Number of participants who are lost to follow up: | Click to enter text. |
| 10. Number of participants who experienced SAEs/SUSARs: | Click to enter text. |

| |
|---|
| 11. Amendments to the original protocol (including dates of approval)<br>**Click to enter text.** |
| 12. Deviations from the approved protocol:<br>**Click to enter text.** |
| 13. Summary of onsite Adverse Events (AE/SAEs) reported:<br>**Click to enter text.** |
| 14. Study objectives:<br>**Click to enter text.** |
| 15. Summary of Results:<br>**Click to enter text.** |
| 16. Conclusions:<br>**Click to enter text.** |
| 17. Actions for dissemination of study results:<br>**Click to enter text.** |

| | | |
|---|---|---|
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT.** | Date: |

**To be filled-out by the REC Primary Reviewer**

**Additional comments:**

| | | |
|---|---|---|
| **RECOMMENDATION:** | ☐ | **APPROVAL** |
| | ☐ | **REQUEST INFORMATION:** (specify) |
| | ☐ | **RECOMMEND FURTHER ACTION:** (specify) |

| | | |
|---|---|---|
| **REC REVIEWER:** | Name & Signature:<br>**CLICK TO ENTER TEXT.** | Review Date: |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
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Email: usth_irb@yahoo.com.ph Website: usthrec.online


## APPLICATION FOR CONTINUING REVIEW & PROGRESS REPORT FORM

| Instructions to the Researcher: This form must be submitted four weeks before the expiration date. Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Submit this F19 Form as a Word document and the cover letter as PDF file via usthrec.online | Receiving Stamp/ Date of Submission: CLICK TO ENTER TEXT. |
|---|---|

| | | | |
|---|---|---|---|
| REC Protocol Reference No.: | CLICK TO ENTER TEXT. | | |
| Protocol No./Title: | Click to enter text. | | |
| Name of Investigator: | Click to enter text. | | |
| Contact No.: | Click to enter text. | Email address: | Click to enter text. |
| Department: | Click to enter text. | Institution: | Click to enter text. |
| Sponsor: | Click to enter text. | CRO: | Click to enter text. |
| Duration of study: (months) | | Study Site: | |
| Tick the appropriate box | Application for Continuing Review ☐ | Progress Report Submission | ☐ |

| | |
|---|---|
| 1. Date of Initial REC Approval: | Click to enter text. |
| 2. Start of study: | Click to enter text. |
| 3. Expected end of study: | Click to enter text. |
| 4. Number of required participants: | Click to enter text. |
| 5. Number of enrolled participants: | Click to enter text. |
| 6. Number of randomized participants: | Click to enter text. |
| 7. Number of participants who completed the study: | Click to enter text. |
| 8. Number of participants withdrawn from the study: | Click to enter text. |
| 9. Number of participants who are lost to follow-up: | Click to enter text. |
| 10. Number of participants who experienced SAEs/SUSARS | Click to enter text. |
| 11. Amendments to the original protocol including dates of approval: 12. Click to enter text. | |

| | | | |
|---|---|---|---|
| 13. Deviations from the approved protocol:<br>**Click to enter text.** | | | |
| 14. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:<br>**Click to enter text.** | | | |
| 15. Issues/problems encountered:<br>**a. Click to enter text.** | | | |
| 16. Progress Status (Provide a short description and indicate completion status, e.g., 50% complete, 75% complete):<br>**Click to enter text.** | | | |
| 17. Action Requested | ☐ | **Renew** - New participant accrual to continue | |
| | ☐ | **Renew** - Enrolled participant follow-up only | |
| | ☐ | **Others** - Specify: | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>CLICK TO ENTER TEXT. | | Date: |
| To be filled-out by the REC Primary Reviewer | | | |
| Is the risk-benefits ratio still favorable? | ☐ **Yes** | ☐ **No** | |
| **Additional comments:** | | | |
| **RECOMMENDATION:** | ☐ | **APPROVAL** | |
| | ☐ | **ADDITIONAL INFORMATION REQUIRED** | |
| | ☐ | **SUBMISSION OF AN EXPLANATION FOR FAILURE TO SUBMIT REQUIRED REPORTS** | |
| | ☐ | **DISAPPROVAL** | |
| **REC REVIEWER:** | Name & Signature:<br>CLICK TO ENTER TEXT. | | Review Date: |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
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Email: usth_irb@yahoo.com.ph Website: usthrec.online

## SITE VISIT REPORT FORM

| **Instructions to the Researcher:** The REC Site Visit Team shall conduct this action for a cause on selected sites of approved protocols that fall within the following established criteria for such: (a) high-risk studies, (b) significant violation reports (c) receipt of complaints from participants and families, (d) nonreceipt of required after-approval reports and (e) multiple studies conducted by a researcher. | **Receiving Stamp/ Date of Submission:** CLICK TO ENTER TEXT. |
|---|---|

| | | | |
|---|---|---|---|
| **REC Protocol Reference No.:** | CLICK TO ENTER TEXT. | | |
| **Protocol No./Title:** | Click to enter text. | | |
| **Name of Investigator:** | Click to enter text. | | |
| **Contact No.:** | Click to enter text. | **Email address:** | Click to enter text. |
| **Department:** | Click to enter text. | **Section:** | Click to enter text. |
| **Sponsor:** | Click to enter text. | **CRO:** | Click to enter text. |
| **Ethical clearance effectivity period:** Click to enter text. | | **Study Site:** Click to enter text. | |
| 1. Date of Initial REC Approval: | Click to enter text. | | |
| 2. Start of study: | Click to enter text. | | |
| 3. Expected end of study: | Click to enter text. | | |
| 4. Number of required participants: | Click to enter text. | | |
| 5. Number of enrolled participants: | Click to enter text. | | |
| 6. Number of randomized participants: | Click to enter text. | | |
| 7. Number of participants who completed the study: | Click to enter text. | | |
| 8. Number of participants withdrawn from the study: | Click to enter text. | | |
| 9. Number of participants who are lost to follow-up: | Click to enter text. | | |
| 10. Number of participants who experienced onsite SAEs/SUSARS: | Click to enter text. | | |
| 11. Amendments to the original protocol including dates of approval: Click to enter text. | | | |
| 12. Deviations from the approved protocol: | | | |

| | | |
|---|---|---|
| Click to enter text. | | |
| 13. Onsite SAE reports:<br>Click to enter text. | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br><br>**CLICK TO ENTER TEXT.** | Date: |
| **To be filled-out by the Site Visit Team** | | |
| 1. Reasons for site visit:<br>Click to enter text. | | |
| 2. Person/s present during visit:<br>Click to enter text. | | |
| 3. Findings:<br>Click to enter text. | | |
| 4. Recommendations:<br>Click to enter text. | | |
| **Site Visit Team Head** | Name & Signature:<br><br>**CLICK TO ENTER TEXT.** | Review Date: |
| **Member 1** | Name & Signature:<br><br>**CLICK TO ENTER TEXT.** | Review Date: |
| **Member 2** | Name & Signature:<br><br>**CLICK TO ENTER TEXT.** | Review Date: |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
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## QUERIES AND COMPLAINTS FORM

**Instructions:** This form should be accomplished by any party communicating queries, notifications, and complaints or grievances for information or action by the USTH-REC. In case of communication from research subjects or participants, the USTH-REC Secretariat can encode the information on their behalf if needed. Information reported in this form is processed either as a study-protocol-related or non-study-protocol-related communication, as the case may be. For protocol-related communication, put the relevant study protocol information below; if not, put **N/A**. If necessary, a letter may be attached to this form by the sending party, but a summary of the nature of communication should still be encoded in this form to allow proper filing of communication. Submit this F21 form as a Word document and other documents as PDF files via usthrec.online

**Receiving Stamp/ Date of Submission:**

CLICK TO ENTER TEXT.

| | |
|---|---|
| REC Protocol Reference No.: | CLICK TO ENTER TEXT. |
| Protocol No./Title: | Click to enter text. |
| Name of Investigator: | Click to enter text. |
| Sponsor/CRO: | Click to enter text. |

| | | | |
|---|---|---|---|
| 1. RECEIVED BY (REC Member or Staff): Click to enter text. | | 2. SIGNATURE OF (REC Member or Staff): Click to enter text. | |
| 3. REQUEST DELIVERED THROUGH: | 3.1 Telephone call | ☐ | Click to enter text. |
| | 3.2 Cellphone call: | ☐ | Click to enter text. |
| | 3.3 E-mail letter dated: | ☐ | Click to enter text. |
| | 3.4 Website | ☐ | Click to enter text. |
| | 3.5 Walk-in (indicate date/time) | ☐ | Click to enter text. |
| | 3.6 Others, specify: | ☐ | Click to enter text. |
| 4. PERSON LODGING THE QUERY OR COMPLAINT: | 4.1 Name: | Click to enter text. | |
| | 4.2 Address: | Click to enter text. | |
| | 4.3 Telephone: | Click to enter text. | |
| | 4.4 Mobile: | Click to enter text. | |
| | 4.5 Email: | Click to enter text. | |
| 5. CONNECTION/ RELATION OF PERSON TO THE STUDY PROTOCOL: | 5.1 Study participant | ☐ | Click to enter text. |
| | 5.2 Other: (specify) | ☐ | Click to enter text. |
| 6. TYPE OF CONCERN: | 6.1 Query (specify) | ☐ | Click to enter text. |
| | 6.2 Complaint (specify) | ☐ | Click to enter text. |
| | 6.3 Others (specify) | ☐ | Click to enter text. |
| 7. TYPE OF REVIEW: | 7.1 Full Board Review | ☐ | 7.2 Expedited Review ☐ |

| To be filled-out by the REC Primary Reviewer | | |
|---|---|---|
| **Additional comments:** | | |
| **REC REVIEWER:** | Name & Signature:<br><br>CLICK TO ENTER TEXT. | Review Date: |

**UNIVERSITY OF SANTO TOMAS HOSPITAL**
**RESEARCH ETHICS COMMITTEE**
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: *usthrec.online*


## CERTIFICATE OF AGREEMENT AND COMPLIANCE

This certifies that the undersigned agrees to comply with the following local and international ethical guidelines for research ethics and to adhere to the REC approved research protocol:

- Declaration of Helsinki 2015
- WHO Operational Guidelines in Biomedical Studies 2011
- International Conference on Harmonization on Good Clinical Practice (ICH-GCP)
- Council for International Organizations for Medical Sciences (CIOMS) 2016
- Good Research Practice (GRP)
- National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022
- Philippine Data Privacy Act of 2012 and its Implementing Rules and Regulations (IRR) of 2016

| | | |
|---|---|---|
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT** | Date: |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT** | Date: |
| **CO-INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT** | Date: |
| **CO-INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT** | Date: |

| | |
|---|---|
| REC Form No. F23 | **Reportable Negative Event Report Form (F23)** |
| Version No: rev2 | |
| Date of Effectivity: June 23, 2025 | |

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RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online

## REPORTABLE NEGATIVE EVENT (RNE) FORM

| | |
|---|---|
| **Instructions to the Researcher:**<br>RNEs are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported to the REC as essential to the continuing concern for a favorable balance of risks and benefits from the study. Submit at the latest 5 days after the event has come to the attention of the researcher along with a cover letter addressed to the REC Head. Submit this F23 form as a Word document and other documents as PDF files via usthrec.online | **Receiving Stamp/ Date of Submission:**<br>CLICK TO ENTER TEXT. |

| | | | |
|---|---|---|---|
| **REC Protocol Reference No.:** | CLICK TO ENTER TEXT. | | |
| **Protocol No./Title:** | Click to enter text. | | |
| **Name of Investigator:** | Click to enter text. | | |
| **Contact No.:** | Click to enter text. | **Email address:** | Click to enter text. |
| **Department:** | Click to enter text. | **Section:** | Click to enter text. |
| **Sponsor/CRO:** | Click to enter text. | | |
| **Ethical clearance effectivity period:**<br>Click to enter text. | | **Study Site:**<br>Click to enter text. | |

**RNE Report:**

| | |
|---|---|
| 1. Start of study: | **Click to enter text.** |
| 2. Expected end of study: | **Click to enter text.** |
| 3. Number of required participants: | **Click to enter text.** |
| 4. Number of enrolled participants: | **Click to enter text.** |
| 5. Description of Negative (harm, risks) Events: | |

| | | |
|---|---|---|
| a. Involving participants<br>**Click to enter text.** | | |
| b. Involving members of the Study Team<br>**Click to enter text.** | | |
| c. Involving Data safety & integrity<br>**Click to enter text.** | | |
| 2. Actions taken to prevent future RNEs, interventions and outcomes:<br>**Click to enter text.** | | |
| 3. Recommendations of PI:<br>**Click to enter text.** | | |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:<br>**CLICK TO ENTER TEXT.** | Date: |
| **To be filled-out by the REC Primary Reviewer** | | |
| **Comments of REC Reviewer:** | | |
| **REC REVIEWER:** | Name & Signature:<br>**CLICK TO ENTER TEXT.** | Review Date: |

UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
6th Floor St. John Macias O.P. Building
A.H. Lacson St., Sampaloc, Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: *usth_irb@yahoo.com.ph*


## EXEMPTION REVIEW APPLICATION FORM

| **Instruction:** Exempt from Review is a decision made by the REC Head and another officer regarding a submitted study proposal based on criteria in the *NEGRIHP 2022 The Research Ethics Review Process Guideline 46-50*. This means that the protocol will not undergo an expedited nor a full review. | **Receiving Stamp/ Date of Submission:** |
|---|---|

| **Category of Study/ Investigator:** | Company Sponsored ☐ | Investigator Initiated/Self-Funded ☐ | Consultants Faculty ☐ | USTH Trainees ☐ | USTH Employees ☐ | UST Students ☐ | Non-UST ☐ |
|---|---|---|---|---|---|---|---|

**REC Protocol Reference No.:** Click here to enter text.

**Protocol No./Title:**
Click here to enter text.

| **Principal Investigator**<br>Click here to enter text. | **Department Section:**<br>Click here to enter text. |
|---|---|
| Office Address: Click here to enter text. | Contact Nos.: Click here to enter text.<br>E-mail Address: Click here to enter text. |
| Co-Investigator:<br>Click here to enter text. | Department/Section:<br>Click here to enter text.<br>Contact Nos.: Click here to enter text. |

**EXEMPTION CATEGORIES**

| | |
|---|---|
| ☐ | ▪ Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review. |
| ☐ | ▪ Research conducted in established or commonly accepted educational settings involving normal educational practices. |
| ☐ | ▪ Research involving educational tests, survey procedures, interview procedures, or observation of public behavior. |
| ☐ | ▪ Research involving benign behavioral interventions. |
| ☐ | ▪ Secondary research using non-identifiable private information or non-identifiable biospecimens. |
| ☐ | ▪ Research and demonstration projects that are conducted, supported by, or otherwise subject to the approval of a Federal department or agency on public benefit or service programs. |
| ☐ | ▪ Taste and food quality evaluation and consumer acceptance studies. |

| TO BE FILLED-UP BY THE USTH- REC REVIEWER: | | |
|---|---|---|
| **Reviewer's comments:** | | |
| **PRIMARY REVIEWER:** | Signature over Printed Name:<br>Click here to enter text. | Date:<br>Click here to enter text. |

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Email: usth_irb@yahoo.com.ph Website: usthrec.online

Date:

**NAME**
Designation
Department Affiliation
Institution

**Re:** Certification Letter to the Request for Exempt from Review
**REC Protocol Reference No.:** YYYY-MM-NNN-CC-EX
**Protocol No./Title:**

Dear _____:

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** acknowledges receipt of your **above-titled research Protocol Version 1**, submitted on **DD-MM-YYY** via online portal.

After review, the REC has determined that your study qualifies for **exemption from review**, in accordance with the criteria set forth in the *National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022 Edition*.

Your study does not involve human participants, identifiable personal data, or human biological materials, and therefore meets the exemption conditions outlined under the said guidelines.

Please be reminded that, although your study is exempt from review, you still have the following responsibilities as researchers:

- To ensure continuous compliance with the exemption criteria stated in the *NEGRIHP 2022;*
- To submit a protocol amendment to the USTH-REC for review should any changes occur in the study's methodology, scope, or objectives, in order to re-assess whether the amended protocol remains exempt;
- To submit a Final Report not later than eight (8) weeks after the completion of the study.

Additionally, failure to comply with the conditions above may result in the withdrawal of the exemption status.

Should you have any questions or need further assistance, please do not hesitate to contact the REC Secretariat.

**For the USTH – Research Ethics Committee:**

(Signature)
(Name)
REC Head

EXEMPTION CERTIFICATE TEMPLATE 0623025-MD-ST-IR-F25rev2
Page **1** of **1**

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**Email:** usth_irb@yahoo.com.ph **Website:** *usthrec.online*


Date:

**NAME**
Designation
Department Affiliation
Institution

**Re:** Approval Letter to the Review of Final Report Protocol
**REC Protocol Reference No.:**
**Protocol No./**
**Title:**
**Sponsor/CRO:**
**REC Initial Approval Date:** < Date_Month_Year >.

**Dear _____:**

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** acknowledges receipt of your **Final Report Protocol Version No. _** and its related documents, submitted online on **<Date_Month_Year>**. The documents were assessed through **<expedited/full review>**.

The REC notes that **< state the summary of results and conclusion of the study >.**

The Final Report is hereby **APPROVED**, and the committee encourages the dissemination of these results through journal presentations and publication, as well as at relevant academic conferences.

Please be advised that your study protocol is now considered completed, and the ethical approval for this study has expired as of today. Consequently, your study protocol will be transferred to the REC archive and classified as an **INACTIVE FILE**. All related protocol records will remain accessible for three (3) years, until **< Date_Month_Year >.**

Thank you for providing us the results of your research.

**For the USTH-Research Ethics Committee:**

(Signature)
(Name)
REC Head

# UNIVERSITY OF SANTO TOMAS HOSPITAL
## RESEARCH ETHICS COMMITTEE
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A.H. Lacson St., Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


## COMMITTEE COMPOSITION

Name of Institution: UNIVERSITY OF SANTO TOMAS HOSPITAL (USTH)

Address of Institution: España Blvd., Manila, Philippines, 1015

| No. | Name of Member | REC Designation/ Department/Expertise | Affiliation w/ the institution | |
|---|---|---|---|---|
| | | | Yes | No |
| 1 | | Head | ☐ | ☐ |
| 2 | | Vice Head | ☐ | ☐ |
| 3 | | Member Secretary | ☐ | ☐ |
| 4 | | Regular Member | ☐ | ☐ |
| 5 | | Regular Member | ☐ | ☐ |
| 6 | | Regular Member | ☐ | ☐ |
| 7 | | Regular Member | ☐ | ☐ |
| 8 | | Regular Member | ☐ | ☐ |
| 9 | | Regular Member<br>Non-medical/Layperson | ☐ | ☐ |

| Signed: | | |
|---|---|---|
| USTH - REC Head | Printed Name & Signature | Date of Approval |
| | REC Head | Date_Month_Year |

PROTOCOL REF. NO. REC-YYYY-MM-NNN-LL


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6th Floor St. John Macias, O.P. Bldg. Building
A.H. Lacson St. Sampaloc Manila 1015 Philippines
Telephone: +63 2 8731-3001 local 2610
Email: usth_irb@yahoo.com.ph Website: usthrec.online


## PROTOCOL SUBMISSION TRACKING FORM

| Category of Study/ Investigator | Company Sponsored ☐ | Investigator Initiated/ Self-Funded ☐ | Consultants Faculty ☐ | USTH Trainees ☐ | USTH Employees ☐ | UST Students ☐ | Non-UST ☐ |
|---|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| **Protocol No./Title:** | Click to enter text. | | | | | |
| **Name of Investigator:** | Click to enter text. | | | | | |
| **Department:** | Click to enter text. | **Section:** | Click to enter text. | | | |
| **Sponsor/CRO:** | Click to enter text. | | | | | |
| **Primary Reviewers:** | 1. Click to enter text. | 2. Click to enter text. | 3. Click to enter text. | | | |
| **Type of Initial Review:** | Expedited Review ☐ | Full Board Review ☐ | Exempted from Review ☐ | | | |

| | | | | |
|---|---|---|---|---|
| **Protocol Version Dates** | Protocol Version 1 Date: Click to enter text. | Protocol Version 2 Date: Click to enter text. | Protocol Version 3 Date: Click to enter text. | Protocol Version 4 Date: Click to enter text. |
| **Review Dates** | 1st Review: Click to enter text. | 2nd Review: Click to enter text. | 3rd Review: Click to enter text. | 4th Review: Click to enter text. |
| **Study Duration:** Click to enter text. | **Initial Approval Date:** **Click to enter text.** | **Validity Date of Initial Approval:** **Click to enter text.** | | |
| **Amendment Submission Dates** | Amendment 1 Version Date: **Click to enter text.** | Amendment 2 Version Date: **Click to enter text.** | Amendment 3 Version Date: **Click to enter text.** | Amendment 4 Version Date: **Click to enter text.** |
| **Amendment Approval Dates** | Amendment 1 Approval Date: **Click to enter text.** | Amendment 2 Approval Date: **Click to enter text.** | Amendment 3 Approval Date: **Click to enter text.** | Amendment 4 Approval Date: **Click to enter text.** |
| **Continuing Review Application Submission Dates** | Continuing Review 1 Submission Date: **Click to enter text.** | Continuing Review 2 Submission Date: **Click to enter text.** | Continuing Review 3 Submission Date: **Click to enter text.** | Continuing Review 4 Submission Date: **Click to enter text.** |
| **Continuing Review Application Approval Dates** | Continuing Review 1 Approval Date: **Click to enter text.** | Continuing Review 2 Approval Date: **Click to enter text.** | Continuing Review 3 Approval Date: **Click to enter text.** | Continuing Review 4 Approval Date: **Click to enter text.** |
| **Final Report Submission Date:** **Click to enter text.** | **Final Report Approval Date:** **Click to enter text.** | **Final Report Archiving Date:** **Click to enter text.** | | |

PROTOCOL REF. NO. REC-YYYY-MM-NNN-LL

| DATE | DOCUMENT PARTICULARS | ISSUED BY | RECEIVED BY | REMARKS |
|---|---|---|---|---|
| | **INITIAL SUBMISSION: Protocol v1** | | | |
| | F08 Assessment Form | | | |
| | REC Action Letter | | | |
| | AGENDA & MINUTES excerpt | | | |
| | **RESUBMISSION: Protocol v2** | | | |
| | F11 Resubmission Form | | | |
| | REC Action/Approval Letter | | | |
| | AGENDA & MINUTES excerpt | | | |
| | **AMENDMENT: Protocol v2** | | | |
| | F14 Amendment Form | | | |
| | REC Action/Approval Letter | | | |
| | AGENDA & MINUTES excerpt | | | |
| | **CONTINUING REVIEW APPLICATION FORM** | | | |
| | F19 Continuing Review Form | | | |
| | REC Action/Approval Letter | | | |
| | AGENDA & MINUTES excerpt | | | |
| | **FINAL REPORT FORM** | | | |
| | F18 Final Report Form | | | |
| | REC Action/Approval Letter | | | |
| | AGENDA & MINUTES excerpt | | | |
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## NOTICE OF MEETING

| | |
|---|---|
| Date of Notice: | |
| Date of Meeting: | |
| Venue: | |
| Time: | |

**Items for Discussion:**

1. **Full Review**
   - 1.1. New Protocols (Initial)
     - 1.1.1. REC Code - Title
       Primary Reviewers
     - 1.1.2. REC Code – Title
       Primary Reviewers
   - 1.2. Resubmissions
     - 1.2.1. REC Code - Title
       Primary Reviewers
     - 1.2.2. REC Code – Title
       Primary Reviewers
   - 1.3. Protocol Amendments
     - 1.3.1. REC Code - Title
       Primary Reviewers
     - 1.3.2. REC Code – Title
       Primary Reviewers
   - 1.4. Deviation/Violation
     - 1.4.1. REC Code - Title
       Primary Reviewers
     - 1.4.2. REC Code – Title
       Primary Reviewers
   - 1.5. SAE/SUSAR Report
     - 1.5.1. REC Code - Title
       Primary Reviewers
     - 1.5.2. REC Code – Title
       Primary Reviewers
   - 1.6. Continuing Review Applications
     - 1.6.1. REC Code - Title
       Primary Reviewers
     - 1.6.2. REC Code – Title
       Primary Reviewers

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1.7. Final Report
  1.7.1. REC Code - Title
  Primary Reviewers
  1.7.2. REC Code – Title
  Primary Reviewers
1.8. Early Termination
  1.8.1. REC Code - Title
  Primary Reviewers
  1.8.2. REC Code – Title
  Primary Reviewers
1.9. Site Visit Report
  1.9.1. REC Code - Title
  Primary Reviewers
  1.9.2. REC Code – Title
  Primary Reviewers

**2. Report on Expedited Review of Proposals**
2.1. New Protocols
2.2. Resubmissions
2.3. Protocol Amendments
2.4. Deviation/Violation
2.5. Continuing Review Applications
2.6. Final Report
2.7. Early Termination

Prepared by:

(Signature)
(Name)
REC Secretariat Staff

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Email: usth_irb@yahoo.com.ph Website: usthrec.online

Date:

**NAME**
Designation
Department Affiliation
Institution

**Re:** Reminder Letter for < Continuing Review & Final Report Submission >
**REC Protocol Reference No.:**
**Protocol No./**
**Title:**
**Sponsor/CRO:**
**REC Initial Approval Date:**

**Dear _____:**

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** would like to remind you that the **< Progress Report /Final Report >** for the above study protocol is due on < Validity of Ethics Approval >. Based on REC records, there had been no communication regarding the progress of this study, which is still in our active file and has an active ethical clearance.

If the study had been concluded or terminated, kindly fill out a *Final Report Form (F18);* or if still ongoing, submit an *Application for Continuing Review (F19)*. Forms may be downloaded from the USTH website: usthrec.online.

Kindly submit the relevant report/form **within thirty (30) days prior to the expiration of the ethical clearance**. If no submission is received within the indicated grace period, the REC will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

Submit your response and the necessary documents as soon as possible.

**For the USTH – Research Ethics Committee:**

(Signature)
(Name)
REC Head

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Date

**NAME**
Designation
Department Affiliation
Institution

**Re: Notification Letter to Conduct Site Visit**
**REC Protocol Reference No.:**
**Protocol No./Title:**
**Sponsor/CRO:**
**REC Initial Approval Date:**

**Dear _____:**

As part of the ongoing monitoring and oversight of the clinical trial referenced above, the **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** would like to inform you that a site visit will be conducted at your study site.

The visit is scheduled for **Date_Month_Year** from _____ to _____. The purpose of this visit is to review of the trial's compliance with ethical guidelines and regulatory requirements. During the visit, the Site Visit Team led by **< Name of Site Visit Team >** will assess various aspects of the trial, including but not limited to:

- Participant recruitment and consent processes
- Data management and documentation practices
- Adherence to the trial protocol
- Safety and monitoring procedures

Kindly prepare your site and ensure that all relevant documents and records are available for review. This includes informed consent forms, participant files, safety reports, and any other documents that the committee may need to review during the visit.

Should you have any questions or require further information, please do not hesitate to contact us at **8731-3001 local 2610** or this email usth_irb@yahoo.com.ph. The REC appreciates your cooperation and looks forward to your support during the site visit.

**For the USTH – Research Ethics Committee:**

(Signature)
(Name)
REC Head

**Conforme of Principal Investigator:**

(Signature)
(Name)
Date

SITE VISIT NOTIFICATION 062325-MD-ST-IR-F30 rev2

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Email: usth_irb@yahoo.com.ph Website: usthrec.online

Date:

**NAME**
Designation
Department Affiliation
Institution

**Re:** Invitation Letter for Clarificatory Interview
**REC Protocol Reference No.:**
**Protocol No./ Title:**

**Sponsor/CRO:**

**Dear _____:**

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** requests for a clarificatory interview with you during the next full review meeting on < Date of Next Full Board meeting > from < requested time > via Zoom.

This is in relation to your protocol received last **<Date_Month_Year>** via online submission. Kindly make yourself available on the given meeting schedule. The REC looks forward to your attendance to the meeting.

See Google Meet link here:

**For the USTH-Research Ethics Committee:**

(Signature)
(Name)
REC Head

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## REQUEST FOR REVISION OF AN SOP OR GUIDELINE

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit to the USTH-REC Secretariat for processing.

| SOP or Guideline Code | SOP or Guideline TITLE |
|---|---|
| Reason for request (cite details of problems or deficiency in current document): | |
| Description of requested changes: | |
| Revision Requested by: (name and signature) | Date: |

**REC Officer comments:**

**Description of requested changes:**

| | |
|---|---|
| ☐ | Revision requirement confirmed, forward to SOP Team |
| ☐ | Request further information (state) |
| ☐ | Forward to content expert for opinion |

| **Name of REC Officer/Reviewer:** | **Date:** |
|---|---|
| | |

# APPENDIX A:
# USTH REC General Policies

## UST HOSPITAL - RESEARCH ETHICS COMMITTEE

### General Policies

1. The USTH–REC adheres to the international and national guidelines for Health Research Ethics, Good Clinical Practice, statutory and regulatory requirements, institutional policies as well as standards to protect and safeguard the human participants in research and to ensure the integrity of the scientific material and data. These guidelines, requirements and standards are the following:
    - World Medical Association Declaration of Helsinki (WMA-DoH)
    - International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: ICH Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP)
    - WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
    - ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) Current Step 4 Version dated 9 November 2016
    - Good Pharmacoepidemiology Practices (GPP)
    - Council for International Organization of Medical Sciences (CIOMS)
    - International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS-Biomedical)
    - Council for International Organization of Medical Sciences International Ethical Guidelines for Epidemiological Studies (CIOMS-Epidemiology)
    - Office of Human Research Protection (OHRP), United States Dept of Health & Human Services
    - Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)
    - Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
    - National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022
    - Department of Science and Technology (DOST) Administrative Order 001 Series of 2007 requiring ethics review of all health researchers involving human participants
    - Department of Science and Technology (DOST) Administrative Order 001 Series of 2008 requiring all Ethics Review Committees (ERB)/Institutional Review Committees (REC) to register with the Philippine Health Research Ethics Board (PHREB)
    -

- Commission on Higher Education (CHEd) Memorandum Order 34 Series 2007 in support of the DOST memorandum requiring all academic institutions engaged in human research to establish ethics review boards/committees.
- Republic Act 10532 of 2013, known as the "Philippine National Health Research System Act of 2017". Section 12 states that the Philippine Health Research Ethics Board (PHREB) shall ensure adherence to the universal principles for the protection of human participants in research studies conducted in the Philippines
- Philippine Food & Drug Administration (FDA) Circular 2012-007 Subject: Recognition of ERB/ERC for Purposes of the Conduct of Clinical Trials on Investigational and Medicinal Products in the Philippines and other Purposes
- Data Privacy Act of 2012 and its implementing rules and regulations in 2016
- International Committee on Medical Journal Editors (ICMJE), Rules on Authorship
- As a Catholic Institution, the USTH-REC strongly adheres to the moral teachings on medical science of the Catholic Church.

2. The USTH-REC shall be composed of highly qualified, competent, multidisciplinary, gender and age-balanced, medical and non-medical members duly appointed by the CEO, upon the recommendation of the Medical Director for a specified period of time.

3. Because of the extensive time commitment required for REC service, the REC Members shall be entitled to an honorarium for reviewing assigned protocols, participating in board meetings, and other tasks related to the functions of the REC. The REC Members shall likewise be provided support for REC-related trainings, seminars and workshops.

4. The USTH-REC shall ensure that all members have the updated required trainings on basic and advanced Good Clinical Practice (GCP), Good Research Practice (GRP), Research Ethics, Standard Operating Procedures (SOPs), research methodologies and other research ethics-related trainings.

5. The USTH-REC, as an ethics committee, shall function as an independent reviewing body where its decision is executed free from bias and influence from the investigators, sponsors, and institutions.

6. The USTH-REC shall review ALL submitted company-sponsored protocols/funded protocols, institutional/investigator-initiated research protocols, protocols submitted by USTH consultants, trainees, hospital employees.

7. All research studies involving UST Hospital patients, personnel, human material (tissue, blood, urine, etc.), data, records, facilities shall require REC review and approval prior to their implementation.

8. The USTH-REC shall review different types of research studies including but not limited to the following:
    - Clinical trials (phases I to IV)
    - Case reports, case series
        - Since some case reports maybe retrospective in nature, where prior REC approval may not be feasible, it is required that investigators doing the case report abide by the Case Report (CARE) Guidelines.
    - Public health research (Epidemiologic research, prevalence, incidence, registries, databases, surveys)
    - Social science research, knowledge, attitude & perceptions (KAPs), behavioral research, impact of public health intervention, focus group discussions (FGD), key informant interviews (KII)
    - Biomedical studies (retrospective, prospective, diagnostic, human material, and data such as medical records or other personal information)
    - Health operations research (health programs and policies)
    - Implementation or action research

10. The USTH - REC shall provide a review process for the following types of studies as Exempt for Review:
    - systematic review
    - meta-analyses

11. The research protocols shall be reviewed and approved based on the full compliance with the following criteria:
    - Completeness of documentation requirements
    - Scientific and technical soundness
    - Social relevance
    - Ethical considerations
    - Plagiarism certificate with similarity index of not more than 20% or depending on the specific requirement of the intended journal for publication
    - Declaration of artificial intelligence (AI) in all aspects of the protocol
    - Adherence to the general policies of USTH-REC
    - Adherence to UST Hospital Policies
    - Adherence to the moral teachings on medical science of the Catholic Church

12. All research protocols submitted to the USTH-REC for ethical review shall only be initiated (patient recruitment or data gathering for chart reviews) after the USTH-REC approval is granted.

13. Secure permission letters from the USTH Medical Director, Data Privacy Officer (DPO), Department Chairs or Unit Head requesting access to confidential information, medical records, facility use and others.

14. Secure MOA/MOU on collaboration terms, data ownership, publication rights, Material Transfer Agreement (MTA) for transfer of biological materials or data between institutions, Coverage insurance for trial participants, if applicable.

15. The approved protocol is valid for one (1) year from the date of the approval. For studies that go beyond one year, a *Continuing Review Application & Progress Report Form* (F19) submission is required thirty (30) days prior to expiration of ethics approval. Only after the REC approval can the study be allowed to continue.

16. Once a protocol is approved, the investigator should strictly adhere to the approved version and is not allowed to make any changes. However, if changes are deemed necessary to protect the research participants or improve the scientific soundness of the protocol, a *Protocol Amendment Form* (F14) shall be submitted and approved by the REC prior to the implementation of the changes.

17. At the end of the study, the Investigator is required to submit a Final Study Report (F18) not later than eight (8) weeks after the completion of the study.

18. The USTH-REC shall provide a list of basic document requirements (*Requirements Checklist Form [F06])*. For clinical trials, all authors require Good Clinical Practice (GCP) certification while for non-clinical trials, all authors require Basic Research Ethics Training (BRET), and either a Good Research Practice Certification (GRP) or Responsible Conduct of Research. Foreign-based online GCP/GRP certification shall not be acknowledged because they do not comply with National guidelines and regulations (NEGRIHP, 2022). Incomplete submission warrants non-acceptance.

19. The USTH-REC shall review and approve the scientific and technical soundness based on the knowledge of basic scientific methods, consultation from experts and certification from the Department's Research Committee, if applicable.

20. The USTH-REC shall review and approve the ethical soundness based on, but not limited to, the following elements:
    - Social value
    - Equitable selection of subjects
    - Protection of vulnerable subjects
    - Management of risks & benefits
    - Adequate safety monitoring and provision for privacy and confidentiality
    - Quality informed consent process and form
    - Community considerations
    - Investigators qualification requirements and certification
    - Management of conflict of interest
    - Adherence to policies on authorship
    - Adherence to the teachings of the Catholic Church

21. The USTH-REC shall require that all research protocols provide a section on Ethical Considerations that declares that the study will be conducted in adherence to the Declaration of Helsinki and compliant with the Good Clinical Practice/Good Research Practice. It should also contain details of the ethical issues and corresponding measures to reduce the risks to human participants, the investigator and other involved individuals (e.g., laboratory personnel, research assistants), the environment and the community. The benefits (direct and indirect) from participation in the study should be clearly described. The investigator should cite the specific ethical guideline relevant to his/her protocol.

22. The USTH-REC shall require a clear description of how the informed consent process shall be conducted. An age-specific informed consent form from all research participants including the documentation of signatures unless waived by the REC is necessary. Only under special circumstances upon the discretion of the majority of the REC members can the informed consent and/or its documentation be waived.

23. The USTH-REC shall require that only the approved informed consent forms (ICFs) bearing the "USTH-REC APPROVED" stamp and "USTH-REC APPROVED VERSION DATE" present on every page of the ICF be utilized by the investigator.

24. The USTH-REC shall process, implement, and manage review procedures of protocol, from initial submission, resubmission, approval, post-approval submissions, documentation, record management, archiving including adverse events, queries and complaints.

25. The USTH-REC shall, after a due process, suspend or withdraw previously approved protocols, disapprove protocols undergoing review if found non-compliant or in violation of the REC Standard Operating Procedures and the ethical conduct of research. Examples of ethical misconduct are the following but not limited to:
    - Non-compliance with REC and USTH research policies
    - **Initiation of the study without REC approval**
    - Non-adherence to an REC-approved protocol
    - Fabrication
    - Falsification
    - Fragmentation of data or "Salami slicing"
    - Piracy
    - Plagiarism and "self-plagiarism"
    - Non-disclosure of negative data
    - Photo manipulation
    - Misappropriation
    - Multiple publication of the same data in different languages, different titles and authors
    - Ghostwriting
    - Provision of incorrect information to scientific journals
    - Undisclosed conflicts of interests

- Authorship violations
- Non-disclosure of conflicts of interest

26. Upon request by the Principal Investigator, an appeal process may be conducted for disapproved protocols and cancelled protocols within six (6) weeks from the time the decision was issued.

27. Personal data originally collected for a declared, specified, or legitimate purpose may be processed further for historical, statistical, or scientific purposes, and, in cases laid down in law, may be stored for longer periods, subject to implementation of the appropriate organizational, physical, and technical security measures required by the *Data Privacy Act of 2012* in order to safeguard the rights and freedoms of the data subject.

28. The REC shall make certain that the protocol is in compliance with the provisions found in international ethical guidelines and the National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022

    National Ethical Guidelines for Research Involving Human Participants (NEGRHIP), 2022 on vulnerable populations:

    "Vulnerable participants shall require special protection, as they have certain characteristics or are in special situations that tend to magnify their vulnerabilities or expose them to risks, they may otherwise be unwilling to take. Vulnerable participants are those who are relatively or absolutely incapable of deciding for themselves whether or not to participate in a study for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, and who are at greater risk for some harms.

    Vulnerable groups shall not be included in research unless such research:

    20.1. Is necessary to promote the welfare of the population represented; and

    20.2. Cannot be performed on non-vulnerable persons or groups

29. Researchers, sponsors, or RECs shall not arbitrarily exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study shall not, in itself, be used as a reason for precluding or limiting women's participation in research (see section on Clinical Research).

    Competent advice and assistance shall be provided to participants who, due to social, economic, political, or medical disadvantages, are more likely to give consent under duress or without the benefit of adequate information. Caution shall be exercised in obtaining informed consent for a research project if the research participant is in a dependent relationship with the researcher (e.g., as a research participant) to ensure that the consent is not given under duress or undue influence."

30. The REC upon its deliberation may require that research involving children or persons below 18 years old must have at least one member who is a paediatrician or child development expert.

31. The USTH-REC shall require all investigational drug trials involving children to obtain the consent of both parents prior to the children's participation. If securing both parents consent would not be possible due to acceptable reasons (single parent or unmarried), proper documentation (e.g., record in source notes) shall be done. Any sign of dissent must be observed, and such children who dissent must not be recruited to the study except when they will directly benefit from the research.

32. The USTH-REC shall safeguard research involving child-bearing potentials, pregnant or breastfeeding women and shall have the following protective mechanisms:

    - The UST Hospital as a Catholic teaching and training institution, strongly advocates the natural birth regulations &/or absolute abstinence for couples involved in investigational drug trials. Men and women in their reproductive years who will participate in investigational drug trials or procedures should be advised against getting pregnant and be informed of the possible risks on their fetus should she become pregnant while taking the investigational drug or undergoing the procedure. The informed consent process should involve both partners. If securing consent from both partners would not be possible due to acceptable reasons, (single or unmarried), proper documentation shall be done.
    - Pregnant or breastfeeding women should in no circumstances be the participants of clinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of research is to obtain new knowledge about pregnancy or lactation.
    - As a general rule, pregnant or breastfeeding women should not be participants of any clinical trial unless designed to protect or advance the health of pregnant or nursing women, as well as the fetus or breastfeeding infants.

33. The USTH-REC shall make certain that prisoners or marginalized populations with serious illness or at risk of serious illness are not arbitrarily denied access to investigational drugs, vaccines, or other agents that show promise of therapeutic or preventive benefit.

34. The USTH-REC shall make sure that research involving underdeveloped communities must have a member or consultant who is thoroughly familiar with the customs and traditions of the community being researched. The board must warrant that research in underdeveloped communities should only be carried out with the following criteria:
    1. The research could not be carried out reasonably well in a developed community
    2. The research is responsive to the health needs and the priorities of the community

3. Informed consent of individual members is obtained and community permission has been secured

35. The USTH-REC adheres to the rules on authorship and the use of artificial intelligence in research cited in the International Committee on Medical Journal Editors (ICMJE):
    - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of the data for the work **AND**
    - Drafting the work or revising it critically for the important intellectual content **AND**
    - Final approval of the version to be published **AND**
    - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

    Investigators who do not fully comply with all the four criteria shall be acknowledged as non-Author Contributors.

    https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

36. All contributions of the proponents of the research should be clearly identified and proper acknowledgement of authorship and non-author contributions should be indicated.

37. For USTH trainees (post-graduate interns, residents and fellows-in-training), the Research Committee of each Department shall issue the technical review certification that the research protocol has been reviewed, approved, did not violate intellectual property regulations and is being endorsed for ethical review and approval. This certification shall be noted by the Department of Medical Education & Research (DMER).

38. The USTH-REC shall require that the Principal Investigator's submission letter is endorsed by his or her department/ section/unit/home institution to conduct the specific research project for which ethical clearance is being sought. This requirement is attested by the signature of the Department Head.

39. For research protocols submitted by senior interns, junior interns/medical clerks, and medical students, the REC will require for an additional GCP/GRP certified medical expert in the field of the study to be included as a co-author in the research team.

40. Other undergraduate (bachelor's degree program) and post-graduate students (Masters, Ph.D., Law) may be subject to the same general principles as outlined in this document. The REC may recommend or require for an additional GCP/GRP certified medical expert in the field of the study to be included as a co-adviser/consultant/collaborator in the research team, if needed, upon assessment of the submitted study protocol.

41. The USTH-REC holds regular meetings every 3rd and last Thursday of the month except in December where year-end reports and SOP reviews are conducted. Special meetings may be conducted as deemed necessary and upon the availability of a quorum.

42. Submission and resubmission of protocols, follow-ups and other queries will be entertained every Wednesday & Friday, 9:00 AM to 3:00 PM only.

43. The timeline for INITIAL protocol submission, review and processing is as follows:

| | **ACTIVITIES** | **Agenda from Review** | **Full Board Review** | **Expedited Review** |
|---|---|---|---|---|
| 1 | ENCODE<br>FILE<br>SORT | 7 working days | 7 working days | 7 working days |
| 2 | CLASSIFY AS EXEMPT, FULL BOARD OR EXPEDITED REVIEW; ASSIGN & DISTRIBUTE TO MEMBERS | 7 working days | 7 working days | 7 working days |
| 3 | REVIEW OF PROTOCOL BY PRIMARY REVIEWERS | | 14 working days | 14 working days |
| 4 | MAY BE CALLED FOR CLARIFICATORY INTERVIEW IN A FULL BOARD MEETING | | 1st come 1st served basis | |
| 5 | SCHEDULE FOR FULL BOARD REVIEW | | 1st come 1st served basis | |
| 6 | COLLATE<br>COMPOSE<br>PREPARE ACTION/APPROVAL LETTER<br>SIGNING & RELEASE OF ACTION/APPROVAL LETTER | 7 working days | 14 working days | 14 working days |

44. The USTH-REC may receive queries, complaints, grievances relevant to research protocols and ethical conduct of research. The REC shall process complaints and grievances and act on them in a speedy, unbiased, and confidential manner, and to recommend resolution of the complaint according to the policies and regulations. Sanctions to ethical violations are limited to disapproval, cancellation, suspension and withdrawal of the ethical approval of the protocol.

45. The USTH-REC does not review protocols for animal studies. These protocols may be submitted to the Institutional Animal Care and Use Committee (IACUC) located at the UST Research Cluster for the Natural and Applied Science Thomas Aquinas Research Center (UST RCNAS – TARC).

46. In the event that a Principal Investigator decides not to continue the application for ethics review, the Principal Investigator must write a letter requesting for withdrawal of research protocol from the USTH-REC. All requests for withdrawal will be discussed during full board meetings regardless of initial review classification. Upon approval of request, study protocol will be archived.

47. If the approved study will be terminated prior to completion, the investigator shall inform the USTH-REC in writing and submit an Early Termination Report (REC F17).

48. The USTH-REC review is subject to a review fee. For continuing review and amendment applications, a corresponding fee is likewise warranted. (See Appendix B – REC Review Fees)

# APPENDIX B:
# Review & Institutional Fees

REC Form No.: Appendix B
Version No: rev7
Date of Effectivity: June 23, 2025

## USTH-REC Review & Institutional Fees

| | REC PAYMENT FEES | DESCRIPTION |
|---|---|---|
| | **1. Company Sponsored Clinical Trials/ Agency/society-funded clinical trial** | Applicable to studies funded by pharmaceutical companies, funding agencies or approved grants |
| | • Initial Review Fee | **Php 60,000** Fixed fee. Must be paid prior to the initial review; Non-refundable. |
| | • Continuing Review Fee | **Php15,000**. Must be paid upon application for renewal of approval thirty (30) days before expiration date of REC approval; Non-refundable. |
| | • Amendment Review Fee | **Php 7,500.** Must be paid upon application of any protocol amendment; Non-refundable. |
| | • Institutional Fee | **10 %** of the study budget for UST Hospital; Non-refundable. |
| | • Administrative & Research Fee<br>• Procedural fees (if applicable) | **Php 150,000** p.a. or 10% of the total budget whichever is higher (storage room, rental utilities (excluding additional refrigerators) maintenance of area; See **Amended REC Fees FI-AC-MEMO NO.005-22 dated 01 Aug 2022** |
| | **2. Investigator-Initiated Research Protocols:** | For locally-developed protocols |
| | • USTH Consultants & Employees | **Php 20,000.** For agency funded protocols; 10% of the administrative cost of the grant or Php 5,000 whichever is higher. |
| | • USTH Trainees (Fellows/Residents/Post Graduate Interns) | **Php 2,500** per protocol |
| | • UST Undergraduate Students<br>• (Currently enrolled under Bachelor's Degree) | 10% of administrative cost of the grant or **Php 3,500** whichever is higher. |
| | • UST Faculty Members (except USTFMS)<br>• UST Post-Graduate Students (currently enrolled under Medicine, Law, Master's Degree) | 10% of the administrative cost of the grant or **Php 7,500** whichever is higher |
| | • UST Doctorate Degree | 10% of administrative cost of the grant or **Php 15,000** whichever is higher. |
| | • Continuing Review Fee<br>- For Consultants & Faculty Members | **Php 2,000**. Must be paid upon application for renewal of approval thirty (30) days before the REC approval expiration date. |
| | **3. Non-UST Research Protocols** | Equivalent to 15% of administrative cost of the grant or as follows whichever is higher.<br>▪ Students/Trainees – Php 10,000<br>▪ Professionals/ Masteral/ Doctorate) – Php 20,000 |
| | **REC PAYMENT INSTRUCTIONS** | |
| | **For ONLINE & CHEQUE payments:**<br>▪ See UST Hospital bank details | **Payee Name/Beneficiary**: University of Santo Tomas Hospital<br>**Bank Name**: Security Bank Corporation<br>**Bank Address**: Q. Pavilion UST Espana Blvd., Sampaloc, Manila, 1008 Philippines<br>**Branch**: UST Branch<br>**Bank Account No.**: 0171-008-008-011<br>**Swift Code**: SETCPHMM |
| | **For CASH & CHEQUE payments:** | Secure an electronic **Service Invoice** to be issued by the USTH-REC Secretariat Staff prior to payment at the Cashier. |
| | **For Issuance of Official Receipt:** | Submit a photocopy/scanned copy of the proof of cheque payment or online payment to the USTH Cashier for issuance of **Official Receipt.** |
| | **For submission of NEW Research Protocol/Clinical Trial:** | Include a photocopy/scanned copy of the proof of cheque payment or online payment &/or Official Receipt as proof of payment together with the REC Initial Submission Application Requirements to be submitted through the USTH-REC portal: **usthrec.online** |
| | ▪ Note that Review Fees are separate from Institutional Fees as required by the USTH as site institution.<br>▪ All REC payments are fixed fees and are **NET** of all applicable taxes | |

# APPENDIX C:
# Honoraria for REC Members & Independent Consultants

## 1. Recommendation of Review Honorarium

Because of the extensive time commitment required for REC service, the REC Head initiates the submission and/or recommendation of review honorarium or increase thereof, either after a dialogue with the members or with the Medical Director.

The honorarium covers for the following:

- fixed amount for each protocol reviewed
- fixed amount for each meeting attended
- fixed amount for attending REC related-activities

The recommendation will be submitted to the Medical Director which will be checked and endorsed for approval by the Director for Finance.

## 2. Approval of Review Honorarium

2.1. The Director for Finance approves the recommendation.

2.2. Approval will be indicated in the REC budget or amendment thereof.

## 3. Communication of Review Honorarium Information

3.1. The Members are informed of the review honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations.

3.2. Members and Independent Reviewers acknowledge the information upon receipt of notification.

## 4. Release of Members' Review Honoraria

4.1. The Office Secretary prepares the request quarterly for Members' Review Honoraria endorsed by the Medical Director.

4.2. The approved request shall be forwarded to the Accounting Department for processing. The Members' Review Honoraria shall be released regularly on a quarterly basis.

4.3. The Office Secretary follows-up the status of review honorarium. The Accounting Department shall notify the REC or Members/Independent Reviewers (payee) that the review honorarium is already available for release.

**5.** As per FA: ME-008-20 Memorandum from the Director for Finance & Administration dated 13 December 2019, effective January 1, 2019, the following honorarium for REC shall be provided:

| | |
|---|---|
| Head | P 10,000 per month |
| Members & Independent Consultants | P 1,500 per meeting |

**6.** Whereas for Clinical Trial reviewed, 10% of the review fee collected shall be given as honorarium to the reviewer.

Complete documentation, attendance and work completed must be attached in the cash requisition every end of quarter.

October 31 January 31
April 30 July 31

**7.** Based on the University of Santo Tomas Hospital – Institutional Research Ethics Board (UST-IREB), **effective May 25, 2023** the following honoraria rates were written as:

7.1. Honoraria per protocol is **70%** of the protocol review fee divided among the reviewers.

7.2. Honoraria for meetings from **28%** of the review fee of all protocols. Honoraria released every July and December.

**8.** Honoraria for REC Head, Vice Head and Member Secretary:

8.1. P10,000/month for Head but no honoraria for meetings and for protocol reviewed

8.2. No honoraria for Vice Head and Member Secretary but with honoraria for meetings attended

8.3. P25,000 for Head, Vice Head and Member Secretary given biannually or 2% of Operational Fund, whichever is higher.

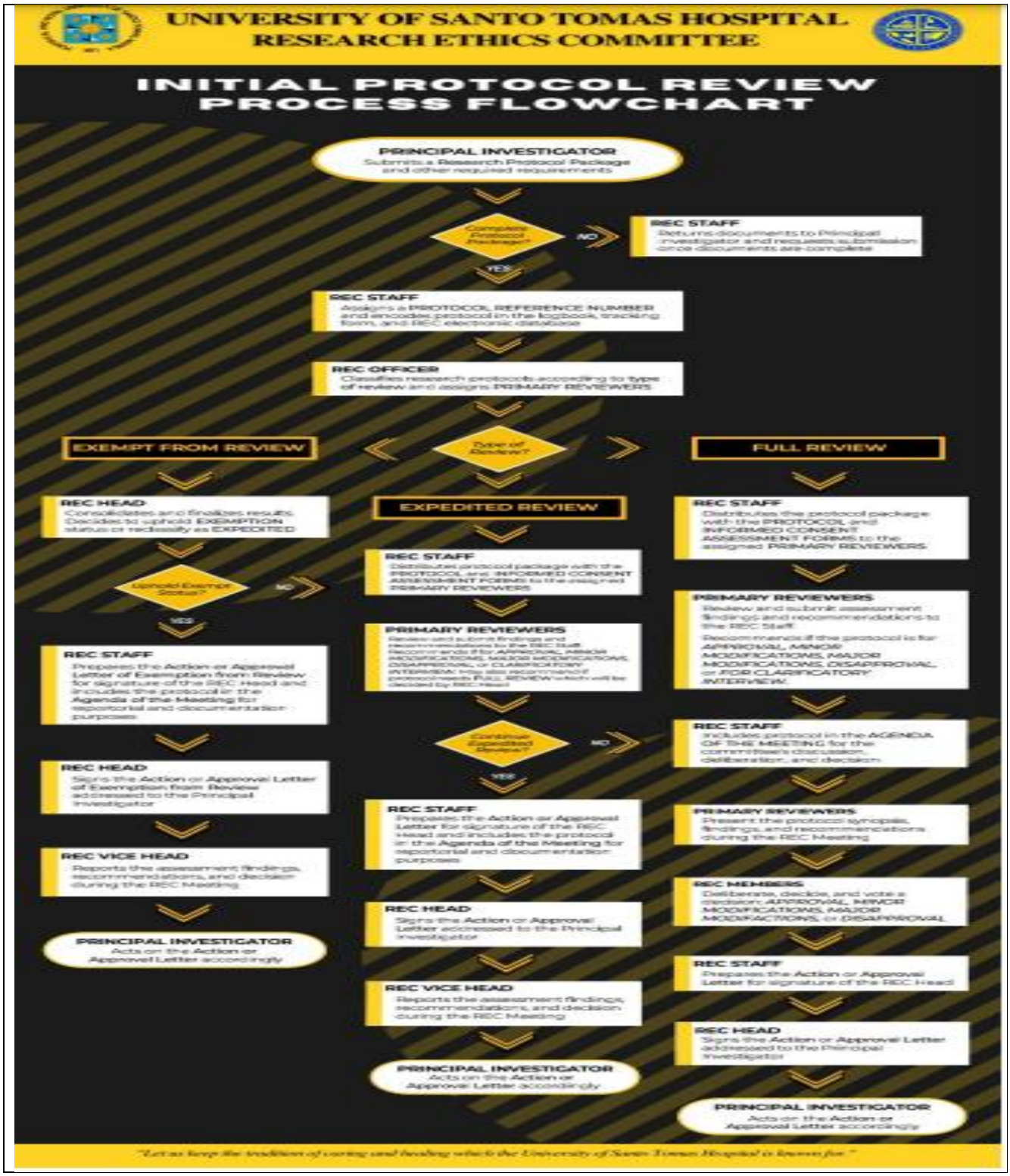
8.4. Plus Honorarium for protocols reviewed and attendance in meetings

**9.** Transportation allowance and internet load for non-affiliated and nonscientific members if needed

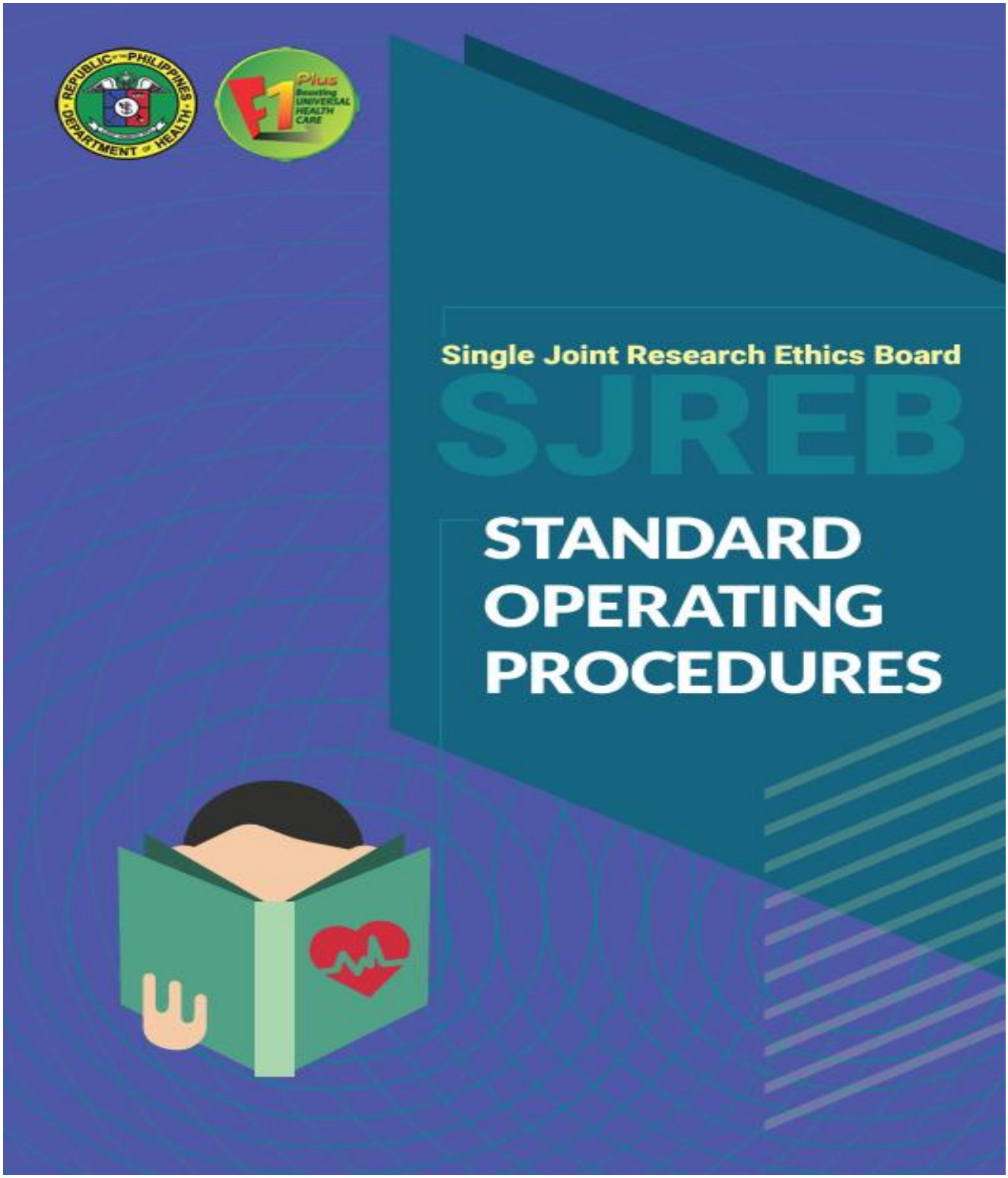
9.1. Transportation allowance ranging from P500-1000 to be given after each meeting depending on distance traveled

9.2. P400/month given at the beginning of month paid to the G cash of non-scientific and non-affiliated member

# APPENDIX D:
# Initial Protocol Review Process Flowchart


UNIVERSITY OF SANTO TOMAS HOSPITAL
RESEARCH ETHICS COMMITTEE
INITIAL PROTOCOL REVIEW PROCESS FLOWCHART
PRINCIPAL INVESTIGATOR
Submits a Research Protocol Package and other required requirements
Complete Protocol Package?
NO
REC STAFF
Returns documents to Principal Investigator and requests submission of re-documents are complete
YES
REC STAFF
Assigns a PROTOCOL REFERENCE NUMBER and encodes protocol in the logbook, tracking form, and REC electronic database
REC OFFICER
Classifies research protocols according to type of review and assigns PRIMARY REVIEWERS
Type of Review?
EXEMPT FROM REVIEW
EXPEDITED REVIEW
FULL REVIEW
REC HEAD
Consolidates and finalizes results. Decides to uphold EXEMPTION status or reclassify as EXPEDITED
Uphold Exempt Status?
NO
YES
REC STAFF
Prepares the Action or Approval Letter of Exemption from Review for signature of the REC Head and includes the protocol in the Agenda of the Meeting for reportorial and documentation purposes
REC HEAD
Signs the Action or Approval Letter of Exemption from Review addressed to the Principal Investigator
REC VICE HEAD
Reports the assessment findings, recommendations, and decision during the REC Meeting
PRINCIPAL INVESTIGATOR
Acts on the Action or Approval Letter accordingly
REC STAFF
Distributes protocol package with the PROTOCOL and INFORMED CONSENT ASSESSMENT FORMS to the assigned PRIMARY REVIEWERS
PRIMARY REVIEWERS
Review and submit findings and recommendations to the REC Staff. Recommends if the protocol is for APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, DISAPPROVAL, or FOR CLARIFICATORY INTERVIEW; the recommend protocol needs FULL REVIEW which will be decided by REC Head
Continue Expedited Review?
NO
YES
REC STAFF
Prepares the Action or Approval Letter for signature of the REC Head and includes the protocol in the Agenda of the Meeting for reportorial and documentation purposes
REC HEAD
Signs the Action or Approval Letter addressed to the Principal Investigator
REC VICE HEAD
Reports the assessment findings, recommendations, and decision during the REC Meeting
PRINCIPAL INVESTIGATOR
Acts on the Action or Approval Letter accordingly
REC STAFF
Distributes the protocol package with the PROTOCOL and INFORMED CONSENT ASSESSMENT FORMS to the assigned PRIMARY REVIEWERS
PRIMARY REVIEWERS
Review and submit assessment findings and recommendations to the REC Staff. Recommends if the protocol is for APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, DISAPPROVAL, or FOR CLARIFICATORY INTERVIEW
REC STAFF
Includes protocol in the AGENDA OF THE MEETING for the committee's discussion, deliberation, and decision
PRIMARY REVIEWERS
Present the protocol synopsis, findings, and recommendations during the REC Meeting
REC MEMBERS
Deliberate, decide, and vote a decision: APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, or DISAPPROVAL
REC STAFF
Prepares the Action or Approval Letter for signature of the REC Head
REC HEAD
Signs the Action or Approval Letter addressed to the Principal Investigator
PRINCIPAL INVESTIGATOR
Acts on the Action or Approval Letter accordingly

# APPENDIX E:
# Single Joint Research Ethics Board Standard Operating Procedures (2021)


Single Joint Research Ethics Board
SJREB
STANDARD
OPERATING
PROCEDURES

Single Joint Research Ethics Board

# SJREB

## STANDARD OPERATING PROCEDURES

Department of Health
Health Policy Development and Planning Bureau
Health Research Division

Published by

Health Policy Development and Planning Bureau
Department of Health
San Lazaro Compound
Rizal Avenue, Sta. Cruz
Manila 1003, Philippines

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# INTRODUCTION

The Single Joint Research Ethics Board (SJREB) was institutionalized in the Department of Health through the issuance of *Administrative Order (AO) No. 2017-0021* in October 2017. This initiative has been put in place to streamline the ethics review process within the Department and contribute in the improvement of the research ethics governance system in the country.

SJREB has started its operations in March 2018. Its primary role is to host and serve as a platform for joint review of multi-site research studies sponsored by DOH and/or to be implemented across various DOH hospitals. In 2019, with the Board's commitment to further improve its processes and promote transparency, SJREB underwent joint accreditation from PHREB and the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP). This accreditation then led to the issuance of the revised *AO No. 2019-0049: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health* in November 2019 which addresses the issues and gaps identified in its pre-existing procedures and reiterates the processes and procedures in the adoption of the single joint review system in the DOH. Further, recognizing the capacity and core functions of the SJREB, the *Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals* was also institutionalized in which the Board's primary responsibility is to assist DOH hospitals research ethics committees in identifying and managing conflict of interest and other study-related complaints.

The SJREB's oversight applies to all DOH units including Centers for Health Development (CHDs), Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), hospitals, and attached agencies with research ethics committees. It also covers private research ethics committees who have agreed to participate in the single joint ethics review process. And with its recent designation by the Sub Technical Working Group (TWG) on Vaccine Development and in accordance with PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal, SJREB shall facilitate the ethics review of all COVID-19 vaccine trials to be implemented in the country following the prescribed process flow set forth by the vaccine experts panel.

This SOPs have been developed based on the DOH harmonized research ethics committee SOPs, PHREB and FERCAP standards, and other relevant local and international guidelines on health research ethics such as:

a. *National Ethical Guidelines for Health and Health Related Research (NEGHHRR)*
   - This PHREB document acknowledges the conduct of a joint review of a group of PHREB accredited ethics committees provided that the review abides by a standard operating procedures (SOPs) approved by PHREB

b. *Council for International Organizations of Medical Sciences (CIOMS)*
   - This international guideline highlights the conduct of single review of multi-site research in one jurisdiction (country) by one ethics committee to avoid lengthy procedures and ensure quality of the review.

The document contains five (5) important chapters such as: (1) Authority, composition, and structure of SJREB; (2) Joint review process for initial submission; (3) Consolidated post-approval procedures; (4) Documentation and archiving; and, (5) Writing and revising SOPs. This SOP will be periodically reviewed and revised to address new issues and gaps that may arise over time. Also, this document will be updated as new local and international regulations, policies and guidelines are published. Meanwhile, the SJREB encourages stakeholders to send feedback and questions through official SJREB email at sjreb.doh@gmail.com.

4 | STANDARD OPERATING PROCEDURES
SINGLE-JOINT RESEARCH ETHICS BOARD

# ETHICAL FRAMEWORK OF THE SINGLE JOINT RESEARCH ETHICS BOARD

The Single Joint Research Ethics Board is guided by in its review, recommendations, and decisions by the following ethical principles:

1. **Respect for Persons** – principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **Beneficence** – principle that requires investigators to protect participants from harm and secure their well-being.
3. **Justice** – principle that refer to the sense of "fairness in distribution" and "what is deserved".

***Source:*** *Belmont Report, 1979*

A. SJREB is guided and informed by the ethical principles, processes and procedures embedded in the following international guidelines:
   - Declaration of Helsinki (2013 and its subsequent revisions)
   - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2
   - Council for International Organizations of Medical Sciences (CIOMS) Guidelines 2016

- Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)

B. SJREB shall function in accordance with the existing national laws, policies, regulations, and guidelines such as:
   - National Ethical Guidelines for Health Research set forth by the Philippine Health Research Ethics Board (PHREB)
   - Policy issuances (i.e., Administrative Orders, Department Orders, etc.) from the Department of Health, Philippine Food and Drug Administration (FDA) and other relevant agencies such as:
     - Administrative Order No. 2019-0049
     - Department Order No. 2019-0063

C. SJREB adopts its own standard operating procedures (SOP) based on:
   - Operational Guidelines for Ethics Committees that review Biomedical Research (2000) by the WHO
   - DOH-REC SOP Templates
   - FERCAP-SOP Templates
   - PHREB SOP Workbook 2020

D. In evaluating protocols and ethical issues, SJREB is cognizant of the diversity of the laws, cultures, and practices governing health research in various local sites and countries around the world.

E. SJREB is strictly aware and abide by the relevant Philippine laws in terms of the conduct of various types of research.

F. SJREB attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed research is being considered.

G. SJREB will take the initiative to be informed, as appropriate, by current state-of-the art researches and publications of the impact of the research that it has approved.

# A. SOP 1 SJREB STRUCTURE AND COMPOSITION

## 1.1 Purpose

1.1.1. To describe the authority, composition and structure of the Single Joint Research Ethics Board (SJREB) related to the ethics review of multi-site researches.

1.1.2. SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB) with the following objectives:

1.1.2.1. To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines.

1.1.2.2. To shorten the turn-around time of ethics review of multi-site protocols.

1.1.2.3. To harmonize the results of ethics review among various site RECs through joint review.

1.1.2.4. To strengthen the ethics review capacity of PHREB accredited RECs to review different types of protocols that are conducted at their sites.

1.1.2.5. To serve as DOH central ethics committee who shall review DOH funded research.

## 1.2 Scope of Authority

1.2.1. SJREB is a joint review mechanism for multi-site protocols to be implemented at various sites and as adopted by duly accredited PHREB Research Ethics Committees (RECs).

1.2.1.1. It serves as a common review platform for all DOH RECs that will sign a letter of intent to participate and accept its review.

1.2.1.2. It also covers the non-DOH hospital RECs from both the public and the private sectors that will sign a letter of intent to participate and accept its review.

1.2.2. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines.

1.2.2.1. All DOH funded research studies shall be reviewed by SJREB.

1.2.2.2. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.

1.2.2.2.1. At least one site is a Level 3 PHREB-accredited hospital with letter of intent.

1.2.2.3. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities.

1.2.2.4. SJREB also accepts and reviews multicenter researches that are community-based.

1.2.3. SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.

1.2.4. SJREB facilitates the ethics review of all COVID-19 vaccine trials to be conducted in the country in compliance with its designation by the Sub-Technical Working Group for Vaccine Development and PHREB's Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal.

1.2.5. It serves as a Central REC to review DOH Central Office funded researches. It invites all site RECs to participate in the review of DOH protocols. However, SJREB may also review the following; (a) for DOH hospital RECs that lack the required level of PHREB accreditation; and, (b) have lost or have pending reaccreditation according to the following procedures:

1.2.5.1. The site REC shall receive submissions and reports from the site PIs, review the issues through expedited or full board as prescribed in their SOPs, and arrive at a recommended decision. There should be an interim agreement between SJREB and the site;

1.2.5.2. The site REC should forward their recommended decision and attach relevant documents (PI submission, site REC assessment forms, minutes, etc.) to SJREB together with a request for SJREB review and oversight.

1.2.5.3. The SJREB secretariat shall receive the request, determine the appropriate review channels and procedures.

1.2.5.4. SJREB shall review the issues and arrive at an appropriate decision to be forwarded to the site REC which in turn will forward the decision to the site investigator.

1.2.6. SJREB may also be involved in resolving conflict of interest issues and other study-related complaints implicating a DOH REC that may be constrained to fulfill its ethical mandate. SJREB may intervene and recommend the course of action to be implemented by the DOH research unit and/ or REC in accordance with Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals.

## 1.3 Structure of the Single Joint Research Ethics Board

**1.3.1. Organizational Structure.** The Single Joint Research Ethics Board shall be placed directly under the Health Policy Development and Planning Bureau (HPDPB), Office of the Director to ensure independence of the board. This Bureau has the responsibility to set-up and support the SJREB office and secretariat to assist the Boards in its day-to-day operations. See Figure 1 for the Organogram of the SJREB.

**1.3.2. HPDPB Roles and Responsibilities**

1.3.2.1. Administrative support to the Board.

1.3.2.1.1. It ensures the independence of the decision making of SJREB.

1.3.2.1.2. It approves the SJREB Standard operating procedures to ensure that it is in agreement with policies of DOH.

1.3.2.1.3. It ensures that SJREB provides a mechanism to educate its reviewers and staff, including site RECs to develop the necessary knowledge, skills and practice to improve the review of various types of protocols submitted.

1.3.2.1.4. It requires progress report from SJREB to assess performance as basis for continuous quality improvement.

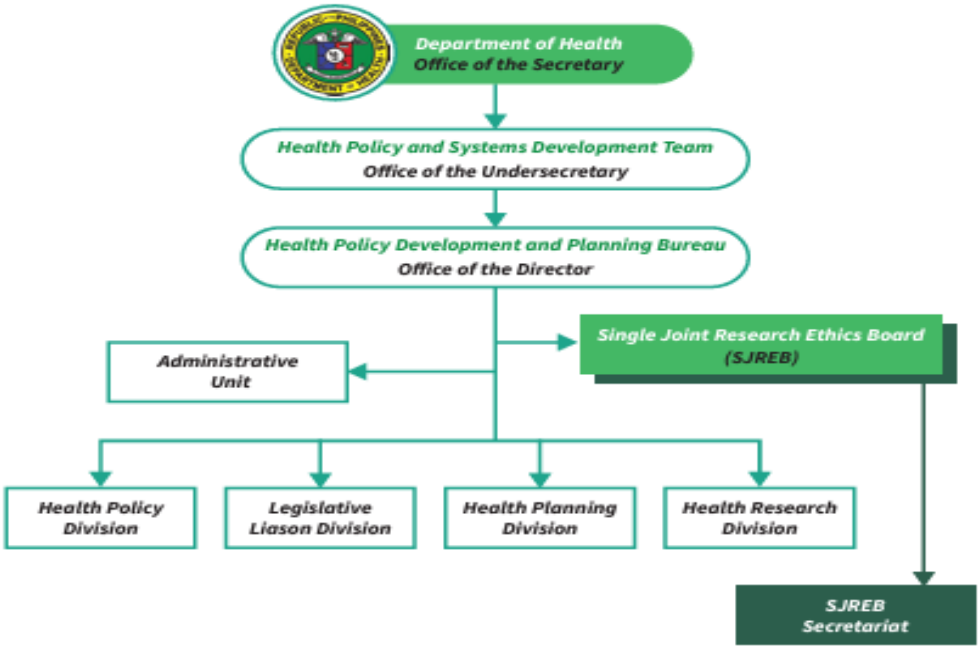
1.3.2.1.5. It provides sufficient staff to support the SJREB operations.

1.3.2.1.6. It allocates space, office equipment, IT infrastructure and all the necessary logistical support to enable SJREB to conduct its joint review functions efficiently and effectively.

1.3.2.1.7. It provides a budget for annual update training to SJREB Members and all DOH RECs and non-DOH RECs that submitted an LOI to the Board.

1.3.2.1.8. It screens nominees and recommends SJREB members to the Secretary of Health.

Figure 1. Organogram of SJREB




### 1.3.3. Process flow and Steps for Appointment of SJREB members

Table 1. Process flow and Steps for Appointment of SJREB members

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Nomination and Selection of SJREB Members | SJREB Chair and permanent members |
| 2 | Screening of Nominees and Recommendations | HPDPB Director |
| 3 | Appointment of the SJREB members | Secretary of Health |

**1.3.4. Nomination Process**

1.3.4.1. The permanent REC members, secretariat, and all participating REC members with an active LOI may nominate potential SJREB members.

1.3.4.2. The identified list of nominees shall be presented to the SJREB members during a regular full board meeting for the Board to finalize such a list.

1.3.4.3. The list of nominees will then be endorsed by the SJREB Chair to the HPDPB Director for final screening.

**1.3.5. Screening of Nominees and Recommendations**

1.3.5.1. The HPDPB Director, upon receipt of the list of nominees for SJREB membership from the SJREB Chair, shall assess the submitted documents and recommends the final list of proposed new set of SJREB members to the Secretary of Health (SOH).

1.3.5.2. The HPDPB Director has the prerogative to recommend the Chair based on his/her knowledge of the competence and capacity of such nominee. This privilege is guided by the common understanding that despite the nature of such recommendation, the independence of the decision making of the Board should still be strictly observed and exercised at all times.

1.3.5.3. A formal endorsement of the HPDPB's recommendation for the SJREB membership shall be forwarded to the Office of the Secretary for approval.

1.3.5.4. After the approval of the of the SOH, the SJREB Secretariat shall prepare the necessary documentary requirements to formalize appointment of the new SJREB members.

**1.3.6. Appointment Process**

1.3.6.1. The SJREB Secretariat shall ensure that the appointment documents are completed prior to engaging the SJREB members as described below.

***1.3.6.2. SJREB Members***

1.3.6.2.1. The Secretary of Health appoints an appropriate number of persons to form the SJREB membership to manage the SJREB operations. It may appoint consultants with relevant skills to help SJREB perform its review functions.

1.3.6.2.2. It appoints the SJREB Chair with a three-year term of office from participating RECs. It ensures that the Chair has sufficient background, training and experience in ethics review of various types of protocols.

1.3.6.2.3. It appoints a non-medical/non-scientific member, depending on the type of review, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

1.3.6.2.4. It ensures that there is a non-affiliated member (i.e representative not coming from any of the hospital sites specified in the research being reviewed) during the SJREB meetings.

1.3.6.2.5. It invites the Philippine Health Research Ethics Network (PHREN) to nominate its representative with a fixed term, preferably from the private sector.

1.3.6.2.6. It appoints an appropriate number of designated subject experts/independent consultants who can assist SJREB review of multi-site protocols.

1.3.6.2.7. It ensures that a representative from a DOH-specialty hospital (e.g. Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.) is invited to attend review meetings related to their expertise.

1.3.6.2.8. It shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.

1.3.6.2.9. It shall have representatives from ages below 50 years old and above 50 years old.

1.3.6.2.10. In order to ensure continuity of functions, at least half of the SJREB shall be retained/re-appointed for at least one (1) year before a new set shall be appointed.

### 1.3.7. SJREB Membership and Secretariat

***1.3.7.1. SJREB Membership.*** The SJREB membership is composed of seven (7) permanent and non-permanent members as indicated below. Independent consultants are also engaged for the review of specialized protocols.

**1.3.7.1.1. Permanent Members**

1.3.7.1.1.1. The **Chair** is a dedicated individual from an REC with experience to review different types of researches with fixed term of three (3) years as stipulated in the joint review SOPs.

1.3.7.1.1.2. A **Vice Chair** may be assigned from the existing permanent members

1.3.7.1.1.3. The **Member Secretary** shall oversee the protocols being reviewed by the Board and ensure the accuracy of the minutes of the meeting. He/she is a plantilla staff affiliated with the DOH.

1.3.7.1.1.4. Designated **Philippine Health Research Ethics Network (PHREN) Representative** from a private institution with a fixed term of three (3) years as stipulated in the joint review SOPs.

1.3.7.1.1.5. The **non-medical or non-scientific member**, depending on the type of protocol submission, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

**1.3.7.1.1.6. Subject matter experts (SME)** on Health Systems, Ethics, Social science, and Public Health.

**1.3.7.1.2. Non-Permanent Members**

1.3.7.1.2.1. The **participating site REC representatives** are identified point persons or subject matter expert from the sites who are knowledgeable on the study protocols being reviewed

**1.3.7.1.2.2. Subject Matter Expert (SME)/Non-medical member from the specialty hospitals** who is a designated representative from the DOH specialty hospitals to review a multi-site research i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.

**1.3.7.1.3. Independent consultant** is an individual who has the specialization that is not present on the permanent members assigned to review a multi-site protocol.

**1.3.7.2. Secretariat**

**1.3.7.2.1. Member Secretary** is an affiliated plantilla technical staff who sits as a permanent member of the Board and ensures compliance with the SOP during the entire review process.

**1.3.7.2.2. Head of Secretariat (HoS)** is a plantilla technical staff who shall supervise the day-to-day operations of the Board

**1.3.7.2.3. Administrative Staff** is a dedicated staff who provides support to the HoS and Member Secretary in the administrative and clerical management of the SJREB.

**1.3.8. Roles and Functions**

**1.3.8.1. SJREB Members**

1.3.8.1.1. The SJREB Chair presides over full board meetings and ensures appropriate review of protocol related documents in accordance with international and national guidelines and regulations. He/she may designate the Vice Chair or a representative from an accredited

REC to preside over a meeting that he/ she cannot attend.

1.3.8.1.2. The SJREB members shall evaluate and manage conflict of interest that cannot be resolved at the institutional level especially for hospitals within the purview of the Department following the processes and procedures in the Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH hospitals

**1.3.8.2. SJREB Secretariat**

**1.3.8.2.1. Member Secretary**

1.3.8.2.1.1. Oversees the conduct of the full board meeting and ensures that the review process is in accordance with the SOP

1.3.8.2.1.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting

**1.3.8.2.2. Head of Secretariat**

1.3.8.2.2.1. Manages the day-to-day activities of SJREB to include office procedures

1.3.8.2.2.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting

1.3.8.2.2.3. Conducts screening and identifies type of review of initial protocol submissions and post approval submissions

1.3.8.2.2.4. Recommends exemption for review to the Chair

1.3.8.2.2.5. Reviews all technical and administrative documents relative to SJREB operations to include but not limited to agenda of the meeting, minutes of the meeting, notification of approval/modifications and other post approval communication letters and documents

**1.3.8.2.3. Administrative Staff**

1.3.8.2.3.1. Communicates with various clients and stakeholders, and ensuring appropriate REC and site representation during the conduct of review.

1.3.8.2.3.2. Invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study.

1.3.8.2.3.3. Ensures completeness of protocols package submitted by the Coordinating PI for SJREB review.

1.3.8.2.3.4. Checks the site REC's level of PHREB accreditation. Only level 3 REC representatives can vote during full board review of clinical trial protocols intended for FDA registration, while both levels 2 and 3 REC representatives can vote during the review of public health protocols and clinical research not intended for FDA registration. Further, it ensures fair representation in terms of the counts of votes; only one (1) vote per site.

1.3.8.2.3.5. Invites observers from study sites, without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

1.3.8.2.3.6. Prepares the meeting agenda and minutes of all SJREB meetings for approval of the Chair.

1.3.8.2.3.7. Checks completeness of all assessment forms accomplished by the designated primary reviewers.

1.3.8.2.3.8. Issues an appropriate decision document (i.e. Notice of Approval, Notice of Protocol Modification, Certificate of Exemption, Notification Letter) to

all participating site RECs as reviewed and approved by the HoS and Member Secretary and duly signed by the SJREB Chair.

1.3.8.2.3.9. Ensures that Letter of Intent to participate in SJREB are secured prior to attendance to any SJREB meetings.

**1.3.8.3. SJREB Participating Sites**

1.3.8.3.1. DOH Hospital RECs and non-DOH RECs need to submit a Letter of Intent (LOI) to SJREB to participate in joint review when their sites are selected by the sponsor for the conduct of multi-site researches. The LOI shall apply for the entire duration of participation of the RECs in the single joint ethics review. In any given circumstances, the REC may opt to withdraw any time from participation in the review process by submitting a letter of withdrawal to the SJREB Secretariat. Should an REC wish to participate in the joint review after withdrawal, they should submit a new LOI to SJREB.

1.3.8.3.2. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. For non-DOH hospitals, their RECs retain the option to accept or reject SJREB decision.

1.3.8.3.3. All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:

1.3.8.3.3.1. Authority is shared by a duly accredited site REC with SJREB to conduct joint review with representatives from site RECs of multi-site researches. Joint review by SJREB is done only for initial review and renewal of approval. SJREB

conducts full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low risk protocols may be exempted from review or may go through expedited review procedures.

1.3.8.3.3.2. All RECs who will participate in joint review should submit their membership list with their CVs and they should identify representatives qualified to do scientific and ethical review for various types of protocols commonly submitted for review.

1.3.8.3.3.3. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/ or site specific concerns that cannot be addressed. All site RECs will issue a Certificate of Approval together with the Notice of Decision from SJREB.

1.3.8.3.3.4. The site REC retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports and final reports, all of which involve events at specific sites. The site REC, meanwhile, has the prerogative to elevate protocol deviation to SJREB and provide corrective actions.

1.3.8.3.3.5. The site REC maintains active collaboration and communication with SJREB for joint review to achieve its stated objectives and for mutual benefit of improving the research environment in the Philippines.

1.3.8.3.3.6. For site RECs that have lost or pending accreditation, the REC should still conduct review of the protocol. The REC then has the responsibility to submit the result of the review to SJREB for any further discussion or approval.

## 1.4 SJREB Letter of Intent and Oversight Function

### 1.4.1. Purpose

To describe the process of engaging participating sites in the joint ethics review process and define the oversight function of the SJREB

### 1.4.2. Scope

The Letter of Intent (LOI) is an agreement between the participating site(s) and SJREB whereby the site acknowledges and agrees to participate in the joint review process being conducted by the SJREB and abide by all its policies and guidelines set forth in this SOP and other relevant issuances.

### 1.4.3. Responsibility

1.4.3.1. It is the responsibility of the participating sites to submit a letter of intent (See SJREB Form 12) to SJREB through its Secretariat expressing the interest to participate in the joint review process

1.4.3.2. The SJREB Secretariat shall receive and facilitate the necessary documents to formalize such engagement. The LOI shall then be endorsed to the Director of the HPDPB for conforme.

1.4.3.3. For sites who have been identified to participate in a clinical trial but do not have the required PHREB accreditation level, the SJREB may assume oversight functions following the conditions below:

1.4.3.3.1. Adopt the SJREB standard operating procedures as part of the REC's SOPs in compliance with AO no. 2019-0049;

1.4.3.3.2. Attend SJREB meetings when the indicated protocol is being discussed.
1.4.3.3.3. Accept the decision of the SJREB for implementation at the site.
1.4.3.3.4. Submit results of the REC review of the protocol to SJREB.
1.4.3.3.5. Monitor the study implementation and submit the REC's recommendations to SJREB about action on reports submitted by the PI.
1.4.3.3.6. Inform SJREB at any time that the REC has been given its PHREB accreditation.

### 1.4.4. Process Flow/Steps

**Table 2. Process flow and Steps for LOI and Oversight Fuction**

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Submit LOI to SJREB Secretariat | Participating site(s) |
| 2 | Receive and process documents formalizing engagement | Secretariat |
| 3 | Issue conforme letter to the participating site | HPDPB Director, Secretariat |

### 1.4.5. Detailed instructions

1.4.5.1. Submit LOI to SJREB Secretariat

1.4.5.1.1. The participating site shall prepare the LOI duly signed by their respective REC Chairperson using SJREB Form 12.
1.4.5.1.2. The signed LOI shall be submitted to the SJREB Secretariat for approval of the HPDPB Director.

1.4.5.2. Receive and process documents

1.4.5.2.1. The SJREB Secretariat shall acknowledge and process the necessary documents

to formalize the engagement with the participating site.

1.4.5.2.2. Issue conforme letter to the participating sites

1.4.5.2.3. The signed conforme letter from the HPDPB Director shall be provided and issued to the participating site by the SJREB Secretariat

## 1.5 Training of SJREB Members and Staff

**1.5.1. Purpose**

To describe **SJREB** procedures to ensure initial and continuing training of members and staff

**1.5.2. Scope**

The SJREB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of SJREB members and staff from initial training to continuing education to maintain and update competence in the review of different types of protocols.

**1.5.3. Responsibility**

1.5.3.1. It is the responsibility of the SJREB members and staff to have themselves educated and trained regularly.

1.5.3.2. It is the responsibility of the SJREB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff. The chair may assign a permanent member to lead capacity building related activities.

1.5.3.3. The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

### 1.5.4. Process Flow/Steps

**Table 3. Process flow and Steps for LOI and Oversight Fuction**

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE | TIMELINE |
|---|---|---|---|
| 1 | Require basic research ethics training for all members and staff | Chair | Needs assessment to be done at the beginning of the year |
| 2 | Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses | Chair, Secretariat | |
| 3 | Track member and staff participation initial and continuing ethics training and file the documents in the Membership File | Members, Secretariat | |

### 1.5.5. Detailed instructions

1.5.5.1. REC members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

1.5.5.2. Require Research Ethics Training for all members and staff

1.5.5.2.1. All members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:

1.5.5.2.2. Member's/Staff's responsibilities;

1.5.5.2.3. Confidentiality and Conflict of Interest Agreement;

1.5.5.2.3.1. Review process and use of Protocol and ICF Assessment forms; and,

1.5.5.2.3.2. SOPs.

1.5.5.2.4. The Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

1.5.5.3. Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

1.5.5.3.1. The Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.

1.5.5.3.2. The Chair and Secretariat plan the training activities for individual members based on their training needs.

1.5.5.3.3. The Chair and Secretariat track and facilitate attendance of members and staff of specific training activities needed to ensure that each one gets training at least once a year.

1.5.5.3.4. The members who participate in research ethics training course or seminar-workshops either through personal or through REC efforts/funding are encouraged to:

1.5.5.3.4.1. Share information with other members during meetings; and,

1.5.5.3.4.2. Distribute photocopies/e-copies of relevant materials to the other members.

1.5.5.4. Track member and staff participation in initial and continuing ethics training and file the documents in the Membership File

1.5.5.4.1. For in-house training, the SJREB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.

1.5.5.4.2. All members and staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the REC Staff for filing.

1.5.5.4.3. Administrative Staff should update the Training Record of individual Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.

1.5.5.5. The joint review process shall serve as an avenue for building capacity of the RECs by exposing them to wide variety of protocols and best review practices from expert primary reviewers. SJREB may also invite observers from study sites without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

# B. SOP 2 JOINT REVIEW OF PROTOCOLS

## 2.1 Purpose

To describe the Single Joint Research Ethics Board (SJREB) requirements and procedures in conducting initial and continuing review of multi-site protocol related documents, vis-a-vis the site RECs.

## 2.2 Scope

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review.

2.2.1. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:

2.2.1.1. Sponsored or funded by the Department of Health
2.2.1.2. Multi-site protocol to be conducted in at least 3 sites with at least one (1) site identified as site with the ff qualifications:

2.2.1.2.1. Level 3 hospital
2.2.1.2.2. At least one (1) site with a Letter of Intent (LOI) which specifies that:

2.2.1.2.2.1. SJREB reviews the country protocol
2.2.1.2.2.2. PIs shall submit to both SJREB and the sites
2.2.1.2.2.3. Sites accept the SOPs of SJREB for the joint review of protocols
2.2.1.2.2.4. Only site specific modifications shall be allowed. No modifications to the approved country protocol shall be required by the participating sites.
2.2.1.2.2.5. Site accepts the decision of SJREB unless there is compelling ethical, legal or scientific concerns. Reasons for site disapproval shall be submitted to SJREB and must be justified.
2.2.1.2.2.6. Disapproval of protocol shall mean that the site is opting out as a site for the study.

2.2.2. SJREB requires an LOI to regularly participate in joint review from all Research Ethics Committees when their sites are selected by the sponsors as a study. The LOI shall be effective unless a withdrawal of the intent to participate is submitted in writing.
2.2.3. SJREB requires the site RECs to agree and abide with the procedures of SJREB
2.2.4. All research sites agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.
2.2.5. In sites with no REC or has a functional REC with PHREB accreditation that is not appropriate for the type of protocol being reviewed, SJREB may either assume the oversight function of the site or choose to assign a PHREB-accredited REC to do the review and oversight. The determination will depend on the type and nature of the protocol to be implemented. The designated oversight REC shall issue the certificate of approval and assume stewardship and monitoring functions.

## 2.3 Responsibility

2.3.1. The permanents members, independent consultant, and participating sites representatives act as primary reviewers and attend board meeting
2.3.2. The members review and decide make decisions on the protocol
2.3.3. The SJREB Secretariat manages all protocol submissions to the SJREB.

## 2.4 Types of Review Classification of Protocols Submitted for Initial Review

SJREB classifies protocols into 3 types to determine the appropriate type of review of multi-site protocols. The Head of Secretariat makes a preliminary assessment of protocols and recommends the type of review to the Chair who approves the classification.

**2.4.1. Detailed procedures for the three review types**

**2.4.1.1. Exemption from Ethics Review:**

2.4.1.1.1. The Head of Secretariat makes a preliminary assessment of the protocol using the SJREB Form 6: Checklist for Exemption from Full Ethical Review Form to determine if it meets the exemption criteria as follows:
2.4.1.1.2. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g. meta-analysis protocols)
2.4.1.1.3. Protocols that involve human participants or identifiable human tissue, biological samples, and data provided that the following do not involve more than minimal risks or harm:

2.4.1.1.3.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation

activities, and consumer acceptability tests;

2.4.1.1.3.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

2.4.1.1.3.3. No disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their final standing, employability, or reputation; and

2.4.1.1.3.4. Information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant

2.4.1.1.3.5. Protocols that involve the use of publicly available data or information

2.4.1.1.4. The Head of Secretariat and a senior member of the board reviews the protocol and makes a determination for exemption. In certain circumstances, exemption may be discussed in an expedited meeting. The protocol for exemption shall be reported in the full board review for the information of the Board. The reviewer(s) submits the SJREB Form 4: Checklist for Exemption to the Secretariat seven (7) calendar days before the full board meeting.

2.4.1.1.5. SJREB issues a Certificate of Exemption (SJREB Form 4.1) signed by the Chair within seven (7) calendar days after the decision.

2.4.1.1.6. Should there be any major protocol change after the issuance of the Certificate of Exemption, the Coordinating PI shall submit an amendment to SJREB to make a decision about change of classification.

**2.4.1.2. Expedited Review:**

2.4.1.2.1. The Head of Secretariat makes a preliminary assessment of the protocol and determines qualification for expedited review based on the following criteria:

- 2.4.1.2.1.1. Does not involve more than minimal risks or harm but does not qualify for exemption
- 2.4.1.2.1.2. About a topic that should not result in causing social stigma
- 2.4.1.2.1.3. Does not involve vulnerable populations
- 2.4.1.2.1.4. Retrospective studies using anonymized data from medical records
- 2.4.1.2.1.5. Studies using simple questionnaires without identifiers
- 2.4.1.2.1.6. Proposals such as:
  - 2.4.1.2.1.6.1. Chart review
  - 2.4.1.2.1.6.2. Survey of non-sensitive nature
  - 2.4.1.2.1.6.3. Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data

2.4.1.2.2. The Head of Secretariat recommends the type of review to the Chair who approves the classification.

2.4.1.2.3. The Head of Secretariat identifies two or more primary reviewers from the permanent members and/or participating sites to conduct initial review through expedited procedures. SJREB may also call for a meeting of the sites to expedite the review.

2.4.1.2.4. The primary reviewer(s) should review within seven (7) calendar days using appropriate SJREB assessment forms. The primary reviewers may recommend modifications and decide on the approval of the protocol documents.

2.4.1.2.5. If any of the PR recommends disapproval, it is automatically elevated to full board.

2.4.1.2.6. The Head of Secretariat may recommend to

hold an expedited meeting when necessary, with the attendance of the secretariat and the primary reviewers. The expedited review report shall be finalized by the Member Secretary for reporting in the full board meeting.

2.4.1.2.7. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating Principal Investigator (PI) within fourteen (14) calendar days after protocol submission.

2.4.1.2.8. The SJREB secretariat endorses the decision of SJREB to participating sites. SJREB expects the participating sites to accept its decision. Each site may add site specific recommendation to SJREB Decision.

2.4.1.2.9. The site REC issues a Certificate of Approval.

**2.4.1.3. Full-Board Review:**

2.4.1.3.1. The Head of Secretariat makes a preliminary assessment of the protocol and identifies more than minimal risk protocols for full board review.

2.4.1.3.2. The Head of Secretariat assigns primary reviewers from site RECs or invites independent consultants to review the protocol and the ICF.

2.4.1.3.3. The SJREB secretariat informs the site RECs of its receipt of protocols for full board joint review. Participating RECs conduct a preliminary assessment of the protocol and prepare comments/ recommendations on the protocol to be presented during the full board review.

2.4.1.3.4. The assigned primary reviewers shall prepare their comments using appropriate SJREB assessment forms and lead the discussion about the protocol during the board meeting. Other SJREB and participating sites representatives contribute to the discussion.

2.4.1.3.5. The SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda and informs the members of the board, the site REC representatives, the assigned primary reviewers, as well as SME from necessary fields of experience to attend the meeting.

2.4.1.3.6. The Coordinating PI shall be invited for a clarificatory interview to answer queries about the protocol.

2.4.1.3.7. The board adopts one of the following decisions during joint review:

2.4.1.3.7.6.1. Approval
2.4.1.3.7.6.2. Minor modification required
2.4.1.3.7.6.3. Major modification required
2.4.1.3.7.6.4. Disapproved

2.4.1.3.8. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating PI and to all the participating sites within fourteen (14) calendar days after the Full Board meeting.

2.4.1.3.9. For protocols with recommendations for modification, the Coordinating PI is given fifteen (15) calendar days to submit a revised protocol.

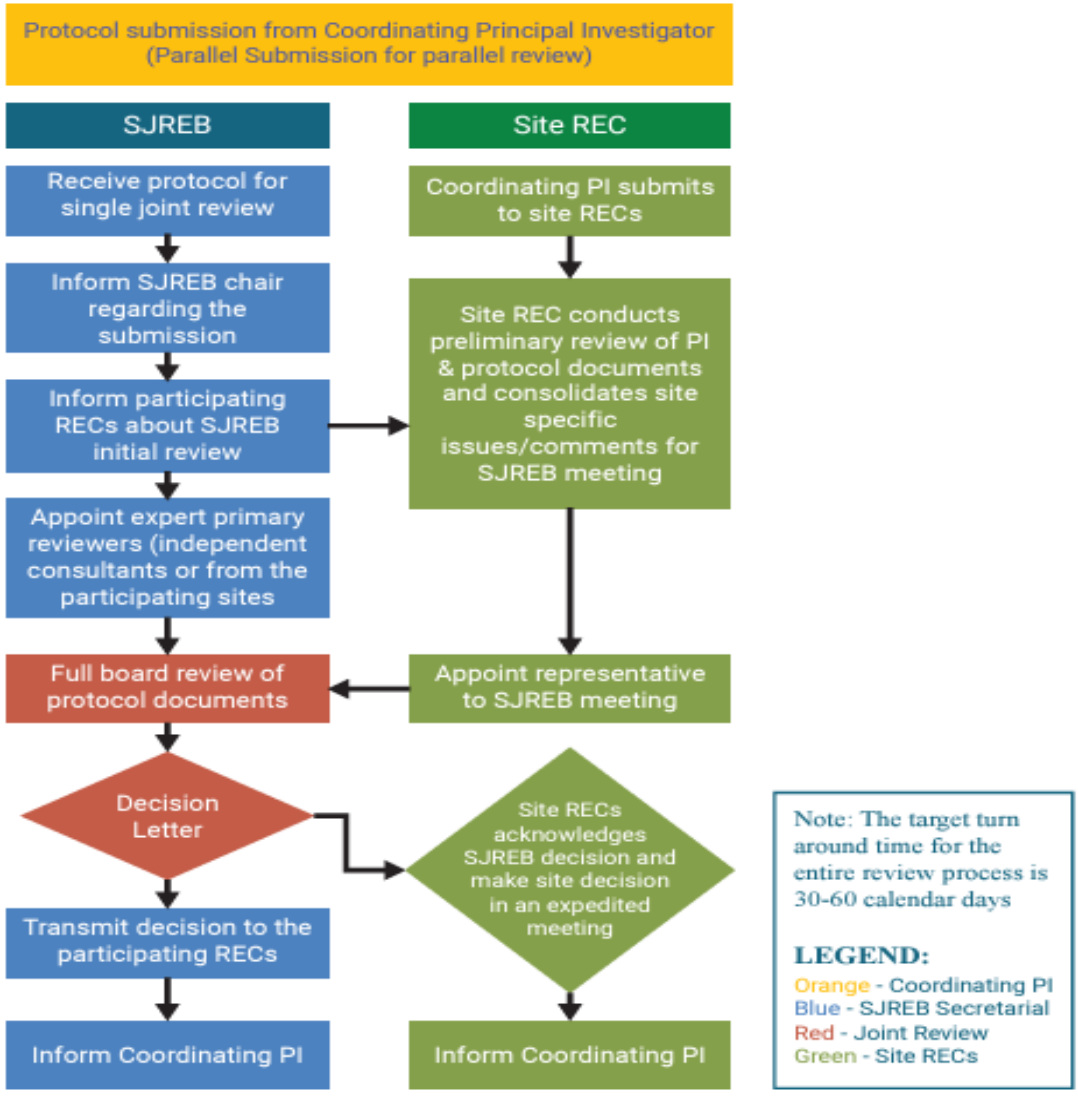
2.4.1.3.10. Site RECs acknowledges SJREB decision and make site-specific decisions in an expedited meeting.

2.4.1.3.11. All DOH Hospital RECs and non-DOH RECs with LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. Each site REC shall issue a Certificate of Approval, or a notice of its decision clearly stating the ethical issues,

if it chooses to disapprove the protocol.

2.4.1.3.12. The site in general can no longer introduce major modification on the country protocol. However, the site RECs can disapprove the protocol only when they think that there are strong ethical issues or site specific concerns that were not addressed. Reasons for disapproval should always be stated in the decision letter. Meanwhile, the ICF may be revised in any manner the site REC requires.

**Figure 2. Initial and Annual Renewal of Approval Review Procedures**



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## 2.5 Management of Initial Protocol Submissions

2.5.1. Receive the initial protocol package for review and check the completeness of the documents submitted

2.5.2. SJREB Secretariat ensures that SJREB Form 1: Application for SJREB Initial Review and SJREB Form 1.2: Protocol Summary Sheet are completely filled out, signed and dated by the Coordinating PI submitting the protocol documents.

2.5.3. The following documents should be submitted in the initial protocol package:

2.5.3.1. Basic Documents:

2.5.3.1.1. Application Form [SJREB Form 1 - Application Form]
2.5.3.1.2. Protocol Summary Sheet [SJREB Form 1.2 - Protocol Summary Sheet]
2.5.3.1.3. Study Protocol
2.5.3.1.4. Informed Consent Forms
2.5.3.1.5. Recruitment and Advertisement Materials
2.5.3.1.6. Data Collection Forms
2.5.3.1.7. Curriculum vitae of principal investigators
2.5.3.1.8. Study Budget
2.5.3.1.9. Technical Clearance
2.5.3.1.10. Proof of submission to at least three (3) study sites

2.5.3.2. Study-specific Documents (submit as needed)

2.5.3.2.1. FDA Approval/ Proof of submission (for clinical trials)
2.5.3.2.2. Patient Information Sheet (for clinical trials)
2.5.3.2.3. Investigator Brochure (for clinical trials)
2.5.3.2.4. Basic Research Ethics Training Certificates of PIs (for non-clinical trials)
2.5.3.2.5. GCP certificates of PIs (for clinical trials)
2.5.3.2.6. Other protocol-related documents

2.5.4. SJREB may require Coordinating PI to submit to SJREB specific protocol-related documents submitted to the local

RECs.

2.5.5. SJREB requires proof of submission of protocol to at least three (3) sites, with at least one (1) DOH hospital or a level 3 REC with LOI identified as site, prior to acceptance for ethics review.

2.5.6. One (1) hard copy and soft copy (sent either via email, flash drive, or CD) of the above documents shall be submitted to the SJREB.

2.5.7. The SJREB full board meeting is scheduled every second Wednesday of the month. The deadline for protocol submission for full board meeting is fourteen (14) calendar days prior (last Wednesday of the preceding month) to the next meeting.

2.5.8. Assign a permanent code to the protocol package

2.5.8.1. For efficient file management, it is necessary for SJREB staff to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: SJREB-yyyy (year) –number (chronological number based on order of receipt).

2.5.8.2. For example, if the protocol entitled "Clinical Drug Trial of XYZ on Pediatric Patients" is the first protocol received in 2017, the code SJREB-2017-01 should be used to identify this protocol. The code shall be used on all communications regarding the protocol.

2.5.9. Determine the Type of Review and assign primary reviewers

2.5.9.1. The Head of Secretariat makes a determination about the appropriate type of review and seeks approval of the Chair on the review classification.

2.5.9.2. The Head of Secretariat identifies one (1) protocol reviewer and one (1) as ICF reviewer from the permanent members or from members of participating site RECs for full board and expedited protocols.

2.5.10. Distribute the Initial Protocol Documents to the Primary Reviewers

2.5.10.1. The SJREB Staff sends copies of protocol documents together with the SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form, with the transmittal letter

to the primary reviewers.

2.5.10.2. The initial protocol documents should be distributed to the Primary Reviewers seven (7) calendar days

## 2.6 Full-Board Review Procedures

**2.6. Full-Board Review Procedures**

**2.6.1. Before Full-Board Meeting**

2.6.1.1. The Coordinating PI submits the multi-site protocol documents to the identified sites at least two (2) weeks prior to submission to SJREB.

2.6.1.2. The site RECs conduct their preliminary review of the protocol documents and identify a representative who will participate in the discussion during the Full-Board SJREB meeting to reflect the views of their own REC.

2.6.1.3. The SJREB staff schedules the Joint Review meeting and checks the availability of the regular SJREB members, independent consultants, and representatives of the participating RECs to determine if quorum will be met. Quorum requires attendance of at least five (5) SJREB voting members inclusive of the presence of at least 4 out of 7 permanent members and at least one (1) participating site representative. Further, there should be at least one (1) member who is non-medical/non-scientific and at least one (1) member who is non-affiliated (from a non-DOH site).

2.6.1.4. Attendance of members through video conference is allowed.

2.6.1.5. The SJREB secretariat prepares and sends the agenda to all participating sites. Prior to dissemination, the HoS should review the prepared agenda of the meeting to check if items are properly classified and presented. The agenda should include information about the following: a. date, time, and venue of the joint SJREB full-board meeting, b. full details about the protocol (number, title, sponsor, coordinating PI,

sites) for initial review and renewal of approval.

2.6.1.6. The SJREB full board meeting is regularly scheduled on the second Wednesday of the month or more frequently depending on the volume of protocol submissions. An emergency meeting may also be conducted to facilitate review of urgent protocols (See Appendix B. Guidelines for review procedures during a public health emergency or during an epidemic) and critical issues needing the Board's immediate decision.

**2.6.2. During Full-Board Meeting**

2.6.2.1. A full-board SJREB meeting is convened to discuss and recommend a decision about the protocol and related documents. The SJREB members attending the full board meeting have to review and comment on the following:

2.6.2.1.1. Protocol;
2.6.2.1.2. Informed Consent;
2.6.2.1.3. PI and research team;
2.6.2.1.4. Study sites covered by the application;
2.6.2.1.5. Advertisements, etc.

2.6.2.2. Designated primary reviewers shall submit the accomplished and signed SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form during the full-board meeting.

2.6.2.3. The SJREB secretariat invites the Coordinating PI to attend the meeting for clarificatory interview to answer questions about the protocol.

2.6.2.4. The SJREB members discuss protocol documents and vote on specific items to arrive at a decision as follows (voting requirements are discussed in Chapter 1):

2.6.2.4.1. Approval (when no further modification is required)

2.6.2.4.2. Minor modification (requires minor changes in the documents such as typographical errors, administrative

issues, additional explanations, etc.)

2.6.2.4.3. Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

2.6.2.4.4. Disapproval (due to ethical, legal or scientific concerns). Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

2.6.2.5. If the study is approved, SJREB determines the frequency of continuing review. All meeting deliberations and decisions regarding a protocol shall be noted in the meeting minutes.

2.6.2.6. Copies of meeting minutes and SJREB decision pertaining to the specific protocol are sent to the site RECs for their information.

2.6.2.7. Site RECs shall submit to SJREB copies of their Certificate of Approval/Notice of Decision.

**2.6.3. After the Full-Board Meeting**

2.6.3.1. The SJREB secretariat communicates the notice of modification decision to the Coordinating PI.

2.6.3.2. Once the SJREB board approves the protocol related documents, the decision of SJREB is communicated to the Coordinating PI and all the participating site RECs.

2.6.3.3. Investigators may appeal the decision of SJREB by writing a letter requesting for reconsideration with reasons clearly stated and submission of a new protocol. Any appeal shall be taken up at full board meeting.

2.6.3.4. All DOH Hospital RECs and non-DOH RECs with an LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. The site REC conducts an expedited review of the approved protocol to address site specific concerns and inform the PI of the local site of the outcome of the SJREB review as well as the outcome of the local REC

review. All site REC decisions should be reported to SJREB and copy of decisions should be provided to the SJREB Secretariat.

2.6.3.5. The SJREB secretariat prepares the Minutes of the SJREB Full-Board Meeting as follows:

2.6.3.5.1. The SJREB secretariat fills out the basic information about each protocol submission for review in the SJREB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.

2.6.3.5.2. As the SJREB meeting proceeds, the SJREB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the SJREB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the SJREB Chair/ Presiding Officer. The SJREB decisions and recommendations are collective in nature. No attribution to specific SJREB member is stated in the minutes. The meeting minutes should include the following items:

2.6.3.5.2.1. Date and venue of the meeting
2.6.3.5.2.2. Presiding Officer
2.6.3.5.2.3. Attendance of REC representatives (medical/scientific; non-medical/non-scientific; non-affiliated with the study site)
2.6.3.5.2.4. Attendance of independent consultants
2.6.3.5.2.5. Attendance of coordinating PI and guests or observers, if any
2.6.3.5.2.6. Time when the meeting was called to order
2.6.3.5.2.7. Status of quorum at the start of the meeting and before every decision making
2.6.3.5.2.8. Discussion of items based on the order

in the meeting agenda

2.6.3.5.2.9. Summary of technical and ethical discussion points and recommendations

2.6.3.5.2.10. SJREB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.

2.6.3.5.2.10.1. If the review decision (for initial and continuing reviews) is "approved", the frequency of submission of progress reports are determined.

2.6.3.5.2.10.2. If the review decision is disapproved, the reasons for the disapproval are stated.

2.6.3.5.2.10.3. If the review decision (for initial and continuing reviews) is "for modification", the items to be revised are identified and the type of review for the resubmission is defined.

2.6.3.5.2.11. Attach the list of protocols for exemption and protocols approved through expedited review report for the information of the board.

2.6.3.5.2.12. Name and signature of the person who prepared the minutes

2.6.3.5.2.13. Name and signature of the Chair who approved the minutes with the date of approval

2.6.3.6. The SJREB secretariat sends the draft meeting minutes to the SJREB Members for their review and comments within 7 calendar days before the succeeding meeting. Prior to dissemination of the minutes of the meeting, the secretariat shall seek approval from the HoS for the release of the document.

2.6.3.7. During the next full board meeting, the Chair asks the members to approve the Minutes.

2.6.3.8. The SJREB Staff files approved meeting minutes in the

## 2.7 Continuing Review Procedures

**2.7. Continuing Review Procedures**

2.7.1. The following documents shall be submitted to SJREB for continuing review:

2.7.1.1. Amendment of the country protocol
2.7.1.2. Progress report
2.7.1.3. Final report
2.7.1.4. Protocol violation/ deviation
2.7.1.5. Early termination report

2.7.2. The SJREB secretariat keeps the continuing review application package together with the review comments of the primary reviewer/s and the SJREB decision in the protocol file folder and updates the Online Database of Active Study Files.

**2.7.3. Detailed Procedures**

2.7.3.1. Amendment of the country protocol
2.7.3.2. The Coordinating PI submits to SJREB any amendments to the previously approved protocol documents.
2.7.3.3. The Head of Secretariat makes a preliminary assessment of the amendment and determines the type of review necessary.
2.7.3.4. Amendments that may potentially alter the risk/ benefit ratio is referred to full board review for discussion, including but not limited to the following:

2.7.3.4.1. Change in study design
2.7.3.4.2. Change in the number of subjects
2.7.3.4.3. Change in the inclusion or exclusion criteria
2.7.3.4.4. Addition or removal of treatments
2.7.3.4.5. Change in the method or route of drug administration
2.7.3.4.6. Change in drug dosage

2.7.3.5. Minor changes that does not potentially alter the risk/benefit ratio is referred to the original Primary

Reviewers.

2.7.3.6. The SJREB secretariat sends the amendment report to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.3.7. The SJREB secretariat notifies all site RECs about the amendment application.

2.7.3.8. Approval of amendment application reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.

2.7.3.9. The SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.3.10. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

**2.7.4. Progress report**

2.7.4.1. Progress reports shall be submitted annually unless an earlier or more frequent schedule is decided by the board.

2.7.4.2. The SJREB secretariat communicates to the Sponsor/ Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.

2.7.4.3. The Coordinating PI submits to SJREB the latest versions of the Investigator

2.7.4.4. Brochure (IB), current versions of the protocol, informed consent forms (ICF) and other relevant documents, along with a summary of all protocol amendments, protocol deviations/ violations and on-site SAEs/SUSARs etc., as well as participant recruitment since the last SJREB approval.

2.7.4.5. The SJREB secretariat notifies all site RECs about the continuing review submissions. The Site RECs collect specific information from their site about protocol amendments, protocol deviations/ violations and local SAEs/ SUSARS, including participant

recruitment data to provide inputs during joint review.

2.7.4.6. The SJREB secretariat sends the progress report package to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.4.7. Primary reviewers refer to the progress report document to determine whether they contain updated information related to patient safety. Review comments should consider the following:

2.7.4.7.1. Risk Assessment: the risks to the subjects are minimized; the risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.

2.7.4.7.2. Adequacy of Informed Consent: Informed consent/Assent forms current (most recent); appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)

2.7.4.7.3. Local Issues: Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials); Evaluation, investigation and resolution of complaints related to the research, if any; Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.); Report from third party observation of the research (including the informed consent process) carried out; Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by

institutional policies), if any.

2.7.4.7.4. Trial Progress: Start date of the study and expected duration; Total subject enrollment (expected enrollment, actual enrollment, enrollment issues), subject withdrawal (number of subjects who withdrew, lost to follow-up, summary of reasons for withdrawal at local site)

2.7.4.8. Progress report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.4.8.1. Renew approval
2.7.4.8.2. Request additional information
2.7.4.8.3. Recommend modification
2.7.4.8.4. Suspend:
2.7.4.8.5. Enrollment of new subjects
2.7.4.8.6. Research procedures in currently enrolled subjects
2.7.4.8.7. Entire study
2.7.4.8.8. Disapprove renewal

2.7.4.9. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.

2.7.4.10. SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.4.11. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

**2.7.5. Final report**

2.7.5.1. Final reports shall be submitted by the Coordinating PI upon completion of the study using SJREB Form 9. Closure/Final Report Form. The final report shall contain consolidated information from all the sites

included in the study.

2.7.5.2. The SJREB secretariat communicates to the Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.

2.7.5.3. The SJREB head of secretariat classifies the submission as either for full board or for expedited review based on the original protocol review classification.

2.7.5.4. The SJREB secretariat sends the final report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.5.5. Primary reviewers refer to the final report document to determine whether they are in accordance with the protocol and related documents approved by the SJREB during initial review and review of amendments, as applicable.

2.7.5.6. Final report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.5.6.1. Approve final report and classify the protocol as inactive

2.7.5.6.2. Request additional information from the coordinating PI

2.7.5.7. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported during the board meeting.

2.7.5.8. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.5.9. The SJREB Secretariat prepares the Notice of Approval for signature of SJREB Chair.

2.7.5.10. The SJREB staff communicates the decision of the

SJREB to the Coordinating PI and site RECs.

**2.7.6. Protocol Violation/ Deviation**

2.7.6.1. Protocol violation or deviation, whether minor or major, from any of the sites included in the study shall be reported to the SJREB by the coordinating PI through the Progress Report Form including relevant documents needed to explain or provide details for the information indicated in the report.

2.7.6.2. The Head of Secretariat classifies the submission as either for full board or for expedited review:

2.7.6.3. Minor Protocol Deviation- are non-systematic protocol noncompliance with minor consequences to the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature

2.7.6.4. Major Protocol Deviation or Protocol Violation - are persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk

2.7.6.5. The SJREB secretariat sends the protocol non-compliance report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.6.6. Primary reviewers refer to the protocol non-compliance report package to determine the appropriate course of action depending on the seriousness of the non-compliance.

2.7.6.7. Non-compliance identified for full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.6.7.1. Uphold Original Approval
2.7.6.7.2. Request Further Information
2.7.6.7.3. Suspension of Ethical Clearance
2.7.6.7.4. Cancellation of Ethical Clearance
2.7.6.7.5. Deferred Action pending major clarification

2.7.6.8. Non-compliance report reviewed by the Primary

Reviewers by expedited procedure is reported during the board meeting.

2.7.6.9. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.6.10. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.

2.7.6.11. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

**2.7.7. Early Termination**

2.7.7.1. Early termination of protocol implementation shall be reported to the SJREB by the coordinating PI through the Early Termination Application Form (SJREB Form 11).

2.7.7.2. The SJREB secretariat sends the early termination report to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.7.3. Primary reviewers refer to the early termination application to determine the appropriate recommendations

2.7.7.4. Early termination application shall be included in the agenda for discussion in the full board meeting to determine the early termination's implication to the participants and arrive at recommendations for continued protection of study participants including follow-up plan to those who are still actively enrolled.

2.7.7.5. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.7.6. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.

2.7.7.7. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

# C. SOP 3 DOCUMENTATION AND ARCHIVING

## 3.1 Purpose

3.1.1. To describe the Single Joint Research Ethics Board (SJREB) procedures in documenting all protocol submissions and archiving completed and inactive studies.

## 3.2 Scope

3.2.1. This procedure applies to documentation and archiving of all protocols submitted to SJREB for ethics review.

## 3.3 Process Flow and Procedures for Documentation

Table 4. Process Flow and Procedures for Documentation

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Input of protocol submission in the online database | Secretariat staff |
| 2 | Input digital and hard copy of protocol related files in their respective storage areas | Secretariat staff |

## 3.4 Documentation

The secretariat staff maintains a protocol file to contain all submissions and action taken on protocols submitted for SJREB review.

**3.4.1. Online database**

3.4.1.1. The secretariat staff It maintains an online database that contains complete and updated information about all protocol submissions.

3.4.1.2. The database should contain the following information:

3.4.1.2.1. Protocol code
3.4.1.2.2. Protocol title
3.4.1.2.3. Type of protocol
3.4.1.2.4. Sponsor
3.4.1.2.5. Study sites
3.4.1.2.6. Coordinating investigator
3.4.1.2.7. Submission date
3.4.1.2.8. Type of review
3.4.1.2.9. Primary reviewers
3.4.1.2.10. Date of meeting
3.4.1.2.11. Review decision
3.4.1.2.12. Date of issuance of decision
3.4.1.2.13. Resubmission date
3.4.1.2.14. Date of decision of resubmission
3.4.1.2.15. Approval date
3.4.1.2.16. Expiration date
3.4.1.2.17. Due date for progress report
3.4.1.2.18. Date of submission of progress report
3.4.1.2.19. Submission of amendment report
3.4.1.2.20. Date of approval of amendment report
3.4.1.2.21. Submission of final report Date of approval of final report
3.4.1.2.22. Other reports (SAEs, protocol violations, etc.)

3.4.1.3. All protocol submissions should be logged in the database.

3.4.2. Digital and hard copies of protocol related files should be submitted to the secretariat staff.

3.4.2.1. All protocol submissions should be properly labeled with protocol code (Refer to chapter 2 on proper labelling, *see 2.5.8*).

3.4.2.2. Digital copies are stored in their separate google drive folders that are password protected.

3.4.2.3. Hard copies are kept in separate folders in the cabinet with locks and keys

3.4.2.3.1. All protocol submission should be stored in separate folders.

3.4.2.3.2. Folders should be properly labeled with their protocol code. For protocols with multiple folders, the label format should be: Protocol Code + letter (in chronological order based on the oldest files).

3.4.2.3.3. Folders should be stored in cabinets properly labeled with active or inactive status. All cabinets should be secured by a lock and key. Only the secretariat staff should have the key and its duplicate.

3.4.2.3.4. Each folder should contain an index at the beginning of the file to identify the protocol documents found in the folder

3.4.2.4. Any document submitted by the investigator is added to the protocol files

## 3.5 Process Flow and Procedures for Archiving

**Table 5. Process Flow and Procedures for Archiving**

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Identify inactive protocols files | Secretariat staff |
| 2 | Update protocol database | Secretariat staff |
| 3 | Affix appropriate label to files for archiving | Secretariat staff |
| 4 | Transfer files to the proper cabinet | Secretariat staff |

## 3.6 Archiving

The secretariat staff will follow the following procedures:

3.6.1. Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by SJREB.

3.6.2. Incomplete studies are classified as inactive when no further communication or submission has been received by SJREB after two years. Studies that are terminated earlier before completion will also be classified as inactive files.

3.6.3. Once the final report has been approved, the Secretariat staff marks the database as completed.

3.6.4. Digital file folders are marked with an I or C to indicate that they are incomplete and complete respectively. Hard copy folders are marked with a red sticker to indicate that they are inactive.

3.6.5. At the end of the year, the secretariat staff transfers all completed/inactive protocol folders to the archive.

3.6.6. Protocols are archived for 3 years. After 3 years in the archive, the protocol files may be transferred to a password protected offline hard disk

## 3.7 Process Flow and Procedures for Retrieval of Documents

Table 6. Process Flow and Procedures for Retrieval of Documents

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Receive requests to access SJREB protocol documents | Secretariat staff |
| 2 | Approve and input all requests and transaction in the database | Secretariat staff |
| 3 | Supervise the use of retrieved documents | Secretariat staff |
| 4 | Return of document to the protocol file folder | Secretariat staff |

## 3.8 Retrieval

The secretariat staff will follow the following procedures:

3.8.1. Receive requests to access SJREB protocol documents.

3.8.1.1. Access to SJREB files is subject to the following limitations:

3.8.1.1.1. Participating site members with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access documents outside of regular protocol review access, upon request.

3.8.1.1.2. Non-members can access specific documents by submitting a formal request. The secretariat staff will require a signed Confidentiality Agreement and Conflict of Interest Disclosure. This request needs to be approved by the Member Secretary.

3.8.1.1.3. Regulatory authorities (e.g. Philippine FDA) can have full access to SJREB documents provided it is within their mandate and within a reasonable notice to make the files available.

3.8.2. Approve and input all requests and transaction in the database.

3.8.2.1. All requests are put into the online database. The following information should be included:

3.8.2.1.1. Protocol code
3.8.2.1.2. Date borrowed
3.8.2.1.3. Name of borrower
3.8.2.1.4. Document requested or copied
3.8.2.1.5. Number of copies made
3.8.2.1.6. Date returned of borrowed documents

3.8.3. Supervise the use of retrieved documents.

3.8.3.1. Access to SJREB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.

3.8.3.2. The secretariat staff makes only the exact number of copies requested.

3.8.4. Return document to the protocol file folder.

3.8.4.1. The secretariat staff is responsible for returning the documents in the protocol file folder in the cabinet after making sure that all documents are complete as per protocol file index

# D. SOP 4 WRITING AND REVISING STANDARD OPERATING PROCEDURES

## 4.1 Writing SOPs

**4.1.1. Purpose**

To describe the procedure for writing and revising SOPs used by the Single Joint Research Ethics Board

**4.1.2. Scope**

This SOP provides instructions on how the new SJREB SOPs are prepared.

**4.1.3. Responsibility**

4.1.3.1. It is the responsibility of the Chair of SJREB to organize an SOP Team to formulate the SOPs of the REC.

4.1.3.2. The SOP Team is an ad hoc committee composed of designated SJREB members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.

4.1.3.3. The Chair convenes an SJREB meeting to review and finalize the draft SOPs and ensures that all SJREB members have an access to current versions of SOPs to guide them in the performance of their functions.

### 4.1.4. Process Flow

**Table 7. Process Flow for Writing SOPs**

| NO. | ACTIVITIES | PERSON/S RESPONSIBLE |
|---|---|---|
| 1 | Organize an SOP Team | SJREB Chair |
| 2 | Identify reference templates with corresponding layout | SOP Team |
| 3 | Draft revised SOPs and submit to Chair | SOP Team |
| 4 | Review and finalize revised SOP in an SJREB meeting and submit to the HPDPB Director | Chair, SJREB Members |
| 5 | Approve and sign revised SOPs | HPDPB Director |
| 6 | Distribute approved SOPs and keep copies in the SJREB files | Secretariat |

### 4.1.5. Detailed Instructions

#### 4.1.5.1. Organized an SOP Team

4.1.5.1.1. HPDPB Director assigns members of the SOP Team, and invites resource persons as needed.

4.1.5.1.2. The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.

4.1.5.1.3. The Chair may organize a SOP Team workshops to facilitate the drafting of SOPs.

#### 4.1.5.2. Identify reference templates with corresponding layout

4.1.5.2.1. Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP Team in drafting new SOPs.

4.1.5.2.2. An SJREB SOP have the following format:

4.1.5.2.2.1. SOP Number

4.1.5.2.2.2. Title

4.1.5.2.2.3. Purpose of the SOP
4.1.5.2.2.4. Scope which defines the extent of coverage of the SOP and its limitations
4.1.5.2.2.5. Responsibility identifies the persons assigned to perform specific tasks during SOP implementation
4.1.5.2.2.6. Process Flow/ Steps
4.1.5.2.2.7. Detailed instructions which elaborates the steps outlined in the process flow
4.1.5.2.2.8. Standard forms and checklist to be used
4.1.5.2.2.9. Glossary
4.1.5.2.2.10. References
4.1.5.2.2.11. List of Acronyms

4.1.5.2.3. Each SOP should be given a number and a title that is self-explanatory and is easily understood.
4.1.5.2.4. The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP Masterfile.
4.1.5.2.5. The typical SOP uses a header with the following elements

4.1.5.2.5.1. Institutional seal or logo
4.1.5.2.5.2. Name of institution
4.1.5.2.5.3. SOP Identifier
4.1.5.2.5.4. SOP Title
4.1.5.2.5.5. Effectivity date
4.1.5.2.5.6. Page number

**4.1.5.3. Draft new SOPs and submit to the Chair**

4.1.5.3.1. The SJREB SOPs should contain details under the following main topics:

4.1.5.3.1.1. Introduction - contains a statement of ethical principles that will guide SJREB
4.1.5.3.1.2. Authority, Composition, and Structure of SJREB - describes the composition of SJREB Membership with specific review functions

4.1.5.3.1.3. Joint Review of Initial Submission - describes types of review and initial review procedures
4.1.5.3.1.4. Continuing Review Procedures - describes how SJREB conducts post-approval review procedure
4.1.5.3.1.5. Documentation, and Archiving - describes administrative procedures that support the review functions
4.1.5.3.1.6. Writing and Revising SOPs - describes how to draft and revise SOPs

4.1.5.3.2. The SOP Team submits completed SOP draft to the Chair.

**4.1.5.4. Review and finalize new SOPs in an SJREB meeting and submit to the HPDPB Director**

4.1.5.4.1. The SJREB Chair or any permanent member presents the draft SOPs during an SJREB meeting for the member to discuss and finalize the draft
4.1.5.4.2. The SJREB Chair submits the approved draft to the Director of HPDPB for approval.

**4.1.5.5. Approve and sign new SOPs**

4.1.5.5.1. The HPDPB Director reviews and approves the SOPs by signing in the designation section.
4.1.5.5.2. The approved SOPs will be implemented after approval by the HPDPB Director.

**4.1.5.6. Distribute approved SOPs and keep copies in the SJREB files**

4.1.5.6.1. The SJREB Secretariat distributes the new SJREB SOPs to all SJREB Members, participating site RECs with active LOI, and Staff and files the original copy in the SJREB storage cabinet.
4.1.5.6.2. The SOP Manual with downloadable forms are uploaded on the SJREB website for the use of and guidance of researchers.

# APPENDICES AND FORMS

## APPENDIX A

| Appendix A. | |
|---|---|
| SJREB FORM 1 | Application for SJREB Initial Review |
| SJREB FORM 1.2 | Protocol Summary Sheet |
| SJREB FORM 2 | Protocol Assessment Form |
| SJREB FORM 3 | Informed Consent Assessment Form |
| SJREB FORM 4 | Checklist of Exemption |
| SJREB FORM 4.1 | Certificate of Exemption from Ethics Review |
| SJREB FORM 5 | Notice for Protocol Modification |
| SJREB FORM 5.1 | Protocol Resubmission Form |
| SJREB FORM 6 | Notice of Approval |
| SJREB FORM 7 | Progress or Annual Report for Philippine Sites |
| SJREB FORM 7.1 | Progress Report for Government Funded Protocols |
| SJREB FORM 8 | Protocol Amendment Application Form |
| SJREB FORM 9 | Closure or Final Report Form |
| SJREB FORM 9.1 | Early Study Termination Application |
| SJREB FORM 10 | Notice for Post-Approval Modification |
| SJREB FORM 11 | Onsite Serious Adverse Event Report |
| SJREB FORM 12 | Protocol Violation_Deviation Report |
| SJREB FORM A | Declaration of Conflict of Interest |

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## SJREB FORM 1
## APPLICATION FOR SJREB INITIAL REVIEW
*To be filled up by the Coordinating Investigator*

| | |
|---|---|
| SJREB Protocol Number *(to be filled-up by secretariat staff)*: | |

| | | | |
|---|---|---|---|
| Sponsor Protocol Number: | | Submission Date: | |

| | |
|---|---|
| Protocol Title: | |

| | | | | | |
|---|---|---|---|---|---|
| Type of Research: | ☐ | Clinical Research | ☐ Clinical Trial | ☐ | Laboratory Research |
| | ☐ | Genetic Research | ☐ Socio-behavioral | ☐ | Public health |
| | ☐ | Others (*specify*): _____ | | | |

| | |
|---|---|
| Study Duration: | |
| Sponsor: | |
| Coordinating Investigator: *(Please assign one person only)* | |
| Sites and Site Principal Investigators: *(List all sites and site investigators)* | |

| | | | |
|---|---|---|---|
| Telephone number: | | Email | |
| Institution: | | | |

| Declaration of Conflict of Interest (COI) | | | | |
|---|---|---|---|---|
| Are you an employee of the sponsor/s? | x | Yes | x | No |
| Did you do consultancy or part time work for the sponsor/s? | x | Yes | x | No |

| | | | | |
|---|---|---|---|---|
| In the past year, did you receive P500,000 or more from the sponsor/s? | x | Yes | x | No |
| Other ties with the sponsor: | | | | |
| **Ethical Responsibility and COI Statement**<br>I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI). | | | | |

| | |
|---|---|
| CI Signature: | |

**Documents submitted:** *(Please check the documents submitted)*

| Basic documents: | |
|---|---|
| | Application Form [SJREB FORM 1 – APPLICATION FORM] |
| | Protocol Summary Sheet [SJREB Form 1.2 – Protocol Summary Sheet] |
| | Informed Consent Forms (in English and in local language) |
| | Recruitment and Advertisement Materials |
| | Data Collection Forms |
| | CVs of PIs |
| | Study Budget |
| | Study Protocol |
| | Technical Clearance |
| | Proof of parallel submission to at least three (3) study sites |

| Study-specific Documents (submit as needed): | |
|---|---|
| | FDA Approval/Clearance (for clinical trials) |
| | Patient Information Sheet (for clinical trials) |
| | Investigator Brochure (for clinical trials) |
| | GCP Certificates of PIs (for clinical trials) |
| | Other protocol-related documents (please specify): |

Received by:
*(SJREB Secretariat)*

Date:

Republic of the Philippines
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## FORM 1.2
## PROTOCOL SUMMARY SHEET

| SJREB Protocol No. | Protocol Title |
|---|---|
| | |

| Coordinating Investigator | Sponsor |
|---|---|
| | |

| | |
|---|---|
| Rationale | |
| Objectives | |
| Study Design/Methodology | |
| Inclusion Criteria | |
| Exclusion Criteria | |
| Data Analysis Plan | |
| Study Outcomes | |
| Ethical Consideration | |

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## SJREB FORM 2
## PROTOCOL ASSESSMENT FORM

*To be filled up by primary reviewer*
*Instructions: Please do literature search to update your knowledge about this protocol*

| | | | |
|---|---|---|---|
| SJREB Protocol No.: | | Date (D/M/Y.): | |
| Protocol Title: | | | |
| Coordinating Investigator: | | | |
| Institution: | | | |
| Total No. of Participants: | | No. of Study Sites: | |
| Expected no. from Philippine sites: | | | |
| Sponsor: | | | |
| Duration of the Study: | | Status: ☐ New ☐ For Renewal of Approval | |
| Reviewers: | | | |

| | | |
|---|---|---|
| ☐ Intervention | ☐ Epidemiology | ☐ Observational study |
| ☐ Document review | ☐ Case study | ☐ Genetic |
| ☐ Social Survey | ☐ Others *(specify)*: | |

Review Type: ☐ Full Board ☐ Expedited ☐ Exempted

Description of the Study in brief: Mark whatever applies to the study.

| | | | | | |
|---|---|---|---|---|---|
| | Randomized | | Drug | | Use of Genetic Materials |
| | Double-blind | | Medical Device | | Multicenter Study |
| | Single-blind | | Vaccine | | Global Protocol |
| | Open-label | | Diagnostics | | Sponsor-initiated |
| | Observational | | Questionnaire | | Investigator-initiated |

A. PROTOCOL DOCUMENT REVIEW (*please put an X before your choice and N/A on the comments if there are no further comments*)

| Questions | Comment/s: |
|---|---|
| 1. Objectives of the study<br>☐ Clear ☐ Not clear | |
| 2. Need for human participants<br>☐ Clear ☐ Not clear | |
| 3. Background information<br>☐ Sufficient ☐ Not sufficient | |
| 4. Methodology<br>☐ Clear ☐ Not clear | |
| 5. Sufficient number of participants<br>☐ Yes ☐ No | |
| 6. Control arms (placebo, if any)<br>☐ Yes ☐ No | |
| 7. Data analysis plan<br>☐ Appropriate ☐ Not Appropriate | |
| 8. Study outcomes<br>☐ Defined ☐ Incomplete ☐ Not defined | |
| 9. Level of risk<br>☐ Low ☐ Medium ☐ High | |
| 10. Risk mitigation in the protocol<br>☐ Appropriate ☐ Not Appropriate | |
| 11. Benefits of the participants in the protocol<br>☐ Appropriate ☐ Not Appropriate | |
| 12. Inclusion criteria<br>☐ Appropriate ☐ Not Appropriate | |
| 13. Exclusion criteria<br>☐ Appropriate ☐ Not Appropriate | |
| 14. Withdrawal criteria | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Appropriate | | Not Appropriate | | | |
| 15. Involvement of vulnerable participants | | | | | | |
| | Yes | | No | | | |
| 16. Protection of vulnerable participants | | | | | | |
| | Appropriate | | Not Appropriate | | | |
| 17. Voluntary, non-coercive recruitment of participants | | | | | | |
| | Yes | | No | | | |
| 18. Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate? | | | | | | |
| | Yes | | No | | | |
| 19. Disclosure of potential conflicts of interest | | | | | | |
| | Yes | | No | | | |
| 20. Facilities and infrastructure of participating sites | | | | | | |
| | Yes | | No | | | |
| 21. Community consultation | | | | | | |
| | Yes | | No | | N/A | |
| 22. Involvement of local researchers and communities in the protocol preparation and implementation | | | | | | |
| | Yes | | No | | N/A | |
| 23. Contribution to local capacity building | | | | | | |
| | Yes | | No | | N/A | |
| 24. Benefit to local community | | | | | | |
| | Yes | | No | | N/A | |
| 25. Sharing of study results | | | | | | |
| | Yes | | No | | N/A | |
| 26. Are blood or tissue samples sent abroad | | | | | | |
| | Yes | | No | | N/A | |

B. RECOMMENDATION

| | | | | |
|---|---|---|---|---|
| Decision: | | Approval | | Minor Revision |
| | | Major Revision | | Disapproval |
| Summary of comments: | | | | |
| Reviewer's Name: | | | Date: | |
| Signature: | | | | |

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## SJREB FORM 3
## INFORMED CONSENT ASSESSMENT FORM

*To be filled up by primary reviewer*

| | | | |
|---|---|---|---|
| SJREB Protocol No. | | Date (D/M/Y): | |
| Protocol Title: | | | |
| Coordinating Investigator: | | | |

A. INFORMED CONSENT DOCUMENT REVIEW (*please put an X before your choice and N/A on the comments if there are no further comments)*

| Questions | Comment/s: |
|---|---|
| 1. Does the Informed Consent document state that the procedures are primarily intended for research? | |
| ☐ Yes ☐ No | |
| 2. Are procedures for obtaining Informed Consent appropriate? | |
| ☐ Yes ☐ No | |
| 3. Does the Informed Consent document contain comprehensive and relevant information? | |
| ☐ Yes ☐ No | |
| 4. Is the information provided in the protocol consistent with those in the consent form? | |
| ☐ Yes ☐ No | |
| 5. Are study related risks mentioned in the consent form? | |
| ☐ Yes ☐ No | |
| 6. Is the language in the Informed Consent document understandable? | |
| ☐ Yes ☐ No | |
| 7. Is the Informed Consent translated into the local language/dialect? | |

| | | | | |
|---|---|---|---|---|
| | Yes | | No | |
| 8. Are there vulnerable participants? | | | | |
| | Yes | | No | |
| 9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? | | | | |
| | Appropriate | | Not appropriate | |
| 10. Are names and contact numbers from the research team and the REC in the informed consent? | | | | |
| | Yes | | No | |
| 11. Does the ICF provide privacy & confidentiality protection? | | | | |
| | Yes | | No | |
| 12. Is there any undue inducement for participation? | | | | |
| | Yes | | No | |
| 13. Is there provision for medical/psychosocial support? | | | | |
| | Yes | | No | N/A |
| 14. Is there provision for treatment of study-related injuries | | | | |
| | Yes | | No | N/A |
| 15. Is the amount paid to participants stated? | | | | |
| | Yes | | No | N/A |

B. RECOMMENDATION

| | | | | |
|---|---|---|---|---|
| Decision: | | Approval | | Minor Revision |
| | | Major Revision/ Resubmission | | Disapproval |
| Summary of comments: | | | | |
| Reviewer's Name: | | | Date: | |
| Signature: | | | | |

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## SJREB FORM 4
## CHECKLIST FOR EXEMPTION FROM FULL ETHICAL REVIEW FORM

*To be filled up by primary reviewer*

| | | | |
|---|---|---|---|
| SJREB Protocol No. | | Date (D/M/Y): | |
| Protocol Title: | | | |
| Coordinating Investigator: | | | |

A. Protocol Assessment

| Questions | Comment/s: |
|---|---|
| 1. Does this research involve human participants? | |
| ☐ Yes ☐ No | |
| 2. Does this research involve use of non-identifiable human tissue/ biological samples? | |
| ☐ Yes ☐ No | |
| 3. Does this research involve use of non-identifiable publicly available data? | |
| ☐ Yes ☐ No | |
| **Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017)* | |
| 4. Does this research involve interaction with human participants | |
| ☐ Yes ☐ No | |
| 5. Type of research (*please tick appropriate box)* | |
| a. Institutional quality assurance | |
| ☐ Yes ☐ No | |
| b. Evaluation of public service program | |
| ☐ Yes ☐ No | |
| c. Public health surveillance | |
| ☐ Yes ☐ No | |
| d. Educational evaluation activities | |
| ☐ Yes ☐ No | |

| | | | | |
|---|---|---|---|---|
| c. Consumer acceptability test | | | | |
| | Yes | | No | |
| *These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk. | | | | |
| 6. What is/are the method/s of data collection *(please tick appropriate box)* | | | | |
| a. Surveys and/or questionnaire | | | | |
| | Yes | | No | |
| b. Interviews or focus group discussion | | | | |
| | Yes | | No | |
| c. Public observations | | | | |
| | Yes | | No | |
| d. Research which only uses existing data | | | | |
| | Yes | | No | |
| e. Audio/video recordings | | | | |
| | Yes | | No | |
| *These 5 have been identified in the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained. | | | | |
| 7. Will the collected data be anonymized or identifiable? | | | | |
| | Anonymized | | Identifiable | |
| | De-identified | | | |
| 8. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2017) *Please refer to section B. Risk Assessment, prior to answering this item | | | | |
| | Yes | | No | |
| *If YES, then this protocol does not qualify for exemption | | | | |

B. Risk Assessment

| Questions | Comment/s |
|---|---|
| 1. Does this research involve the following: *(please check all that applies)* | |
| a. Any vulnerable groups? | |
| Yes / No | |
| b. Sensitive topics that may make participants feel uncomfortable *(i.e. sexual behaviour, illegal activities, racial biases, etc.* | |

| | | | | |
|---|---|---|---|---|
| | Yes | | No | |
| c. Use of drugs | | | | |
| | Yes | | No | |
| d. Invasive procedure (e.g. blood sampling) | | | | |
| | Yes | | No | |
| e. Physical stress/distress, discomfort | | | | |
| | Yes | | No | |
| f. Psychological/mental stress/distress | | | | |
| | Yes | | No | |
| g. Deception of/or withholding information from subjects | | | | |
| | Yes | | No | |
| h. Access to data by individuals or organizations other than the investigators | | | | |
| | Yes | | No | |
| i. Conflict of interest issues | | | | |
| | Yes | | No | |
| j. Or any other ethical dilemmas | | | | |
| | Yes | | No | |
| k. Is there any blood sampling involved in the study | | | | |
| | Yes | | No | |

C. RECOMMENDATION

| | | |
|---|---|---|
| Decision: | | Qualified for Exemption |
| | | Unqualified for Exemption |

| | | | |
|---|---|---|---|
| Summary of comments: | | | |
| Reviewer's Name: | | Date: | |
| Signature: | | | |

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## SJREB FORM 4.1
## CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

Date:

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the SJREB for implementation

| | | | |
|---|---|---|---|
| SJREB Protocol No.: | | Sponsor Protocol No.: | |
| Coordinating Investigator: | | Sponsor: | |
| Title: | | | |
| Protocol Version No.: | | Version Date: | |
| ICF Version No.: | | Version Date: | |
| Other Documents: | | | |

This protocol is exempted from review for the following reasons: *(check the NEGHHR)*

1.

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

**NOTE**:

- Final/Closure Reports should be submitted at the end of the study.
- Any amendment to the protocol should be submitted to SJREB for re-evaluation of exemption.

Received by:

Name: _____

Signature: _____ Date: _____

Republic of the Philippines
Department of Health
**SINGLE JOINT RESEARCH ETHICS BOARD**

## SJREB FORM 5
## NOTICE OF PROTOCOL MODIFICATION

Date: 2020

To *(name of PI)*: _____

Contact Details: _____

Protocol Title: _____

SJREB Protocol Code _____

Sponsor Protocol No. _____

Protocol Version No. and Version Date: _____

ICF Version No. and Version Date _____

Type of Submission
☐ Initial Submission
☐ Resubmission
☐ Others

This is to inform you of the SJREB decision related to the documents you have submitted:

| ITEMS FOR REVISION | REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR |
|---|---|
| Protocol | |
| Informed Consent Form | |
| Others | |

**Please submit the revised documents on or before _____**

| Type of review | |
|---|---|
| | Exempted |
| | Expedited |
| | Full Board |

| SJREB Decision | | | |
|---|---|---|---|
| | Minor revisions required | | Approved |
| | Major revisions required | | Others: |
| | More information required | | |

| Meeting Date: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| Dr. Jacinto Blas Mantaring III | | |

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## SJREB FORM 5.1
## PROTOCOL RESUBMISSION FORM
*To be filled by investigator*

| | |
|---|---|
| SJREB Protocol Number | |

| | | | |
|---|---|---|---|
| Sponsor Protocol Number | | Submission Date | |

| | |
|---|---|
| Protocol Title: | |

| | | | | |
|---|---|---|---|---|
| Documents revised | | Protocol (*latest version number and date*) | | ICF (*latest version number and date*) |
| | | Others (specify): | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Type of Initial Review | | Exempted | | Expedited | | Full Board |

| | | | | |
|---|---|---|---|---|
| Channel of review for resubmission | | Expedited | | Full Board |

| | | | |
|---|---|---|---|
| Coordinating PI | | Sponsor | |
| Contact Numbers | | Email | |

| | |
|---|---|
| Institution | |

| REC Recommendations | Revisions made by the PI | Reviewer Comments *(to be filled up by primary reviewers)* |
|---|---|---|
| | | |

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| | |
|---|---|
| Co-PI Signature: | Date: |
| Received by SJREB Secretariat: | Date: |

| FOR REC USE: | |
|---|---|
| Summary of comments: | |

| Recommendations: | |
|---|---|
| | Approve |
| | Request for further information/modification |
| | Others |

| Name of reviewer: | | Signature: | | Date: | |
|---|---|---|---|---|---|

| Final Decision: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

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## SJREB FORM 6
## NOTICE OF APPROVAL

Date:

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation in accordance with the International Conference on the Harmonization of Good Clinical Practice and the National Ethical Guidelines on Health and Health-related Research

| | | | |
|---|---|---|---|
| SJREB Protocol No.: | | Sponsor Protocol No.: | |
| Coordinating Investigator: | | Sponsor: | |
| Title: | | | |
| Protocol Version No.: | | Version Date: | |
| ICF Version No.: | | Version Date: | |
| Other Documents: | | | |
| Members of research team: | | | |
| Study sites: | | | |

| | | | |
|---|---|---|---|
| Type of Review: | ☐ Expedited<br>☐ Full Board<br>Meeting date: | Duration of Approval From – To *(date)*<br>December 28, 2018 to December 28, 2019 | Frequency of continuing review<br>Annual |

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

Investigator Responsibilities after Approval:

- Submit country protocol amendments to the SJREB and site REC for approval before implementing them;
- Submit site-specific amendments to site REC for approval before implementing them;
- Submit annual report for renewal of approval to SJREB;
- Submit SAE and SUSAR reports to the site REC within 7 days;
- Submit progress report every 12 months;
- Submit final report after completion of protocol procedures at the study site;
- Report protocol deviation/violation to the REC study sites;
- Comply with all relevant international and national guidelines and regulations; and
- Abide by the principles of good clinical practice and ethical research

Received by:

Name: _____

Signature: _____ Date: _____

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## SJREB FORM 7
## PROGRESS/ANNUAL REPORT FOR PHILIPPINE SITES

| | | | |
|---|---|---|---|
| SJREB Protocol No.: | | Initial Approval Date: | |
| Protocol Title: | | | |
| Coordinating Investigator: | | Sponsor: | |

| | | | | |
|---|---|---|---|---|
| Any amendment since the last review? Describe briefly. | | Yes | | No |
| Any change in participant population, recruitment or selection criteria since the last review? Explain the changes. | | Yes | | No |
| Any change in the Informed Consent process or documentation since the last review? Please explain. | | Yes | | No |
| Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize. | | Yes | | No |
| Any unexpected complication or side effect noted since the last review? Summarize. | | Yes | | No |

| | | | | |
|---|---|---|---|---|
| Were there protocol deviation/ violation reports? Summarize. What corrective actions were taken? | | Yes | | No |
| Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators. | | Yes | | No |

| Summary of recruitment: | |
|---|---|
| | Accrual ceiling set by REC |
| | New participants accrued since last review |
| | Total participants accrued since protocol began |
| | No. of participants who are lost to follow up |
| | No. of participants withdrawn from the study |
| | No. of participants who experienced SAEs/ SUSARs |

| | | | | |
|---|---|---|---|---|
| Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. | | Yes | | No |

**FOR SJREB USE**

| | |
|---|---|
| Name of Primary Reviewer | |

**Assessment by the Primary Reviewer:**

| Questions: | Yes | No | Comments: |
|---|---|---|---|
| Do the risks to the study participants remain reasonable in relation to anticipated benefits? | | | |
| Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent? | | | |

| | | | |
|---|---|---|---|
| Is there need to revise the ICF? | | | |
| Is there need to re-consent subjects enrolled in the study? | | | |
| Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety? | | | |
| Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation? | | | |

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI

| Recommended Action: | |
|---|---|
| | Approve |
| | Request further information, *specify* |
| | Recommend further action, *specify* |
| Other comments: | |

| Primary Reviewer: | Signature: | Date: |
|---|---|---|
| | | |

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## SJREB FORM 7.1
## PROGRESS REPORT FOR GOVERNMENT FUNDED PROTOCOLS

| | | | |
|---|---|---|---|
| SJREB Protocol No.: | | Initial Approval Date: | |
| Protocol Title: | | | |
| Coordinating Investigator: | | Sponsor: | |

**Summary of Accomplishments**

| Objectives | Activities (for each objective) | Targets | Accomplishments |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**Results and Discussion**
(Detailed discussion of outputs / findings for the period based on target activities)

**Problems / Difficulties Encountered**
(Obstacles/hurdles met and experienced during implementation, explanatory notes for deviation(s) in targets and accomplishments, changes in dates of implementation, etc.)

**Proposed or Suggested Solutions**
(Proposed action(s) to solve problems encountered)

*Please submit an endorsement letter from the end-user/sponsor that they have fully received and accept the progress of the study*

**FOR SJREB USE**

| | |
|---|---|
| Name of Primary Reviewer | |

**Assessment by the Primary Reviewer:**

| Recommended Action: | |
|---|---|
| | Approve |
| | Request further information, *specify* |
| | Recommend further action, *specify* |
| Other comments: | |

| Primary Reviewer: | Signature: | Date: |
|---|---|---|
| | | |

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## SJREB FORM 8
## PROTOCOL AMENDMENT APPLICATION FORM

| Date of submission | SJREB Protocol No. | Sponsor Protocol No |
|---|---|---|
| | | |
| **Principal Investigator** | **Email/ Mobile No.** | **Sponsor** |
| | | |

| Title of Study | |
|---|---|

| Study Site/s: | | Date of Initial Approval | |
|---|---|---|---|
| | | Type of Initial Review: *(Full Board, Expedited, Exempted)* | |

| Items to be Amended | List of Amendments | Reasons |
|---|---|---|
| | | |

| Signature of PI: | |
|---|---|
| Date: | |

| FOR REC USE: | | | | |
|---|---|---|---|---|
| Assessment of Primary Reviewers | 1. Type of amendments: | | | |
| | | Minor | | Major |
| | Comment/s: | | | |
| | 2. Does the amendment decrease the risks to participants | | | |
| | | Yes | | No |
| | Comment/s: | | | |
| | 3. Does the amendment decrease the benefits to participants? | | | |

| | | | | |
|---|---|---|---|---|
| | | Yes | | No |
| | Comment/s: | | | |
| | 4. Is there favorable benefit/ risk ratio? | | | |
| | | Yes | | No |
| | Comment/s: | | | |

| | Recommendations: |
|---|---|
| | Approve |
| | Request for further information/modification |
| | Others |

| | Type of review |
|---|---|
| | Expedited |
| | Exempted |
| | Full Board |

| Name of reviewer: | | Signature: | | Date: | |
|---|---|---|---|---|---|

| Final Decision: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

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# FORM 9
# CLOSURE/FINAL REPORT FORM
*(Consolidated report from all sites included in the study)*

| | | | |
|---|---|---|---|
| **PROTOCOL CODE:** | | | |
| **PROTOCOL TITLE:** | | | |
| **(INITIAL) APPROVAL DATE:** | | | |
| **COORDINATING INVESTIGATOR:** | | | |
| **Email:** | | **Mobile:** | |
| **STUDY SITES:** | | | |
| **SPONSOR:** | | | |
| **SPONSOR CONTACT PERSON:** | | **Email:** | |

| | |
|---|---|
| 1. Study Arms: | |
| 2. Summary of Recruitment: | |
| Accrual ceiling set by REC | |
| • New participants accrued since last review | |
| • Total number of participants accrued since protocol began | |
| • No. of participants who are lost to follow up | |
| • No. of participants withdrawn from the study | |
| • No. of participants who experienced SAEs/SUSARs | |
| 3. Number of participants who completer the study: | |
| 4. Amendments to the original protocol (including dates of approval): | |
| 5. Summary of onsite SAEs reported: | |
| 6. Summary of participants' complaints or grievances documented regarding conduct of study: | |

| | |
|---|---|
| 7. Summary of benefits to participants: | |
| 8. Summary of indemnifications of study related injury (If Applicable): | |
| 9. If terminated early, specify reason for termination: | |
| 10. Progress reports submitted (with dates of approval): | |
| 11. Duration of the study (months): | |
| 12. Informed consent form used (with version no./date) and attach most recent version: | |
| 13. Study objectives and summary of results: | |

| | |
|---|---|
| SIGNATURE OF PI: | |
| DATE: | |
| RECEIVED BY: | |
| REPORT SUBMISSION DATE: (to be filled out by REC) | |

| FOR REC USE ONLY: |
|---|
| **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study) |

| Recommendations: | |
|---|---|
| | Approve |
| | Request for further information/modification |
| | Others |

| Type of review | |
|---|---|
| | Expedited |
| | Exempted |
| | Full Board |

| Name of reviewer: | | Signature: | | Date: | |
|---|---|---|---|---|---|

| Final Decision: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

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## SJREB FORM 9.1
## EARLY STUDY TERMINATION APPLICATION
*(Consolidated report from all sites included in the study)*

| | | | |
|---|---|---|---|
| **SJREB PROTOCOL CODE:** | | | |
| **PROTOCOL TITLE:** | | | |
| **(INITIAL) APPROVAL DATE:** | | | |
| **COORDINATING INVESTIGATOR:** | | | |
| **Email:** | | **Mobile:** | |
| **STUDY SITES:** | | | |
| **SPONSOR:** | | | |
| **SPONSOR CONTACT PERSON:** | | **Email:** | |
| **TERMINATION DATE:** | | | |
| 1. No. of participants | | | |
| 2. No. of enrolled | | | |
| 3. Reason/s for early termination | | | |
| 4. Summary of results | | | |
| Accrual data | | | |
| • How many have completed the study? | | | |
| • How many are still active? | | | |
| • What are the plans for those who are still active in the study? | | | |

| | |
|---|---|
| SIGNATURE OF PI: | |
| DATE: | |
| RECEIVED BY: | |
| REPORT SUBMISSION DATE: (to be filled out by REC) | |

| FOR REC USE ONLY: |
|---|
| **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study) |

| | Recommendations: |
|---|---|
| | Approve |
| | Request for further information/modification |
| | Others |

| | Type of review |
|---|---|
| | Expedited |
| | Exempted |
| | Full Board |

| Name of reviewer: | | Signature: | | Date: | |
|---|---|---|---|---|---|

| Final Decision: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

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**SINGLE JOINT RESEARCH ETHICS BOARD**

## SJREB FORM 10
## NOTICE OF POST-APPROVAL MODIFICATION

Date:

To *(name of PI)*: _____

Contact Details: _____

Protocol Title: _____

SJREB Protocol Code _____

Sponsor Protocol No. _____

Protocol Version No. and Version Date: _____

ICF Version No. and Version Date _____

Initial Approval Date _____

Type of Submission
- ☐ Annual Progress Report
- ☐ Amendment
- ☐ Final Report

This is to inform you of the SJREB decision related to the documents you have submitted:

| ITEMS FOR REVISION | REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR |
|---|---|
| Protocol | |
| Informed Consent Form | |
| Others | |

**Please submit the revised documents on or before** _____

| Type of review | |
|---|---|
| | Exempted |
| | Expedited |
| | Full Board |

| SJREB Decision | | | |
|---|---|---|---|
| | Minor revisions required | | Approved |
| | Major revisions required | | Others |
| | More information required | | |

| Meeting Date: | |
|---|---|

| SJREB Chair | Signature | Date |
|---|---|---|
| | | |

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## SJREB FORM 11
## ONSITE SERIOUS ADVERSE EVENT REPORT

| | |
|---|---|
| Coordinating Principal Investigator: | |
| SJREB Protocol Code: | |
| Study Title: | |
| Sponsor: | |
| Name of Study Medicine: | |
| Report Date: | |
| Onset Date: | |
| Date of First Use: | |

| Patient Number | Age | Sex |
|---|---|---|
| | | |
| | | |

| | |
|---|---|
| Patient's History: | |
| Laboratory Findings: | |
| SAE: | |
| Treatment Outcome: | |
| Management of Adverse Reaction: | |

Please check the ones applicable:

| Seriousness: | | Relation to: | | | | | |
|---|---|---|---|---|---|---|---|
| | Life Threatening | | Drug | | Device | | Study |
| | Death | | Not related | | | | |
| | Hospitalization | | Possibly | | | | |
| | Disability/Incapacity | | Probably | | | | |
| | Congenital Anomaly | | Definitely related | | | | |

| | | | |
|---|---|---|---|
| | Others (please specify) | | Unknown |

*Please attach standard CIOMS report form

FOR REC USE

| Reviewer's Name | Signature | Date |
|---|---|---|
| | | |

| | | | |
|---|---|---|---|
| Changes in the protocol recommended? | | Yes | Comments: |
| | | No | |
| Changes to the informed consent form recommended? | | Yes | Comments: |
| | | No | |

| REC Final Action | |
|---|---|
| | Request an amendment to the protocol or the consent form |
| | Request further information |
| | Suspend enrollment of new research participants |
| | Suspend all trial-related procedures |
| | Termination of study |
| | Take note and continue monitoring |
| | Conduct study site visits |
| | Others (please specify) |

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## SJREB FORM 12
## PROTOCOL VIOLATION/DEVIATION REPORT

| | |
|---|---|
| Coordinating Principal Investigator: | |
| SJREB Protocol Code: | |
| Study Title: | |
| Sponsor: | |
| Date of Submission: | |
| Reported by: | |

| | |
|---|---|
| Protocol deviation: | |
| Corrective measures done: | |

FOR REC USE

| Reviewer's Name | Signature | Date |
|---|---|---|
| | | |

Please check the ones applicable:

| Deviation from the protocol: | | Participant non-compliance: | |
|---|---|---|---|
| | Minor | | Yes |
| | Major | | No |
| | | | N/A |

| REC Recommendation: | |
|---|---|
| | Noted (no further action needed) |
| | Correction action needed |
| | Site visit needed |
| | Others (please specify) |

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## SJREB FORM A
## DECLARATION OF CONFLICT OF INTEREST

| | |
|---|---|
| Coordinating Principal Investigator: | |
| SJREB Protocol Code: | |
| Study Title: | |
| Sponsor: | |

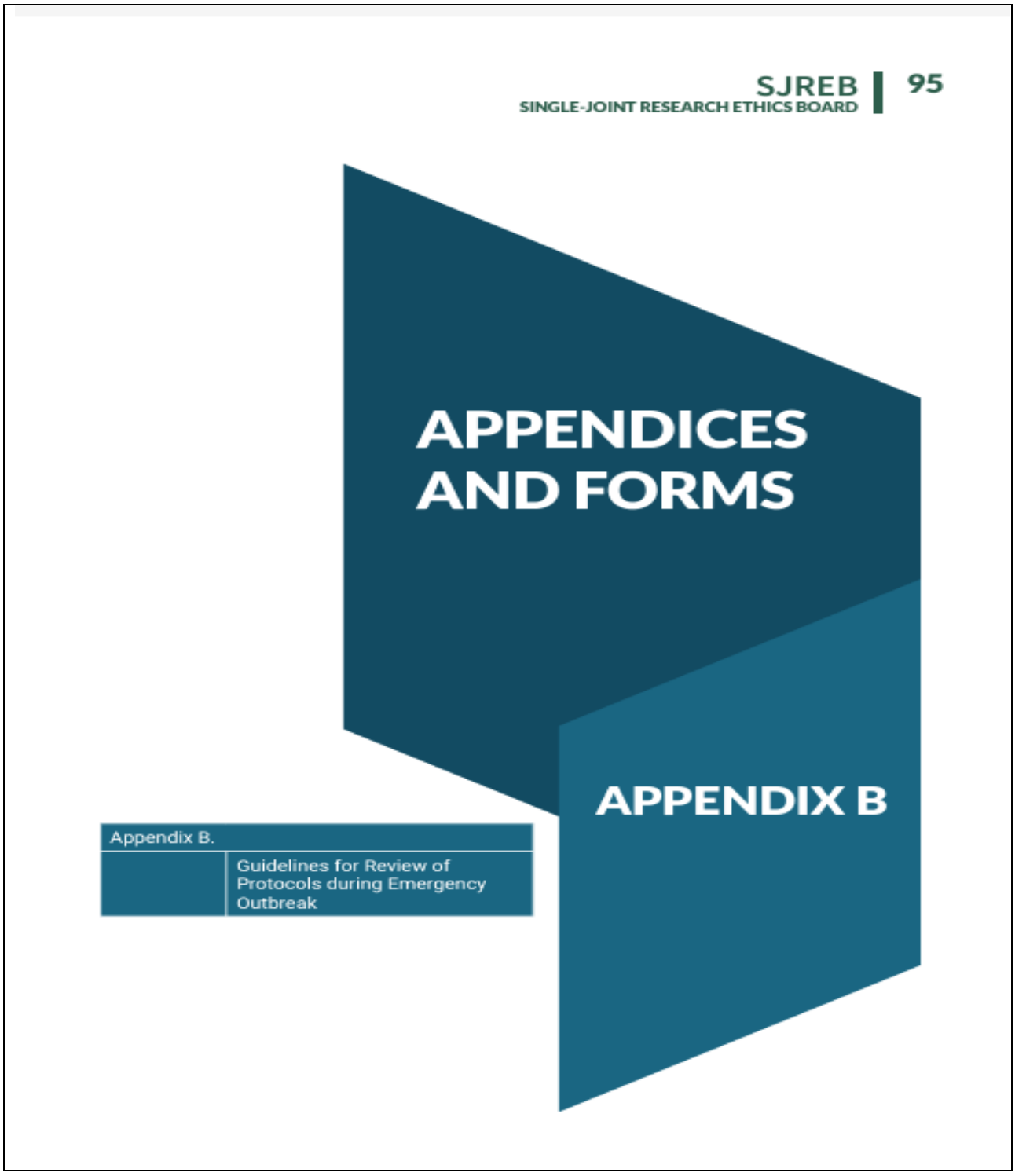
| Declaration of Conflict of Interest | | | | |
|---|---|---|---|---|
| Are you an employee of the sponsor/s? | | Yes | | No |
| Have you done consultancy or part time work for the sponsor/s in the past? | | Yes | | No |
| In the past year, did you receive P500,000 or more from the sponsor/s? | | Yes | | No |

| Other information | |
|---|---|
| Do you have other financial or non-financial ties with the sponsor (e.g. employment of relative to the 4th level of consanguinity) | |
| Are you a member of a policy-determining/recommendatory body that is convened by the DOH, DOST, and other national agencies who lead on COVID-19 response? | |

| List of all studies you are currently managing | | | |
|---|---|---|---|
| **Title of study** | **Sponsor** | **Status of implementation** | **% of time allotted for the study** |
| | | | |
| | | | |

**Ethical Responsibility and COI Statement**
I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI)

| SIGNATURE | DATE |
|---|---|
| | |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APPENDICES AND FORMS
APPENDIX B
Appendix B.
Guidelines for Review of Protocols during Emergency Outbreak

## APPENDIX B. Guidelines for Review of Protocols during Emergency Outbreak

*Adapted from the WHO Guidelines for Rapid Review of COVID-19 Research*

**Background**

To date, there are no approved treatments or prophylactic products known to be safe and effective for COVID 19, which is similar to previous outbreaks such as Ebola, Zika, or Lassa fever. Consequently, conducting research on new medications or vaccines during this pandemic is essential. Research conducted during pandemics or outbreaks, while in the best interests of communities that are presently affected or could be affected in the future, raises many unique ethical issues.

Different countries will be in different stages of readiness to review epidemic-relevant research. Regardless of preparatory work that has been done so far, there are things that ethics committees can and should do now to prepare for rapid review of COVID-19 protocols. It is necessary that research ethics committees be prepared to rapidly review COVID-19 research.

There have been many articles and reports published after the 2014 Ebola outbreak that address ethical issues in research during outbreaks and research ethics governance[1,2,3,4,5]. Of note, issues were raised about time sensitivity and the balance between the quality and time to review and ensuring the protection of participants in clinical trials, many of whom are in desperate need for any management protocols, lest they lose their lives.

Recently, two workshops were held to address important issues in this context: 1) "Ethics preparedness": Facilitating *Ethics Review During Outbreaks*, organized by ALERRT[6] (**A**frican coa**L**ition for **E**pidemic **R**esearch, **R**esponse and **T**raining)& WHO (World Health Organization) in Dakar, Senegal in March 2018, and 2) "*Ethics review of research on Lassa & other infectious disease outbreaks*", organized by WHO in Abuja, Nigeria in October 2018. These workshops provided

recommendations for addressing how National/Institutional (Research) Ethics Committees (N(R)ECs) and other research review committees should prepare for changes that may be necessary to their Standard Operating Procedures (SOPs) in order to respond efficiently during this pandemic.

**Specific Guidelines**

To facilitate the rapid or time-sensitive reviews, the following additions or changes to the ethics committees' existing standard operating procedures are being recommended.

> **It is important to note that this guidance should come into action once an outbreak is declared as a public health emergency. This declaration will come from the public health authority of the country. To speed up time to start the research, many processes (e.g., drafting documents, translations, approvals, etc.) will be happening in parallel rather than sequentially as is the case in non-emergencies.**

When a protocol is being considered for submission in a language different from that in which the review is conducted, the synopsis, plan, documents of consent/assent, and data collection tools/ forms at a minimum should be submitted in the official language of the country where the review will take place. Other documents in the reviewing country's language should be submitted as soon as possible.

1 World Health Organization (WHO). Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. WHO 2016. ISBN 978 92 4 154983 7
2 Schopper D, Ravinetto R, Schwartz L, et al. Research Ethics Governance in Times of Ebola. Public Health Ethics 2016; doi: 10.1093/phe/phw039 First published online: November 1, 2016.
3 Nuffield Council of Bioethics. Conducting research and innovation in the context of global health emergencies: what are the ethical challenges? Notes of workshop held on 9 December 2016: 10:00–13:30 28 Bedford Square, London WC1B 3JS.
4 Upshur R, Fuller J. Randomized controlled trials in the West African Ebola virus outbreak. Clinical Trials 2016: 1-3. DOI: 10.1177/1740774515617754.
5 The Challenge of Timely, Responsive and Rigorous Ethics Review of Disaster Research: Views of Research Ethics Committee Members. Matthew Hunt, Catherine M. Tansey, James Anderson, Renaud F. Boulanger, Lisa Eckenwiler, John Pringle, Lisa Schwartz. PLOS ONE | DOI:10.1371/journal.pone.0157142 June 21, 2016.
6 Abha Saxena, Peter Horby, John Amuasi, Nic Aagaard, Johannes Köhler, Ehsan Shamsi Gooshki, Emmanuelle Denis, Andreas A. Reis. The ALERRT-WHO Workshop and Raffaella Ravinetto. Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Medical Ethics 2019; 20:29

**Documentary Requirements**

A checklist including the following items should be included in addition to the ethics review form (if used by the research ethics committee):

An option to identify the research as epidemic/outbreak-related in order to facilitate fast-tracking;

An opportunity to describe whether prior research data about the disease exists;

Inclusion of at least one PI or co-PI of the country where research and review is taking place;

Qualification of key investigators, including a description of previous track record with outbreak-relevant research among the research group; and,

An indication whether the protocol is part of a multicenter trial. If yes, an opportunity should be provided to describe the status of ethics approval of the master protocol or the ethics approval of the sponsoring country.

Apart from the basic documents submitted for review (Protocol, CVs, etc.), the following should also be submitted:

Letter of collaboration in the form of a Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) with sponsor institution(s) and the funder(s) of the research along with declarations of Conflict of Interest when possible;

Monitoring and safety management plan for the project, as provided by the study sponsor;

Both data sharing and material transfer agreements (MTA) for data and human biological material, especially if samples are being exported out of the country, while honoring the laws of the land (a draft may be submitted initially);

Clear processes and procedures/expectations for follow-up dissemination and publication, co-authorship, co-presentation, and Intellectual Property Rights;

Procedures for dissemination of findings to the affected community (important to ensure maintaining contact and upholding trust of the

affected populations, especially research participants); and,

May include local requirements on insurance policies, particularly on trials/interventions.

**Meeting Requirements and Procedures**

***Considerations***

To prepare for the review of COVID-19 research, RECs should agree on a process for rapid review and communicate this to researchers (and communicate any anticipated delays for non-COVID-19 research).

Also, practical aspects like: identify surge capacity for review, set up systems for remote discussions (which software platform, does everybody who needs it have access and know how to use it, what will you do if internet isn't functioning etc.)

***Membership and Quorum***

It is essential that a certain number of members be pre-identified who will share the major burden of review. These members would require specialized training (or equivalent experience) in reviewing research in outbreaks so that they are able to rapidly review research proposals without compromising the ethics. Additional members should be identified and called for review at times when demand increases.

Once an outbreak is imminent or ongoing, the chair or the secretary of the review committee should alert members and ascertain which members would be available for the rapid review.

Identification as well as contacting in advance subject experts (technical) and people with strong knowledge of ethics (both in-country and abroad) willing to serve as ad hoc or co-opted members during outbreaks, as there is a likelihood of receiving multiple projects that need to be reviewed in a short time.

The quorum shall abide by the ICH-GCP requirements.

If pre-identified REC member submits their review but is unable to join the meeting, they should be considered as part of the quorum requirement.

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***Procedures***

The new SOPs should be circulated to all members of the review committee.

The review meetings could be virtual or electronic especially if the risk of face-to-face meeting in highly infectious outbreak like COVID-19 may be risky to the members.

Protocol submission **should** be done electronically to save time with submission of the hard copy, which if mandatory can follow. PIs should contact RECs as soon as possible to communicate their intention to submit as well as a high-level overview of research (is it a trial of new medicine, vaccine, observational study, survey, etc.) so that RECs are aware of protocols that may be forthcoming.

Face to face meetings with the PIs should not be mandatory and if necessary electronic and or virtual venues may be adopted.

***Timelines***

Protocols should be sent to reviewers within **24-hours of submission**.

Each reviewer should complete their reviews within a specified period of time (usually **3 calendar days** is sufficient and appropriate during an outbreak).

Consolidated review and suggestions (or approval) should be communicated to the PI within a specified period of time (usually **within 5 calendar days**).

The complete review process until issuance of approval should not exceed **14 calendar days**.

**Communication**

Electronic or telephonic communication with PIs **should** be initiated to seek clarifications, thus saving time.

The PI **should** respond to the review within 48-hour

Focal points/persons for communication in respective institutions and RECs/NECs should be identified as early in the process as possible.

**Documentation and Archiving**

All communications **should** be documented and archived following the research ethics committee's standard operating procedures.