ST. PAUL'S HOSPITAL OF ILOILO, INC.

INSTITUTIONAL REVIEW BOARD

2025 | 13th Edition

STANDARD OPERATING PROCEDURES

serving in Excellence

MOVING FORWARD

(Based on Philippine Health Research Ethics Board Standard Operating Procedures Workbook, 2020)

ST. PAUL'S HOSPITAL OF ILOILO, INC.

INSTITUTIONAL REVIEW BOARD

2025 | 13th Edition

STANDARD OPERATING PROCEDURES

Authored by:	**IRB SOP TEAM** *(Based on **Philippine Health Research Ethics Board Standard Operating Procedures Workbook, 2020**)*
Approval Date:	**July 08, 2025**
Approved by:	**Dr. Jaime Manila** *Chair, Institutional Review Board*
Approved by:	**Sr. Arcelita Sarnillo, SPC** *Hospital Administrator*
Effective Date	**July 15, 2025**

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **Table of Contents**

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **Table of Contents**

I. Saint Paul's Hospital Iloilo: History, Vision, Mission, Organizational Chart, Workflow of IRB submission

HISTORY:

The solicitude for the sick of the late Msgr. Dennis J. Dougherty of Philadelphia, who was then Bishop of Jaro, was the original motivating force that brought about the foundation of St. Paul's Hospital of Iloilo. As early as 1909 he asked the Sisters of St. Paul of Chartres, who were just starting their work in the Philippines, to establish a hospital in Iloilo.

It was not until February 15, 1911 when four pioneer sisters, Mother Marie Donatien, Sister Antoine du Sacre Coeur, Sister Augustine De Marie and Sister Felix de Marie came and answered the clergy. Their first convent was a former warehouse of the Ynchausti Y Compania on Calle Rosario. Two adjacent residential homes were made the seats of the hospital where they were to establish. Three more nuns, Sister Marie Scholastique, Sister Marie Estelle and Sister Adrien joined them some months later. The latter was formally installed as the first superior of the establishment. On May 20 of the same year, their doors open to the sick. Dr. Samuel Carson of the Philippine Railway brought in the first patient.

This was followed by Drs. Gilchrist, Kilayko and Arroyo. Dr. Carson became the first Medical Director and was pioneer doctor succeeded by Dr. Arroyo who held the position up to the outbreak of World War II. These generous French Religious pioneers made rapid adjustment to their new environment. They endeared themselves to the Ilonggos who fondly called them "Madres de San Pablo".

After two years of hard work, they found it necessary to expand their accommodations for the sick who sought their care. Msgr. Dougherty followed closely the progress of the hospital with enthusiasm. In 1913 he went back to his native States to secure funds for putting up the hospital. The project was placed under the patronage of the little flower whose beautification was under study. In less than a year's time, the bishop came back with the needed funds.

Bishops Foley and Mc. Closky carried on the work because the founder was recalled to become Bishop of Buffalo and later Cardinal of Philadelphia. The hospital building was completed and formally occupied in 1916. Msgr. Dougherty never lost his interest, however, in the growing institution up to his death in 1951. Recognizing the dedicated services of the Sisters, he turned over to them full ownership and administration in a written statement executed in 1941.

Today, St. Paul's Hospital Iloilo is a tertiary level training general hospital with a capacity of 265 beds. It caters to the health needs of the inhabitants of Iloilo City, its neighboring towns and provinces like Aklan, Antique, Capiz, Palawan and Negros Occidental. The Hospital has been counted as one of the best hospitals and received both local and national awards for its cleanliness and quality services.

I. Saint Paul's Hospital Iloilo: History, Vision, Mission, Organizational Chart, Workflow of IRB submission

VISION:

We envision St. Paul's Hospital of Iloilo, Inc. as a Christ-centered, excellent, innovative, global healthcare and training hospital.

MISSION:

We commit ourselves to:

1. Offer Christ-centered excellent healthcare upholding the bioethical principles and the teaching of the Catholic Church;

2. Innovate & develop competencies of health care professionals through continuing relevant training and research programs;

3. Continually implement and sustain operational and financial excellence through Christian stewardship & good governance.

CORE VALUES: C-A-R-E

1. **C**ompassion – capacity and readiness to suffer with those who suffer; to feel one with the suffering and those in pain, to be moved with one's deepest interiority "may pagmamalasakit".

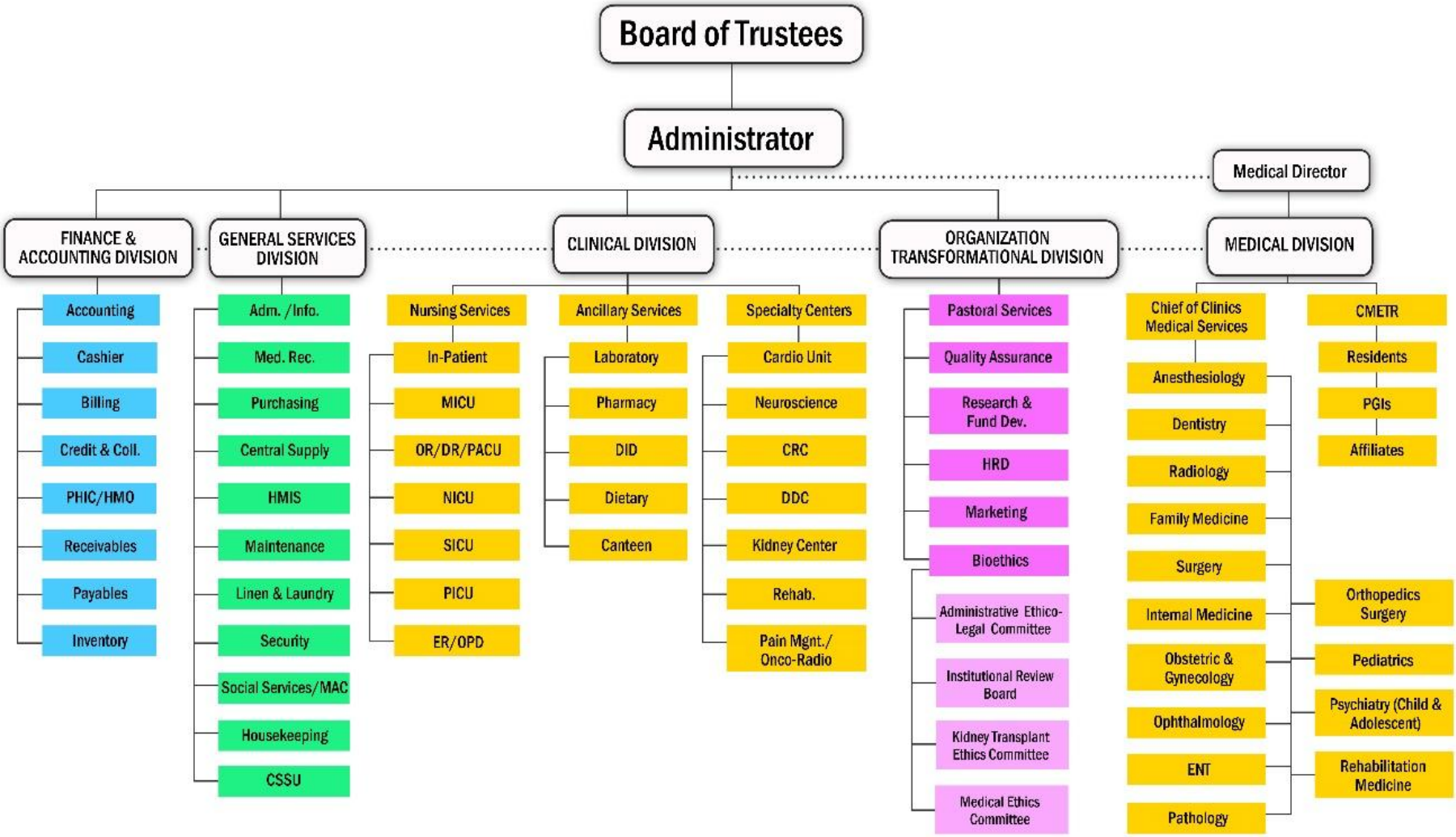
2. **A**ccountability – the capacity and readiness to accept consequences of one's decision/action and the responsibility of stewardship in caring and serving.

3. **R**espect – showing appreciation towards the value of another person; manifest a differential regard to the values; principles and beliefs of others.

4. **E**xcellence – doing the right thing all the time; error free state; quality of doing things efficiently.

ST. PAUL'S HOSPITAL OF ILOILO, INC

FUNCTIONAL ORGANIZATIONAL CHART



II. SPHI IRB: History, Vision, Mission and Organizational Chart

HISTORY:

In 1996, St. Paul's Hospital of Iloilo, Inc. (SPHI) established its Ethics Committee, marking the beginning of its Bioethics Committee. On June 27, 2006, the Ethics Committee revised its policies for the comprehensive and efficient review of research involving human participants, ensuring that clinical research conformed to ethical and scientific standards, with informed consent and the freedom for participants to withdraw at any stage.

On November 1, 2007, the committee was renamed the St. Paul's Hospital Ethics Review Board (IERB), with members including Chairman Msgr. Paul Solomia, Co-Chair Dr. Jaime Manila, Secretary Joy Braza, and members Sr. Donatilla Torres, Atty. Luisito Hofilena, Dr. Levy Suyo, and Ms. Jemmayma Maybay. In 2008, Ms. Joan Marie Chiu replaced Ms. Joy Braza as IERB Secretary.

In January 2011, Msgr. Paul Solomia, Ms. Joan Marie Chiu, Sr. Donatilla Torres, Dr. Levy Suyo, and Ms. Jemmayma Maybay were reappointed, with Atty. Jose Mari Benjamin Tirol added as a new member. By August 2013, Sr. Rosamond Marie Abadesco, SPC hired Ms. Eden Shiz Parpa as a part-time staff, who became the full-time Office Secretary in November.

On July 15, 2013, new members were appointed, including Chairman Dr. Levy Suyo, Secretary Eden Shiz Parpa, and members Msgr. Paul Solomia, Dr. Jaime Manila, Mrs. Maria Thelma Servidad, Sr. Rowena Rodil, SPC, and Atty. Jose Mari Benjamin Tirol.

In July 2014, Sr. Henrietta Esmero, SPC replaced Sr. Rowena Rodil, SPC, and the committee was renamed the Institutional Review Board Committee.

On February 27, 2015, the Philippine Health Research Ethics Board (PHREB) requested accreditation applications, and SPHI applied for Level 3 Accreditation on April 30. By August 18, a new standard operating procedure (SOP) was approved, and Dr. Jaime Manila was appointed as Chair, with members including Dr. Rowena Cosca, Sr. Henrietta Esmero, SPC, Maria Thelma Servidad, Atty. Jose Mari Benjamin Tirol, Msgr. Paul Solomia, and Ms. Eden Shiz Parpa.

On October 24, 2015 the Administrator appointed Dr. Ma. Cecilia Divinagracia Florete (Gastroenterologist), Dr. Venerio Gasataya Jr. (Surgeon) and Mr. Christopher Tabsing (School Principal), as new members of the board. Likewise, Dr. Ma. Cecilia Divinagracia Florete was appointed Member-Secretary. On November 9, 2015 Msgr. Paul Solomia ended his term. With grateful hearts, the Administration and the IRB thanked Msgr. Paul for his commitment and dedication to the service of the IRB. On the same month, the Administrator hired Ms. Queenie Macalalag as clerk secretary to be with Sr. Maria Kristina Bergonia, SPC in the IRB.

From February 17-19, 2016, PHREB conducted an accreditation visit. Following the visit, an action plan was created and sent to PHREB on March 29.

On May 13, 2016 Sr. Joselina R. Bonono, SPC replaced Sr. Ma. Kristina Bergonia, SPC, and on August 9, SPHI IRB received provisional Level III Accreditation. In January 2017, SOP version 3 was approved.

On August 9, 2017 SPHI IRB received a two-year Level III Accreditation, and on August 10 Sr. Edith Christine Aguirre, SPC replaced Sr. Henrietta Esmero, SPC. In April 2018, independent consultants were reappointed, with Dr. Amee Lourdes Ponje added.

On May 19, 2018 Sr. Ma. Jessica Formacion, SPC replaced Sr. Edith Christine Aguirre, SPC.

In October 2018, SPHI IRB applied for Level III Re-accreditation, and SOP version 4 was approved. From March 12-15, 2019, PHREB conducted a re-accreditation visit, with the final report received on March 25. In June 2019, a statistician, Mrs. Ma. Romy Alexis Consulta, was appointed as new IRB member, and SOP 5th Edition was approved. In September 2019, PHREB granted a one-year Level 3 Accreditation, and SOP 7th Edition was approved on December, 2019 with Dr. Joselito Caso added as an Independent Consultant.

In 2020, Sr. Joselina Bonono, SPC was reassigned, and Sr. Ma. Jessica Formacion, SPC became the new IRB Office Manager. On January 13, 2021, the SPHI IRB received a two-year Level 3 Accreditation.

In April 2021, Sr. Gertrude Caryls Kuebler, SPC was appointed IRB Office Manager. By June 2022, she was reappointed as IRB Office Manager. In January 2023, the accreditation expired, but extensions were granted. From September 18-22, PHREB conducted an online accreditation.

In January 2024, Mrs. Maria Thelma Servidad was appointed as a lay-affiliate. In April 2024, Dr. Ronald Latap added as new IRB member, Mrs. Imelda L. Olaguer, Dr. Luis Serafin Thomas Dabao III were appointed as alternate members. Dr. Ken Hilario Lapastora III and Dr. Marie Hazel Ivy M. Mueño appointed as new independent consultants.

In September 2024, SPHI-IRB was granted Level 2 accreditation status.

II. SPHI IRB: History, Vision, Mission and Organizational Chart

SPHI IRB GUIDING PRINCIPLES IN THE ETHICAL EVALUATION OF RESEARCHES:

The St. Paul's Hospital of Iloilo IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents such as the Declaration of Helsinki (2024), CIOMS (2016). The IRB functions in accordance with national laws, regulations, and guidelines and provides its own standard operating procedures based on Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO); National Ethical Guidelines for Research Involving Human Participants (2022); WHO 2023 Tool for Benchmarking Ethics oversight of health related research involving human participants; International Conference on the Harmonization of Good Clinical Practice (ICH-GCP 2023); and Philippine Food and Drug Authority regulations and other relevant laws and regulations. It also takes the initiative to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research that it has approved.

GENERAL ETHICAL PRINCIPLES:
(Based on CIOMS 2016)

All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence and justice. It is generally agreed that these principles, w/c in the abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. The present guidelines are directed at the application of these principles to research involving human subjects.

Respect for persons incorporates at least two fundamental ethical considerations, namely:

a. Respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
b. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefit and to minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigation be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, ***non-maleficence*** (do no harm)

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to ***distributive justice***, which requires the equitable distribution of both the burdens and the benefits of participation in

research. Differences In distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons: one such distinction is vulnerability. "Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

Sponsors of research or investigators cannot, In general, be held accountable for un just conditions where the research is conducted, but they must refrain from practices that they are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resources countries or vulnerable population to protect their own interests, by conducting research inexpensively and avoiding complex regulatory system of industrialized countries in order to develop products for the lucrative markets of those countries.

In general, the research project should leave low-resources countries or communities better off than previously or, at least, no worse off. It should be responsive to their health needs and priorities in that any product developed is made reasonably available to them, and as far as possible leave the population in a better position to obtain effective health care and protect its own health.

Justice requires also that the research be responsive to the health conditions or needs of vulnerable subjects. The subjects selected be the least vulnerable necessary to accomplish the purposes of the research. Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subjects is representative.

Ethical Principle for Medical research Involving Human Subjects
(Based on DECLARATION OF HELSINKI 2024)

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research using identifiable human material and data.

   The Declaration is intended to be read as a whole, and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. While the Declaration is adopted by physicians, the WMA holds that these principles should be upheld by all individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.

General Principles

3. The WMA Declaration of Geneva binds the physician with the words, "The health and well-being of my patient will be my first consideration," and the WMA International Code of Medical Ethics declares "The physician must commit to the primacy of patient health and well-being and must offer care in the patient's best interest."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include participants. Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

6. Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

   Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

   Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

7. The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health.

   These purposes can never take precedence over the rights and interests of individual research participants.

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, autonomy, privacy, and confidentiality of personal information of research participants. The responsibility for the protection of research participants must always rest with physicians or other researchers and never with the research participants, even though they have given consent.

10. Physicians and other researchers must consider the ethical, legal and regulatory norms and standards for research involving human participants in the country or countries in which the research originated and where it is to be performed, as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research participants set forth in this Declaration.

11. Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.

12. Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher.

    Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research will not adversely affect the health of the patients who serve as research participants.

15. Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured.

VISION:
A Christ-centered accredited board for ethical review and monitoring of researches.

MISSION:

1. Receive and evaluate research proposals as to adherence to accepted ethical principles.
2. Assure that evaluation is based on local, national and international guidelines.
3. Update members on latest national and international guidelines.

II. SPHI IRB: History, Vision, Mission and Organizational Chart

ST. PAUL'S HOSPITAL OF ILOILO, INC.
General Luna St., Iloilo City

SPHI-ADM-04-22-01

MEMO: 24 – 2024
DATE: APRIL 22, 2024
TO: ALL SPHI CONSTITUENTS
FROM: OFFICE OF THE ADMINISTRATOR
RE: SUPPORT FOR INDEPENDENT INSTITUTIONAL REVIEW BOARD (IRB)

Peace be with you!

The St. Paul's Hospital of Iloilo- Institutional Review Board (SPHI-IRB) is an independent body created by St. Paul's Hospital of Iloilo, INC under the Office of the Hospital Administrator. The SPHI-IRB plays a crucial role in ensuring that all research involving human subjects is conducted ethically and in compliance with the applicable national/international regulations. It has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval.

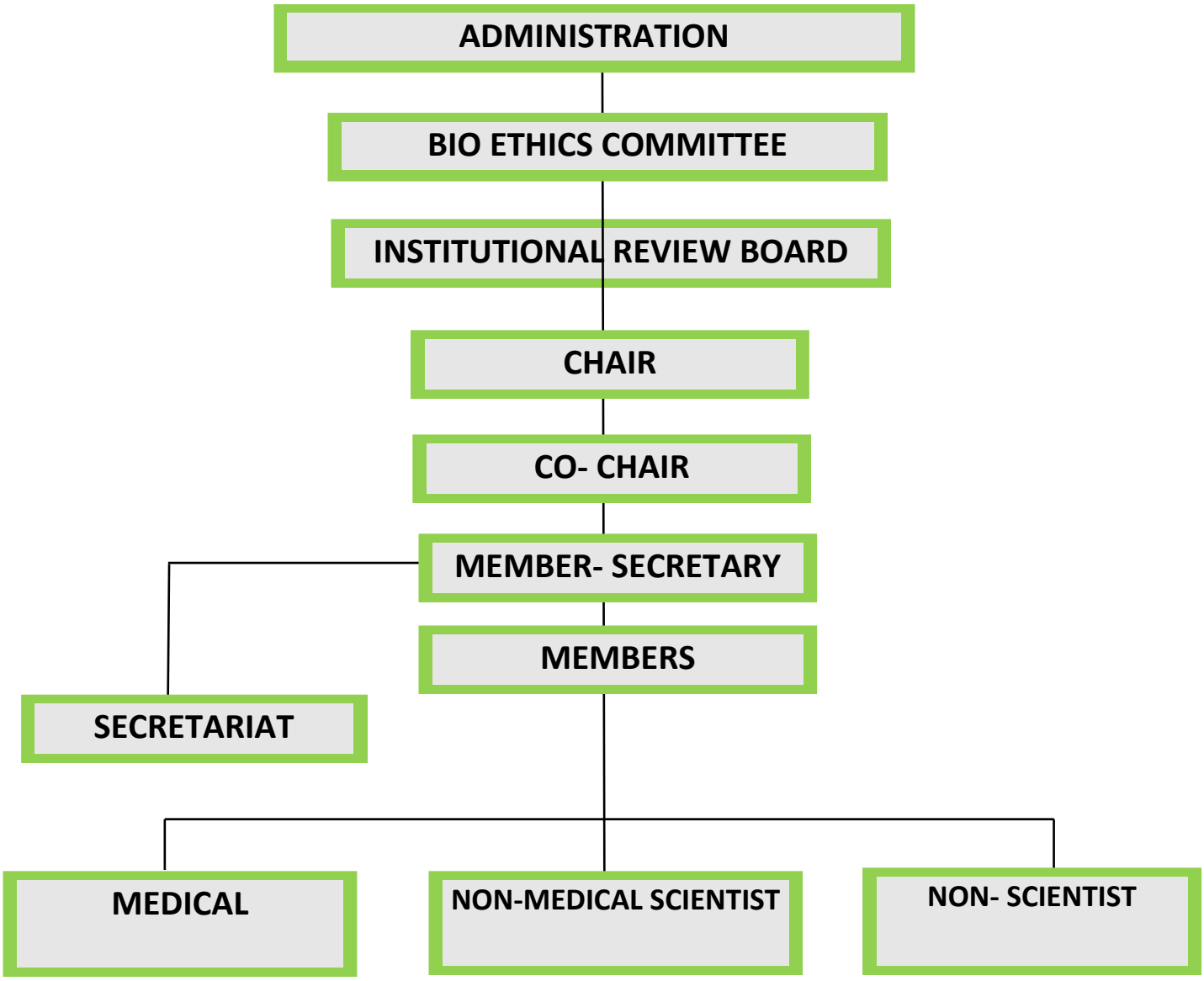
As part of our commitment to upholding the highest standards of ethical conduct in research, the administration shall fully support the day-to-day activities of the IRB. This includes providing the necessary resources for training and development as well as budgetary support to enable the IRB to carry out its responsibilities effectively.

All members of the organization are urged to cooperate with the IRB and to adhere to its guidance and recommendations in all research activities involving human subjects. By working together, we can ensure the protection of the rights and well-being of research participants and uphold the integrity of our research endeavors.

Thank you for your attention to this matter. God bless!

SR. ARCELITA S. SARNILLO, SPC
Hospital Administrator

II. SPHI IRB: History, Vision, Mission and Organizational Chart



II. SPHI IRB: History, Vision, Mission and Organizational Chart

INSTITUTIONAL REVIEW BOARD
"FLOW CHART OF PROTOCOL SUBMISSIONS"

PROTOCOLS SUBMISSIONS TO SPHI-IRB

Three (3) hard copies for submission and electronic copy

Protocol package for Clinical trial and/or Sponsor-initiated studies:

- ☐ **Letter of Application & Complete Protocol**
- ☐ **Protocol Summary**
- ☐ **Investigator's Brochure (for Clinical Trials)**
- ☐ **Data collection form/s**
- ☐ **Informed Consent Forms (English, Tagalog, and local dialect (Hiligaynon))**
- ☐ **CV (for clinical trials- Principal Investigator and his/her co-investigators), (for Researcher Initiated protocol-Researcher and Adviser).**
- ☐ **GCP Certificate of the Principal Investigator (PI) and his/her co-investigators**
- ☐ **Declaration of No Conflict of Interest for Principal Investigators/Researchers (Form 2.2)**
- ☐ **Valid PRC License**
- ☐ **COI Declaration and Confidentiality Agreement**
- ☐ **GANTT Chart (as necessary)**
- ☐ **Advertisement, Diary card and other related documents (for Clinical Trials)**
- ☐ **Case report form/s, trial Materials (for Clinical Trials)**
- ☐ **Certificate of Technical Review (for Researcher Initiated protocol)**
- ☐ **Insurance Certificate (for Clinical Trials)**
- ☐ **Technical review approval/endorsement of the Department**
- ☐ **Decision of Ethics Review if reviewed by other Research Ethics Committee/s**
- ☐ **Material Transfer Agreement (for Clinical Trials if applicable)**
- ☐ **Budget**
- ☐ **Clinical Trial Agreement- Draft is acceptable (for Clinical Trials)**
- ☐ **Letter of Approval from Hospital Administrator and Data Protection Officer**
- ☐ **Waiver of Informed Consent Form (if applicable)**

IRB Secretariat receives the complete documents. Assigns IRB Protocol Number. Issues Acknowledgement Receipt Form. (Day 1)

IRB Secretariat forwards to the Chair or Member-Secretary the documents to determine if the protocol is for Full Board, Expedited, SJREB or Exempt from Review. (Day 1)

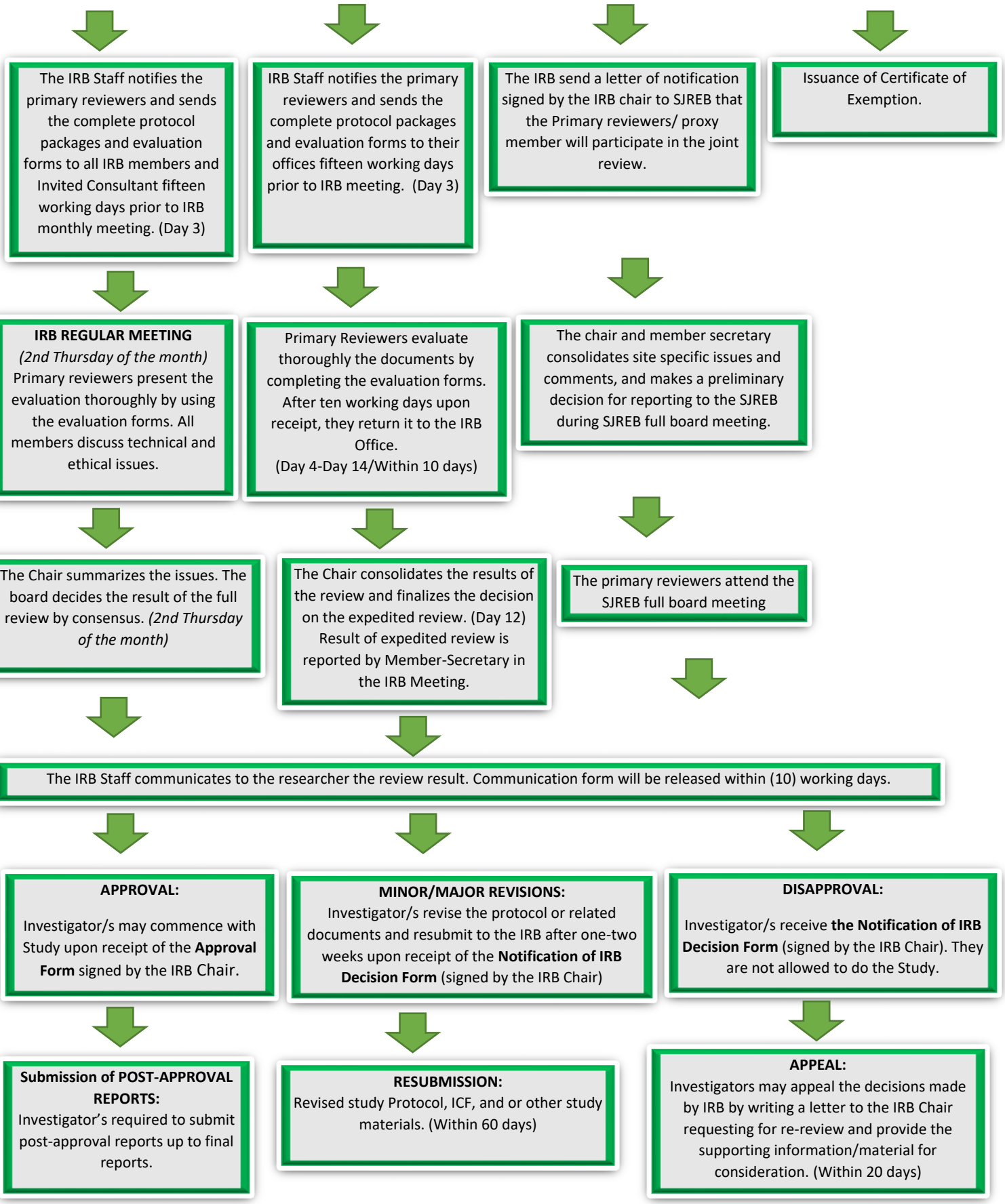
FULL BOARD REVIEW:
Chair/Member-Secretary assigns primary reviewers and independent consultant (as needed) for the full-board review. Deliberation & dissemination of Decision within six (6) weeks after submission. (Day 2)

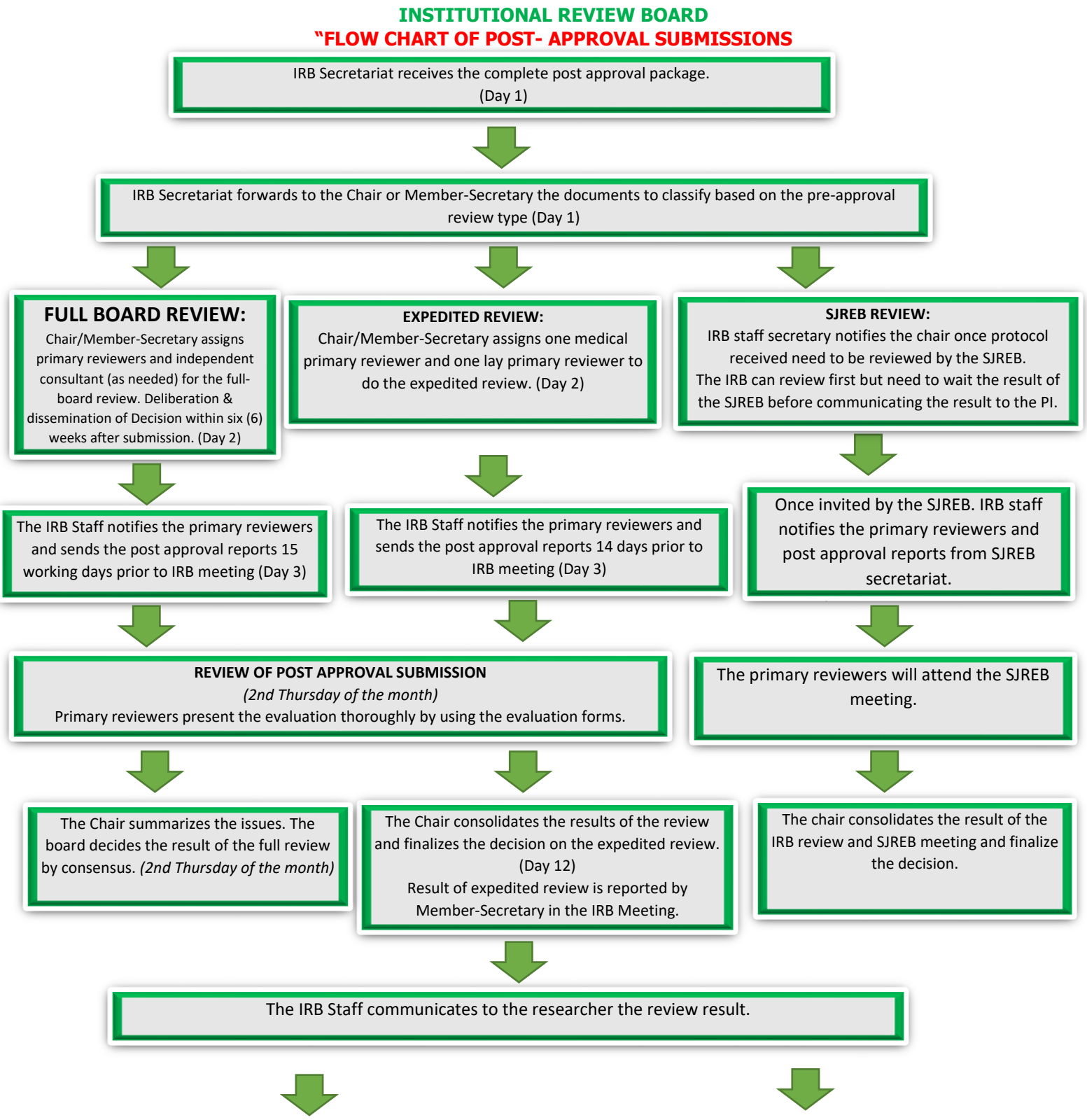
EXPEDITED REVIEW:
Chair/Member-Secretary assigns one medical primary reviewer and one lay primary reviewer to do the expedited review. (Day 2)

SJREB REVIEW:
The chair assigns two (2) primary reviewers. Aside from the review of protocols, the primary reviewers will be notified of their attendance and participation in the SJREB joint review.

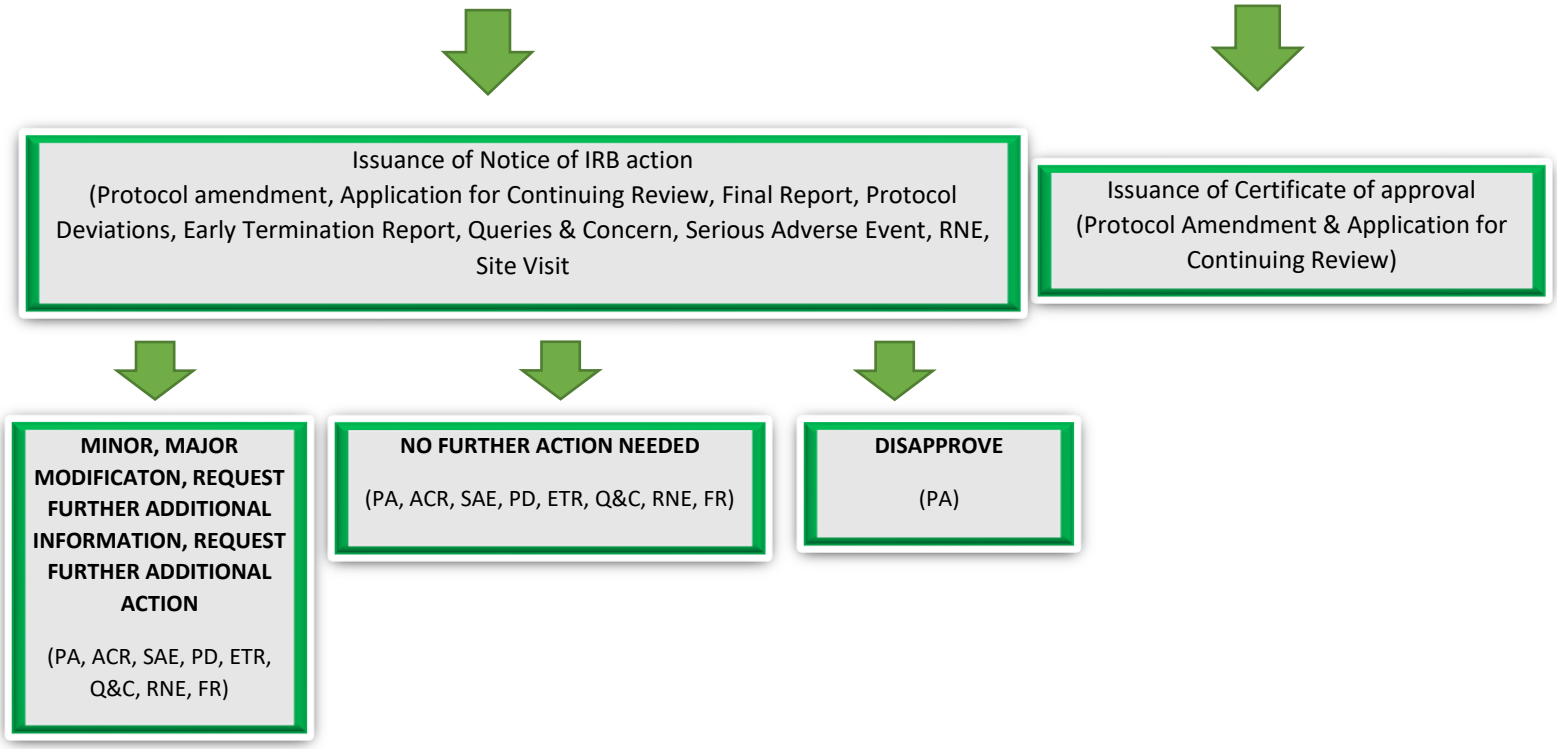
EXEMPT FROM REVIEW:
Chair/Member-Secretary will assess if the protocol submitted is application for exempt from review based on Exempt from review checklist (Day 2)

II. SPHI IRB: History, Vision, Mission and Organizational Chart




INSTITUTIONAL REVIEW BOARD
"FLOW CHART OF POST- APPROVAL SUBMISSIONS
IRB Secretariat receives the complete post approval package. (Day 1)
IRB Secretariat forwards to the Chair or Member-Secretary the documents to classify based on the pre-approval review type (Day 1)
FULL BOARD REVIEW:
Chair/Member-Secretary assigns primary reviewers and independent consultant (as needed) for the full-board review. Deliberation & dissemination of Decision within six (6) weeks after submission. (Day 2)
EXPEDITED REVIEW:
Chair/Member-Secretary assigns one medical primary reviewer and one lay primary reviewer to do the expedited review. (Day 2)
SJREB REVIEW:
IRB staff secretary notifies the chair once protocol received need to be reviewed by the SJREB.
The IRB can review first but need to wait the result of the SJREB before communicating the result to the PI.
The IRB Staff notifies the primary reviewers and sends the post approval reports 15 working days prior to IRB meeting (Day 3)
The IRB Staff notifies the primary reviewers and sends the post approval reports 14 days prior to IRB meeting (Day 3)
Once invited by the SJREB. IRB staff notifies the primary reviewers and post approval reports from SJREB secretariat.
REVIEW OF POST APPROVAL SUBMISSION
(2nd Thursday of the month)
Primary reviewers present the evaluation thoroughly by using the evaluation forms.
The primary reviewers will attend the SJREB meeting.
The Chair summarizes the issues. The board decides the result of the full review by consensus. (2nd Thursday of the month)
The Chair consolidates the results of the review and finalizes the decision on the expedited review. (Day 12)
Result of expedited review is reported by Member-Secretary in the IRB Meeting.
The chair consolidates the result of the IRB review and SJREB meeting and finalize the decision.
The IRB Staff communicates to the researcher the review result.

II. SPHI IRB: History, Vision, Mission and Organizational Chart



Version No: 13	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: July 08, 2025	**SOP No: 01** **Selection and Appointment of IRB Members**
Effective Date: July 15, 2025	

1.Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board selection and appointment of IRB members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists, medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution. The SPHI IRB shall have at least seven members, which shall include at least one whose primary concern is in the medical sciences, at least one whose primary concern is in non-medical or non-scientific, at least one with expertise in legal matters, at least one who is not affiliated with SPHI, and at least one who is a Sister of St. Paul of Chartres. Members shall be classified as regular or alternate members.

The members shall be appointed for a period of either one (1) year, two (2) years, or three (3) years, and may be renewed for three (3) consecutive terms of three (3) years. To ensure the continuity, development and maintenance of the IRB work, they shall be appointed on a staggered basis. Alternate members may also be appointed on a case-by-case basis.

The selection and appointment of members shall comply with the provisions of the World Health Organization (WHO) Operational Guidelines, Council for International Organizations of Medical Sciences (CIOMS), Guidelines International Conference on Harmonization- Good Clinical Practice (ICH-GCP), Declaration of Helsinki and the National Ethical Guidelines for Health Research on the composition of independent ethics review committees.

2. Objective of the Activity

The selection and appointment process aims to ensure that the members are from diverse backgrounds and sectors as stated above, and of lay people who will represent the interest and concerns of the communities from which study participants are likely to be drawn from.

3. Scope

This SOP begins with the call for nominations and ends with the filing of appointment letters, CVs, and other relevant documents of IRB members in the membership file.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Nomination of candidates	*Chair and IRB members*	*1 day*
Step 2: Preparation and submission of the list of nominees to the Hospital Administrator	*Chair*	*1 day*
Step 3: Preparation of appointment letter of new members	*Office Manager*	*1 day*
Step 4: Receipt of appointment letter of new IRB Regular and Alternate Members and collection of their CVs (Form 1.9) and COI (Form 1.8)	*Office Manager and Staff*	*1 day*
Step 5: Filing of appointment documents and CVs in the membership file	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Nomination of candidates

The current IRB members, headed by a Chair nominates candidates who have the necessary qualifications for the position

1.1 Members are selected based on their:

- Good moral character
- Personal capacities
- Upholds the values of SPHI
- Ethical and/or scientific knowledge and expertise
- Willingness to volunteer their time and effort to perform their functions in the IRB
- Prior training in Good Clinical Practice, research methodology and research ethics, or are willing to undergo such training during their membership.

1.2 The Chair shall inform prospective members that they have been nominated for membership in the SPH IRB and inquire if they are interested to become members. If they manifest their interest, the Office Manager shall provide them with the terms of reference (TOR) specific to their sector (i.e. scientist/medical member, non- medical/non-scientist member, alternate member, independent consultant). The said TOR shall also contain their specific duties and responsibilities if they are appointed as members:

a. Attend IRB meetings consistently.
b.Participate in the ethical review of research proposals and other related reports.
c. Reviews, discusses and considers research proposals submitted for evaluation
d. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate and the after-review activities, e.g., continuing review, progress report, site visit, etc.
f. Maintains confidentiality of the documents and deliberations of the IRB meetings
g.Declares any conflict of interest in the review of research proposals.
h.Participates in continuing education activities in health research and ethics education
i. Performs other duties designated by the Chair
j. Leads the prayer during the meeting
k.Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.

IRB Alternate Member Responsibilities:
a. Attend IRB meetings if Regular IRB member with the same expertise is absent.
b. Substitutes for a regular IRB member in the absence of regular member.
c. Receives, and reviews the same materials that the regular member receives.
f. Maintains confidentiality of the documents and deliberations of the IRB meetings
g.Declares any conflict of interest in the review of research proposals.
h.Participates in continuing education activities in health research and ethics education

i. Performs other duties designated by the Chair
j. Leads the prayer during the meeting
k. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.
k. Participates in making decisions and is included as part of the quorum if invited to substitute for an absent regular member.

1.3 Prospective members shall be requested to disclose in writing any financial, professional or personal interest or involvement in a project or proposal under consideration by the SPHI IRB, which is in or may be in conflict with their functions as a member.

1.4 The Chair and the IRB members in a special meeting discuss the qualifications of the nominees based on their expertise, trainings, ethical and/or scientific knowledge; upholding the Corporate Values of the Institution; with commitment and willingness to volunteer the necessary time and effort for the IRB's work and in maintaining the confidentiality and integrity of the IRB.

Step 2: Preparation and submission of the list of nominees to the Hospital Administrator

The Chair prepares a shortlist list of possible members and submits to the Hospital Administrator. The Hospital Administrator selects the new member/s from the list and inform the Chair of her decision. The Chair informs the Office Manager of the decision of the Hospital Administrator.

Step 3: Preparation of appointment letter of new members

3.1 The Office Manager prepares the Appointment letter (Form 1.0, Form 1.1 and Form 1.2) of the new member/s which shall include their term of office and duties and responsibilities.

3.2 The Office Manager submits the appointment letter to the Chair for signature prior to submission to the Hospital Administrator for her signature.

Step 4: Receipt of appointment letter of new IRB Regular and Alternate Members and collection of their CVs and COI

4.1 The Office Manager and Staff, upon receipt of the appointment letter that has been signed by the Hospital Administrator informs the newly appointed member/s and request them to sign the same to manifest their acceptance.

4.2 New members shall submit their signed and dated Curriculum vitae (Form 1.9), and update the same at least once every two (2) years.

4.3 The New members signs a COI (Form 1.8) at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.

Step 5: Filing of appointment documents and CVs in the membership file

The Office Manager or Staff files the documents (Appointment letter (Form 1.0, Form 1.1 and Form 1.2), Agreement on Confidentiality and COI (Form 1.8) and Curriculum Vitae (Form 1.9) and

training certificates of newly appointed member/s in their specific membership file folder. All of these documents are kept securely in locked "SPHI IRB Documents" cabinet.

6. Forms

Appointment letter for Regular Members (Form 1.0)
Appointment letter for Alternate Member (Form 1.1)
Appointment letter for Non-scientific Member (Form 1.2)
Agreement on Confidentiality and COI (Form 1.8)
Curriculum Vitae (Form 1.9)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Added responsibilities of IRB officers, members and Staff*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History, Changed IRB Forms Header. Selection and tenure of appointment of the Board.*
05	*2019 June 13*	*IRB SOP TEAM*	*Described qualifications of Chair, Co- Chair and Secretary. Transferred section 1.2.4.5 to Step 1 of SOP 1.1. Deleted non-relevant forms (form 1.1- 1.6). Deleted SOP 1.5*
06	*2019 July 26*	*IRB SOP TEAM*	*Only IRB members and Staff cited in the Workflow*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Harmonized Workflow and description of procedures. Include form no. of template of the letter of appointment in step 5 and in section 1.1.7.*
08	*2020 Oct. 20*	*IRB SOP TEAM*	*Removed step 1 in the workflow and transfer step 2 to step 1. Harmonized workflow and description of procedures. Added responsibilities of Office Manager.*
09	*2024 Feb. 22*	*IRB SOP TEAM*	*Added step 3 in description of procedures. Added timeline in calendar days in the workflow.*
10	*2025 May 15*	*Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis*	*Revised SOP 01 Selection and Appointment of Members.*

		Serafin Thomas Dabao III	

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 02** **Designation of Officers**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have a Chair, Co-chair and a Member Secretary. They shall be selected among the members, recommended by the Chair and designated by the Hospital Administrator. The appointment shall be based on competency, expertise, trainings and ethical and/or scientific knowledge upholding the corporate values of the institution and with commitment and willingness to volunteer the necessary time and effort for the IRB's work.

2. Objective of the Activity

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

3. Scope

The scope of this activity includes of Chair, Co-chair and Member-Secretary. It starts with a call for the meeting and ends with filing of appointment documents of the said officers.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Call for the meeting	*Chair or Co-chair*	*1 day*
Step 2: Nomination for appointment of IRB officer	*IRB members*	*1 day*
Step 3: Election of new officer	*IRB members*	
Step 4: Endorsement	*Chair or Co-chair*	*1 day*
Step 5: Signing of appointment letters Appointment letters (Form 1.4- Form 1.6)	*New Officers*	*1 day*
Step 6: Receipt and signing of conforme	*Office Manager or Staff*	*1 day*
Step 7: Filing of appointment documents and CVs in the membership file Curriculum Vitae (Form 1.9)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Call for a meeting

The Chair or Co-chair calls for a meeting to members of IRB.

Step 2: Nomination for appointment of IRB officer

The Chair or Co-chair presides over the nomination of officer.

Step 3: Election of new officer

The IRB Members elect the officer by votation.

Step 4: Endorsement

The Chair or Co-chair endorses the elected officer to the Hospital Administrator.

Step 5: Signing of appointment letters

The Hospital Administrator signs the Appointment letters (Form 1.2).

Step 6: Receipt and signing of conforme

6.1 The new officer receives and signs the conforme in the appointment letter (Form 1.2) and Agreement on Confidentiality and COI (Form 1.8).

6.2 Submit the updated CV, Certificates of Research Ethics Training.

Step 7: Filing of appointment documents and CVs in the membership file

The Office Manager or Staff files the documents in their specific membership file folder (Appointment letter, Agreement on Confidentiality and COI, Research Ethics Training certificates and curriculum vitae) in the membership file.

6. Forms

Appointment Letter for IRB Chair (Form 1.4)
Appointment Letter for IRB Co-Chair (Form 1.5)
Appointment Letter for IRB Member-Secretary (Form 1.6)
Agreement on Confidentiality and COI (Form 1.8)
Curriculum Vitae (Form 1.9)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Added responsibilities of IRB officers, members and staff*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Change IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Describe qualifications of Chair, Co- Chair and Secretary. Transferred section 1.2.4.5 to Step 1 of SOP 1.1. Deleted non-relevant forms (form 1.1- 1.6). Deleted SOP 1.5*
06	*2020 Oct. 20*	*IRB SOP TEAM*	*Revise sequencing*
07	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow*
08	*2025 June 5*	*Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis Serafin Thomas Dabao III*	*Revised SOP 02 Designations of Officers.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 03** **Appointment of Independent Consultants**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall invite an independent consultant whose expertise is not within the area of competence or specialization of the IRB members, but is needed in a study under review. He/she need not be affiliated with the institution.

2. Objective of the Activity

This activity aims to ensure that the appointment of independent consultants conforms with international, national and institutional guidelines and complements the pool of the IRB members.

3. Scope

This SOP pertains to the selection and designation of independent consultants in the review of research protocols of the IRB. The SOP begins with identification of the study that requires an independent consultants and ends with the inclusion of the name of the independent consultant in the pool of consultants.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Identification of a study that requires an Independent Consultant	*Chair or Member Secretary*	*1 day*
Step 2: Identification of the Independent consultant	*Chair or Member Secretary*	*1 day*
Step 3: Invitation to the Independent Consultant	*Chair*	*1 day*
Step 4: Delivery and receipt of appointment letter, COI/ Confidentiality agreement to the Independent consultant (Agreement on Confidentiality and COI Form 1.8)	*Staff*	*1 day*
Step 5: Inclusion of the Independent Consultant in the IRB meeting	*Office Manager or Staff*	*1 day*
Step 6: Filing of documents of Independent Consultant in the IC File	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Identification of a study that requires an Independent Consultant

The Chair or Member Secretary identifies a study that requires expertise which cannot be provided by the current members of the IRB.

Step 2: Identification of the Independent Consultant

The Chair identifies the consultant with the necessary expertise to provide relevant technical and ethical information for a comprehensive review of a study.

Step 3: Invitation to the independent consultant

The Chair invites the Independent Consultant through an invitation letter prepared by the Staff for his agreement.

Step 4: Delivery and receipt of appointment letter, COI/ Confidentiality agreement to the Independent consultant

4.1 The Office Manager or Staff delivers the Form 1.7 Appointment Letter, Form 1.8 COI/ Confidentiality agreement to the Independent Consultant.

4.2 The Independent Consultant signs and dates the conforme, Form 1.8 COI/ Confidentiality agreement and submits Form 1.9 Curriculum Vitae.

Step 5: Inclusion of the Independent Consultant in the IRB meeting

The Office Manager or Staff includes the Independent Consultant in the IRB meeting. The Independent Consultant is provided with study protocol, related protocol documents and Evaluation form (Form 3.2).

Step 6: Filing of documents of Independent Consultant in the IC File

The Office Manager or Staff files the documents (Form 1.7 Appointment letter with Form 1.8 COI/Confidentiality agreement, research ethics training certificates and Form 1.9 curriculum vitae) in the IC File folder.

6. Forms

Appointment Letter of Independent Consultant (Form 1.7)
Agreement on Confidentiality and COI (Form 1.8)
Curriculum Vitae (Form 1.9)
Protocol Evaluation (Form 3.2)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures on the review of SAE and SUSAR reports.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header. Edited duration of time to report SAE/SUSARs on-site.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early Termination report.*
06	*2019 Dec. 30*	*IRB SOP TEAM*	*Revise sequencing*

07	*2025 June 5*	*Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis Serafin Thomas Dabao III*	*Revised SOP 03 Appointment of Independent Consultants.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: July 08, 2025	**SOP No: 04 Management of Initial Submissions**
Effective Date: July 15, 2025	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board Shall require a set of documents (three hard copies and electronic copy) listed in a checklist for initial submission, and resubmission. Only complete documents submitted shall be accepted. The SPHI IRB Chair shall do a preliminary evaluation to determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGRIHP 2022.

2. Objective of the Activity

The management of initial submission and resubmission aims to ensure that study documents which are submitted by researchers for initial review are properly received, identified, and recorded.

3. Scope

This This SOP begins with the Receipt of complete protocol and ends with filing of the documents in the protocol file and update protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of protocol and protocol related documents for Initial Review	*Office Manager or Staff*	*1 day*
Step 2: Recording of the protocol in the logbook	*Office Manager or Staff*	*1 day*
Step 3: Coding of the protocol	*Office Manager or Staff*	
Step 4: Submission of the protocol to the Chair for preliminary evaluation	*Office Manager or Staff*	*1 day*
Step 5: Determination of type of review and assign Primary reviewers *a. Expedited Review* *b. Full Board*	*Chair*	*1 day*
Step 6: Preparation of the protocol file folder	*Office Manager or Staff*	*1 day*
Step 7: Entry in the database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of protocol and protocol related documents for Initial Review

1.1 The Office Manager or Staff receives the submitted protocol and protocol related documents for review and determines completeness of documents being submitted based on the IRB Checklist for Initial Submission (Form 2.0) and Application for Ethics Review of a New Protocol Form (2.1) .

1.2 The Checklist for Initial Submission (Form 2.0) has to include the following:

- Letter of Application & Complete Protocol
- Protocol Summary
- Investigator's Brochure (for Clinical Trials)
- Data collection form/s
- Informed Consent Forms (English, Tagalog, and local dialect (Hiligaynon))
- CV (for clinical trials- Principal Investigator and his/her co-investigators), (for Researcher

Initiated protocol-Researcher and Adviser).

- ☐ GCP Certificate of the Principal Investigator (PI) and his/her co-investigators
- ☐ Declaration of No Conflict of Interest for Principal Investigators/Researchers (Form 2.2)
- ☐ Valid PRC License
- ☐ COI Declaration and Confidentiality Agreement
- ☐ GANTT Chart (as necessary)
- ☐ Advertisement, Diary card and other related documents (for Clinical Trials)
- ☐ Case report form/s, trial Materials (for Clinical Trials)
- ☐ Certificate of Technical Review (for Researcher Initiated protocol)
- ☐ Insurance Certificate (for Clinical Trials)
- ☐ Technical review approval/endorsement of the Department
- ☐ Decision of Ethics Review if reviewed by other Research Ethics Committee/s
- ☐ Material Transfer Agreement (for Clinical Trials if applicable)
- ☐ Budget
- ☐ Clinical Trial Agreement- Draft is acceptable (for Clinical Trials)
- ☐ Letter of Approval from Hospital Administrator and Data Protection Officer
- ☐ Waiver of Informed Consent Form (if applicable)

Step 2: Recording of the protocol in the logbook

2.1 The IRB Office Manager or Staff records the protocol in the incoming logbook.

2.2 The following information are recorded in the Incoming Communications Logbook for protocol and protocol related documents:

- ☐ Date of Receipt
- ☐ IRB Protocol Code
- ☐ Principal Investigator/Researcher
- ☐ Title of protocol and Document Submitted
- ☐ Name and signature of the submitter
- ☐ Name and signature of the Receiver
- ☐ Action Taken

Step 3: Coding of the Protocol

The Office Manager and Staff assigns an IRB protocol code upon the Receipt of complete protocol package. The study files are coded SPHI- IRB-___-___

Wherein:

SPHI - stands for St. Paul's Hospital Iloilo
IRB -stands for Institutional Review Board
xxxx -refers to the year of submission (ex. 2025)
yy - chronological number based on order of Receipt (01, 02, 03, etc.)

Example: SPHI-IRB-2025-01

Step 4: Submission of the protocol to the Chair for preliminary evaluation

The Office Manager or Staff submits the protocol and protocol related documents to the Chair for preliminary evaluation to determine exempt from review. The Chair may designate the Member-

Secretary to determine exemption of a protocol from review.

Step 5: Determination of type of review and assign Primary reviewers

The Chair determines the type of review a protocol should undergo. The basis for the classification as to type of review is stated in SOP 6 Expedited Review, and SOP 7 Full Board Review

Step 6: Preparation of the protocol file folder

The Office Manager or Staff prepares the protocol file folder labelled with protocol code and title. The staff files the protocol and related documents and makes a protocol file index.

Step 7: Entry in the database

The Office Manager or Staff enters the submission information in the database. The contents of the Initial Submissions Database are the following:

- IRB Protocol Code
- Protocol Title
- Sponsor Code
- Principal Investigator
- Sponsor
- Type of Research
- Date Received
- Type of Review (Exempt, Expedited, Full Board, and SJREB)
- Date of IRB Meeting when Protocol is discussed
- Primary Reviewers
- IRB Decision
- Date of Action of Letter to PI/Researcher
- Resubmission 1 (Document submitted, Date of submission, Date of Review, Review Decision)
- Resubmission 2 (Document submitted, Date of submission, Date of Review, Review Decision)
- Date of IRB Approval
- Date of Expiration of Approval
- 1st Amendment (Document, date of submission & review, Review decision, date of Approval)
- 2nd Amendment (Document, date of submission & review, Review decision, date of Approval)
- 3rd Amendment (Document, date of submission & review, Review decision, date of Approval)
- 4th Amendment (Document, date of submission & review, Review decision, date of Approval)
- 5th Amendment (Document, date of submission & review, Review decision, date of Approval)
- Progress Report (Due date of PR, Date of Submission, Date of Review & IRB Action/Recommendation)
- SAE Submissions (Date of Submission, Date of Review, & IRB Action/recommendation)
- SUSAR Submission
- RNE
- Protocol Deviation/Violation (Date of submission, Date of Review, & IRB action/ recommendation)
- Early Termination Report (Date of submission, Date of Review, IRB action/recommendation)

- Application for Continuing Review (Date due, Actual DOS, Date of Review & IRB action/recommendation)
- Final Report (Date of submission, Date of Review, IRB action/Recommendation)
- Date of Archiving
- Date of Shredding

6. Forms

IRB Checklist for Initial Submission (Form 2.0)
Application for Ethics Review of a New Protocol Form (2.1)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures on management of initial and resubmission of research studies.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header. Edited number of copies required for Initial Clinical Trial submission.*
05	*2019 June 13*	*IRB SOP TEAM*	*Added Declaration of No COI of Investigators/ Researchers. Added procedure in Exempt from Review, Review of Resubmission, timeline and checklist.*
06	*2019 July 26*	*IRB SOP TEAM*	*Added Exempt from Review and Only IRB members and staff cited in the workflow.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Change title of Management of Submissions.*
08	*2020 Oct. 20*	*IRB SOP TEAM*	*Added Step 6: Use of Study Assessment Forms*
09	*2022 June 28*	*IRB SOP TEAM*	*Completed the details in the Form 2.2 IRB Checklist for Initial Submission). Added 2.4 in step 2. Edited the SPH-IRB History.*
10	*2024 Feb 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
11	*2024 June 28*	*IRB SOP TEAM*	*Include waiver of consent in step 6.4*
12	*2025 May 15*	*Dr. Jaime Manila, Atty. Jose Mari Benjamin Francisco Tirol, and Dr.*	*Revised SOP 04 on Management of Initial Submission.*

		Luis Serafin Thomas Dabao III	

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 05** **Exempt from Review**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall classify studies (with negligible to not more than minimal risk) that will be exempted from review based on the criteria from the National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

2. Objective of the Activity

This aims to review protocols that qualify for exemption.

3. Scope

This SOP begins with the receipt of the application for initial review and ends with the filing of the documents to the protocol file.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1. Receipt of a submitted protocol for initial review	*Office Manager or Staff*	*1 day*
Step 2: Determination of the submitted protocol for exempt from review (Checklist for Exemption Form (Form 3.4))	*Chair*	*1 day*
Step 3: Preparation of Certificate of Exemption (Certificate of Exempt from Review (Form 3.0))	*Office Manager or Staff*	*1 day*
Step 4: Signing of the Certificate of Exemption	*Chair*	*1 day*
Step 5: Communication of the Certificate of Exemption to the researcher	*Office Manager or Staff*	*1 day*
Step 6: Filing of the documents in the protocol file	*Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of a submitted protocol for initial review

The Office Manager or Staff receives the submitted protocol, determines completeness of documents being submitted based on the IRB Checklist for Initial Submission (Form 2.0) and Application for Ethics Review of a New Protocol Form (2.1), encode documents in the incoming communication, assign IRB protocol code, and forward protocol to the Chair or Member-Secretary.

Step 2: Determination of the submitted protocol for exempt from review (Checklist for Exemption Form (Form 3.6))

The Chair determines if the protocol is exempt from review using the criteria (Checklist for Exemption Form (Form 3.4))

The following are the types of protocols that may be exempt from review:

- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events

- ☐ Research involving large statistical data without identifiers
- ☐ Research not involving humans or human data

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Step 3: Preparation of Certificate of Exemption (Certificate of Exemption (Form 3.1))

The Office Manager or Staff prepares the Certificate of Exemption (form 3.1) which requires the submission of an Amendment Report if there are changes in the protocol which may change the risk benefit ratio; any change or alteration in the protocol requires submission of revised protocol for IRB review and submission of final report at the end of the study.

Step 4: Signing of the Certificate of Exemption

The Chair signs the certificate of exemption.

Step 5: Communication of the Certificate of Exemption to the researcher

a. The Office Manager or Staff communicates to the researcher and will issue the certificate of exemption, and ensures its receipt by the researcher.

5.2 The Office Manager or Staff includes the approved protocols for exempt in the meeting agenda.

Step 6: Filing of the documents in the protocol file

The Staff file the copy of the document in the protocol file and keep in the locked cabinet.

6. Forms

IRB Checklist for Initial Submission (Form 2.0)
Application for Ethics Review of a New Protocol Form (2.1),
Certificate of Exempt from Review (Form 3.0)
Checklist for Exemption Form (Form 3.4)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2019 July 26*	*IRB SOP TEAM*	*First draft*
02	*2024 Feb.22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
03	*2024 Apr 29*	*IRB SOP TEAM*	*Added checklist for Exemption form and Investigators Responsibilities after approval.*
04	*2025 May 15*	*Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba*	*Revised SOP 05 on Exempt from Review.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 06** **Expedited Review**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct an expedited review for study protocols that do not entail more than minimal risk to the study participants, the study participants do not belong to a vulnerable group and does not generate vulnerability. The results of the initial review shall be released to the principal investigator 20 working days after the submission of all the required documents. The approved study protocol that underwent expedited review shall be reported in the subsequent regular committee meeting. This SOP shall also apply to post-approval report submissions if classified for expedited review.

2. Objective of the Activity

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

3. Scope

This SOP begins with the assignment of reviewers or independent consultant/s and ends with the Inclusion of the approved protocols by expedited review in the agenda of the next meeting.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Assignment of Primary Reviewers or Independent Consultant/s (SOP 3 Appointment of IC)	*Chair*	*1 day*
Step 2: Notification of Primary Reviewers or IC	*Office Manager or Staff*	*1 day*
Step 3: Provision of study documents and evaluation form (Protocol Evaluation Form (Form 3.1) and Informed Consent Evaluation Form (Form 3.2) to reviewers	*Office Manager or Staff*	*1 day*
Step 4: Accomplishment and submission of evaluation forms	*Primary Reviewers*	*10 days*
Step 5: Finalization of review results	*Chair*	*2 days*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions) Approval Letter (Form 6.1) Notification of IRB Decision (Form 6.3)	*Office Manager or Staff*	*1 day*
Step 7: Filing of documents in the file folder (SOP on Management of Active Files (SOP 30))	*Office Manager or Staff*	*1 day*
Step 8: Inclusion of the approved protocols by expedited review in the agenda (SOP 25 Preparing the Notice of IRB Meeting with Agenda) Notice of IRB Meeting (Form 5.0)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Assignment of Primary Reviewers or Independent Consultant/s (SOP 3 Appointment of IC)

1.1 The Chair assigns one medical/scientist member and one non-medical/non-scientist member to do

the expedited review of the submitted protocols for initial review.

1.2 The Chair assigns Primary Reviewers for initial review the member with expertise on the protocol. If there is no expert among the IRB members for the protocol, the Chair assigns a member with the nearest expertise to the protocol being reviewed and invites an Independent Consultant (SOP 3 Appointment of IC).
For expedited post-approved protocols, the primary reviewers initially assigned are identified.

Step 2: Notification of Primary Reviewers or IC
The Office Manager or Staff notifies the assigned Primary Reviewers. The Reviewers confirm their availability and without conflict of interest to do the expedited review.

Step 3: Provision of study documents and evaluation form

3.1 The Office Manager or Staff delivers the documents and evaluation forms to the offices of the assigned reviewers.

3.2 The Office Manager or Staff provides pertinent documents (complete protocol package for initial submission; post- approval reports for expedited review e.g (Amendment (Form 4.0) Protocol Deviations/Violations (Form 4.4)) etc.

Step 4: Accomplishment and submission of evaluation forms

4.1 The Primary Reviewers accomplish and submit the evaluation forms that has been reviewed and completed in the most comprehensive and informative manner within ten working days after receipt thereof.

4.2 The Primary Reviewers submit all the documents
a. to the IRB office
b. send via email to the IRB
c. inform the Staff to pick-up the pertinent documents from their Offices

Step 5: Finalization of review results
The Chair finalizes the review results after the Primary Reviewers discuss and submit their findings. The Staff prepares the communication to be signed by the Chair.

Step 6: Communication of IRB decision/action to PI/Researcher

6.1 The Office Manager or Staff communicates to the PI/researcher through SMS or messenger the Decision of the IRB.

6.2 The Office Manager or Staff advises the PI to pick up the official document, Notification of IRB Decision (Form 6.2) or Approval Letter (Form 6.1) from the IRB Office.

6.3 The Office Manager or Staff includes the approved protocols for expedited review in the next meeting agenda.

Step 7: Filing of documents in the file folder

The Office Manager or Staff files the protocol and related documents in the protocol file folder, makes a protocol file index (Form 7.0) and updates the protocol database.

Step 8: Inclusion of the approved protocols by expedited review in the agenda

The Office Manager or Staff includes the approved protocols by expedited review in the next meeting agenda.

6. Forms

IRB Protocol Evaluation Form (Form 3.1)
IRB Informed Consent Evaluation Form (Form 3.2)
Approval Letter (Form 6.1)
Notification of IRB Decision (Form 62)
Notice of IRB Meeting (Form 5.0)
Protocol Deviation/Violation (Form 4.4)
Index of Files Content (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug.18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of Expedited Review*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Included in 4.1.3 the post approval submissions. Updating of protocol file index and electronic database. Stated in step 8 the review of expedited procedure.*
06	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
07	*2025 May 15*	*Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba*	*Revised SOP 06 on Expedited Review.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: July 08, 2025	**SOP No: 07** **Full Review**
Effective Date: July 15, 2025	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct a full-board review when a proposed study entails more than minimal risk, participants belong to the vulnerable group or when the study generates vulnerability. Only protocols submitted for, at least, fifteen working days before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a Primary Reviewer system. The Independent Consultants (IC) shall be invited during the meeting to clarify certain issues. The Principal Investigator/proponents may also be invited for clarification. The decision shall be communicated to the PI/proponent within three working days after the meeting.

This SOP shall apply to the review of Full board post approval report submissions. The IRB Chair shall assign the initial primary reviewers to review post approval reports classified as full board.

2. Objective of the Activity

A full review aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials.

3. Scope

This SOP begins with the assignment of Primary Reviewers or Independent consultant/s and ends with the filing of protocol-related documents.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Assignment of Primary Reviewers or Independent Consultant/s (SOP 3 Appointment of IC)	*Chair*	*1 day*
Step 2: Notification of Primary Reviewers and IC	*Office Manager or Staff*	*1 day*
Step 3: Provision of protocol and protocol-related documents and assessment forms to the Primary Reviewers / IC	*Office Manager or Staff*	*1 day*
Step 4: Provision of protocol summary to the rest of the committee members	*Office Manager or Staff*	*1 day*
Step 5: Presentation of the protocol summary, review findings and recommendations during the IRB regular meeting (SOP 26 Conduct of Meeting)	*Primary Reviewers*	*1 day*
Step 6: Discussion of technical and ethical issues	*IRB members*	*1 day*
Step 7: Summary of issues and resolutions	*Chair*	*1 day*
Step 8: IRB action	*IRB members and Chair*	*1 day*
Step 9: Documentation of the Board deliberation and action (SOP 27 Preparing the Minutes of the Meeting)	*Office Manager or Staff*	*1 day*
Step 10: Preparation of the Board action/decision	*Office Manager or Staff*	*1 day*
Step 11: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 12: Filing of protocol related materials and updating of protocol data base	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Assignment of primary reviewers or Independent Consultant/s

1.1 The Chair assigns Primary Reviewers with the necessary expertise to be responsible for the review of the protocol and related submissions in a comprehensive manner.

1.2 The Chair invites an Independent consultant if none of the IRB members have expertise that the protocol requires.

1.3 The Chair assigns the initial primary reviewers for post-approval report submissions.

Step 2: Notification of Primary Reviewers and IC

The Office Manager or Staff notifies the Primary Reviewers and the IC if needed, the protocol to be reviewed, receives the confirmation/acceptance and prepares copies of the protocols, protocol related documents.

Step 3: Provision of protocol and protocol-related documents and assessment forms to the Primary Reviewers / IC

3.1 The Office Manager or Staff provides the protocol and protocol-related documents and assessment forms to the Primary Reviewers /IC; assessment forms (IRB Protocol Evaluation Form (Form 3.1) IRB Informed Consent Evaluation Form (Form 3.2) for delivery to the Primary Reviewers and IC if applicable.

3.2 The Primary Reviewers submit their evaluation forms (IRB Protocol Evaluation Form (Form 3.1) IRB Informed Consent Evaluation Form (Form 3.2) to the Staff two days before the IRB meeting.

Step 4: Provision of protocol summary to the rest of the committee members

The Office Manager or Staff provides the rest of the members of the IRB with the protocol summary in ten working days before the IRB meeting.

Step 5: Presentation of the protocol summary, review findings and recommendations during the IRB regular meeting

The Primary Reviewers present their protocol summary, review findings and recommendations during the IRB regular meeting (Protocol Evaluation Form 3.1 and Informed Consent Evaluation Form 3.2). If the Primary Reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the Primary Reviewer so that the meeting can proceed.

Step 6: Discussion of technical and ethical issues

The Chair leads the discussion of the technical and ethical issues using the (Protocol Evaluation Form 3.1 and Informed Consent Evaluation Form 3.2) and the assessment of the Primary Reviewers and IC (if applicable) as guides for an orderly exchange of ideas.

Step 7: Summary of issues and resolutions

The Chair summarizes the technical and ethical issues that were identified, and presents the recommendations and decision for approval.

Step 8: Approval of the IRB Action

8.1 The Members approve the IRB Decision action by voting. The approval of the IRB recommendations/decision is done after a motion is made and duly seconded with simple majority vote.

8.2 IRB Decision points for initial review are:

8.2.1 Approval (when no further modification is required) Approval letter includes one (1) year validity. It includes the start and end dates of effectivity).

8.2.2 Minor revisions, (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.

8.2.3 Major revisions (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

8.2.4 Disapproval (due to ethical or legal concerns). Reasons for vote of disapproval should be noted in the minutes of meeting and communicated to the PI.

8.3 IRB Decision points for post-approval review:

8.3.2 For the amendments, the decision will be:

- ☐ Approved
- ☐ Additional justification/information required
- ☐ Reconsent required
- ☐ Disapproved

8.3.3 The action of the IRB for progress reports may be one of the following:

- ☐ Accepted
- ☐ Request further information
- ☐ Require specific action

8.3.4 For the SAE/SUSAR the decision will be:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information
- ☐ Recommend further Action (indicate action)
- ☐ Take Note and No Further Action needed
- ☐ Others:

8.3.5 For the RNE, the decision will be:

- ☐ recommend 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

8.3.6 For the protocol deviation/violation, the decision will be:

- ☐ Submission of additional information

- Submission of corrective/Preventive actions
- Invitation for a clarificatory interview with the Principal Investigator
- Site visit
- Suspension of recruitment
- Withdrawal of Ethical Clearance
- Suspension of the study
- Acknowledge with no further action

8.3.7 For early termination reports given by the Principal Investigator and/or the Sponsor, the IRB decision may be to:

- acceptance of the decision with no further action;
- request for additional information; or
- requirement for further action

8.3.8 For the final reports, the decision will be:

- to accept, or
- to require submission with Corrections

8.3.9 For the application for continuing review, the decision will be:

- Approved,
- Additional information required,
- Submission of an explanation for failure to submit required reports or
- Disapproved.

Step 9: Documentation of the Board deliberation and action

The Office Manager or Staff documents the Board deliberations and action in real-time. An audio-recorder is also used to ensure the proper documentation of the discussion during the meeting (SOP 27 Preparing the Minutes of the Meeting).

Step 10: Preparation of the Board action/decision

The Office Manager or Staff prepares the communication and submits to the Chair for finalization and approval.

Step 11: Communication of IRB decision/action to PI/Researcher

11.1 The Office Manager or Staff communicates to the PI/Researcher through SMS or messenger the Decision of the IRB.

11.2 The Office Manager or Staff advises the PI/Researcher to pick up the official document**,** (Approval Letter (Form 6.1), Notification of the IRB Decision Form (Form 6.2), IRB Communication Letter (Form 6.3) from the IRB Office.

Step 12: Filling of protocol related materials and updating of protocol data base

The Office Manager or Staff files the protocol and related documents in the protocol file folder, makes protocol file index (Form 7.0) and updates the protocol database.

6. Forms

IRB Protocol Evaluation Form (Form 3.1)
IRB Informed Consent Evaluation Form (Form 3.2)
Approval Letter (Form 6.1)
Notification of the IRB Decision Form (Form 6.2)
Communication Letter (Form 6.3)
Index of Files Content (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of Full Review*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Stated the responsibilities/tasks of the primary reviewers. Included in Step 5 the discussion of technical and ethical issues Included in step 10 updating of protocol file index and electronic database. Deleted 1.4-1.6 repetition of sub steps*
06	*2020 Oct. 20*	*IRB SOP TEAM*	*Transfer 3.4.4.4. Communication of IRB Decision from Section 3.3.4 – Responsibilities to Section 3.3.6 Description of Procedure Step 7. Added Annual Progress report, Final report, Protocol Deviation, On-site SAE, SUSAR report, Early Termination report, Site visit and Review of Appeal in Full Board review.*
07	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow. Revise scope.*
08	*2024 June 28*	*IRB SOP TEAM*	*Change timeline in sending Protocols for initial review of full board. Added a statement regarding alternate member.*
09	*2025 May 15*	*Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba*	*Revised SOP 07 on Full Review.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 08** **Review of SJREB**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall participate in the Single Joint Ethics Review Board (SJREB) review process of protocols conducted at multiple sites in the Philippines, that includes SPHI as a study site.

2. Objective of the Activity

This aims to streamline and harmonize the results of ethics review among various site IRBs through joint review.

3. Scope

This SOP begins with the receipt of management of research protocols qualified for SJREB joint review, the review process, and coordination with SJREB. This SOP begins with the Receipt of complete protocol and ends with filing of the documents in the protocol file and update protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of complete protocol package for Initial Review and determination of SJREB Review	*Office Manager or Staff*	*1 day*
Step 2: Notification of Chair	*Office Manager or Staff*	*1 day*
Step 3: Assignment of the Primary Reviewers	*Chair*	*1 day*
Step 4: Coordinates with SJREB regarding primary reviewers	*Office Manager or Staff*	*1 day*
Step 5: Conduct full board review	*IRB Members*	*1 day*
Step 6: Primary Reviewers attend the SJREB full board meeting	*Primary Reviewers*	*1 day*
Step 7: Obtain minutes of the meeting and notification of the SJREB decision	*Office Manager or Staff*	*1 day*
Step 8: Communication of decision/action to PI (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*7 days after the SJREB full board meeting*
Step 9: Filing of the documents in the protocol file and update protocol database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of complete protocol package for Initial Review and determination of SJREB Review

The Office Manager or Staff receives the submitted protocol, determines completeness of documents being submitted based on the IRB Checklist for Initial Submission (Form 2.0) and Application for Ethics Review of a New Protocol (Form 2.1) , encode documents in the incoming communication, assign IRB protocol code, and forward protocol to the Chair or Member-Secretary.

Step 2: Notification of Chair

2.1 The Office Manager or Staff notifies the Chair regarding the new protocol submission. Forward the protocol to the Chair or Member-Secretary.

2.2 The Chair verifies whether the research protocol qualifies for joint review. To be eligible for join review, the research protocol must be implemented in a least three sites in the Philippines in at least one DOH Hospital.

2.3 The Chair informs the Staff that protocols qualified for joint review will be accepted by the IRB for review provided that the protocol will also be submitted to SJREB.

2.4 The Chair assigns two primary reviewers. Aside from the review of protocols, the primary reviewers will be notified of their attendance and participation in the SJREB joint review.

Step 3: Assignment of the Primary Reviewers

The IRB sends a letter of notification signed by the chair to the SJREB, indicating the participation of the Primary Reviewers/ representative.

Step 4: Coordinates with SJREB regarding primary reviewers

4.1 The Office Manager or Staff informs the IRB chair regarding the request from SJREB and coordinates with the SJREB secretariat upon receipt of the request for Primary Reviewers/ representatives from IRB.

4.2 The Staff, in coordination with the Chair, provides the names of the assigned Primary Reviewers/representatives who will attend the SJREB full board meeting. The Staff then requests the meeting details to be communicated to the reviewers.

Step 5: Conduct full board review

a. The Primary Reviewers report the review results during IRB full board meeting and discuss site specific issues and concerns. (e.g., PI qualifications and conflict of interest, clinical trial sites, types of participant, community-based research, etc.)

b. The Chair and Member-Secretary consolidate site-specific issues and comments, and prepare a preliminary decision to be reported by the primary reviewers/representatives during the SJREB full board meeting.

Step 6: Primary Reviewers attend the SJREB full board meeting

6.1 The Primary Reviewers complete the SJREB assessment forms (SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form).

6.2 The assigned primary reviewers attend and participate in the protocol discussion, documents, and vote on specific items to reach a decision.

Step 7: Obtain minutes of the meeting and notification of the SJREB decision

7.1 The decision of the SJREB precedes the IRB's decision.

7.2 The Office Manager or Staff obtains the SJREB meeting minutes and decision notification from the SJREB secretariat seven days after the SJREB full board meeting.

7.3 The Chair and Member-Secretary conduct an expedited site-specific review within 7 days of receipt make a local site decision based on SJREB outcomes.

7.4 The Chair consolidated decisions of the IRB and SJREB are presented during the next IRB full board meeting.

Step 8: Communication of decision/action to PI

The Office Manager or Staff notifies the PI of the review outcome:

- ☐ Approval
- ☐ Minor Modification: The PI is granted 15 days to comply with the IRB recommendation.
- ☐ Major Modification: The PI is granted 60 days to comply. Resubmitted documents shall be referred to the primary reviewers and discussed in the full board meeting before approval.
- ☐ Disapproval

Step 9: Filing of the documents in the protocol file and update protocol database.

The Office Manager or Staff files all reports, creates copies for the protocol file, and updates the protocol database.

6. Forms

SJREB Form 3.1 (COI)
SJREB Form 2 (Protocol Assessment Form)
SJREB Form 3 (Informed Consent Assessment Form)
Checklist for Initial Submission (Form 2.0)
Application for Ethics Review of a New Protocol (Form 2.1)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2024 Feb. 22*	*IRB SOP TEAM*	*First draft*
02	*2024 Apr. 29*	*IRB SOP TEAM*	*Revised SJREB*
03	*2025 June 3*	*Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba*	*Revised SOP 08 on Review of SJREB.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 09** **Resubmission**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct a review of resubmission of the revised protocol and related documents initially reviewed prior to final approval. The board shall require the investigator to submit the revisions within twenty working days for the major revisions and within ten working days for minor revisions. The IRB shall notify the researcher (researcher initiated protocol) to submit the revision within the prescribed period of time. Failure to resubmit after three months, the protocol will be considered as inactive.

Major revisions shall be discussed in full board and approved protocols by expedited review will be reported during the regular meeting. The IRB shall require 3 sets of Resubmission (Form 3.3).

2. Objective of the Activity

A review of resubmission aims to ensure that the required modification will be addressed.

3. Scope

This SOP pertains to the resubmission of revised or modified protocols that have been previously reviewed by the IRB. The procedure begins with the receipt of the revised protocol documents and ends with filing of the documents in the protocol file and the entry of the submission in the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of resubmission and entry into the logbook	*Office Manager or Staff*	*1 day*
Step 2: Coding of Resubmitted protocol documents	*Office Manager or Staff*	*1 day*
Step3: Evaluation of the resubmission by the Chair and notification of primary reviewers	*Chair and Staff*	
Step 4: Review of Resubmission by SOP 6 Expedited review or SOP 7 Full board review	*Primary Reviewers*	*10 days*
Step 5: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 6: Filing of the documents in the protocol file folder and update the protocol database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of resubmission and entry into the logbook

The Office Manager or Staff receives and checks the resubmission documents. The Office Manager or Staff logs the protocol documents in the incoming communication logbook.

Step 2: Coding of Resubmitted protocol documents

The Office Manager or Staff codes the resubmitted documents following the original protocol code assigned.

Step 3: Evaluation of the resubmission by the chair and notification of primary reviewers

3.1 The Chair evaluates the resubmission package.

3.2 The Chair instructs the staff to notify the primary reviewers.

3.3 The Staff retrieves the pertinent documents and notifies the primary reviewers of the resubmission.

Step 4: Review of Resubmission by expedited review (SOP 7) or full board review (SOP 8)

4.1 In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the previous recommendations. Minor modifications as previously recommended during full board meeting shall go to expedited review. Approved resubmission is included in the agenda of the next meeting.

4.2 For major modifications, the resubmission undergoes full board review. The primary reviewers may recommend approval if the PI has substantially complied with the recommendations for approval of the IRB.

4.2.1 The Primary Reviewers present their assessment and recommendations on the resubmitted documents to the IRB.

4.2.2 The IRB discusses the recommendations and make decisions.

4.2.3 Decision can be any of the following:

a. Approved
b. Require additional information

Step 5: Communication of IRB decision/action to PI/Researcher

The Office Manager or Staff communicates the IRB decision action to the PI/researcher formulated by the chair (Approval letter (Form 6.1), Notification of IRB Decision (Form 6.2).

Step 6: Filling of the documents in the protocol file folder and update the protocol database

The Office Manager or Staff files a copy of the approved protocol documents in the protocol file folder and updates the protocol file index and database.

6. Forms

IRB Protocol Resubmission Form (Form 3.3)
Approval Letter (Form 6.1)
Notification of IRB Decision (Form 62)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2019 Jul 25*	*IRB SOP TEAM*	*First draft* *Added SOP 3.4 (Management of Resubmission)*

			Added IRB Checklist for Resubmission (Form 3.4), IRB Protocol Resubmission Form (Form 3.5).
02	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow. Revised scope.*
03	*2025 June 5*	*Dr. Jaime Manila, Atty. Jose Mari Benjamin Francisco Tirol, and Dr. Luis Serafin Thomas Dabao III*	*Revised SOP 09 on Resubmission.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 10** **Protocol Review during Emergency Situations**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) shall require the review of protocol during emergency situations such as Covid-19 pandemic, typhoon, fire, and earthquake. The IRB shall create an ad hoc committee to review the protocols classified under emergency situation. The SPHI IRB Chair shall act as the head of the ad hoc committee. The ad hoc committee shall determine their frequency of meetings or call for special meetings as deemed necessary. All protocols related to the Emergency Situation shall undergo Full Ad hoc committee review virtually, in person, or in mixed platform as determined by the committee.

2. Objective of the Activity

The SOP aims to facilitate the efficient ethical review of protocols related to the emergency situations.

3. Scope

This SOP provides instructions for review and approval of protocol review during emergency situations. This SOP begins with the receipt and documentation of submission of protocols via electronic means and ends with the filing of all related documents and updating the database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submission of protocols via electronic means to the official IRB email address (SOP 4 Management of Initial Submission) Application for ethics review of a new protocol Form 2.2)	*Office Manager or Staff*	*1 day*
Step 2: Notification of Chair	*Office Manager or Staff*	*1 day*
Step 3: Creation of an Ad hoc committee for the review of emergency situation protocols	*Chair*	*1 day*
Step 4: Notify members of the Ad hoc committee	*Office Manager or Staff*	*1 day*
Step 5: Call for a special meeting to review emergency protocols	*Chair*	*1 day*
Step 6: Discuss the emergency protocol during the special meeting	*Ad hoc Committee*	*1 day*
Step 7: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Staff*	*1 day*
Step 8: Filing of all related documents to the protocol file (SOP 30 Managing Active Files) and updating database	*Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of submission of protocols via electronic means to the official IRB email address

The Office Manager or Staff receives the complete documents from the PI/Sponsor via electronic means and records it in the logbook and in a protocol Database.

Step 2: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through SMS (text) or messenger.

Step 3: Creation of an Ad hoc committee for the review of emergency situation protocols

The Chair creates an Ad hoc committee to review submitted protocols classified as emergency. The Chair Identifies the IRB members who qualify to be members of the ad hoc committee based on expertise. The Chair selects the ad hoc committee member secretary to supervise the staff for documentation of the minutes of meetings. May invite Independent Consultants when necessary. The ad hoc committee shall consist of at least 1/3 of all members of the ethics committee (pre-determined to include non-scientist, non-affiliated and Independent Consultant if applicable).

Step 4: Notify members of the Ad hoc committee

The Office Manager or Staff notifies the members of the ad hoc committee and sends the submitted protocol package via email. The members of the Ad hoc Committee review the protocol using the Protocol Evaluation (Form 3.1) and Informed Consent Evaluation (Form 3.2).

Step 5: Call for a special meeting to review emergency related protocols

The Chair calls for a special meeting to review the emergency related protocols. The special meeting is conducted via zoom. The quorum is at least five of the ad hoc committee members including the non-scientist/non affiliated member.

Step 6: Discuss the emergency protocol during the special meeting

The Ad hoc Committee discusses the submitted documents using the Evaluation forms (Form 3.1 and Form 3.2) presided by the IRB Chair.

The Ad hoc Committee makes recommendations and decides by voting. The following are the decision points.

- ☐ Approved
- ☐ Major Modification
- ☐ Minor Modification
- ☐ Disapproved

Step 7: Communication of IRB decision/action to PI/Researcher

7.1 The Office Manager or Staff communicates the Decision of the Ad hoc Committee (Notification of IRB Decision (Form 6.2) or Approval Letter (Form 6.1)) to the PI/Researcher through SMS or messenger after the decision is signed by the Chair.

7.2 The Office Manager or Staff sends the decision to the PI/Researcher via email.

Step 8: Filing of all related documents to the protocol file

The Office Manager or Staff files the protocol and related documents in the protocol file folder, makes a protocol file index (Form 7.0) and updates the protocol database.

6. Forms

Protocol Evaluation (Form 3.1)
Informed Consent Evaluation (Form 3.2)
Approval Letter (Form 6.1)
Notification of IRB Decision (Form 6.2)
Protocol File Index (Form 7.0)
Application for Ethics Review of a New Protocol (Form 2.1)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2024 Jan*	*IRB SOP TEAM*	*First draft*
02	*2025 June 5*	*Sr. Gertrude Caryls Kuebler, SPC, and Ms. Queenie Crisostomo*	*Revised SOP 10 on Protocol Review during Emergency Situations.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 11** **Review of Medical Device Protocol**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the review of medical device protocols in full board or expedited review depending on the level of risk involved in the study. The review of Medical Device shall be based on the ASEAN harmonized technical requirements according to risk: A (low), B (low to moderate), C (moderate), D (high) as stated in the DOH Administrative Order No. 2018-0002.

2. Objective of the Activity

The SOP aims to ensure the safety and welfare of the human participants in medical device protocols.

3. Scope

This SOP provides instructions for review and approval of protocols on medical devices intended for human participants. This SOP begins with the receipt and documentation of submission of medical device protocols in the logbook/data base and ends with the filing of all related documents and updating of the database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submission of medical device protocols in the logbook/data base	*Office Manager or Staff*	*1 day*
Step 2: Notification of Chair	*Office Manager or Staff*	*1 day*
Step 3: Determination of type of review: Expedited (SOP 6 Expedited Review), Full review (SOP 7 Full Review)	*Chair*	*1 day*
Step 4: Review and discuss protocols and make recommendations	*Primary Reviewers*	*1 day*
Step 5: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 6: Filing of all related documents to the protocol file (SOP 30 Managing Active Files) and updating database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of submission of medical device protocols in the logbook/data base

The Office Manager or Staff receives the complete documents from the PI/Sponsor and records it in the logbook and in the protocol Database.

Step 2: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through SMS (text) or messenger.

Step 3: Determination of type of review and Primary Reviewers

3.1 The Chair determines the type of review and identifies the Primary Reviewers of the protocol.

3.2 The Chair reviews the medical device protocol package to determine whether it is for full board (moderate to high risk) or expedited review (low risk). The assessment of risk is based on ASEAN risk

classification.

CLASSIFICATION OF MEDICAL DEVICES

Medical devices shall be classified into the following four classes

Class Risk Level:

Class A - Low risk

Class B - Low-moderate risk

Class C - Moderate-high risk

Class D - High risk

3.3 The Chair determines the Primary Reviewers based on expertise and invites Independent Consultant with knowledge and expertise on the medical device.

Step 4: Review and discuss protocols and make recommendations

4.1 The Primary Reviewers and IC reviews the submitted documents.

4.1.1 For expedited review protocols, the Primary Reviewers and IC submit their Evaluation forms (Form 3.1 and Form 3.2) to the IRB 10 working days after receipt of the documents.

4.1.2 For full board review protocols, the Primary Reviewers and the IC submit their Evaluation forms (Form 3.1 and Form 3.2) two days before the meeting. The protocol and findings are discussed in full board.

4.1.3 Consider the following in the review of medical device protocols:

a. Proposed investigational plan (use of the device in the study)

b. Informed Consent Form/s

c. Description of the device/ Product information (Medical device brochure) including handling and storage requirements.

d. Description of study participant selection criteria

e. Safety monitoring procedures

f. Reports of prior investigations conducted with the device

g. Principal Investigator's curriculum vitae

h. Risk assessment determination for new investigational device

i. Statistical plan and analysis

j. Copies of all labelling for investigational use

k. FDA approval of the medical device, if applicable

4.1.4 For expedited review protocols, the Chair confirms the decision of the Primary Reviewers.

4.1.5 For full board review, the Chair summarizes the findings and recommendations. The final Decision is presented for IRB approval by votation.

The following are the decision points:

- Approved
- Major Modification
- Minor Modification
- Disapproved

Step 5: Communication of IRB decision/action to PI/Researcher

5.1 The Office Manager or Staff communicates to the PI/researcher through SMS or messenger the Decision of the IRB.

5.2 The Office Manager or Staff advises the PI to pick up the official document, Notification of IRB Decision (Form 6.2) or Approval Letter (Form 6.1) from the IRB Office.

Step 6: Filing of all related documents to the protocol file

The Office Manager or Staff files the protocol and related documents in the protocol file folder, makes a protocol file index (Form 7.0) and updates the protocol database.

6. Forms

Approval Letter (Form 6.1)
Notification of IRB Decision (Form 6.2)
Protocol file index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2024 Feb. 22*	*IRB SOP TEAM*	*First draft*
02	*2024 Apr 29*	*IRB SOP TEAM*	*Revised Medical Device Protocol.*
03	*2025 May 15*	*Sr. Gertrude Caryls Kuebler, SPC, and Ms. Queenie Crisostomo*	*Revised SOP 11 Review of Medical Device Protocol.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022. September-2015-ASEAN-Medical-Device-Directive.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 12** **Review of Public Health Protocols**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall requires the review of public health protocols.

2. Objective of the Activity

This SOP aims to ensure the safety and welfare of human participants.

3. Scope

This SOP provides instructions for review and approval of protocols on public health intended for human participants. This SOP begins with the receipt and documentation of submission of public health protocols in the logbook/database and ends with the filing of all related documents and update the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submission of public health protocols in the logbook/data base	*Office Manager or Staff*	*1 day*
Step 2: Notification of Chair	*Office Manager or Staff*	*1 day*
Step 3: Determination of type of review: Expedited (SOP 6 Expedited Review), Full review (SOP 7 Full Review)	*Chair*	*1 day*
Step 4: Review public health protocols and make Recommendations	*Primary Reviewers*	*10 days*
Step 5: Discuss the results of the review during full board meeting	*Primary Reviewers*	*1 day*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of documents in the file folder and update the protocol database (SOP 30 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of submission of public health protocols in the logbook/database

The Office Manager or Staff receives the complete documents from the PI/Researcher and records it in the logbook and in a protocol Database.

Step 2: Notification of Chair

The Office Manager or Staff notifies the Chair via SMS or messenger of the submitted protocols.

Step 3: Determination of type of review

The Chair determines the Primary Reviewers of the protocol. The Chair determines whether the protocol is for Full board or Expedited review.

Step 4: Review public health protocols and make Recommendations.

The primary reviewers check the submitted documents.

When reviewing a public health protocol, the reviewer should also consider the following:

a. Is it research?
b. Which aspects are research?
c. Is research ethics committee review required?
d. Are there adequate plans to manage any conflicts of interest?
e. Where relevant, what is the study intervention?
f. What are the procedures for data collection? Who are the research participants?
h. From whom is informed consent required, or is a waiver of consent appropriate?
i. Is permission from a "gatekeeper" required?
j. Is group or community engagement required?
k. Are there adequate plans for protection of privacy and confidentiality?
l. Are the potential benefits and risks of the study acceptable?
m. Are concerns about justice and equity adequately addressed?
n. What are relevant and are there satisfactory plans for access to interventions after the study, and roll-out of successful interventions on a wider scale?
n. References.

Step 5: Discuss the results of the review during full board meeting

The Primary Reviewers discuss their findings and submit their decision to the Chair.

If appropriate to the discussions, the Chair calls for a consensus on whether to:

- ☐ Approved
- ☐ Major Modification
- ☐ Minor Modification
- ☐ Disapproved

Step 6: Communication of IRB decision/action to PI/Researcher

6.1 The Office Manager or Staff communicates to the PI/researcher through SMS or messenger the Decision of the IRB.

6.2 The Office Manager or Staff advises the PI to pick up the official document, Notification of IRB Decision (Form 6.2) or Approval Letter (Form 6.1) from the IRB Office.

6.3 The Office Manager or Staff includes the approved protocols for expedited review in the next meeting agenda.

Step 7: Filing of documents in the file folder

The Office Manager or Staff files the protocol and related documents in the protocol file folder, makes a protocol file index (Form 7.0) and updates the protocol database.

6. Forms

Review of Public Health Protocol (Form 3.5)
Approval Letter (Form 6.1)

Notification of IRB Decision (Form 6.2)
Index of Files Content (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug.18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of Expedited Review.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Included in 4.1.3 the post approval submissions.* *Updating of protocol file index and electronic database. Stated in step 8 the review of expedited procedure.*
06	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
07	*2025 June 5*	*Sr. Gertrude Caryls Kuebler, SPC, and Ms. Queenie Crisostomo*	*Revised SOP 12 on Review of Public Health Protocols.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 13** **Review of Amendments**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter. The protocol amendment shall be reviewed by Expedited or Full Board Review based on risk/benefit.

2. Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments 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 on-going. This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filling of the amendments and committee decision in the protocol file.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and entry into logbook of the submission of amendments(SOP 30 on Management of Active Files)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Primary Reviewer	*Office Manager or Staff*	*1 day*
Step 4: Determination of type of review: Expedited (SOP 6 Expedited Review), Full Board Review (SOP 7 Full Review)	*Chair*	*1 day*
Step 5: Review of Amendment Report	*Primary Reviewers*	*10 days*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of Amendments and decision letter and update of the protocol database (SOP 30 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and entry into logbook of the submission of amendments

The Office Manager or Staff receives Application for Review of Amendments (Form 4.0) and enters the date and pertinent information in the logbook of incoming documents (SOP 30 Management of Active files).

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the corresponding protocol file for reference of the Chair and Primary Reviewers.

Step 3: Notification of the Chair and Primary Reviewers

The Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.

Step 4: Determination of type of review

The Chair determines the type of review and informs the Staff.
(Expedited Review (SOP 6) and Full Review (SOP 7)).

4.1 Amendments for Expedited Review

4.1.1 do not impact on study results or scientific soundness,
4.1.2 do not affect safety and wellbeing of the participants,
4.1.3 no change in the inclusion/exclusion criteria,
4.1.4 positive benefit/risk ratio,
4.1.5 no vulnerability issues

4.2 Amendments for Full Board Review

4.2.1 change in study design
4.2.2 significant change in the number of participants
4.2.3 increases risk that change the benefit/risk ratio

Step 5: Review of Amendment Report

The Primary Reviewers review the Amendment report within 10 working days.

5.1 For Expedited Review:

5.1.1 The Primary Reviewers submit their Evaluation Form within 10 working days after receipt of the Protocol Amendment (Form 4.0).
5.1.2 The Chair evaluates the Protocol Amendment Report Form submitted by the Primary Reviewers for finalization.

5.2 For Full Board Review:

5.2.1 The Primary Reviewers submit their Evaluation Form two days before the IRB meeting.
5.2.2 The Primary Reviewers presents their findings during the board meeting for discussion.

5.3 The IRB board make a decision

5.4 The Office Manager or Staff prepares a draft of the committee decision based on either the expedited review report or minutes of the meeting. The Chair signs the decision letter as follows:

- Approval,
- request for additional justification/information or
- specific action/s e.g. reconsent required or disapproved.

Step 6: Communication of decision/action to PI/researcher

6.1 The Office Manager or Staff communicates to the PI/Researcher through SMS or messenger the Decision of the IRB.

6.2 The Office Manager or Staff advises the PI/Researcher to pick up the official document, (Approval Letter (Form 6.1), Notification of the IRB Decision Form (Form 6.2) from the IRB Office.

Step 7: Filing of all related documents to the protocol file

The Office Manager or Staff files the Amendment Report (Form 4.1) and committee decision Approval letter (Form 6.1), Notification of IRB Decision (Form 6.2), excerpt of the minutes of the meeting in the protocol file folder, makes a protocol file index (Form 7.2) and updates the protocol database.

6. Forms

Protocol Amendment (Form 4.0)
Approval Letter (Form 6.1)
Notification of IRB Decision (Form 6.2)
Protocol file index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.*
06	*2019 July 26*	*IRB SOP TEAM*	*Separate procedures for review of Protocol amendment.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Revise step 3. Delete step 3.2 (except A) in section 4.1.6. Clarify step 4.1.*
08	*2020 Oct. 20*	*IRB SOP TEAM*	*Delete step 3.2.*
09	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow. Revise scope, revised description of procedures step 4, 4.3*
10	*2025 May 15*	*Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer*	*Revised SOP 13 on Protocol Amendment.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 14** **Review of Progress Report**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of progress report at a frequency based on the level of risk of the study but not less than once a year. Depending upon the degree of risk to the participants, the nature and duration of the study, and the vulnerability of the study participants, the IRB shall review or monitor the protocols more frequently. The frequency of the progress report is indicated in the Approval Letter (Form 6.1).

2. Objective of the Activity

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

3. Scope

This SOP begins with the receipt and entry to logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and entry into the incoming logbook of progress reports submissions. (Progress Report Form 4.1)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Primary Reviewers	*Office Manager or Staff*	*1 day*
Step 4: Determination of the type of Review (SOP 6 Expedited Review), (SOP 7 Full Board Review)	*Chair*	*1 day*
Step 5: Review of the progress report	*Primary Reviewers*	*1-2 days*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of progress report and decision letter and update protocol database and index	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and entry into the incoming logbook of progress reports submissions.

The Office Manager or Staff receives the submitted Progress report (Form 4.1) and logs in the incoming logbook.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the pertinent protocol file and reference materials for the Chair and reviewers to ensure the availability of complete documents to facilitate the review.

Step 3: Notification of Chair and Primary Reviewers

The Office Manager or Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.

Step 4: Determination of type of review

The Chair or Member-Secretary determine the type of review See Expedited Review (SOP 6) and Full Review (SOP 7). The Staff forwards the Progress report submission to the primary reviewers.

Step 5: Review of the progress report

5.4 The Primary Reviewers for Expedited Protocols review the progress report and submits findings to the IRB. The Chair confirms the decision of the Primary Reviewer.

5.5 The Primary Reviewer for Full Board Protocols presents the progress report and findings to the board for discussion and decision. The Progress Report is reviewed by the Primary Reviewer for 10 working days.

5.6 The committee action for progress reports are the following:

- Accepted
- Request Further Information
- Require Specific Action

Step 6: Communication of decision/action to PI/researcher

6.1 The Office Manager or Staff communicates the IRB decision/action to the PI/Researcher through a Communication letter (Form 6.3) signed by the Chair. For expedited review, the Chair approves and signs the evaluation form of the Primary Reviewer. For Full Board Review, the IRB approves the progress report and signed by the Chair

Step 7: Filing of progress report and decision letter and update protocol database and index.

The Office Manager or Staff files the progress report in the protocol file folder and updates protocol file and updates the protocol database.

6. Forms

Progress Report Form (4.1)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at*

			the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.*
06	*2019 July 26*	*IRB SOP TEAM*	*Separate procedures for review of progress report.*
07	*2019 Dec 30*		*Revised sequencing of SOPs on Post- Approval Reviews.*
08	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
09	*2025 May 15*	*Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer*	*Revised SOP 14 on Progress Report.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 15** **Review of SAE and SUSAR Reports**

1. Policy Statement

This SOP applies to the review of On-site Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) reports submitted by the Principal Investigator (PI) and sponsor to the St. Paul's Hospital of Iloilo Institutional Review Board. The IRB shall require the submission of on-site reports of SAEs and SUSARS. Fatal or life- threatening on-site SAEs shall be reported within 24 hours, and other SAEs within ten working days after the event has come to the attention of the researcher. The Member-Secretary and the Primary Reviewers shall review and analyze the on-site SAEs and SUSARs. The consolidated recommendations of the Member-Secretary and the Primary Reviewers are reported to the IRB during the regular monthly meeting for discussion. Review of SAE and SUSAR shall adhere to the national (NEGRIHP 2022) and international guidelines (ICH GCP).

2. Objective of the Activity

This activity reviews the SAEs and SUSARs reports to ensure the safety and protection of the human participants enrolled in the study. It also aims to properly document and evaluate the information submitted and to safeguard its contents.

3. Scope

This SOP applies to the reporting and review of the SAEs and SUSARs reports of various studies and clinical trials that occurred on-site. It begins with Receipt and documentation of submission of report of SAEs and SUSARs in the logbook and end with the filing of all related documents and update the database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submitted report of SAEs and SUSARs in the logbook	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Member-Secretary	*Office Manager or Staff*	
Step 4:Submission of report to the Member- Secretary and Primary Reviewers (SAE/SUSAR (Form 4.2))	*Office Manager or Staff*	*1 day*
Step 5: Report and discussion and the SAEs and SUSARs during the board meeting	*Member- Secretary, IRB*	*1 day*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of all related documents and update of the database (SOP 30 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of submitted report of SAEs and SUSARs in the logbook

1.1 The Office Manager or Staff receives the SAE/SUSARs (Form 4.2) from the PI/Sponsor and records it in the logbook. They check the submission date and note whether they comply with submission timeline.

1.2 The Office Manager or Staff includes the SAE/SUSARs reports in the agenda of the next meeting.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves pertinent information about the protocol, such as the approved protocol, and previous SAE/SUSAR reports and identify the primary reviewers.

Step 3: Notification of Chair and Member-Secretary

The Office Manager or Staff notifies the Chair and Member-Secretary about the submitted reports through SMS or email.

Step 4: Submission of report to the member-secretary and primary reviewers

The Office Manager or Staff submits to the Member-Secretary and the primary reviewers the SAEs/SUSARs reports fifteen working days before the regular meeting. The SAE/SUSAR reviewers submit to the staff their evaluation two days prior to the meeting for the consolidation of the recommendations by the Member-Secretary.

Step 5: Report and discussion and the SAEs and SUSARs during the board meeting

5.1 During the meeting, the Member-Secretary reports on the summary of the SAEs/SUSARs. The report includes:

- ☐ the number of studies that have SAES and SUSARs,
- ☐ the number of SAEs that occurred on-site,
- ☐ the number of the type of Safety report: SUSAR or SAE,
- ☐ the nature of the report if drug related or study related,
- ☐ the event that occurred, and
- ☐ the inclusion or exclusion/termination of the subject with SAEs/SUSARs.
- ☐ the effect of the SAE to the participant
- ☐ the outcome of SAE on the participant
- ☐ the action of the Principal Investigator

5.2 The Member-Secretary recommends appropriate action by filling up the Section 2 of the Protocol Report Updates Form (Form 4.2) submitted by the PI.

5.3 The Member-Secretary discusses the relatedness and expectedness of the SAE to the investigational drug/s. Assess the effect of the SAE on the participant and its outcome. Make recommendations appropriate for the SAE/SUSAR.

5.4 The IRB adopts appropriate response depending on the site where the SAE/ SUSAR happened.

5.4.1 For multicenter, international and national studies, note the trend of occurrence and nature of SAE/ SUSAR in study sites in foreign countries and other local sites.

5.4.2 For SAEs that occur onsite, the IRB analyzes the Investigator/ Sponsor's assessment (related, unexpected) and may need to recommend some form of action to the Investigator to ensure the safety of the participants.

5.5 The Member Secretary and the primary reviewers after presentation of the report give their recommendations to the board. The Chair presides over the board for the discussion of the recommendations.

5.6 The Chair calls for approval of decision by votation. The following are the decision points:

( ) Request and amendment to the protocol or the consent form.
( ) Request further information.
( ) Recommend further action (indicate action)
( ) Take note and no further action needed.
( ) Other: _____

Step 6: Communication of IRB decision to PI/Researcher

6.1 The Office Manager or Staff communicates the IRB decision to the PI/Researcher through SMS (text), phone call or email after filling up the IRB Communication Letter (Form 6.4).

6.2 The IRB Chair checks and signs the IRB Communication Letter (Form 6.3) before the Office Manager or Staff forwards it to the PI.

6.3 The Office Manager of Staff ensures that the PI signs the receiving copy of the letter.

Step 7: Filing of all related documents and update the electronic database

The Office Manager or Staff files all reports, makes a copy of all related documents in the protocol file and update the database.

6. Forms

SAE/SUSARs (Form 4.2)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures on the review of SAE and SUSAR reports.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header. Edited duration of time to report SAE/SUSARs on-site.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early Termination report.*
06	*2019 Dec. 30*	*IRB SOP TEAM*	*Revised sequencing.*

07	*2025 May 15*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 15 on SAE /SUSAR reports.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 16** **Review of Reportable Negative Events Report**

1. Policy Statement

St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of RNE reports within three days after the event has come to the attention of the researcher. RNE shall be reviewed in full board. For RNEs with more than minimal risk, a special meeting shall be considered.

2. Objective of the Activity

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

3. Scope

This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submission of report of RNEs in the logbook RNE Report (Form 4.3)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair	*Office Manager or Staff*	
Step 4: Call for a Special Meeting	*Chair*	*1 day*
Step 5: Deliberation on the RNE	*IRB Members*	*1 day*
Step 6: Communication of IRB decision/action to Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of all related documents and update of the database (SOP 30 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of submission of report of RNEs in the logbook

The Office Manager or Staff receives the accomplished RNE report (Form 4.3) from the PI/Sponsor and records it in the logbook and in the protocol Database. The staff notes whether the submission is within the required timeline.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves pertinent information about the protocol.

Step 3: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through SMS (text) or messenger.

Step 4: Call for a special meeting

4.1 The Chair calls for a special meeting.

4.2 The Office Manager or Staff prepares for a special meeting and notifies the IRB members. The IRB

members are provided with the RNE report for review.

4.3 The Researcher or other stakeholders may be invited to clarify on the RNE report.

Step 5: Deliberation on the RNE

The IRB Members deliberate on the RNE. The Primary Reviewers present and discuss the RNE report. The safety issues are evaluated regarding the incident (e.g. identification, management and prevention of risks to participants and other stakeholders.

The IRB members decides on the RNE which are as follows:

- Recommend 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 6: Communication of IRB decision to Researcher

6.1 The Office Manager or Staff communicates to the Researcher through SMS or messenger the Decision of the IRB.

6.2 The Office Manager or Staff advises the Researcher to pick up the Communication Letter (Form 6.4) from the IRB Office.

Step 7: Filing of all related documents and update the electronic database

The Office Manager or Staff files the RNE report and related documents in the protocol file folder, updates the Protocol file index (Form 7.0) and protocol database.

6. Forms

RNE Report (Form 4.3)
Communication Form (Form 6.3)
Protocol file index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures on the review of SAE and SUSAR reports.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header. Edited duration of time to report SAE/SUSARs on-site.*

05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early Termination report.*
06	*2019 Dec. 30*	*IRB SOP TEAM*	*Revised sequencing.*
07	*2025 June 4*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 16 on review RNE report.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 17** **Review of Protocol Deviations/Violations**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the Investigators to submit reports on protocol deviation or violations of the approved researches within seven working days after the occurrence of the incident. To include corrective/preventive action and proof of the corrective action and violation. The Protocol Deviation/Violation report shall undergo either expedited or full board review based on the impact of the non-compliance of the protocol on the health and wellbeing of the participants and/or on the science/study results.

2. Objective of the Activity

The activity of reviewing the protocol deviation/violations aims to ensure that the safety and well-being of the human participants are safeguarded and that the credibility of the data is 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 logbook and ends with the filing of all related documents and update of the database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of report of protocol deviation/violation in the logbook	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of the Chair and Primary Reviewers	*Office Manager or Staff*	*1 day*
Step 4: Determination of type of review: Expedited (SOP 6 Expedited Review), Full review (SOP 7Full Review)	*Chair*	*1 day*
Step 5: Inclusion of the report in the agenda of the next IRB meeting (SOP on Preparing the Meeting Agenda (SOP 25); SOP on Conduct of Meetings (SOP 26))	*Chair and Staff*	*2 days*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of all related documents to the protocol file(SOP 30 Managing Active Files) and updating database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt and documentation of report of Protocol Deviations/ Violations in the logbook

The Office Manager or Staff receives the report on protocol deviation/violation in the appropriate report form (Form 4.4) and records this in the logbook for incoming documents.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the approved protocol and checks the identity of the Primary Reviewers for reference and guidance of the Chair in the selection/ designation of reviewers. The

Primary Reviewers who reviewed the initial submission are designated to review the protocol deviations/violations.

Step 3: Notification of the Chair and Primary Reviewers

The Office Manager or Staff notifies and sends the Protocol deviation/violation report (Form 4.4) to the Chair and the Primary Reviewers.

Step 4: Determination of type of review

The Chair or Member-Secretary determine the type of review such as major protocol deviations undergo Full Review. Otherwise, the protocol deviations and violations undergoes expedited review. See Expedited Review (SOP 6) and Full Review (SOP7).

Step 5: Inclusion of the report in the agenda of the next IRB meeting

a. The Chair includes the report on protocol deviations and violations classified for full review in the Agenda of the next meeting if it is for Full review or the decision report if expedited review.

5.2 The IRB members are given the report for review 15 working days prior to the meeting.

Step 6: Communication of decision/action to PI/researcher

6.1 The Office Manager or 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:
( ) Submission of additional information
( ) Submission of corrective/Preventive actions
( ) Invitation for a clarificatory interview with the Principal Investigator
( ) Site visit
( ) Suspension of recruitment
( ) Withdrawal of Ethical Clearance
( ) Suspension of the study
( ) Acknowledge with no further action

6.2 The Office Manager or Staff informs the Investigators through SMS (text), phone call or email that the decision IRB Communication Letter (Form 6.3) of the IRB is available and is ready for pick up.

Step 7: Filing of all related documents to the protocol file

The 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

6. Forms

Protocol Deviation/Violation Form (4.4)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed reviews of protocol deviations or violations reports.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.*
06	*2019 Dec. 20*	*IRB SOP TEAM*	*Revise sequencing of SOPs on Post- Approval Reviews.*
07	*2024 Feb. 22*	*IRB SOP TEAM*	*Edited scope. Added timeline in calendar days in the workflow.*
08	*2024 June 28*	*IRB SOP TEAM*	*Revised sequencing of post approval reports*
09	*2025 May 15*	*Dr. Rowena Cosca, Mr.C hristopher Tabsing, and Ms.Imelda Olaguer*	*Revision SOP 17 on Protocol deviations/violations reports.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 18** **Review of Early Termination Report**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the PI to notify the board, and submit an early termination report when a decision of such has been made. The well-being and safety of study participants that have already been recruited shall be a primary consideration of the IRB and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

2. Objective of the Activity

The 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. This SOP begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of the early termination report and entry into the logbook (Early Termination Report Form 4.5)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Primary Reviewers	*Primary Reviewers* *Primary Reviewers* *Chair and IRB Members*	*1 day*
Step 4: Full review (Early Termination Report 4.5, SOP 7 Full Review)	*IRB Members*	*1 day*
Step 5: Communication of committee action (SOP 28 Communicating IRB Decisions) and update of the protocol database (SOP 30 Management of Active Files, Communication Letter (Form 6.3)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of the early termination report and entry into the logbook

The Office Manager or Staff receives the early termination report (Early Termination Report Form 4.5) and enters the appropriate information into the log book.

Step 2: Retrieval of pertinent protocol file

2.1 The Office Manager or Staff retrieves the relevant protocol file folder and earmarks pertinent Documents (e.g. Protocol, Post Approval Reports, etc.)

Step 3: Notification of Chair and Primary Reviewers

3.1 The Office Manager or Staff:

a. notifies the Chair and the primary reviewers by email or messenger about the early termination report.

b. sends hard copies of the Early Termination Report (Form 4.5) to the Primary Reviewers.

3.2 The Chair 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.

Step 4: Full review (Early Termination Report 4.5, SOP on Full Review

4.1 The IRB Members review and discuss in full board the Early Termination Report (SOP 8 Full Review). The review should ensure the rights, safety, and welfare of the study participants and confidentiality of data. The safety monitoring procedures for the protection of participants should be in place and properly implemented.

4.2 The IRB Members make a decision through votation. The following possible decisions in the review of an early termination report:
a. acceptance of the decision with no further action;
b. request for additional information;
c. require for further action.

4.3 The Staff prepares a draft of the committee decision based on the minutes of the meeting.

Step 5: Logging of the response and inclusion in the Agenda of the IRB Meeting
The Office Manager or Staff:

5.1 Communicates (SOP 28 Communicating IRB Decisions) the committee action using IRB Communication Letter (Form 6.3) duly signed by the Chair.

5.2. Updates the protocol database.

6. Forms

Early Termination Report Form 4.5)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*

04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.*
06	*2019 July 26*	*IRB SOP TEAM*	*Separate procedures for review of Early Termination report.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Revised sequencing of SOPs on Post- Approval Reviews.*
08	*2024 Feb. 22*	*IRB SOP TEAM*	*Edited policy statement, objectives and scope. Added timeline in calendar days in the workflow.*
09	*2024 June 28*	*IRB SOP TEAM*	*Revised sequencing of post approval reports*
10	*2025 May 15*	*Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer*	*Revised SOP 18 on Review of Early Termination Reports.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 19** **Review of Final Report**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full board 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. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of final report and entry into logbook (SOP 30 Management of Active Files (Final Report Form 4.6)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair	*Office Manager or Staff*	*1 day*
Step 4: Determination of type of review	*Chair*	
Step 5: Notification of the Primary Reviewers	*Office Manager or Staff*	
Step 6: Review of Final Report by Expedited or Full Board Review (SOP 6 Expedited Review, SOP 7 Full Board Review)	*Chair*	*1 day*
Step 7: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions, IRB Communication Letter Form 6.3)	*Office Manager or Staff*	*10 days*
Step 8: Filing of the Final Report and related documents and updating of the protocol files	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of final report and entry into logbook (SOP on Management of Active Files)

The Office Manager or Staff receives and enters the date of receipt of the final report into the logbook.

Step 2: Retrieval of pertinent protocol file

The Office Manager or staff retrieves the corresponding protocol file as reference for the review of the Final Report.

Step 3: Notification of Chair

The Office Manager or Staff notifies the Chair or Member-Secretary regarding the final report through phone or SMS within the day of the receipt of the report.

3.1 The Office Manager or Staff forwards the Final Report Form 4.7 to the Primary Reviewers.

3.2 The Office Manager or Staff includes the final report submission for Full Board Review in the agenda for the next IRB monthly meeting for discussion and final decision.

Step 4: Determination of type of review

The Chair determines the type of review based on the type of review done initially or on post approval reports that rendered the protocol more than minimal risk.

Step 5: Notification of the Primary Reviewers

The Office Manager or the staff notifies the Primary Reviewers who reviewed the protocol initially regarding the Final Report submission.

Step 6: Review of Final Report by Expedited or Full Board Review

6.1 The Primary Reviewers and the Chair review protocols for Expedited Review for 10 days (SOP 7 Expedited Review).

6.1.1. The Primary Reviewers submit their Evaluation (Form 4.6) ten working days after receipt of the report.

6.1.2. The Chair reviews the Evaluation Form of the Primary Reviewers and finalizes the decision.

6.2 The Primary Reviewers review the protocols for Full Board Review in 10 working days (SOP 8 Full Board Review).

4.2.1.The Primary Reviewers present their findings during the Full Board meeting.

4.2.2.The IRB members discuss the final report during the full board meeting and make decisions.

6.3 The following are the decision points for Final Report:

- Accept, or
- Require submission with Corrections

Step 7: Communication of IRB decision/action to PI/Researcher

The Office Manager or Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the IRB Communication Letter (Form 6.3).

Step 8: Filing of the Final Report and related documents and updating of the protocol files

The Office Manager or Staff files the Final Report (Form 4.6), Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, and updates the protocol file index (Form 7.0) (SOP 30 Managing Active Files).

The Office Manager or Staff updates the protocol database.

6. Forms

Final Report (Form 4.6)
IRB Communication Letter (Form 6.3)
Approval Letter (Form 6.1)
Protocol File Index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.*
06	*2019 July 26*	*IRB SOP TEAM*	*Separate procedures for review of Final report.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Revised sequencing of SOPs on Post- Approval Reviews. Harmonize steps in workflow and description of procedures.*
08	*2024 Feb. 22*	*IRB SOP TEAM*	*Edited policy statement, objectives and scope. Added timeline in calendar days in the workflow.*
09	*2024 June 28*	*IRB SOP TEAM*	*Revised sequencing of post approval reports.*
10	*2025 June 3*	*Dr. Rowena Cosca, Mr. Christopher Tabsing and Ms. Imelda Olaguer*	*Revised SOP 19 on Review of Final Report.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 20** **Management of an Application for Continuing Review**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of an application for Continuing Review at least 20 working days before the expiration of the one (1) year ethical clearance of a 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 that have no Post-Approval Reports which may reclassify the protocol for full board review, shall undergo Expedited review.

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. This SOP begins with the receipt of an application for continuing review and ends with the entry in the logbook and protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of the application for continuing review and entry to the logbook (Application for Continuing Review (Form 4.7) (SOP 20 Management of Application for Continuing Review)	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol files	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Primary Reviewers	*Office Manager or Staff*	
Step 4: Determination of type of review: Expedited (SOP 6 Expedited Review) or Full review (SOP 7Full Review)	*Chair or Member-Secretary*	*1 day*
Step 5: Review of the Application for Continuing Review	*Chair* *Primary Reviewers* *IRB Members*	*10 days*
Step 6: Communication of the IRB Decision/action to the PI/researcher (SOP 28 Communicating IRB Decision)	*Office Manager or Staff*	*1 day*
Step 6: Filing of documents in the appropriate protocol folder and update of the protocol database	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of the application for continuing review and entry in the logbook

The Office Manager or Staff receives and logs the application for continuing review.

Step 2: Retrieval of pertinent protocol files

The Office Manager or Staff retrieves the pertinent files written in the continuing review forms and prepares them for the Chair and Primary Reviewers for review. The files include the approved protocol and Informed Consent Form versions, amendments, related past submissions, progress reports, protocol deviations/violations reports, safety reporting, SAE/SUSAR reports, site visit (if applicable) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

Step 3: Notification of Chair and Primary Reviewers

The Office Manager or Staff notifies the Chair and Primary Reviewers about the submission of application for continuing review and the summary of the post approval reports submitted and decisions made during the period of effectivity of initial ethical clearance.

Step 4: Determination of type of review

The Chair or Member-Secretary determines the type of review based on the policy that protocols that underwent Full review in its initial submission shall undergo Full review in its application for continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review (see SOP 6 Expedited Review and SOP 7 Full Review).

Step 5: Review of the Application for Continuing Review

5.1 The Primary Reviewers and the Chair review protocols for Expedited Review for 10 days (SOP 6 Expedited Review).

5.1.1 The Primary Reviewers submit their Evaluation (Form 4.7) ten (10) days after receipt of the report.

5.1.2 The Chair reviews the Evaluation Form of the Primary Reviewers and finalizes the decision.

5.2 The Primary Reviewers review the protocols for Full Board Review in 10 days (SOP 7 Full Board Review).

5.2.1 The Primary Reviewers present their findings during the Full Board meeting.

5.2.2 The IRB members discuss the application for continuing review during the full board meeting and make decisions.

5.3 The following are the decision points for Application for Continuing Review:

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

Step 6: Communication of the IRB Decision/action to the PI/researcher

The Office Manager or Staff prepares the draft decision based on the report of the expedited review or includes the protocol in the minutes of the meeting in the full review. During the IRB meeting, the Chair finalizes and signs the decision letter (Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3)

Step 6: Filling of documents in the appropriate protocol folder and update of the protocol database.

The Office Manager or Staff files the Application for Continuing Review (Form 4.7), Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, and updates the protocol file index (Form 7.0) (SOP 30 Managing Active Files). The Office Manager or Staff updates the protocol database.

6. Forms

Application for Continuing Review (Form 4.7)
Approval Letter (Form 6.1)
IRB Communication Letter (Form 6.3)
Protocol File Index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2020 Oct. 20*	*IRB SOP TEAM*	*First draft*
02	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
03	*2024 June 28*	*IRB SOP TEAM*	*Revise sequencing of post approval reports*
04	*2025 June 3*	*Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer*	*Revised SOP 20 on Continuing Review Application.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 21** **Conduct of Site Visits**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: (a) high risk studies, (b) receipt of significant number of protocol deviations/violations and SAEs, (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports from the PI/researcher and (e) multiple studies conducted by a PI/researcher.

2. Objective of the Activity

Site visits aims to monitor IRB compliance with approved protocols, ICF process and continuing protection and promotion of participant's dignity, rights and well-being.

3. Scope

This SOP begins with the selection of the site to be visited and ends with the filing of Site-Visit Reports in the protocol folder and updating of the protocol database

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Selection of site to visit	*IRB Member*	*1 day*
Step 2: Notification of PI/researcher	*Office Manager or Staff*	*1 day*
Step 3: Creation of Site Visit Team	*Chair*	*1 day*
Step 4: Conduct of site visit	*Site Visit Team (members)*	*1 day*
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	*Site Visit Team (members)*	*1 day*
Step 6: Transmittal of Final Report and Recommendations to the PI/Researcher	*Chair and Staff*	*1 day*
Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database	*Staff*	*1 day*

5. Description of Procedures

Step 1: Selection of site to visit

The IRB Members select the site to be visited after citing certain provision/s in the criteria. The IRB members discuss the merits of the site visit and agree to conduct it.

The following are the criteria:

- high risk studies,
- receipt of significant number of protocol deviations/violations and SAEs,
- receipt of complaints from participants and families,
- non-receipt of required after-approval reports from the PI/Researcher and
- multiple studies conducted by a PI/Researcher.

Step 2: Notification of PI/Researcher

3.1 The Office Manager or Staff notifies the PI/researcher concerning the planned site visit.

3.2 The Chair checks and signs the IRB Communication Letter (Form 6.3) before it is forwarded to the PI. The site visit will be done ten working days after the PI/Researcher has received the communication letter.

Step 3: Creation of Site Visit Team

3.1 The Chair creates the site visit team composed of at least two, but not more than four of its members to perform the site visit.

3.2 The Site visit team prepares for the visit by doing the following:

- Coordinate with the PI as to the time for the site evaluation visit,
- Review the appropriate documents for the site visit,
- Prepares Site Visit Form (Form 4.8)

Step 4: Conduct of site visit

The IRB Team conducts the Site visit

During the Site Visit: The team does the following:

- Fills up the Site Visit Form (Form 4.8)
- Reviews the relevant documents based on findings that warranted the site visit
- Reviews randomly the subject files to ensure completeness
- Check documentation, filing and storage of the site
- Checks the on-site facilities
- Debriefs the PI/Researcher about the site visit findings and comments

Step 5: Draft of report and presentation of report during meeting and discussion for recommendations

The Head of the Site Visit Team drafts the report using the Site Visit Form (Form 4.8) within five working days. The Team leader forwards the draft report to the other members of the visit team for concurrence. The Staff includes the conduct of the Site Visit under the agenda item on Site Visit in the next board meeting.

Step 6: Transmittal of Final Report and recommendations to the PI/Researcher

The Staff transmits the results of the Site Visit to the PI/Researcher (SOP 28 Communicating IRB Decision) Communication Letter (Form 6.3).

Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database

The Staff files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly (SOP 28 Management on Active Files).

6. Forms

Site Visit Form (Form 4.8)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of Site Visit.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Indicated in step 1.2 the maximum number of protocols.*
06	*2019 July 26*	*IRB SOP TEAM*	*Only IRB members and Staff cited in the Workflow.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Revised sequencing of SOPs on Post- Approval Reviews.*
08	*2024 Feb. 22*	*IRB SOP TEAM*	*Revised scope and added timeline in calendar days in the workflow. Revise description of procedures step 2, 2.1.*
09	*2025 May 15*	*Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba*	*Revised SOP 21 on Conduct of Site Visit.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 22** **Management of Queries and Complaints**

1. Policy Statement

St. Paul's Hospital of Iloilo, Inc. Institutional Review Board Queries and complaints from PI/Researcher, research participants, third parties and other research stakeholders shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the IRB staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

2. Objective of the Activity

SPHI-IRB aims to manage queries and complaints:

1. To promptly, diligently, adequately, and appropriately address the specific queries and complaints that the IRB may receive from research participants, stakeholders, and other concerned sectors about the conduct of studies and protocols submitted to it for review
2. To promote public trust and confidence in the Institution, especially the IRB and to ensure that the rights and well-being of participants are attended to.

3. Scope

This SOP 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 IRB meeting.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt, logging and acknowledgement of queries and complaints	*Office Manager or Staff*	*1 day*
Step 2: Referral of query or complaint to competent authority *2.1 Referral of all queries and complaints to the IRB Chair* *2.2 Referral of protocol related queries and complaints to Primary Reviewers*	*Office Manager or Staff*	*1 day*
Step 3: Formulation of response *3.1 Minimal risk queries and complaints* *3.2 More than minimal risk queries and complaints*	 *Primary Reviewers* *Chair and IRB Members*	 *3 days* *1 day*
Step 4: Communication of Response (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 5: Logging of the response and inclusion in the Agenda of the IRB Meeting (SOP 25 Preparing the Meeting Agenda)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt, logging and acknowledgement of queries and complaints

The Office Manager or Staff receives the queries and complaints (Queries and complaints form 4.9) signed by the complainant and logs in the incoming logbook.

Step 2: Referral of query or complaint to competent authority

The Office Manager or Staff refers queries and complaints to the IRB Chair who determines the level of risk. For minimal risk, the queries and complaints are referred to the Primary Reviewers. For more than minimal risk, they are referred to the Committee through a special meeting that shall be called within 48 hours. The Office Manager or Staff includes the Queries and Complaints in the meeting agenda. The Staff notifies the concerned Primary Reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

Step 3: Formulation of response

3.1 The Primary Reviewers accomplish the Queries and Complaints Form 4.9 for expedited review within three days and submits to the IRB.
The Chair reviews and approves the response of the Primary Reviewers.

3.2 For Full Board (more than minimal risk), the committee may choose any of the following decisions:
The Primary Reviewers review and formulate response using the Queries and Complaints Form 4.9 and submit to the IRB within 24 hours.

3.2.1 Designate the Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution if necessary.

3.2.2 The following are the decisions of the IRB:

- request for explanation/justification from researcher
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- site visit SOP 22 (Form 4.9)(Constitute a site visit team to gather more information, verification and clarification regarding the source and cause/s of the complaint for each early resolution)
- others (Designate the Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution if necessary).

Step 4: Communication of Response

4.1 The Office Manager or Staff transfers the recommendations and/or decisions of the board to the IRB Communication Letter (Form 6.3).

4.2 The Chair reviews and signs the communication before forwarding it to the investigators, sponsors, institutions, regulatory agencies, etc.

Step 5: Logging of the response and inclusion in the Agenda of the IRB Meeting

The Office Manager or Staff logs the documents to be signed by the receiving party on the Queries and Complaints Log.

6. Forms

Queries and Complaints Form (Form 4.9)
IRB Communication Letter (Form 6.3)
Site Visit (Form 4.8)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2016 May 20*	*IRB SOP TEAM*	*First draft*
02	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
03	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
04	*2019 June 13*	*IRB SOP TEAM*	*Split Step 2 into two separate task.*
05	*2019 July 26*	*IRB SOP TEAM*	*Added management of appeals.*
06	*2019 Dec. 30*	*IRB SOP TEAM*	*Revise sequencing of SOPs on Post- Approval Reviews.*
07	*2020 Oct. 20*	*IRB SOP TEAM*	*Separate Management of Appeals.*
08	*2024 Feb. 22*	*IRB SOP TEAM*	*Added timeline in calendar days in the workflow.*
09	*2025 May 15*	*Dr. Venerio Gasataya Jr.* *Sr. Gertrude Caryls Kuebler, SPC, and* *Dr. Mark Leonard Flores*	*Revised SOP 22 on Management of Queries and Complaints.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: July 08, 2025	**SOP No: 23** **Management of Appeal**
Effective Date: July 15, 2025	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall consider the perspective of the Principal Investigator/Researcher regarding the feasibility and acceptability of IRB recommendations including its disapproval. Appeals of researchers shall undergo full review and shall be resolved within 20 working days 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

This SOP begins with the receipt of the appeal and ends with communicating the committee's action to the PI/Researcher and updating of the protocol file folder.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of an appeal	*Office Manager or Staff*	*1 day*
Step 2: Retrieval of pertinent protocol file	*Office Manager or Staff*	*1 day*
Step 3: Notification of Chair and Primary Reviewers	*Office Manager or Staff*	*1 day*
Step 4: Inclusion in the Agenda of the next regular meeting	*Chair*	*1 day*
Step 5: Discussion of and deliberation on the appeal	*Chair and IRB Members*	*1 day*
Step 6: Communication of IRB decision/action to PI/Researcher (SOP 28 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 7: Filing of all related documents to the protocol file (SOP 30 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Receipt of an appeal

The Office Manager or Staff receives the letter of Appeal from the PI/Sponsor and records it in the logbook.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the corresponding protocol file for reference of the Chair and Primary Reviewers.

Step 3: Notification of Chair and Primary Reviewers

The Office Manager or Staff notifies the Chair and the Primary Reviewers about the letter of Appeal.

The Chair reviews and evaluate the appeal together with the supporting information or materials and the previous minutes of the meeting where the decision of disapproval was made. The Chair decides the review of protocol in full board.

Step 4: Inclusion in the Agenda of the next regular meeting

4.1 The Office Manager or Staff includes the appeal in the agenda of the next IRB monthly meeting.

4.2 The Office Manager or Staff informs the PI/Researcher to be available on the scheduled meeting in case there is a need for further clarification.

Step 5: Discussion of and deliberation on the appeal

5.1 The Primary Reviewers presents the protocol summary, their assessment and recommendations on the revised documents to the IRB.

5.2 The PI/Researcher may be called in for further clarification of issues. The PI/Researcher is asked to step out after the committee has taken up the issues for clarification.

5.3 The IRB members shall deliberate on the recommendations by the Primary Reviewers and decide on the appropriate actions by votation.

5.4 Based on the deliberations, the Chair summarizes the decision points and instructs the IRB Staff to prepare the draft decision letter either Approval Letter (Form 6.1), Notification of IRB Decision (Form 6.2). The following are the decision points:

- Approval (when no further modification is required) Approval letter includes one (1) year validity. It includes the start and end dates of effectivity).
- Minor revisions, (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.
- Major revisions (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)
- Disapproval (due to ethical or legal concerns). Reasons for vote of disapproval should be noted in the minutes of meeting and communicated to the PI/Researcher.

5.5 If the PI/Researcher is given the decision of final disapproval, the said decision will no longer be appealed again. The PI/Researcher may submit new proposals for initial review.

Step 6: Communication of IRB decision/action to PI/Researcher

6.1 The Office Manager or Staff communicates to the PI/Researcher through SMS or messenger the Decision of the IRB.

6.2 The Office Manager or Staff advises the PI/Researcher to pick up the Notification of IRB Decision (Form 6.2) or Approval Letter (Form 6.1) from the IRB Office.

Step 7: Filing of all related documents to the protocol file

The Office Manager or Staff files all the documents into the appropriate folder and updates the protocol database.

6. Forms

Approval Letter (Form 6.1)
Notification of IRB Decision (Form 6.2)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2020 Oct. 20*	*IRB SOP TEAM*	*First draft*
02	*2024 Feb. 22*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow.*
03	*2025 June 4*	*Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores*	*Revised SOP 23 on Management of Appeal.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 24** **Preparing for a Meeting**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have a regular scheduled meetings every 2nd Thursday of the month. All face to face meetings shall be held within the premises of the institution. Meetings can be virtual or hybrid. Special meetings shall be held any day to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity.

2. Objective of the Activity

The preparation for a meeting aims to contribute to a smooth, orderly and efficient conduct of board meetings.

3. Scope

This SOP covers all activities prior to the conduct of an IRB meeting. This SOP begins with the preparation of the agenda and ends with the notification of IRB Members and confirmation of attendance.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Preparation of the Agenda (SOP 24 Preparing the Meeting Agenda) Notice of Meeting (Form 5.0)	*Office Manager or Staff*	*2 days*
Step 2: Coordination with the physical plant division	*Office Manager or Staff*	*1 day*
Step 3: Assembly of materials and documents needed for the meeting	*Office Manager or Staff*	*1 day*
Step 4: Preparation of presentation and recording equipment, food arrangements for the meeting	*Office Manager or Staff*	*1 day*
Step 5: Notification of IRB Members and confirmation of attendance	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Preparation of the Agenda

a. The Office Manager or Staff prepares the draft of the Notice of IRB Meeting (Form 5.0) for checking of IRB Chair.

Step 2: Coordination with the physical plant division

The Office Manager or Staff coordinates with the hospital staff in charge of the Cancer Center conference room regarding the upcoming IRB meeting, if the IRB cannot accommodate all attendees in the IRB office, fifteen working days before the scheduled meeting.

Step 3: Assembly of materials and documents needed for the meeting

3.1 The Office Manager or Staff assembles all the materials (hard or electronic copies) for the meeting which includes, but not limited to the meeting agenda, minutes of the previous meeting, protocols and other documents/reports for review.

3.2 The Office Manager or Staff delivers the documents to the offices of the members fifteen working days prior to the scheduled IRB meeting.

Step 4: Preparation of logistics for the meeting

4.1 The Office Manager or Staff prepares the logistics for the meeting (honoraria, snacks, LCD projector, laptop) three working days before the meeting

4.2 The Staff prepares the IRB Office one day before the IRB regular meeting.

Step 5: Notification of IRB Members and confirmation of attendance

The Office Manager or Staff informs the IRB members of the scheduled meeting through SMS (text) or messenger to confirm their attendance and the presence of quorum during the distribution of the meeting agenda and minutes of meeting three working days before the meeting.

6. Forms

Notice of IRB Meeting with Agenda Template (Form 5.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Added detailed preparation of the IRB meeting.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2024 Feb. 22*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow. Revise step 3 (3.2) and step 5, (5.4 & 5.6).*
06	*2024 Apr 29*	*IRB SOP TEAM*	*Added statements in the description of procedures.*
07	*2025 May 15*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 25 on Preparing for a Meeting.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 25** **Preparing the Notice of the Meeting with Agenda**

1. Policy Statement

The meeting agenda of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board the meeting agenda shall be based on the submissions received, at the latest, fifteen working days before the scheduled regular meeting. It shall follow an established template for Notice of IRB Meeting Form 5.1. The provisional agenda shall be included in the Notice of IRB 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 IRB determines what items are to be included in the agenda of regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Preparation of the draft of the meeting agenda (Notice of IRB Meeting Form 5.0)	*Office Manager or Staff*	*2 days*
Step 2: Approval of the draft meeting Agenda	*Chair*	*2 days*
Step 3: Distribution of the provisional meeting agenda (SOP 26 Preparing of a Meeting)	*Office Manager or Staff*	*1 day*
Step 4: Approval of the provisional meeting agenda	*IRB members*	*1 day*
Step 5: Filing of the final Meeting Agenda (SOP 32 Management of Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Preparation of the draft of the meeting agenda

a. The Office Manager or Staff prepares the draft of the agenda using the Notice of the Meeting (Form 5.0) The contents of the agenda of the regular meeting are as follows:

1. Opening Prayer
2. Call to Order
3. Determination of a Quorum
4. Approval of the Agenda
5. Reading and Approval of the Minutes of the previous Meeting
6. Business Arising from the Minutes of the Previous Meeting
7. Disclosure of Conflict of Interest among Members
8. Protocol Review
    - 8.1 New Protocols for Initial Review of Full Board
    - 8.2 Resubmission
    - 8.3 Post-Approval Reports
        - 8.3.1 Amendments
        - 8.3.2 Progress Report

8.3.3 Progress Reports
8.3.4 SAE/SUSAR Reports
8.3.5 Review of Reports on Negative Events (RNE)
8.3.6 Protocol Deviations and Violations
8.3.7 Early Termination Reports
8.3.8 Final Reports

9. Application for Continuing Review
10. Site Visit
11. Queries and Complaints/ Appeal
12. Exempt from Review Protocols
13. Report of the Approved new protocols by Expedited Review
14. Report of the Approved post-approval reports by Expedited Review
15. Notification
16. Other Matters
17. Checking of Quorum
18. Adjournment

Step 2: Approval of the draft meeting Agenda

The Chair approves the draft Meeting Agenda, signs the Notice of the Meeting (Form 5.0). The approved draft Meeting Agenda becomes the Provisional Meeting Agenda that is part of the Form 5.0 Notice of the Meeting.

Step 3: Distribution of the provisional meeting agenda

The Office Manager or Staff distributes the Notice of IRB Meeting (Form 5.0) that includes the Provisional Meeting Agenda and the other documents to the offices of the IRB members three working days before the scheduled meeting.

Step 4: Approval of the provisional meeting agenda

The IRB Members approved the provisional agenda at the start of the meeting after the necessary corrections or additions are made. The approved Provisional Meeting Agenda becomes the Final Meeting Agenda.

Step 5: Filing of the final Meeting Agenda

The Office Manager or Staff files the final meeting agenda in the protocol file folder and updates the Protocol file index (Form 7.0) and database.

6. Forms

Notice of IRB Meeting (Form 5.0)
Index of Files Content (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed preparation, distribution and filing of IRB Notice of the meeting with Agenda.*

03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2024 Feb. 22*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow. Revise description of Procedures 5.2.5 step 1.*
06	*2024 June 28*	*IRB SOP TEAM*	*Revise sequencing in the Notice of the IRB Meeting template.*
07	*2025 May 15*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 25 on Preparing the Notice of the Meeting with Agenda.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 26** **Conduct of Meetings**

1. Policy Statement

The meetings of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall be presided by the Chair or a designated substitute, shall proceed only when a quorum of six members ((50% + 1) present of the total members with the inclusion of the following members: medical/scientist, non-scientist/non-medical, and affiliate/ non-affiliate) is declared, and shall be guided by the approved agenda. The presence of the conflict of interest among the members shall be disclosed prior to the discussion of protocol for review.
The conduct of meetings shall abide by the national and International guidelines. The meetings shall be conducted either face to face, virtual platform or hybrid.

2. Objective of the Activity

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

3. Scope

This SOP describes the manner by which the IRB conducts all its meetings. It covers IRB actions and activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Distribution of meeting materials	*Staff*	*1 day*
Step 2: Opening Prayer	*IRB Members*	*1 day*
Step 3: Call to Order	*Chair*	
Step 4: Determination of quorum	*Member-Secretary*	
Step 5: Approval of the provisional agenda	*IRB Members*	
Step 6: Approval of minutes of the previous meeting	*IRB Members*	
Step 7: Discussion of "business arising from the minutes of the previous meeting	*IRB Members*	
Step 8: Disclosure of conflict of interest (COI)	*IRB Members (who have COI)*	
Step 9: Review of protocols and protocol-related Submissions	*Chair and Members*	
Step 10: Report on approved expedited review	*Chair*	
Step 11: Report on the Exempted Protocols	*Chair*	
Step 12: Site Visit Report	*Site visit team leader*	
Step 13: Discussion of Other Matters	*Chair*	
Step 14: Adjournment	*Chair*	
Step 15: Collection, storage, and disposal of meeting materials	*Staff*	*1 day*

5. Description of Procedures

Step 1: Distribution of meeting materials

5.2 The Office Manager and Staff prepare all the materials 14 working days prior to the IRB regular meeting. These include meeting agenda, minutes of the previous meeting, protocols for initial review, resubmission, and post approval reports

5.3 The Staff distributes the meeting materials twelve working days prior to the meeting.

Step 2: Opening Prayer

The Chair requests any member or staff to lead the opening prayer.

Step 3: Call to order

The Chair calls the meeting to order.

Step 4: Determination of quorum

4.1 The Member-Secretary determines the quorum by the presence of (50% + 1) of the total members with the inclusion of the following members: medical/scientist, non-scientist/non-medical, and affiliate/ non-affiliate.

4.2 Presence of a quorum is announced and the formal meeting starts. The members present sign the Attendance Sheet (Form 5.1).

Step 5: Approval of the provisional agenda

5.1 The Chair asks the members if there are items that they would like to include, correct or delete from the agenda.

5.2 The Provisional agenda is approved by the IRB members after a motion from a member and duly seconded accordingly.

Step 6: Approval of minutes of the previous meeting:

The IRB Members approve the provisional minutes of the previous meeting after a motion for approval is made and duly seconded (Minutes of the meeting Form 6.1)

Step 7: Discussion of business arising from the minutes of the previous meeting

7.1 The Chair asks for any matters arising from the minutes of the previous meeting.

7.2 The Member-Secretary reports on business arising from the previous minutes and the IRB members discuss and resolve the issues.

Step 8: Disclosure of Conflict of Interest

8.1 The Chair asks members if there is conflict of interest with any protocol to be discussed. All members ensure to disclose and manage COI. This is documented in the minutes each time before reviewing a new protocol and before making a decision.

8.2 The Chair manages the conflict by asking the concerned member to leave the conference room while the protocol is being discussed. The Staff calls back the member with COI after a decision has been made.

8:3 The Member-Secretary checks the quorum every time a member leaves the room.

Step 9: Review of protocols and protocol-related submissions

Review of new Protocols for Initial Review of Full Board, Resubmission, Review of SJREB Protocols, Appeal, Amendments, Progress Reports, SAE/SUSAR Reports, Review of Reports on Negative Events (RNE), Protocol Deviation/Violation, Early Termination Reports, Final Reports, Application for Continuing Review, Site Visit, Queries and Complaints, Report on the Results of the Expedited Review, Reports of Exempt from Review Protocols and Others/Notification.

9.1 The Primary Reviewers present the summary of the protocol and his/her findings based on the Protocol Evaluation (Form 3.1). The non-scientist/non-affiliated member presents the ICF evaluation findings using the ICF Evaluation (Form 3.2).

9.2 The IRB discusses protocol issues/findings facilitated by the Chair. The presentation and the discussion follow the structure of the Evaluation forms namely the technical, ethical, and ICF.

9.3 When an Independent Consultant is invited, he/she clarifies technical issues and answers queries by the IRB members. However, he/she cannot participate in the voting process during the IRB meetings.

9.4 The Principal Investigator can only be invited for clarificatory purposes. The PI is not asked to present the protocol.

9.5 The Chair or Member-Secretary summarizes the recommendations before making a decision. A member makes a motion for approval of a decision and seconded accordingly.

9.6 The Members approve by voting and the position which obtains the majority vote prevails. The result of the voting is documented.

9.7 The Site visit team leader discusses the result of the site visits, if there is any.

9.8 The Member-Secretary and the Primary Reviewers review, analyze and make recommendations on the SAE/SUSAR/RNE report.

9.9 The IRB discusses and finalizes the recommendations on Initial review, Resubmission (SOP 10), post-approval submissions Amendments (SOP 14), Progress Reports (SOP 15), SAE/SUSAR Reports (SOP 16), Review of RNE (SOP 17), Protocol Deviation/Violation (SOP 18), Early Termination Reports (SOP 19), Final Reports (SOP 20), Application for Continuing Review (SOP 21), Site Visit (SOP 22), Queries and Complaints (SOP 23), Appeal (SOP 24), and Others/Notification.

Step 10: Report on results of expedited review

10.1 If there are protocols assigned for expedited review, the assigned reviewers submit the evaluation forms (Protocol Evaluation (Form 3.1) and ICF Evaluation (Form 3.2).

10.2 The Chair reports the approved expedited review.

Step 11: Report on the Exempted Protocol

The Chair reports the protocols that are exempted from review as stated in the Meeting Agenda in the Notice of IRB meeting (Form 5.0).

Step 12: Site Visit Report

The Site visit team leader presents the site visit report for discussion.

Step 13: Discussion of Other Matters

The Chair presents other matters listed for discussion.

Step 14: Adjournment

If there are no other matters to be discussed, the Chair adjourns the meeting after the member-secretary determines the presence of quorum.

Step 15: Collection, storage, and disposal of meeting materials

15.1 The Staff is tasked to collect all the documents used during the meeting.

15.2 A copy of every document shall be filed in its proper study file folder while extra copies are brought to the Shredding Room for proper disposal every third Friday of the month.

6. Forms

Attendance Sheet (Form 5.1)
Notice of IRB meeting (Form 5.0)
Protocol Evaluation (Form 3.1)
ICF Evaluation (Form 3.2)
Minutes of Meeting (Form 6.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures related to conduct of the meeting.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at*

			the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Stated in step 9 the responsibility of chair or member secretary during IRB review meeting.*
06	*28 June 2022*	*IRB SOP TEAM*	*Added 1.4 in the description of procedures in step 1. Added gender representation in step 4, 4.1.*
07	*2024 Feb. 22*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow.). Added in the description of procedures step 1 (1.4), step 9 (9.1-9.4 & 9.7).*
08	*2024 June 28*	*IRB SOP TEAM*	*Revised sequencing in step 9.*
09	*2025 May 15*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 26 on Conduct of Meetings.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 27** **Preparing the Minutes of the Meeting**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board minutes of meeting shall be based on the approved agenda and the proceedings of the IRB meeting shall be the basis of the decision letter on protocols. The Minutes of Meeting shall be recorded in real time during the board meeting.

2. Objective of the Activity

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

3. Scope

This SOP begins with the entry of preliminary information on the minute's template and ends with the filing of the approved minutes.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Entry of preliminary information on the Minutes template	*Office Manager or Staff*	*2 days*
Step 2: Preparation of the draft Minutes	*Office Manager or Staff*	*1 day*
Step 3:Notation of the draft Minutes	*Member-Secretary*	
Step 3: Attestation of the draft of Minutes of the Meeting	*Chair and Member-Secretary*	*1 day*
Step 4: Approval of the provisional minutes in the next IRB meeting	*Chair and IRB Members*	*1 day*
Step 5: Filing of the approved Minutes (SOP 30 Managing Active Files)	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Entry of preliminary information in the Minutes of Meeting template

The Office Manager or Staff enters the information in the Minutes of Meeting Template (Form 6.0) by filing it out with preliminary or relevant information using the SPHI-IRB Agenda three days before the IRB meeting.

Step 2: Preparation of the draft Minutes

The Office Manager or Staff drafts the Minutes of Meeting using the real time recordings during the conduct of meeting.

Step 3: Notation of the draft Minutes

3.1 The Member-Secretary checks the draft Meeting Minutes (Form 6.0) made by the Staff to ensure complete and correct information three days after the IRB meeting for approval by the Chair.

3.2 The contents of the minutes of the meeting are enumerated in the Minutes of the Meeting (Form 6.0).

Step 4: Approval of the provisional minutes in the next IRB meeting

The IRB approves the provisional minutes after it has been initiated through a motion by an IRB member which is duly seconded.

Step 5: Filing of Minutes of the Meeting

5.1 The Office Manager or Staff files a copy of the final minutes in the Minutes file folder. Relevant excerpts of the Minutes of the meeting are inserted in the appropriate protocol file.

5.2 The Office Manager or Staff maintains a central file of all meeting minutes by year to facilitate retrieval.

6. Forms

Minutes of the Meeting Template (Form 6.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Revised the preparation of the minutes of the SPHI-IRB full-board meeting to ensure proper documentation of the procedures and decisions during the meeting.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2024 Feb. 22*	*IRB SOP TEAM*	*Revised scope and added timeline in calendar days in the workflow.*
06	*2024 June 28*	*IRB SOP TEAM*	*Revised sequencing in the Minutes of Meeting template*
07	*2025 May 15*	*Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo*	*Revised SOP 27 on Preparing the Minutes of the Meeting.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 28** **Communicating IRB Decisions**

1. Policy Statement

St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall communicate its decisions (Approval Letter (Forms 6.1) to the researcher within eight (8) weeks after the receipt of the complete set of documents. The chair shall sign the communication letters/documents.

2. Objective of the Activity

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

3. Scope

This SOP covers IRB actions related to communicating IRB decisions using the official IRB Communication Forms (Approval Letter (Forms 6.1), Notification of IRB Decision (Form 6.2), and IRB Communication Letter (Form 6.3)).This SOP 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	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Finalization of the IRB recommendations (in case of full review) (SOP 7 Full Review) or Finalization of recommendations of reviewers (in case of expedited review) (SOP 6 Expedited Review)	*Chair*	*2 days*
Step 2: Transfer of information from minutes or assessment forms to IRB Communication forms or templates	*Member-secretary, Office Manager and Staff*	*2 days*
Step 3: Approval of the IRB Communication Forms decision document	*Chair*	*1 day*
Step 4: Communication of IRB decision/action to PI/Researcher (SOP 30 Communicating IRB Decisions)	*Office Manager or Staff*	*1 day*
Step 5: Filing of the document in the protocol file folder	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Finalization of the IRB recommendations (in case of full review) (SOP 8 Full Review) or Finalization of recommendations of reviewers (in case of expedited review) (SOP 7 Expedited Review)

The Chair finalizes the IRB recommendations and decisions in the minutes of the meeting after the Member-Secretary verifies their accuracy.

For expedited reviews, the Chair finalizes the reviewers' recommendations and decisions.

Step 2: Transfer of information from minutes or assessment forms to IRB Communication forms or templates

The Office Manager or Staff transfers the recommendations and/or decision to the IRB Communication Forms or templates Approval Letter (Form 6.1), Notification of the IRB Decision

Form (Form 6.2), IRB Communication Letter (Form 6.3) and the member-secretary checks the correctness of the communication. The transfer of information is done within 2 days.

Step 3: Approval of the IRB Communication Forms decision document

The Chair approves and signs the IRB Communication forms Approval Letter (Form 6.1), Notification of the IRB Decision Form (Form 6.2), IRB Communication Letter (Form 6.3).

Step 4: Communication of IRB decision/action to PI/Researcher

4.1 The Office Manager or Staff informs the Investigators through SMS (text), phone call or email that the decision of the IRB is available and is ready for pick up.

4.2 The Office Manager or Staff logs the documents to be signed by the receiving party on the Out-going Communications Logbook. A copy of a communication letter is signed by the PI/site staff for filling.

Step 5: Filing of the document in the protocol file folder

The Office Manager or Staff updates the protocol file index and the database of the specific protocol file and keeps the document/s in the protocol file folder.

6. Forms

Approval Letter (Form 6.1)
Notification of the IRB Decision Form (Form 6.2)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed instructions related to the preparation and management of IRB communication.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Added Management of Appeals of IRB Decision.*
06	*2024 Feb. 22*	*IRB SOP TEAM*	*Revised scope and added timeline in calendar days in the workflow.*
07	*2025 May 16*	*Dr. Venerio Gasataya Jr., Sr. Gertrude Caryls*	*Revised SOP 28 on Communicating IRB Decision.*

		Kuebler, SPC, and Dr. Mark Leonard Flores	

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: July 08, 2025	**SOP No: 29** **Managing IRB Incoming and Outgoing Communications**
Effective Date: July 15, 2025	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board communications shall be recorded accurately and appropriately in a physical log book and database. There shall be a protocol and protocol-related incoming and an outgoing logbook. Another incoming logbook shall record incoming and outgoing administrative communications.

2. Objective of the Activity

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

3. Scope

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

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Sorting of incoming/outgoing communications	*Office Manager or Staff*	*1 day*
Step 2: Recording of incoming/outgoing communications	*Office Manager or Staff*	*1 day*
Step 3: Acting on communications	*Office Manager or Staff*	*1 day*
Step 4: Filing of incoming/outgoing communications and Updating of respective databases	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Sorting of incoming/outgoing communications

1.1 The Office Manager or Staff, under the supervision of the Member-Secretary, sorts all the communications received and issued by the IRB.

1.2 Upon the receipt of the communications, they classify the document/s such as:

- documents for review;
- progress report;
- final report;
- SUSARs/SAE report;
- protocol deviations;
- requests;
- letters;
- memorandums;
- others e.g complaints, notifications

Step 2: Recording of incoming/outgoing communications

2.1 The Office Manager or Staff records the incoming and outgoing communications in its specific logbook.

2.2 The Contents of the Incoming Communications Logbook for protocol and protocol related documents are:

- Date of Receipt
- IRB Protocol Code
- Principal Investigator/Researcher
- Title of protocol and Document Submitted
- Name and signature of the submitter
- Name and signature of the Receiver
- Action Taken

2.3 The Contents of the Outgoing Communications protocol and protocol related documents Logbook are:

- IRB Protocol Code
- Date released
- IRB Communication
- Principal Investigator
- Name of the person endorsing the document
- Name and signature of the recipient

2.4 Content of Incoming and Outgoing administrative logbook

- Date of Receipt/Released
- Nature of administrative document
- Name of the person endorsing the document
- Name and Signature of Recipient

Step 3: Acting on communications

3.1 The Office Manager or Staff acts by presenting the protocol and protocol-related incoming communications to the IRB Chair for further actions

- Reviews the submission
- Determines the type of review
- Determines the Primary Reviewers

3.2 The Office Manager or Staff notifies the Primary Reviewers of the submission and prepares the documents for distribution.

3.2 The Chair reviews and approves the IRB protocol, protocol-related and administrative outgoing communications before forwarding them to the PI/Researcher, sponsors, institutions, agencies.

Step 4: Filing of incoming/outgoing communications and updating of databases

The Office Manager or Staff files all incoming and outgoing protocol and protocol-related communications after it has been acted upon by the Chair or Primary Reviewers in the protocol file folder. Creates or updates the protocol file index (Form 7.0) and the protocol database. Administrative communications are kept securely in a cabinet labelled as "SPHI IRB Administrative Documents".

6. Forms

Protocol File Index (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of incoming and outgoing communications*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow.*
06	*2025 May 15*	*Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores*	*Revised SOP 29 on Managing IRB Incoming and Outgoing Communications.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 30** **Managing Active Files**

1. Policy Statement

Active files of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board 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 on (SOP 34 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 begins with the classification and coding of active files and ends with the periodic updating of the file

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Classification and coding of active files	*Office Manager or Staff*	*1 day*
Step 2: Updating of corresponding protocol folder	*Office Manager or Staff*	*1 day*
Step 3: Periodic updating of the Protocol File	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Classification and coding of active files

1.1 The Office Manager or Staff under the supervision of the office manager classifies and organizes active files as follows:

1.1.1 Initial Submission
1.1.2 Resubmission
1.1.3 Progress Report
1.1.4 Amendment
1.1.5 Protocol Deviation / Violation
1.1.6 Serious Adverse Event (SAE)
1.1.7 SUSAR – Suspected Unexpected Serious Adverse Reaction
1.1.8 Report of Negative Event (RNE)
1.1.9 Early Termination
1.1.10 Continuing Review
1.1.11 Final Report/ Close Out Report

1.2 The Office Manager or Staff labels the assigned code to the initial protocol submission and indicates the same for the rest of the related submissions.

Step 2: Updating of corresponding protocol folder

2.1 The Office Manager or Staff ensures that the protocol documents are filed properly in a sturdy file folder (one folder per study protocol) that is labelled on the front cover and along the spine with:

- IRB Protocol Code,
- Study Title,

- PI,
- Date of Approval

2.2 The Staff attaches a protocol Index of File Contents (Form 7.0) in the inside front cover that indicates the contents of the folder for easy monitoring and reference of the IRB. A labelled paper/divider is used to separate the documents in the protocol file folders.

Step 3: Periodic updating of the Protocol File

3.1 The Office Manager or Staff updates the protocol file and ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:

3.1.1 Protocol (Original and Revised) versions
3.1.2 Informed consent (Original and Revised) versions
3.1.3 Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR/RNE, Amendment, Early Termination, Site Visit Reports, Continuing Review and Final
3.1.4 Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
3.1.5 Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
3.1.6 Decision and Approval Letters
3.1.7 Communications

3.2 Office Manager or Staff updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness every Friday. The Staff also updates the database.

3.3 The Office Manager or Staff updates the a back-up system (in the form of portable hard-drive) of all active files and documents twice a month. The hard drives are kept in the Administrator's office and the IRB office and can be accessed by the Member-Secretary, Office Manager and Staff.

6. Forms

Index of File Contents (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of Active Files.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Expand data fields in database.*

06	*2025 May 15*	*Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores*	*Revised SOP 30 on Managing Active Files.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 31** **Archiving**

1. Policy Statement

Files of studies which are researcher initiated which have been completed, terminated or declared inactive (SOP 09 Resubmission) shall be kept in an archive room for three years. For Clinical trials, the protocol files shall be kept for five years.

2. Objective of the Activity

Archiving inactive, terminated, and completed files ensures efficient and effective storing of these documents for retrieval of information and in compliance with national and international guidelines.

3. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and 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	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Acceptance of Final report (Form 4.6) or Early Termination report (Form 4.5)	*Office Manager or Staff*	*1 day*
Step 2: Updating of corresponding protocol folder	*Office Manager or Staff*	*1 day*
Step 3: Transfer of the protocol folder in the archives and update of the protocol database	*Office Manager or Staff*	*1 day*
Step 5: Maintenance of Archives	*Office Manager or Staff*	*1 day*

5. Description of Procedures

Step 1: Acceptance of Final or Early Termination reports

1.1 The Office Manager and Staff:

a. Accepts the Final report (Form 4.6) or Early Termination report (Form 4.5) from the PI/researcher.
b. Notifies the chair and the Primary Reviewers of the submissions
c. Sends the submissions to the Primary Reviewers for review (SOP on Final Report (Form 4.6), or Early Termination Report (Form 4.5)

1.2 The IRB approves or accepts the final or early termination report protocol during the monthly meeting.

1.3 Unfinished or incomplete studies that have remained inactive for three years without any follow-up from the investigators/researches are also classified as documents for archiving with the recommendation of the IRB.

Step 2: Updating of corresponding protocol folder

2.1 The Office Manager or Staff files a copy of the approved Final or Early Termination report in the protocol file folder including the excerpts of the minutes that approved the report or declared the

protocol as inactive.

2.2 The Office Manager or Staff reclassifies the protocols for archiving by putting a sticker on the protocol file folder with a word "INACTIVE" and archiving date on the spine of the folder for easy retrieval and identification of studies.

2.3 The Office Manager or Staff checks the completeness of the protocol file.

Step 3: Transfer of the protocol folder in the archives and Update of the Protocol Database

3.1 The Office Manager or Staff transfers the protocol marked as inactive to the archiving cabinets.

3.2 The Office Manager or Staff enters the archiving date in the database.

Step 4: Maintenance of Archives

4.1 The Office Manager or Staff maintains the protocol folders of the inactive, terminated and completed studies that are kept and secured and well- locked IRB Archives Room, with access limited only to Office Manager and Staff for confidentiality and security purposes.

4.2 Protocol files in the Archives are kept for three years for researcher-initiated studies and five years for clinical trials, for retrieval of information and in compliance with national and international guidelines before shredding for proper disposal. The protocol files are shredded and the electronic documents related to the protocol are deleted after the retention period.

6. Forms

Early Termination report (Form 4.5)
Final report (Form 4.6)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of terminated, inactive, and completed files for archiving.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Added archiving date to the IRB protocol No.*
06	*2025 May 15*	*Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and*	*Revised SOP 31 on Archiving.*

		Dr. Mark Leonard Flores	

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 32** **Managing Access to Confidential Files**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board access to the IRB confidential files shall be regulated and limited to IRB 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. The files shall be for room use only and not to be brought outside of the office. The Office Manager or Staff shall supervise the access and use of the confidential files. Investigators/Researchers shall be allowed access only to their own protocol files upon request.

2. Objective of the Activity

Management of access to confidential files aims to help protect the intellectual property rights of researchers/sponsors and uphold data privacy and confidentiality to enhance the credibility and integrity of the IRB.

3. Scope

This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and logging of request for access to confidential files	*Office Manager or Staff*	*1 day*
Step 2: Approval of requests for access and retrieval of documents	*Chair or Member-Secretary*	*1 day*
Step 3: Supervision of use of retrieved document	*Office Manager or Staff*	*1 day*
Step 4: Return of document to the files	*Office Manager or Staff*	

5. Description of Procedures

Step 1: Receipt and logging of request for access to confidential files

1.4 The Office Manager or Staff:

a. Receives the request from the PI/Sponsor to access specific files
b. Logs the request in the incoming protocol logbook
c. Refers to the Chair or Member-Secretary

Step 2: Approval of requests for access and retrieval of documents

The Chair or Member-Secretary:

a. approves the request
b. Informs the Office Manager or Staff regarding the requested document for retrieval from protocol file folder.
c. Instructs the Office Manager or Staff to supervise the use of the document

Step 3: Supervision of use of retrieved document

The Office Manager or Staff supervises the use of the documents requested.

The Office Manager or Staff ensures that:

a. only specific documents requested is retrieved and made available for the requesting PI/Researcher/Sponsor.
b. the documents remain in the office but it can be reproduced or can be photocopied if requested by the PI/Researcher/Sponsor.
c. the requested documents are complete after its use
d. the documents are organize before returning to the protocol file folder
e. the requesting person signs the outgoing logbook stating the reproduced or photocopied documents.

Step 4: Return of document to the files

The Office Manager or Staff returns appropriately the retrieved documents in the protocol file folder.

6. Forms

IRB Borrowers Log (Form 7.1)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed management of incoming and outgoing communications.*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History. Changed IRB Forms Header.*
05	*2019 June 13*	*IRB SOP TEAM*	*Revise scope and added timeline in calendar days in the workflow.*
06	*2025 June 4*	*Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores*	*Revised SOP 32 on Managing Access to Confidential Files.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

Version No: 13 Approval Date: July 08, 2025 Effective Date: July 15, 2025	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 33** **Writing and Revising SOP**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall review/revise the Standard Operating Procedures (SOP) every three years or as necessary by reason of changed circumstances, compliance with government regulations, and others. The REC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

2. Objective of the Activity

Writing and revising SOPs establishes quality assurance of IRB functions.

3. Scope

This SOP begins with the proposal and approval for the 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	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Proposal and approval for revision of a new SOP	*IRB Member*	*1 day*
Step 2: Designation of SOP Team	*Chair*	*1 day*
Step 3:Drafting of the revision or new SOP	*SOP Team*	*7 days*
Step 4: Review and finalization of SOP	*IRB Members*	*2 days*
Step 5: Submission of finalized SOP to the Hospital Administrator	*Chair*	*2 days*
Step 6: Inclusion of Revised SOP in the SOP Manual and its dissemination	*Office Manager or Staff*	*2 days*

5. Description of Procedures

Step 1: Proposal and approval for revision of a new SOP

The IRB member may propose the revision of its Standard Operating Procedures to the IRB during a meeting. The IRB identifies, discusses and decides for the revision of the SOPs.

Step 2: Designation of SOP Team

The Chair designates members to compose a team for the revision of the SOP. The Team is an ad hoc committee composed of IRB members. The team elects a team leader to supervise the SOP revision.

Step 3: Drafting of the revision or new SOP

The IRB SOP Team drafts the revision basing on the SOP Template consisting of the following:

a. Header that includes the SOP number and title, logo, effectivity and approval date, version number 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 steps and timeline.
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. History which tabulates the different versions (from draft to finals versions) of the document by author, version, date, and description of main changes
i. References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies.

Step 4: Review and finalization of SOP

4.1 The SOP Team submits their draft to the IRB Chair who initiates the finalization process by presenting the draft to the IRB during a board meeting for its review, with the assistance of the Office Manager and Staff.

4.2 The IRB Team approves the revised SOP.

Step 5: Submission of finalized SOP to the Hospital Administrator

5.1 The Chair submits through the Office Manager the final version of the revised SOP to the Hospital Administrator for final approval. The Hospital Administrator approves the revised SOP, she shall affix her signature in the appropriate section in the cover.

5.2 The Approved revised SOP will be implemented seven days from date of approval of the Hospital Administrator.

Step 6: Inclusion of Revised SOP in the SOP Manual and its dissemination

6.1 The Office Manager or Staff sends electronic copies of the approved SOPs to the IRB members upon approval by the Hospital Administrator.

6.2 The Office Manager and Staff maintains the original hard copy and electronic copy of the revised SOP. The newly revised SOP is made available in the IRB Website. The old version of the SOP is kept in the Administrative Inactive Files.

6. Forms

IRB SOP Template

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	*2015 Aug. 18*	*IRB SOP TEAM*	*First draft*
02	*2016 May 20*	*IRB SOP TEAM*	*Detailed procedures of the revision of the SOP*
03	*2016 Oct. 26*	*IRB SOP TEAM*	*Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.*
04	*2018 Dec. 07*	*IRB SOP TEAM*	*Edited the SPHI-IRB History, Changed IRB Forms Header. Selection and tenure of appointment of the Board.*

05	*2019 June 13*	*IRB SOP TEAM*	*Added in step 6 the Retrieval of Obsolete/Superseded SOPs.*
06	*2019 July 26*	*IRB SOP TEAM*	*Only IRB members and Staff cited in the Workflow.*
07	*2019 Dec. 30*	*IRB SOP TEAM*	*Harmonized Workflow and description of procedures. Delete step 3.2 in Protocol 4.1. Revised sequencing of SOPs on Post- Approval Reviews.*
08	*2020 Oct. 20*	*IRB SOP TEAM*	*Separate Management of Appeals. Added definition and responsibilities of IRB Office Manager. Edited Approval Letter, Resubmission form and Informed Consent. Corrected numbering of steps in the description of procedures. Added in the SOP 1.2 the responsibilities of IRB chair, co-chair and Member secretary. Edited SOP forms. Added Management of Application for Continuing Review. Edited IRB forms.*
09	*2022 June 28*	*IRB SOP TEAM*	*Edited SPH-IRB History. Edited IRB Checklist for Initial Submission. Added 1.4 in the description of procedures in step 1. Added gender representation in step 4, 4.1.*
10	*2024 Feb. 22*	*IRB SOP TEAM*	*Revised scope and added timeline in calendar days in the workflow.*
11	*2025 June 5*	*Sr. Gertrude Carys Kuebler, SPC, and Ms. Queenie Crisostomo*	*Revised SOP 33 on Writing and Revising SOP.*

8. References

A Workbook for Developing Standard Operating Procedures" 2020 by Philippine Health Research Ethics Board; National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

APPOINTMENT LETTER FOR IRB REGULAR MEMBERS (Form 1.0)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as a **REGULAR IRB MEMBER OF THE INSTITUTIONAL REVIEW BOARD** for a period of ___ years from _____– _____.

The following are your responsibilities as an ***IRB Member:***

a. Attend IRB meetings consistently.
b. Participate in the ethical review of research proposals and other related reports.
c. Reviews, discusses and considers research proposals submitted for evaluation
d. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate and the after-review activities, e.g., continuing review, progress report, site visit, etc.
e. Maintains confidentiality of the documents and deliberations of the IRB meetings
f. Declares any conflict of interest in the review of research proposals.
g. Participates in continuing education activities in health research and ethics education
h. Performs other duties designated by the Chair
i. Leads the prayer during the meeting
j. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB ALTERNATE MEMBER (Form 1.1)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as an **ALTERNATE MEMBER OF THE INSTITUTIONAL REVIEW BOARD** for a period of ____ years from _____– _____.

The following are your responsibilities as an ***Alternate Member of the IRB:***

a. Attend IRB meetings if Regular IRB member with the same expertise is absent.
b. Substitutes for a regular IRB member in the absence of regular member.
c. Receives, and reviews the same materials that the regular member receives.
d. Evaluate all research final reports and outcomes
e. Maintains confidentiality of the documents and deliberations during IRB meetings
f. Declares any conflict of interest
g. Participates in continuing education activities in health research and ethics
h. Performs other duties designated by the Chair
i. Leads prayer during the meeting
j. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.
k. Alternate member is included in the quorum and participates in making the decision.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of **SAINT PAUL'S HOSPITAL ILOILO**, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB NON-SCIENTIFIC MEMBER (Form 1.2)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as an **IRB NON-SCIENTIFIC MEMBER OF THE INSTITUTIONAL REVIEW BOARD** for a period of _____ years from _____– _____.

The following are your responsibilities as a ***NON-SCIENTIFIC MEMBER:***

a. Attend IRB meetings consistently.
b. Reviews, presents, discusses the Informed Consent Form of the protocol assigned by the
c. Chair and evaluates its conformity with the content of the protocol.
d. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate and the after-review activities, e.g., continuing review, progress report, site visit, etc.
e. Maintains confidentiality of the documents and deliberations during IRB meetings
f. Declares any conflict of interest
g. Participates in continuing education activities in health research and ethics
h. Performs other duties designated by the Chair
i. Leads prayer during the meeting
j. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR OFFICE MANAGER (Form 1.3)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as **IRB OFFICE MANAGER OF THE INSTITUTIONAL REVIEW BOARD** for a period of ____ years from _____– _____.

The following are the responsibilities as an ***IRB OFFICE MANAGER:***

a. Receives research proposals and documents for review and other important documents for IRB
b. Ensures completeness of Initial Submission package and creates a protocol specific file
c. Organizes an effective and efficient tracking procedure for each proposal received
d. Communicates with IRB officers and members
e. Entries preliminary information on the minutes of the meeting template and assists Member-
f. Secretary in documenting the proceedings of the regular meeting
g. Prepares minutes of special meeting
h. Transfers information from minutes or reports to IRB Communication forms (approval letters, notification
i. of IRB decision, request to the principal investigators and others.)
j. Organizes protocol file folders
k. Maintains confidentiality of the documents of the IRB and deliberations during IRB meetings.
l. Maintains the cleanliness and orderliness of the Office.
m. Requests supplies and materials for IRB.
n. Responsible for IRB accounts
o. Archives protocols with Final or Early Termination reports
p. Maintains good IRB documentation and archives.
q. Accountable for all documents and office files and secures all files under lock and key.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the

actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB CHAIR (Form 1.4)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as **IRB CHAIR OF THE INSTITUTIONAL REVIEW BOARD** for a period of ____ years from _____–_____.

The following are the responsibilities as an ***IRB Chair:***

a. Represent the IRB in internal and external meetings and conferences.
b. Presides over the IRB meetings and is accountable to the Hospital Administrator
c. Oversee review of protocols
d. Initially reviews all submitted protocols and other documents to decide which protocols may be expedited or full board review
e. Assigns primary reviewers for protocols and other documents from among IRB members
f. Reviews Protocol and protocol-related submissions (Protocols for Initial Review of Full Board, Resubmission, Amendments, Progress Reports, Final Reports, Protocol Deviations, Site Visits, etc.)
g. Invites independent consultants for the protocols for review that are not within the area of competence or expertise of the IRB members
h. Checks and signs provisional agenda, outgoing IRB communications such as approval letter, notification of IRB decision, requests, inquiries and others
i. Maintains confidentiality of the documents and deliberations during IRB meetings
j. Declares any conflict of interest
k. Participates in continuing education activities in health research and ethics
l. Acts on operations-related communications
m. Approves request for access and retrieval of documents
n. Prepares an annual report summarizing IRB activities and decision outcomes to the Hospital Administrator
o. Supervise development and revisions of SOPs.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB CO-CHAIR (Form 1.5)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as an **IRB CO-CHAIR OF THE INSTITUTIONAL REVIEW BOARD** for a period of ____ years from _____– _____.

The following are your responsibilities as an ***IRB Co-Chair:***

a. Presides over meetings in the absence of the Chair
b. Performs other duties designated by the Chair in the absence of the latter.
c. Participates in IRB meetings
d. Reviews, discusses and considers research proposals submitted for evaluation
e. Reviews protocols and protocol-related reports assigned by the Chair.
f. Maintains confidentiality of the documents and deliberations during IRB meetings
g. Declares any conflict of interest
h. Participates in continuing education activities in health research and ethics
i. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB MEMBER-SECRETARY (Form 1.6)

Date

Name of the Appointee
Profession/Expertise
Address

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has approved your appointment as **IRB MEMBER-SECRETARY OF THE INSTITUTIONAL REVIEW BOARD** for a period of ____ years from _____– _____.

The following are your responsibilities as an ***IRB Member-Secretary:***

a. Supervises the IRB Office Manager and Staff
b. Assist the Chair in assigning Primary Reviewers
c. Attends IRB meetings
d. Determines the presence of quorum during the meeting
e. Assesses SAE and SUSAR reports submitted to the IRB and Reports SAE/SUSARs during the IRB meeting and Recommends appropriate action
f. Oversees/assists the documentation by real time the conduct of the full board meeting
g. Oversees/assists the office Manager and staff in the preparation of the draft minutes of regular IRB meetings
h. Oversees the protection and maintenance of IRB documents and ensures filing and archiving procedures are followed
i. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate
j. Maintains confidentiality of the documents and deliberations during IRB meetings
k. Declares any conflict of interest
l. Participates in continuing education activities in health research and ethics education

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of SAINT PAUL'S HOSPITAL ILOILO, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Signature of Appointee Date

APPOINTMENT LETTER FOR IRB INDEPENDENT CONSULTANT (Form 1.7)

Date

Name of the Appointee
Department and Position
Institutional Affiliation

Dear _____:

Greetings!

We are pleased to inform you that the Administration of SAINT PAUL'S HOSPITAL ILOILO has appointed you as an **INDEPENDENT CONSULTANT OF THE INSTITUTIONAL REVIEW BOARD** for a period of ___ years from _____– _____ unless sooner revoked by the SPHI Administration.

As Independent Consultant, your responsibilities are as follows:

a. Attends IRB meeting when invited as Independent Consultant of a protocol.
b. Reviews the protocol and submits the Protocol Evaluation Report
c. Participates in the discussion of the protocol and clarifies technical issues during the full board meeting.
d. Declare any conflict of Interest (COI) in the review of research proposals.
e. Maintain confidentiality of the documents and deliberations of the IRB meetings.

We are confident that you will faithfully, dynamically, and cooperatively contribute for the continuous development of Institutional Review Board and the hospital. Further, we trust that you will continue to uphold the Corporate Values of **SAINT PAUL'S HOSPITAL ILOILO**, and fully support the programs and activities for the actualization of its Vision and Mission. Further, we hope that you will uphold and value Christian virtues and be a model worthy of emulation by our colleagues.

We look forward to a mutually fulfilling and meaningful relationship with you. Please indicate your acceptance of this appointment by signing in the space below.

God bless.

Very truly yours,

_____
Hospital Administrator

ACCEPTED:

_____ _____
Name and signature of Appointee Date

INSTITUTIONAL REVIEW BOARD

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST (FORM 1.8)

To the Undersigned: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the St. Paul's Hospital IRB. A copy will be given to you for your records.

I sign this document as _____ of the St. Paul's Hospital IRB 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 IRB, 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 IRB 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 days after notification.

_____ _____
Signature over printed Name Date

_____ _____
IRB Chair Date

INSTITUTIONAL REVIEW BOARD

CURRICULUM VITAE

(FORM 1.9)

Name:	Date of birth:	Gender: M F Civil Status: M S W
Address:	Contact No. EMAIL Address:	

IRB Appointment: (officer, regular or alternate member, non-affiliated, non-scientist/lay/non-medical)	Present Position:	Present term of appointment:
	Past IRB appointment:	Previous term of appointment:
Position in Institution: Academic: Administrative: (e.g. Dept. Chair, Med Specialist, Admin Officer, Clerk, etc)		Specialty:
Highest Educational Attainment :	Graduate degree:	Name of Institution & Year/s attended:
	Undergraduate degree:	
Postgraduate Training :		Name of Institution & Year/s attended:
Present Work:		Name of Institution or Company & Date

Past Work Experience:		Name of Company Date
Research Ethics Trainings		Training Agency Date
Research Experience		Publication Date

DATE OF APPOINTMENT:	
TERM OF OFFICE:	
CURRENT WORK:	

Name and Signature Date:

IRB Seminar, Training and Workshop Monitoring Sheet Year____ (Form 1.10)

	Name	Role in the IRB	Expertise	GCP Training Venue Date	Basic Research Ethics Training Venue Date	Continuing advanced Training Venue Date	SOP Training Venue Date	Training for Office Manager and Staff on research ethics office procedures (e.g. filing, management of database, etc.)	Quality review of protocols including Risk/Benefit Assessment, Vulnerability issues in Research, and review of ICF	Post approval review	Other relevant seminar/training/workshop Venue Date	Remarks
1												
2												
3												
4												
5												
6												
7												

INSTITUTIONAL REVIEW BOARD

IRB CHECKLIST FOR INITIAL SUBMISSION (FORM 2.0)

Protocol package for Clinical trial and/or Sponsor-initiated studies:

- ☐ Letter of Application & Complete Protocol
- ☐ Protocol Summary
- ☐ Investigator's Brochure (for Clinical Trials)
- ☐ Data collection form/s
- ☐ Informed Consent Forms (English, Tagalog, and local dialect (Hiligaynon))
- ☐ CV (for clinical trials- Principal Investigator and his/her co-investigators), (for Researcher Initiated protocol-Researcher and Adviser).
- ☐ GCP Certificate of the Principal Investigator (PI) and his/her co-investigators
- ☐ Declaration of No Conflict of Interest for Principal Investigators/Researchers (Form 2.2)
- ☐ Valid PRC License
- ☐ COI Declaration and Confidentiality Agreement
- ☐ GANTT Chart (as necessary)
- ☐ Advertisement, Diary card and other related documents (for Clinical Trials)
- ☐ Case report form/s, trial Materials (for Clinical Trials)
- ☐ Certificate of Technical Review (for Researcher Initiated protocol)
- ☐ Insurance Certificate (for Clinical Trials)
- ☐ Technical review approval/endorsement of the Department
- ☐ Decision of Ethics Review if reviewed by other Research Ethics Committee/s
- ☐ Material Transfer Agreement (for Clinical Trials if applicable)
- ☐ Budget
- ☐ Clinical Trial Agreement- Draft is acceptable (for Clinical Trials)
- ☐ Letter of Approval from Hospital Administrator and Data Protection Officer
- ☐ Waiver of Informed Consent Form (if applicable)

**** Note: Three (3) hard copies of this protocol package should be submitted to the IRB and electronic copy through sphirbresearch@gmail.com***

- ***For submissions you may submit your application at SPH-IRB office located at 4th Floor Cancer Center Building and look for Sr. Gertrude Caryls Kuebler, SPC or Ms. Queenie Crisostomo. You may contact us also through our telephone number 337-2742 local 7306.***

Application for Ethics Review of a New Protocol * (Form 2.1)

Instructions to the PI/Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked below (in Section 3. Checklist of Documents).

<table>
<tr><th colspan="4">1. General Information</th></tr>
<tr><td>*Title of Study</td><td colspan="3"></td></tr>
<tr><td>*IRB Code
(To be provided by IRB)</td><td></td><td>*Study Site</td><td></td></tr>
<tr><td>*Name of PI/Researcher)</td><td></td><td rowspan="4">Contact Information</td><td>*Tel No:</td></tr>
<tr><td>*Co-researcher (if any)</td><td></td><td>*Mobile No:</td></tr>
<tr><td>*Institution</td><td colspan="2"></td><td>*Fax No:</td></tr>
<tr><td>*Address of Institution</td><td colspan="2"></td><td>*Email:</td></tr>
<tr><td rowspan="2">*Type of Study</td><td colspan="3">☐ Clinical Trial (Sponsored)
☐ Clinical Trials (Researcher-initiated)
☐ Health Operations Research (Health Programs and Policies)
☐ Social / Behavioral Research
☐ Public Health / Epidemiologic Research
☐ Others
☐ Biomedical research (Retrospective, Prospective and diagnostic studies)
☐ Stem Cell Research
☐ Genetic Research
☐ Others _____
_____</td></tr>
<tr><td colspan="3">☐ Multicenter (International)
☐ Multicenter (National)
☐ Single Site</td></tr>
</table>

*Source of Funding	☐ Self-funded ☐Government-Funded ☐ Scholarship/Research Grant ☐ Others _____		☐ Sponsored by a Pharmaceutical Company Specify: _____ ☐ Institution-Funded	
*Duration of the study	Start date:		No. of study participants:	
	End date:			
*Has the Research undergone Technical Review?		☐ Yes (please attach technical review results) ☐ No		
*Has the Research been submitted to another IRB?		☐ Yes ☐ No		

2. Brief Description of the study

3. Checklist of Documents

Basic requirements:

☐ Letter request for review

☐ Endorsement/Referral Letter

☐ Full proposal / study protocol

☐ Technical Review Approval

☐ Curriculum Vitae of PI/Researcher/s

Supplementary Documents:

☐ Questionnaire (if applicable)

☐ Data Collection Forms (if applicable)

☐ Product Brochure (if applicable)

☐ Philippine FDA Marketing Authorization or Import License (if applicable)

☐ Permit/s for special populations (please specify)

*Adapted from PHREB Workbook, 2020

ST. PAUL'S HOSPITAL OF ILOILO, INC.
General Luna Street, Iloilo City 5000 Philippines
Tel. Nos. (033) 337 2741-49 Fax. No. (033) 338 0676
www.sphi.com.ph sphiloilo@gmail.com

☐ Informed Consent Form	_____
☐ English version ☐ Filipino version	_____
☐ Hiligaynon version	☐ Others (please specify)
☐Assent Form (if applicable)	_____
☐ English version ☐ Filipino version	_____
☐ Hiligaynon	

Accomplish

_____

Signature

Date submitted _____

---------- To be filled by the IRB Staff ----------

Completeness of Document	☐ **Complete** ☐ **Incomplete**	
Remarks		
Date Received:		
Received by:		

*Adapted from PHREB Workbook, 2020

INSTITUTIONAL REVIEW BOARD

DECLARATION OF NO CONFLICT OF INTEREST OF INVESTIGATORS/RESEARCHERS (FORM 2.2)

To the Undersigned: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the St. Paul's Hospital of Iloilo Institutional Review Board (SPHI-IRB). A copy will be given to you for your records.

Principal Investigator:	
IRB Protocol Code:	
Protocol Title:	
Protocol No.	

In the course of my activities as Principal Investigator of the *St. Paul's Hospital of Iloilo*, I hereby declare that I nor any of my research team member has No Conflict of Interest. I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including notes I have made as part of my investigator's duties) to the IRB upon termination of my functions as a Principal Investigator/Researcher in this Institution.

Whenever I have a conflict of interest, I shall immediately inform the Institutional Review Board.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

Name _____ _____

Principal Investigator Date

Name _____ _____

IRB Chair Date

APPLICATION TO WAIVE WRITTEN AND VERBAL INFORMED CONSENT FORM (Form 2.3)

IRB Protocol Code:		Date:	
Protocol Title:		Sponsor:	
Principal Investigator:		Contact no./ Email:	

I am requesting a waiver of written and verbal informed consent. I believe that this protocol is eligible for waiver or alteration of all required elements of informed consent because the protocol meets all of the following criteria:	
Criteria	Reviewer's Comments
1. The risk to the subject's privacy is minimal.	
The investigator of this study will use the minimum amount of protected health information necessary to conduct the research.	
This study will only need charts of eligible subjects. There will be no sensitive information (e.g. illegal drug use, sexual practices) to be collected.	
There is an assurance written below that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.	
2. This research cannot practicably be conducted without the use of the protected information.	
3. This research cannot practicably be conducted without the waiver.	
a. The number of research subjects proposed.	
b. Difficulty of obtaining individual authorization and time since last contact with the research subjects.	

RESEARCH ASSURANCES:

As a principal investigator of the research described above, I make the following assurance to the Institutional Ethics Review Board regarding the use and disclosure of protected health information.

"The investigators and research staff who used the disclosed protected health information in connection with this research will not reuse the protected health information or disclose to any other person or entity other than those authorized to receive it, except:

1. As required by law,
2. For authorized oversight of the research study, or
3. For other research which the use or disclosure of protected health information would be permitted by the Privacy Rule"

_____ _____

Principal Investigator /Researcher Date

Summary of Recommendation:

Decision:

( ) Approved
( ) Need additional information
( ) Disapproved

CERTIFICATE OF EXEMPT FROM REVIEW (Form 3.0)

This is to certify that the following protocol and related documents have been reviewed and is hereby granted EXEMPTION FROM REVIEW by the St. Paul's Hospital of Iloilo– Institutional Review Board (SPHI-IRB) for implementation.

IRB Protocol Code: _____ Date: _____

Protocol Title: _____

Principal Investigator: _____

Sub- Investigators: _____

Sponsor: _____

Protocol Version No. _____ Version Date _____

ICF Version No. _____ Version Date _____

Other Documents: _____

Investigator/Researcher Responsibilities after given the Exempt from Review:

Submit an Amendment Report if there is a change in the protocol for evaluation.
Implementation of the change/s should not be done without the approval of the IRB.
Submit a final report at the end of the study.

_____
Chairman
Institutional Review Board

Endorsed By:	Received By:
_____	_____
Signature over Name	Signature over Name
_____	_____
Date:	Date:

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IRB PROTOCOL EVALUATION FORM* (Form 3.1)

IRB Protocol Code: | Date (D/M/Y):

Protocol Title: | Sponsor:

Date of Submission:

Principal Investigator: | Contact no./ Email

Adviser: | Contact no./ Email

Study Coordinator/s: | Contact no./ Email

Type of Study:

( ) Intervention ( ) Epidemiology ( ) Observational study
( ) Document review ( ) Individual based ( ) Genetic
( ) Social Survey ( ) Others, specify

Review Status:

( ) Full Board
( ) Expedited

Description of the Study in brief: Mark whatever applies:

( ) Double blind ( ) Multicenter study ( ) Single blind ( ) Open label
( ) Sponsor Initiated ( ) Global protocol ( ) Investigator Initiated ( ) Vaccine ( ) Diagnostics
( ) Observational ( ) Questionnaire ( ) Use of Genetic Materials ( ) Medical Device

	To be filled out by the Primary Reviewer				
ASSESSMENT POINTS				**REVIEWER'S FINDINGS/COMMENTS**	**REVIEWER'S RECOMMEND-ATIONS**
1. SOCIAL VALUE					
1.1 Review of relevance of the study to an existing social or health problem such that the results are expected to bring about a better understanding of related issues, or contribute to the promotion of well-being of individuals, their families and communities. *(NEGRIHP 2022 page 15)*	☐ Clear	☐ Unclear			
2. SCIENTIFIC DESIGN					
2.1 Objectives Are the objectives attainable, S.M.A.R.T.?	☐ Clear	☐ Unclear			
2.2 Literature review Does review of literature of describe previous studies in the Philippines/foreign countries show gaps in knowledge regarding the topic. *NEGRIHP 2022 page 46)*	☐ Complete	☐ Incomplete			
2.3 Research design Can the objective be attained using the research design? *(NEGRIHP 2022 page 108)*	☐ Clear	☐ Unclear			
2.4 Sampling design Is the sampling technique as describe in the research design appropriate? *(ICH GCP 6.9.1)*	☐ Clear	☐ Unclear			
2.5 Sample size and site recruitment or accrual ceiling Review of justification of sample size. *(ICH GCP 6.9.2)*	☐ Clear	☐ Unclear			
2.6 Procedures for recruitment Statement on who, when and how the recruitment process is done. If you are the caregiver of the participants, how are you going to recruit?	☐ Clear	☐ Unclear			
2.7 Process of securing Informed Consent	☐ Clear	☐ Unclear			

Statement on who, when and how to secure the IC process. If you are the caregiver of the participants, how are you going to secure the IC?					
2.8 Data analysis plan Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized. *(NEGRIHP 2022 page 46)*	☐ Clear	☐ Unclear			
2.9 Inclusion criteria Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection. *(NEGRIHP 2022 page 46)*	☐ Clear	☐ Unclear			
2.10 Exclusion criteria Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion. *(NEGRIHP 2022 page 46)*	☐ Clear	☐ Unclear			
2.11 Withdrawal criteria Review of the withdrawal criteria whether it is precise both for scientific merit and safety concerns. *(NEGRIHP 2022 page 108)*	☐ Clear	☐ Unclear			
3. CONDUCT OF STUDY					
3.1 Data collection plan Review of appropriateness of data collection tool, (e.g chart review, survey, CRF) including description of personal data to be collected. *(NEGRIHP 2022 page 46)*	☐ Clear	☐ Unclear			
3.2 Specimen handling Review of specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and	☐ Clear	☐ Unclear			

destruction for biobanked samples. *(NEGRIHP 2022 page 231)*					
3.3 PI qualifications Review of CV and relevant certifications to ascertain capability to manage study methods and study related risks. *(NEGRIHP page 32)*	☐ Qualified	☐Unqualified			
3.4 Suitability of site Review of adequacy of qualified staff and infrastructures. *(NEGRIHP 2022 page 51)*	☐ Suitable	☐ Not Suitable			
3.5 Duration of participant involvement Review of length/extent of human participant involvement in the study. *(NEGRIHP 2022 page 108)*	☐ Clear	☐ Unclear			
4. ETHICAL CONSIDERATIONS					
4.1 Transparency and Conflict of interest Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site. *(NEGRIHP page 51)*	☐ Clear	☐ Unclear			
4.2 Privacy, confidentiality, and data protection plan Review of measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research	☐ Clear	☐ Unclear			

assistants, transcribers, or translators) *(NEGRIHP 2022)*; Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use. *(NEGRIHP 2022 page 50 Data Privacy Act of 2012)*					
4.3 Informed consent process Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances. *(NEGRIHP 2022 page 46)*	☐ Clear	☐ Unclear	☐ N/A		
4.4 Waiver of informed consent Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risk to participants, collection of data, and mechanisms to ensure confidentiality and anonymity. *(NEGRIHP 2022 page 134)*	☐ Clear	☐ Unclear	☐ N/A		
4.5 Justification for the involvement of vulnerable groups Review of involvement of vulnerable study populations and impact on informed consent. Vulnerable groups include the minors, elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or	☐ No	☐ Yes	☐ N/A		

junior members of a hierarchical group. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants. *(NEGRIHP 2022 page 23)*					
4.6 Assent for elderly For adults who are not competent to consent (for example, elderly or adults with conditions that prevent appropriate consent), review feasibility of obtaining assent vis à vis incompetence to consent. *(NEGRIHP 2022 page 47)*	☐ No	☐ Yes	☐ N/A		
4.7 Assent for minors Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children: •< 7 y/o- No need for assent •7 to < 12 y/o- Verbal Assent •12 to <15 y/o: Simplified written assent •15 to < 18 y/o- the minor can co-sign the consent signed by the parents. (NEGRIHP 2022 page 141)	☐ No	☐ Yes	☐ N/A		
4.8 Recruitment Review of manner of recruitment including appropriateness of identified recruiting parties. *(NEGRIHP 2022 page 31)*	☐ Clear	☐ Unclear	☐ N/A		
4.9 Risks Review of level of risk and measures to mitigate these risks (including physical, psychological, social, economic), including plans for adverse event management; Review of justification for allowable	☐ Clear	☐ Unclear			

use of placebo as detailed in the Declaration of Helsinki (as applicable); Review of course of action in case of breach of data (as applicable). *(NEGRIHP 2022 page 46; page 50)*					
4.10 Are the provisions for the mitigation of risks in the ICF consistent with what is in the protocol?	☐Consistent	☐Inconsistent			
4.11 Benefits Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant. *(NEGRIHP 2022 page 46; page 50)*	☐ Clear	☐ Unclear			
4.12 Safety monitoring plan Review of appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants. *(NEGRIHP 2022 page 50)*	☐ Clear	☐ Unclear			
4.13 Post-trial access Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable. *(NEGRIHP 2022 page 71)*	☐ No	☐ Yes	☐ N/A		
4.14 Incentives, compensation or Reimbursement Review of amount and method of compensations, financial incentives, or reimbursement of study-	☐ No	☐ Yes	☐ N/A		

related expenses. *(NEGRIHP 2022 page 26)*					
4.15 Compensation for study-related injuries Review of amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials. *(NEGRIHP 2022 page 26, page 196)*	☐ No	☐ Yes	☐ N/A		
4.16 Community considerations Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study. *(NEGRIHP 2022 page 51)*	☐ No	☐ Yes	☐ N/A		
4.17 Collaborative study terms of reference Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building. *(NEGRIHP 2022 page 47)*	☐ No	☐ Yes	☐ N/A		
4.18 Dissemination / data sharing plan/ statement Review of appropriateness and the practicability of the dissemination plan, as well as the suitability of the recipient(s) of the information to achieving social value. *(NEGRIHP 2022 page 15)*	☐ Clear	☐ Unclear			

4.19 Other issues Review of issues not addressed by item 1-4.18					

SUMMARY OF FINDINGS:

SUMMARY OF RECOMMENDATIONS:

DECISION:

☐ Approved ☐ Major Revisions ☐ Minor Revision ☐ Disapproved

_____

Name and Signature of Primary Reviewer

_____

Date

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www.sphi.com.ph sphiloilo@gmail.com

INFORMED CONSENT EVALUATION FORM* (Form 3.2)

IRB Protocol Code: _____ Date (D/M/Y): _____

Protocol Title: _____ Type of Review: ( ) Full Board ( ) Expedited

Principal Investigator: _____ Sponsor: _____

Date of Submission: _____

A. INFORMED CONSENT DOCUMENT REVIEW

	To be filled out by the Primary Reviewer				
Essential Elements (as applicable to the study)	**Indicate if the ICF has the specified element**			**REVIEWER'S FINDINGS/COMMENTS**	**REVIEWER'S RECOMMEND-ATIONS**
1. Statement that the study involves research. *(ICH GCP 4.8.10.a)*	☐ Yes	☐ No	☐ N/A		
2. Statement describing the purpose of the study. (ICH GCP 4.8.10.b)	☐ Clear	☐ Unclear			
3. Study-related treatments and probability for random assignment. *(ICH GCP 4.8.10.c)*	☐ Clear	☐ Unclear			
4. Procedures for recruitment Statement on who, when and how the recruitment process is done.	☐ Clear	☐ Unclear			

5. Process of securing Informed consent Statement on who, when and how to secure the IC process.	□ Clear	□ Unclear			
6. Study procedures including all invasive procedures. *(ICH GCP 4.8.10.d)*	□ Clear	□ Unclear			
7. Responsibilities of the participant. *(ICH GCP 4.8.10.e)*	□ Clear	□ Unclear			
8. Expected duration of participation in the study. *(ICH GCP 4.8.10.s)*	□ Clear	□ Unclear			
9. Approximate number of participants in the study. *(ICH GCP 4.8.10.t)*	□ Clear	□ Unclear			
10. Study aspects that are experimental. *(ICH GCP 4.8.10.f)*	□ Yes	□ No			
11. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure. *(ICH GCP 4.8.10.g)*	□ Clear	□ Unclear			
12. Risks from allowable use of placebo (as applicable). *(NEGRIHP 2022 page 108)*	□ Clear	□ Unclear			
13. Are the provisions for the mitigation of risks in the protocol consistent with what is in the ICF?	□ Yes	□ No			
14. Reasonably expected benefits; or absence of direct benefit to participants, as applicable. *(ICH GCP 4.8.10.h)*	□ Clear	□ Unclear			
15. Expected benefits to the community or to society, or contributions to scientific knowledge. *(NEGRIHP 2022 page 135)*	□ Clear	□ Unclear			

16. Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable. *(NEGRIHP 2022 page 71)*	☐ Yes	☐ No	☐ N/A		
17. Alternative procedures or treatment available to participant. *(NEGRIHP 2022 page 225)*	☐ Yes	☐ No			
18. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount. *(NEGRIHP 2022 page 71)*	☐ Clear	☐ Unclear			
19. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries. *(ICH GCP 4.8.10.j)*	☐ Yes	☐ No			
20. Anticipated expenses, if any, to the participant in the course of the study. *(ICH GCP 4.8.10.l)*	☐ Clear	☐ Unclear			
21. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled. *(ICH GCP 4.8.10.m)*	☐ Clear	☐ Unclear			
22. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study, as applicable. *(NEGRIHP 2022 page 138)*	☐ Clear	☐ Unclear	☐ N/A		
23. Statement that the study monitor(s), auditor(s), the SPHI-IRB Ethics Review Panel, and regulatory authorities will	☐ Yes	☐ No	☐ N/A		

be granted direct access to participant's medical records for purposes ONLY of verification of clinical trial procedures and data. *(ICH GCP 4.8.10.n)*					
24. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality. *(ICH GCP 4.8.10.o)*	☐ Yes	☐ No	☐ N/A		
25. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage). *(NEGRIHP 2022 page 26)*	☐ Clear	☐ Unclear			
26. Description of policy regarding the use of genetic tests and familial genetic information, as applicable, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant. *(NEGRIHP 2022 page 198-204)*	☐ Clear	☐ Unclear	☐ N/A		
27. Possible direct or secondary use of participant's personal data, medical records and biological specimens taken in the course of clinical care or in the course of this study, as applicable. *(NEGRIHP 2022 page 19)*	☐ Yes	☐ No	☐ N/A		

28. Plans to destroy collected personal data, medical records, and biological specimen at the end of the specified storage period, as applicable; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed. *(NEGRIHP 2022 page 19)*	☐ Yes	☐ No			
29. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development. *(NEGRIHP 2022 page 19)*	☐ Yes	☐ No	☐ N/A		
30. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation. *(ICH GCP 4.8.10.p)*	☐ Yes	☐ No			
31. Foreseeable circumstances and reasons under which participation in the study may be terminated *(ICH GCP 4.8.10.r)*	☐ Yes	☐ No			
32. Sponsor, institutional affiliation of the investigator/researcher, and nature and sources of funds. *(NEGRIHP 2022 page 19)*	☐ Yes	☐ No			
33. Statement whether the investigator/researcher is	☐ Yes	☐ No	☐ N/A		

serving only as an investigator or as both investigator and the participant's healthcare provider. *(NEGRIHP 2022)*					
34. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury. *(ICH GCP 4.8.10.q)*	☐ Yes	☐ No			
35. Comprehensibility of language used. *(NEGHHR 2022)*	☐ Yes	☐ No			
36. Statement that the SPHI-IRB Ethics Review Panel (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: Name of SPHI-IRB Chair Address: 4th Floor, Cancer Center Building, St. Paul's Hospital of Iloilo, Inc. Genral Luna St., Iloilo City Email: sphirbresearch@gmail.com Tel: 337-2742-29 local 7306 *(NEGRIHP 2022)*	☐ Yes	☐ No			
37. Other comments not addressed by items 1-36.					

B. DECISION:

☐ Approval ☐ Minor Revision

☐ Major Revisions ☐ Disapproval

_____

Name and Signature of Primary Reviewer

_____

Date

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www.sphi.com.ph sphiloilo@gmail.com

IRB PROTOCOL RESUBMISSION FORM (Form 3.3)

IRB Protocol Code: _____ Date (D/M/Y): _____

Protocol Title: _____ Sponsor: _____

Type of Revision: ( ) Full Review ( ) Expedited

Principal Investigator: _____ Sub- Investigator: _____

Date of Submission: _____ ( ) 2nd Review ( ) 3rd Review

Documents to be revised: ( ) Protocol ( ) Data Collection Forms ( ) Others:_____
( ) ICF ( ) Advertisement

IRB Recommendations from last review	Response of Researcher Section and page of Protocol	Comment of Primary Reviewer (To be accomplished by Reviewer)

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY PRIMARY REVIEWER

Were all the recommendations from last review addressed?

☐ YES
☐ NO (explain/ comments)

DECISION: ☐ Approval ☐ Major Revisions ☐ Minor Revisions ☐ Disapproval

Name and Signature of Primary Reviewer:

Date:

CHECKLIST FOR EXEMPTION FORM* (Form 3.4)

IRB Protocol Code: _____ Date (D/M/

Protocol Title: _____ Sponsor: _____

Principal Investigators: _____

A. CRITERIA FOR EXEMPTION REVIEW

CRITERIA FOR EXEMPTION	To be filled out by the IRB Chair/Member-Secretary		
	Indicate if the Criteria for Exemption applies to the study protocol		REVIEWER COMMENTS
PROTOCOL ASSESSMENT	**YES**	**NO**	
1. Does this research involve human participants			
2. Does this research involve use of non-identifiable human tissue/biological samples?			
3. Does this research involve the use of non-identifiable publicly available data? **Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGRIHP 2022)*			
4. Does this research involve interaction with human participants?			
5. Type of research • Institutional quality assurance • Evaluation of public service program • Public health surveillance • Educational evaluation activities • Consumer acceptability test **These 5 have been identified in the NEGRIHP as exemptible, as long as they do not involve more than minimal risk.*			

6. What is/are the method/s of data collection (please tick appropriate item) • Surveys and/or questionnaire, interviews, or observations of public behavior • Audio/video recordings of public behavior • Research which only uses existing data **These have been identified in the NEGRIHP as exemptible, as long anonymity and/or confidentiality is maintained.*			
7. Will the collected data be anonymized or de-identified?			
8. Is there a data protection plan? *Measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans and the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. Providing adequate instructions to research assistants, transcribers, or translators)(NEGRIHP 2022); Plan on processing personal data, storage of data, access, disposal, and terms of use (Data Privacy Act of 2012)*			
9. Does this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHHR 2022) **Please refer to Section 2. Risk Assessment, prior to answering this item.* **If YES, then this protocol does not qualify for exemption.*			
RISK ASSESSMENT	**YES**	**NO**	
10. Does this research involve the following *(please select all that apply):* • Any vulnerable groups?			
• Sensitive topics that may make participants feel uncomfortable (*i.e., sexual behavior, illegal activities, racial biases, etc.)*			
• Use of drugs			
• Invasive procedure (e.g., blood sampling) and specify			
• Physical stress/distress, discomfort			
• Psychological/mental stress/distress			
• Deception of/or withholding information from subjects			
• Access to data by individuals or organizations other than the investigators			
• Conflict of interest issues			

• Any other ethical dilemmas			
• Is there any blood sampling involved in the study?			

B. Recommendations

Decision: ☐ QUALIFIED FOR EXEMPTION ☐ NOT QUALIFIED FOR EXEMPTION

Comments
(Identify ite
For revision

Summary of Recommendations:

1.

2.

3.

4

5.

_____

Name & Signature of IRB Chair:

Date:

REVIEW OF PUBLIC HEALTH PROTOCOL* (Form 3.5)

IRB Protocol Code:		Date (D/M/	
Protocol Title:		Sponsor:	
Principal Investigator:		Primary Reviewe	

A. REVIEW ON PUBLIC HEALTH PROTOCOL

	To be filled out by the Researcher	To be filled out by the IRB Primary Reviewer
Indicate if the questions applies to the study protocol		**REVIEWER COMMENTS**
11. Is it research?		
12. Which aspects are research?		
13. Is research ethics committee review required?		
14. Are there adequate plans to manage any conflicts of interest?		
15. What is the study intervention?		
16. What are the procedures for data collection?		
17. Who are the research participants?		
18. From whom is informed consent required, or is a waiver of consent appropriate?		

*Adapted from Ethical considerations for health policy and systems research of WHO, 2019

19. Is permission from a "gatekeeper" required?		
20. Is group or community engagement required?		
21. Are there adequate plans for protection of privacy and confidentiality?		
22. Are the potential benefits and risks of the study acceptable?		
23. Are concerns about justice and equity adequately addressed?		
24. What are relevant and are there satisfactory plans for access to interventions after the study, and roll-out of successful interventions on a wider scale?		
25. References.		

Comments (Identify items For revisions)

Summary of Recommendations:

1.

2.

3.

4

5.

Decision: ☐ Approved ☐ Minor Modification ☐ Major Modification ☐ Disapproved

Acknowledged by:

_____

Name and Signature of Primary Reviewer

_____

Date

*Adapted from Ethical considerations for health policy and systems research of WHO, 2019

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www.sphi.com.ph sphiloilo@gmail.com

PROTOCOL AMENDMENT FORM (FORM 4.0)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Primary Reviewers:	

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

Please check (√) each of the boxes that pertains to your amendment request.

1. PROTOCOL AMENDMENT

- ☐ Major
- ☐ Minor

2. METHODS OR PROCEDURES

- ☐ I am requesting changes to the research methodology previously approved by the IRB.

3. RISKS

- ☐ The changes that I am requesting may result in increased risks to some or all of my research subjects.

4. HUMAN SUBJECTS/SPECIMENS

- ☐ I am requesting changes to the number of human subjects/specimens that I am authorized to use in my research.

5. RECRUITMENT PROCEDURES

- ☐ I am requesting changes to the recruitment procedures that I am using.

6. CHANGES IN THE INFORMED CONSENT FORM/ASSENT PROCEDURES OR FORM

☐ I am requesting changes to the informed consent form /assent procedures or form that have been approved for my research.

7. CONFIDENTIALITY

☐ I am requesting changes to the confidentiality of participation previously approved by the IRB.

8. CONFLICT OF INTEREST

☐ Events that have occurred which have changed the conflict of interest on the study personnel previously approved in the protocol.

9. STUDY PERSONNEL

☐ I am requesting the following personnel changes to my protocol.

Add	Delete	Name	Position

10. OTHER CHANGES

☐ I am requesting changes to research protocol that are not addressed above.

ORIGINAL	AMENDMENT	JUSTIFICATION	REVIEWER'S COMMENTS

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this application is complete, accurate and necessary. The changes will not be implemented until IRB approval has been obtained.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE PRIMARY REVIEWERS

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

- ☐ overall risk/benefit assessment
- ☐ impact on the safety & welfare of participants
- ☐ continuity of the study

Decision:

( ) Approved
( ) Additional justification/information required
( ) Reconsent required
( ) Disapproved

Acknowledged by:

_____
Name and Signature of Primary Reviewer

_____
Date

ST. PAUL'S HOSPITAL OF ILOILO, INC.
General Luna Street, Iloilo City 5000 Philippines
Tel. Nos. (033) 337 2741-49 Fax. No. (033) 338 0676
www.sphi.com.ph sphiloilo@gmail.com

PROGRESS REPORT FORM (FORM 4.1)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Primary Reviewers:	

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

Please check (√) each of the boxes that pertains to your report.

1. Recruitment History:
   - ____Accrual ceiling set by Sponsor
   - ____The total number recruited
   - ____Numbers screened
   - ____Screen Failure
   - ____Number of enrolled participants
   - ____Withdrawn
   - ____Active participants
   - ____Number of participants completed the study

2. Number of Amendments:

3. Number of Protocol Deviations/Violations from the approved protocol:

4. Number of on-site SAE's and SUSARs:

5. Any change in participant population, recruitment or selection criteria since the last review?
____Yes ____No
(Explain the changes)

6. Any change in the Informed consent process or documentation since the last review?
____Yes ____No
(Explain the changes)

7. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?
____Yes ____No
(Explain the changes)

8. Any new investigator that has been added to or removed from the study research since the last review?
____Yes ____No
(Pls. submit the name, CV and GCP Certificates of the new investigators.)

9. Are there other new sites that were added or deleted since the last review?
____Yes ____No
(Pls. identify the sites and note the addition or deletion.)

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____
Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____
Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Decision:

( ) Accepted
( ) Request further information
( ) Require specific action

Acknowledged by:

_____
Name and Signature of IRB MEMBER

_____
Date

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SAE/SUSARS (Form 4.2)

IRB Protocol Code: | Date Received (D/M/Y):

Protocol Title: | Sponsor:

Principal & Sub Investigators:

Type of AE: ☐ SAE ☐ SUSAR

Site of SAE:
☐ On-site
☐ Off site (International)
☐ Off site (National)

A: SUMMARY OF SIGNIFICANT DATA:

Name of the study medicine/medical device:	**Date Reported to Principal Investigator:** **Type of report:** ☐ Initial ☐ Follow-up ☐ Final	
Date of first use:	**Date of Event:**	
Patient's Initial/Number:	**Age:**	☐ Male ☐ Female
Patient's Date of Birth:	**Weight:** kg **Height:** cm	**SAE/SUSAR Severity:** ☐ Mild ☐ Moderate ☐ Severe
Relevant medical history and concurrent conditions:		

I. SAE CRITERIA:

Check all appropriate adverse event: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity	☐ Life threatening ☐ Congenital anomaly

II. SUSPECT DRUG/S INFORMATION:

Suspect drug/s (include generic name):		**Did reaction abate after stopping drug?** ☐ Yes ☐ No ☐ NA
Daily dose/s:	**Route/s of administration:**	**Did reaction appear after reintroduction?** ☐ Yes ☐ No ☐ NA
Indication/s for use:		
Therapy date/s: (from/to)	**Therapy duration:**	
Is this reaction ☐ Unexpected ☐ Expected ☐ Related ☐ Unrelated		
Treatment given for Adverse Event (Corrective and Preventive Action):		
Causality Assessment by Investigator (Using WHO-UMC Causality Assessment System) ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable		
Outcome of reaction/event at the time of last observation: ☐ Recovered ☐ Death ☐ Recovering with sequelae ☐ Unknown ☐ On-going		

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY MEMBER-SECRETARY & PRIMARY REVIEWERS

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Decision:

( ) Request an amendment to the protocol or the consent form.
( ) Request further information
( ) Recommend further Action (indicate action)
( ) Take Note and No Further Action needed
( ) Others: _____

Acknowledged by:

_____
Name and Signature of Member- Secretary

_____
Date

_____
Name and Signature of Primary Reviewer

_____
Name and Signature of Primary Reviewer

_____
Date

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www.sphi.com.ph sphiloilo@gmail.com

REPORTABLE NEGATIVE EVENT REPORT (Form 4.3)

IRB Protocol Code: _____ Date Received (D/M/Y): _____

Protocol Title: _____ Sponsor: _____

Principal & Sub Investigators: _____

A: TITLE OF REPORT: _____Date of Event: _____

B. SUMMARY OF SIGNIFICANT DATA:

☐ With Full Document Attachment ☐ With Partial Data Attachment

RNE Report	
Start of the Study:	Expected end of the study:
Number of enrolled participants:	Number of required participants:
Description of Negative (harm, risk) Events: a. Involving Participants b. Involving members of the Study Team c. Involving Data Safety and Integrity	Actions taken to prevent future RNEs, interventions and Outcomes

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____
Signature Over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____
Signature Over Printed Name Date

*Adapted from PHREB SOP 2020 RNE Report Form

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Final Action:

( ) Request an amendment to the protocol or the consent form.
( ) Request further information
( ) Recommend further Action (indicate action)
( ) Take Note and No Further Action needed
( ) Others: _____

Acknowledged by:

_____	_____	_____
Name of Primary Reviewer	**Signature**	**Date**

*Adapted from PHREB SOP 2020 RNE Report Form

PROTOCOL DEVIATION/VIOLATION FORM (Form 4.4)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Primary Reviewers:	

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

1. NATURE OF THE REPORT

☐ **Major** ☐ **Minor**

2. DETAILED DESCRIPTION OF REPORTED DEVIATION/VIOLATION AND EXPLANATION WHY IT HAPPENED

3. DEVIATIONS FROM THE APPROVED PROTOCOL

4. EXPLANATION FOR DEVIATION/VIOLATION

5. IMPACT OF DEVIATION/VIOLATION ON PARTICIPANTS' RISKS/HARMS AND INTEGRITY OF DATA

6. CORRECTIVE ACTIONS and PREVENTIVE ACTIONS

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Decision:

( ) Submission of additional information
( ) Submission of corrective/Preventive actions
( ) Invitation for a clarificatory interview with the Principal Investigator
( ) Site visit
( ) Suspension of recruitment
( ) Withdrawal of Ethical Clearance
( ) Suspension of the study
( ) Acknowledge with no further action

Acknowledged by:

_____
Name and Signature of IRB MEMBER

_____
Date

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www.sphi.com.ph sphiloilo@gmail.com

EARLY TERMINATION REPORT FORM (FORM 4.5)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Primary Reviewers:	

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

IRB Approved Date:		Date of Last Report	
Starting Date of Research:		Termination Date	
No. of Participants Enrolled			

Reason/s for Early Termination (Pls. use separate sheet to explain the reason/s for early termination.)

A. Justification

___ poor recruitment
___ high number of SUSARs
___ safety or benefit is doubtful or at risk
___ undue or significant SAEs
___ Conduct Breaches
___Others

B. Mechanism on care for and follow up of participants

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Reviewer's Recommendations:

Decision:

( ) Accept
( ) Request further additional information
( ) Request further additional action
( ) Others: _____

Acknowledged by:

_____

Name and Signature of IRB MEMBER

_____

Date

FINAL REPORT FORM (FORM 4.6)

IRB Protocol Code: | Date Received (D/M/Y):

Protocol Title: | Sponsor:

Principal & Sub Investigators: | Primary Reviewers:

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the following documents:

Basic requirements:

☐ Full proposal / study protocol
☐ Summary of Amendments and the dates
☐ Total number of SAE's on-site from the time of approval up to present
☐ Total number of SUSARs off-site from the time of approval up to present
☐ Number of Safety reporting and the dates
☐ Number of Protocol deviations submitted and the dates
☐ Number of progress reports and the dates
☐ Number of site visits and the dates

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

1. Total number of subjects who participated in the research

1. Target number of subjects approved _____
2. Number of subjects who were screened _____
3. Number of subjects who withdrawn/discontinued the research _____
4. Number of subjects who completed the study _____

2. Occurrence of Serious Adverse Events (SAEs) or unanticipated problems involving risks to subjects, withdrawal of subjects from the research, or complaints about the research

____If present, pls. explain ____None

3. Please provide a summary of your research findings to include a summary of recent literature or modifications to the research since the last IRB review (if not previously reported).

4. Date of permanent closure of the research_____

5. Dissemination plan on outcome/result of the Study.

- ☐ **Submission of paper for publication**
- ☐ **Presentation in institutional/national/international conferences**

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Decision:

( ) Accept
( ) Requires submission with corrections
( ) Others: _____

Acknowledged by:

_____

Name and Signature of IRB MEMBER

_____

Date

APPLICATION FOR CONTINUING REVIEW (FORM 4.7)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal & Sub Investigators:		Primary Reviewers:	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the following documents:

Basic requirements:

☐ Letter request for review
☐ Full proposal / study protocol
☐ Summary of Amendments and the dates
☐ Total number of SAE's on-site from the time of approval up to present
☐ Total number of SUSARs off-site from the time of approval up to present
☐ Number of Safety reporting and the dates
☐ Number of Protocol deviations/violations submitted and the dates
☐ Number of progress reports and the dates
☐ Number of site visits and the dates

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

Please filled up and check (√) each of the boxes that pertains to your report.

1. Start of the study _____ Expected end of study _____

2. Number of enrolled participants _____

   Number of required participants _____

3. Any change in participant population, recruitment or selection criteria since the last review?
____Yes ____No
(Explain the changes)

4. Any change in the Informed consent process or documentation since the last review?
____Yes ____No
(Explain the changes)

5. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?
____Yes ____No

6. Are there any unsuspected complications or side effects noted since the last review?
____Yes ____No

7. Did any participant withdraw from this study since the last approval?
____Yes ____No
(If Yes, state the number of participants who withdrew and give the reasons for withdrawal.)

8. Any new investigator that has been added to or removed from the study research since the last review?
____Yes ____No
(Pls. submit the name, CV and GCP certificate of the new investigators.)

9. Summary of protocol participants:
____ Accrual ceiling set by Sponsor
____ New participant accrued since last review
____ Total participant accrued since protocol began

10. Total participants excluded since protocol began
ACCRUAL EXCLUSION
_____None
_____Male
_____Female

11. Are there other new sites that were added or deleted since the last review?
____Yes ____No
(Pls. identify the sites and note the addition or deletion.)

12. Impaired Participants
_____None
_____Physically
_____Cognitively
_____Both

13. Deviations from the approved protocol

14. Issues/ problems encountered

15. Justification for application for Continuing Review

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

_____ _____

Signature over Printed Name of Principal Investigator Date

(IRB Use only) Received by:

_____ _____

Signature Over Printed Name Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited ☐ **Full Board** ☐

Summary of Recommendations:

Decision:

( ) Approved
( ) Request additional information
( ) Submission of an explanation for failure to submit required reports
( ) Disapproved

Acknowledged by:

_____
Name and Signature of IRB MEMBER

_____
Date

SITE VISIT REPORT FORM (4.8)

IRB Protocol Code: | Approval Date:

Protocol Title: | Study Site:

Principal Investigator: | Contact no. / Email:

Sponsor: | Sponsor Contact Person:

Institution:

Address of Institution:

Ethical clearance effectivity period:

1. Start of Study
2. Expected end of study
3. Number of enrolled participants
4. Number of required participants
5. Reason for Site Visit
6. Person/s present during visit
7. Findings
8. Recommendations
☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST FURTHER INFORMATION FROM THE PRINCIPAL INVESTIGATOR (specify) ☐ RECOMMEND FURTHER ACTION: (specify)

Site Visit TEAM:

1. –

2. –

3. –

Report submitted by:

Name and Signature:	Date:

QUERIES AND COMPLAINTS (FORM 4.8)

IRB Protocol Code:		Date Received (D/M/Y):	
Protocol Title:		Sponsor:	
Principal Investigator:		Contact Number/ Email Address	
Primary Reviewers:			
Source of Queries and Complaints:			

1. What are the Queries? What are the Complaints?

SECTION 2: TO BE FILLED UP BY PRIMARY REVIEWERS

Type of Review

Expedited ☐ **Full Board** ☐

Reviewer's Response and Recommendations:

Decision:

( ) Request for explanation/ justification from researcher
( ) Accept request/demand of participant
( ) Suspension of further recruitment
( ) Amendment of protocol and re-consent of participants
( ) Site Visit (SOP 22 Site Visit)
( ) Others (Designate the Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution if necessary).

Acknowledged by:

_____
Name and Signature of Primary Reviewers

_____
Date

_____
Name and Signature of IRB Chair

_____
Date

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www.sphi.com.ph sphiloilo@gmail.com

INSTITUTIONAL REVIEW BOARD

Notice of IRB Meeting SPH.IRB-00_- 20__
(Form 5.0)

Date

FROM: _____
Chair, IRB

TO: **ALL IRB MEMBERS**

RE: **IRB REGULAR MEETING**
Institutional Review Board Office
Date of the Meeting and Time

AGENDA:

1. **Opening Prayer**
2. **Call to Order**
3. **Determination of Quorum**
4. **Approval of the Agenda**
5. **Reading and Approval of the Minutes of the last meeting (Date)**
6. **Business Arising from the Minutes of the Previous Meeting**
7. **Disclosure of Conflict of Interest among Members**
8. **Protocol Review**
   - **8.1 New Protocols for Initial Review of Full Board**
     - **8.1.1**

IRB Protocol Code:			
SJREB Protocol Code:			
Sponsor Code:			
Protocol Title:			
Principal Investigator:			
Primary Reviewers:			
Name of Sponsor:			
Documents:			
Date of submission			
Specify elements of review (under Issue)	**elements of review**	**findings**	**recommendations**
i. Scientific review ii. Ethical Review iii. ICF Review			

8.2 Resubmission

8.2.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Date of initial submission:	
Date of initial review:	
Date of resubmission:	
Documents:	

8.3 Post-Approval Reports

8.3.1 Amendments

8.3.1.1

IRB Protocol Code:				
Sponsor Code:				
Protocol Title:				
Principal Investigator:				
Primary Reviewers:				
Name of Sponsor:				
Documents:	**ORIGINAL**	**AMENDMENT**	**JUSTIFICATION**	**REVIEWER'S COMMENTS**
Specify the amendment:				
Classification of amendment:				

8.3.2 Progress Reports

8.3.2.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Accrual History:	
SAE/SUSAR reports:	
Protocol Deviations/Violations:	
Amendments:	

8.3.3 SAE/SUSAR reports

8.3.3.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
indicate the elements of review i.e. type of SAE/SUSAR, indicate onsite, relatedness to intervention, outcome of SAE on the participant, how SAE was managed	

8.3.4 Review of Reports on Negative Events (RNE)

8.3.4.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

8.3.5 Protocol Deviations/Violations Reports

8.3.5.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

8.3.6 Early Termination Report

8.3.6.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	

Documents:	

8.3.7 Final Report

8.3.7.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Date of permanent closure of the study/research:	
Date when the final report was received:	
Documents:	

9. Application for Continuing Review

9.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

10. Site Visit

10.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

11. Queries and Complaints/Appeal

11.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

12. **Exempt from Review Protocols**

12.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

13. **Report of the Approved new protocols by Expedited Review**

13.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

14. **Report of the Approved post-approval reports by Expedited Review**

14.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

15. **Notifications**

15.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	

16. **Other Matters**
17. **Checking of Quorum**
18. **Adjournment**

THANK YOU VERY MUCH!

INSTITUTIONAL REVIEW BOARD

ATTENDANCE SHEET (FORM 5.1)

IRB MEETING

(DATE)

(TIME)

MEMBERS	AFFILIATION					SIGNATURE	DATE
	scientist		nonscientist/ non-medical	non-affiliated	affiliated		
	medical	Non-medical					
IRB STAFF							

INSTITUTIONAL REVIEW BOARD
Minutes of the Meeting SPH.IRB-00_- 20__
(Form 6.0)

Date

ATTENDANCE:

Name of IRB Members	Role	Expertise	Present	Absent
Name	Position, medical/scientist, affiliated/non-affiliated	specialty	√	

Name of Guest/IC	Role	Expertise	Present	Absent
Name	Position, medical/scientist, affiliated/non-affiliated	specialty	√	

PROCEEDINGS:

1. **Opening Prayer**
   _____ led the opening prayer.

2. **Call to Order**
   _____ called the meeting to order at ____.

3. **Determination of the Quorum**
   The Chair declares the presence of quorum with ____ out of ___members present inclusive of the non-scientist and non-affiliated.

4. **Approval of the Agenda**
   Upon the motion of _____ and seconded by_____ the provisional agenda is approved after votation by the IRB.

5. **Reading and Approval of the Minutes of the Previous Meeting**
   Upon the motion of _____ and seconded by_____ the provisional minutes of the previous meeting dated _____ is approved after votation by the IRB.

6. **Business Arising From the Minutes of the Meeting**

7. **Disclosure of Conflict of Interest among Members:**

8. **Protocol Review**

8.1 New Protocols for Initial Review of Full Board

8.1.1

IRB Protocol Code:			
SJREB Protocol Code:			
Sponsor Code:			
Protocol Title:			
Principal Investigator:			
Primary Reviewers:			
Name of Sponsor:			
Documents:			
Date of submission			
Specify elements of review (under Issue) i. Scientific review ii. Ethical Review iii. ICF Review	**elements of review**	**findings**	**recommendations**
Summary of Findings and recommendations			
Decision:	☐ Approved ☐ Major Revisions ☐ Minor Revisions ☐ Disapproved		
Documentation of voting			

8.2 Resubmission

8.2.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Date of initial submission:	
Date of initial review:	
Date of resubmission:	
Documents:	
Discussion:	
Decision:	☐Approved

	☐ Major Revisions ☐ Minor Revisions ☐ Disapproved

8.3 Post-Approval Reports

8.3.1 Amendments

8.3.1.1

IRB Protocol Code:				
Sponsor Code:				
Protocol Title:				
Principal Investigator:				
Primary Reviewers:				
Name of Sponsor:				
Documents:	**ORIGINAL**	**AMENDMENT**	**JUSTIFICATION**	**REVIEWER'S COMMENTS**
Specify the amendment:				
Classification of amendment:				
Discussion:				
Summary of Findings:				
Recommendation/s:				
Decision:	☐ Approved ☐ Additional justification/information required ☐ Reconsent required ☐ Disapproved			

8.3.2 Progress Reports

8.3.2.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Accrual History:	
SAE/SUSAR reports:	
Protocol Deviations/Violations:	
Amendments:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ Accepted ☐ Request Further Information ☐ Require Specific Action

8.3.3 SAE/SUSAR reports

8.3.3.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
indicate the elements of review i.e. type of SAE/SUSAR, indicate onsite, relatedness to intervention, outcome of SAE on the participant, how SAE was managed	
Corrective and Preventive Action:	
Discussion:	
Decision:	☐ Request an amendment to the protocol or the consent form. ☐ Request further information ☐ Recommend further Action (indicate action) ☐ Take Note and No Further Action needed ☐ Others: _____

8.3.4 Review of Reports on Negative Events (RNE)

8.3.4.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ recommend 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

8.3.5 Protocol Deviations/Violations Reports

8.3.5.1

IRB Protocol Code:	

Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Corrective/preventive action:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ Submission of additional information ☐ Submission of corrective/Preventive actions ☐ Invitation for a clarificatory interview with the PI ☐ Site visit ☐ Suspension of recruitment ☐ Withdrawal of Ethical Clearance ☐ Suspension of the study ☐ Acknowledge with no further action

8.3.6 Early Termination Report

8.3.6.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐acceptance of the decision with no further action; ☐request for additional information; or ☐requirement for further action

8.3.7 Final Report

8.3.7.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Date of permanent closure of the study/research:	
Date when the final report was received:	

Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ to accept, or ☐ to require submission with Corrections

9 Application for Continuing Review

9.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ Approved ☐ Request additional information ☐ Submission of an explanation for failure to submit required reports ☐ Disapproved

10 Site Visit

10.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐ Uphold original approval with no further action ☐ Request further information from the principal investigator (specify) ☐ Recommend further action: (specify)

11 Queries and Complaints/Appeal

11.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	

Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Summary of Findings:	
Recommendation/s:	
Decision:	☐Request for explanation/ justification from researcher ☐Accept request/demand of participant ☐Suspension of further recruitment ☐Amendment of protocol and re-consent of participants ☐Site Visit (SOP 22 Site Visit) ☐Others (Designate the Primary Reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution if necessary).

12 Exempt from Review Protocols

12.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Decision:	

13 Report of the Approved new protocols by Expedited Review

13.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Decision:	

14 Report of the Approved post-approval reports by Expedited Review

14.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	

Name of Sponsor:	
Documents:	
Discussion:	
Decision:	

15 Notifications

15.1

IRB Protocol Code:	
Sponsor Code:	
Protocol Title:	
Principal Investigator:	
Primary Reviewers:	
Name of Sponsor:	
Documents:	
Discussion:	
Recommendation/s:	
Decision:	

16 Other Matters

17 Checking of Quorum

18 Adjournment

Prepared By:

_____

IRB Member- Secretary

Attested by:

_____

IRB Chair

ST. PAUL'S HOSPITAL OF ILOILO, INC.
General Luna Street, Iloilo City 5000 Philippines
Tel. Nos. (033) 337 2741-49 Fax. No. (033) 338 0676
www.sphi.com.ph sphiloilo@gmail.com

APPROVAL LETTER (Form 6.1)

IRB Protocol Code: | Date of Approval:

Protocol Title:

Pri

Type of Review:

( ) Full Board ( ) Expedited
Date of IRB review:

Sponsor:

Sub- Investigators:

Protocol Version No. | Version Date

ICF Version No. | Version Date

Start of the Study | End of the Study

Validity of Approval

Start of Validity | End of Validity

Type of Submission:

( ) Initial Review ( ) Protocol Amendment ( ) Others: _____
( ) Resubmission ( ) Informed Consent Amendments

Approved Documents:

Investigator/Researcher Responsibilities after Approval:

> Submit document amendments for IRB Approval before implementing them.
> Submit SAE/SUSAR/RNE reports.
> Submit Protocol Deviation/Violation.
> Submit Annual Progress Report ( ) Annual, ( ) Bi- annual, ( ) Quarterly
> Application for Continuing Review 30 days before the expiry of Approval letter.
> Submit Final Report after completion of the study.
> Comply with all relevant international and national guidelines and regulations.
> Abide by the principles of good clinical practice and ethical research.

We also confirm that we are a Review Board constituted in agreement and in accordance with ICH-GCP. The Members of the Institutional Review Board of St. Paul's Hospital of Iloilo who reviewed and approved the study are as follows:

Review Board	Specialty	Affiliation	Role	Tick if present

_____
Chairman
Institutional Review Board

Endorsed By: Received By:

_____ _____
Signature over Name Signature over Name

_____ _____
Date: Date:

ST. PAUL'S HOSPITAL OF ILOILO, INC.
General Luna Street, Iloilo City 5000 Philippines
Tel. Nos. (033) 337 2741-49 Fax. No. (033) 338 0676
www.sphi.com.ph sphiloilo@gmail.com

NOTIFICATION OF IRB DECISION FORM (Form 6.2)

Date:

Name of PI:
(Principal Investigator)

Contact No.

This is to inform you of the IRB decision related to your application for review of the following documents:

Protocol Title:

Type of Review:

( ) Full Board ( ) Expedited Meeting
Date:

Type of Submission:

( ) Initial review ( ) Amendment
( ) Resubmission ( ) Others

IRB Protocol Code:

Sponsor and Sponsor Protocol Code:

Protocol Version No.

Version Date

ICF Version No.

Version Date

Other Documents

IRB Decision

( ) **Disapproved**
( ) **Minor revisions required** ( ) **Major revisions required**

Details of Action Required from the PI/Researcher	

_____

Chairman
Institutional Review Board

Submitted By:	**Received By:**
_____	_____
Signature Over Name	Signature Over Name
_____	_____
Date:	Date:

INSTITUTIONAL REVIEW BOARD
COMMUNICATION LETTER (Form 6.3)

Date

Name of the Principal Investigator
Address

IRB Protocol Code:
Sponsor Code:
Protocol Title:
Principal Investigator:
Re:

Dear _____,

Greetings!

Sincerely yours,

_____
Chair
Institutional Review Board
St. Paul's Hospital

INSTITUTIONAL REVIEW BOARD

INDEX OF FILE CONTENTS (FORM 7.0)

SPHI Protocol Code: _____ **Sponsor Code: _____**

Principal Investigator: _____

Protocol Title:

_____

_____

_____

Sponsor: _____ **Approval Date: _____**

DATE OF THE LETTER	DOCUMENT NAME	VERSION NUMBER	CLASSIFICATION (Incoming/ Outgoing)

INSTITUTIONAL REVIEW BOARD

***IRB BORROWERS LOG* (FORM 7.1)**

Study File Code	
Date of The Letter of Request To The Chair	
Date Of Approval From The Chair	
Date Borrowed	
Document/s Borrowed	
Name of Borrower and Signature	
Name And Signature of SPHI IRB Secretariat ***(Who Retrieved The Document)***	
Name and Signature of SPHI IRB Secretariat ***(Upon Return of Document Copied)***	
Number of Copies Made/Signature of IRB Secretariat	

(Please attached formal letter of request signed by the Chair and Confidentiality Agreement)

Version No:	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date:	**SOP No:**
Effective Date:	

1. **Policy Statement**

2. **Objective of the Activity**

3. **Scope**

4. **Workflow**

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)

5. **Description of Procedures**

   Steps:

6. **Forms**

7. **History of SOP**

Version No.	*Date*	*Authors*	*Main Change*

8. **References**

Active Files – an electronic or hard copy file of study documents submitted to the Institutional Review Board and contains active records.

Active File Database - Systematically organized or structured repository of indexed information (usually as a group of linked data files) that allows easy retrieval, updating, analysis and output of data stored usually in a computer. This data could be in the form of graphics, report, scripts, tables and text, etc., representing almost every kind of information.

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

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".

Administrative Communication – refers to the in-coming and out-going communications acted upon by the Institutional Review board thru its Chair or the Secretariat.

Adverse Events – any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. This is not necessarily caused by the treatment. See also drug reaction, serious adverse event and suspected unexpected serious adverse reaction.

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.

Anonymized Biological Specimen - biological specimens that have been stripped of all identifiers (including codes) that would link directly to the individual. However, health and demographic data are retained, such as height, weight, age, diagnosis, socio-ethnic group, etc.)

Approval - favorable or affirmative decision of the Institutional Review Board following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee, CPG, the institution, and relevant regulatory terms.

Approved Minutes – a written records of the proceedings of the meetings (either special or regular meeting) conducted by the IRB which is adopted and approved by the majority of the members during the subsequent meeting of the IRB.

Archiving – storing of a collection of information or documents such letters, official papers or any recorded material considered permanently valuable, and recorded on a media suitable for long terms storage.

Assent - authorization for one's own participation in research given by a minor or another subject who lacks the capability to give informed consent. The assent is a requirement for research in addition to consent given by a parent or legal guardian; it is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired person to participate in research. It is the review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:
0-under 7: No assent
7-under 12: Verbal Assent
12-under15: Simplified Assent Form
15-under18:Co-sign informed consent form with parents
(*See also child's assent and surrogate assent.)*

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

Business arising from the minutes- are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

Child Assent - An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of a research study. Assent is the child's way of saying that he/she agrees to take part in the research to the degree that he/she understands it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them (Retrieved from www.caringforkids.cps.ca/healthybodies/ HealthResearch.htm and http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC2606084/). The factors to be considered by the IRB are "age, psychologic state, and the maturity of the children involved" and to understand and determine whether and how assent must be documented. The assent can be an interactive process between the child and the researcher, involving disclosure, discussion, obtaining an understanding of the proposed research activity, and determining the child's preference regarding participation. The process involves "(a) providing information about the proposed research to the minor, (b) establishing shared decision-making by the child and the proxy concerning participation together with the proxy, (c) making an assessment of the child's understanding of the proposed research, and (d) soliciting an expression of the child's willingness to participate in the proposed research" (Kon, A. A. (2006). Assent in Pediatric Research. Pediatrics, 117, 1806—1810. Retrieved from http://www. pediatrics.org/cgi/content/full/117/5/1806). (*See also assent and surrogate assent.)*

Clinical Research- is a study undertaken involving a particular person or group of people with the purpose of increasing knowledge and determining how well treatment or diagnostic test works in a particular patient population. This research can include: Studies of mechanisms of human disease; Studies of therapies or interventions for disease; Clinical trials and Studies to develop new technology related to disease.

Clinical trial- is a planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products) It is also defined as investigative work to evaluate new drugs, medical devices, biologics, or other interventions to patients in strictly scientifically controlled settings.

Collegial Decision - marked by power or authority vested equally in each of the member of the IRB to arrive at a certain decision in a meeting.

Complaint- the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Confidentiality - Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure

Confidentiality Agreement - A letter sent to the investigator/institution to document their agreement to treat all information regarding the investigational product and the clinical trial in a confidential manner.

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

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

Corporate Values - The operating philosophies or principles that guide an organization's internal conduct as well as its relationship with its customers, partners, and stakeholders. It is usually summarized in the mission statement or in the company's statement of core values.

Database- a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analysed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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

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 IRB Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017. The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.

Expedited review – review of studies that do not entail more than low risk to study participants and those involving participants not belonging to a vulnerable groups aim to demonstrate due to diligence and high standards in the system of protection of human participants. The scope of the Expedited review applies to initial and post-approval submissions on protocols which have been classified as not involving more than low risk to study participants and whose participants do not belong to vulnerable groups.

Full board review - review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Good Clinical Practice (GCP) - International ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting studies. Insures that the data reported is credible and accurate, and that subject's rights and confidentiality are protected.

Honorarium - a voluntary payment for professional services for which no fees are nominally due. (Webster's Universal Dictionary; 2006, p.253).

Inactive Study - a study whose proponent has not communicated with the IRB with regard to issues pertaining to the approval or implementation of the study – within the period of time required by the IRB.

Incoming Communications - are documents which are directed to and received at the IRB office.

Independent Consultant - an expert who gives advice, comments and suggestions upon review of the study protocols with no affiliation to the institution or investigator proposing the research proposal.

Informed Consent - The voluntary verification of a patient's willingness to participate in a clinical trial, along with the documentation thereof. This verification is requested only after complete, objective information has been given about the trial, including an explanation of the study's objectives, potential benefits, risks and inconveniences, alternative therapies available, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.

Initial Review – the ethical assessment of the first complete set of the study documents submitted to the IRB for assessment that can be expedited or full review.

Initial Submission – refers to all new study protocols or researches submitted to the Institutional Review Board for review.

Institution - Location of research. Retains ultimate responsibility for human subject regulation compliance.

Investigator - a person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6, R1); It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products); The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site or group of sites. (See principal investigator).

Institutional Review Board - is an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and

material to be used in obtaining and documenting informed consent of the trial subjects. International Conference on Harmonization (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.27) (*See also SPHI Institutional Review Board)*

Investigator's Brochure- compilation of all relevant clinical and non-clinical information and data on the investigational product.

IRB Protocol Number – a series of coded number assigned to submitted protocols for review.

IRB Staff – refers to the Staff and Clerk Secretaries hired by the administration to work full time in the IRB office.

Logbook- a real-time chronological record of incoming protocols that includes the Date/Time ofReceipt, 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.

Medical Members – are individuals with academic degrees in the medical profession and a master's in the nursing profession.

Minimal risk - A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minutes of the Meeting – an official record of the proceedings in a meeting.

Monitoring - is the process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or research and/or to check researcher's compliance with the protocol and regulatory requirements in which the protocol is given ethical approval.

Non- Affiliated Member - Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty and who will represent the interest and concerns of the community. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, and homemaker).

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.

Outgoing Communications - are documents generated within the IRB office intended for individuals or officers related to the operations of the IRB.

Post approval reports - are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required to be submitted by the researcher to the IRB for monitoring purposes.

Phase I Clinical Trial - refers to the first introduction of a drug into humans. Normal volunteer participants are usually studied to determine the levels of drugs at which toxicity is observed. Such studies are followed by doseranging studies in research participants for safety and, in some cases, early evidence of effectiveness.
Phase I studies can involve one or a combination of the following (Guidelines on General Considerations for Clinical Trials (ICH-E8). Published in the Federal Register on December 17, 1997 (62 FR 66113)). US Department of Health and Human Services, Food and Drug Administration):
a) Estimation of Initial and Safety Tolerability
b) Pharmacokinetics assessing the drug's absorption, distribution, metabolism, and excretion either a separate study or part of an efficacy, safety and tolerability
c) Pharmacodynamics to provide an estimate of the activity and potential efficacy and may guide the drug's dosage and dose regimen
d) Early measurement of drug's activity

Phase II Clinical Trial - consists of controlled clinical trials designed to demonstrate efficacy and relative safety of the investigative new drug. Normally, these are performed on a limited number of closely monitored patients suffering from a disease or condition for which the active ingredient is intended.
This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships to provide an optimal background for the design of extensive therapeutic trials (WHO).
Some innovative pharmaceutical companies have added an additional layer called Phase Ib/IIa before proceeding to Phase II. The former employs a placebo arm and employs surrogate biomarkers assumed to predict the drug's therapeutic or adverse effects in the disease target population. This allows the right endpoint to be selected for Phases II and III. Participants employed are patients with the target disease but some bridging studies employ additional normal healthy participants. The main objective of this transition phase is to evaluate the safety and establish the pharmacokinetics of multiple doses of the drug and monitor any effects on biological markers of disease activity.

Phase III Clinical Trial – in larger (and possibly varied) research participant groups with the purpose of determining the short- and long-term safety/ efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. This is performed after a reasonable probability of a drug's effectiveness has been established. These trials should

preferably be of a randomized double-blind design, but other designs may be acceptable (e.g., long-term safety studies).
The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g., clinically relevant drug interactions, factors leading to differences in effect such as age). Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use (WHO).

Phase IV Clinical Trial - research conducted after the national drug registration authority (i.e., FDA) has approved a drug for distribution or marketing. This phase is carried out on the basis of the product characteristics on which the marketing authorization was granted and is normally in the form of post-marketing surveillance or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, among others, are normality considered as trials for new pharmaceutical products (WHO).

Philippine Health Research Ethics Board - the national policymaking body on health research ethics, created under DOST Special Order No. 091, which is mandated to ensure that all phases of health research shall adhere to the universal ethical principles that value the protection and promotion of the dignity of health research participants.

Placebo- a substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual; it may be an inactive pill, liquid, or powder that has no treatment value.

Placebo-Controlled Trials- clinical trials that assign the administration of a placebo to the control group while the test drug is given to the experimental group.

Primary reviewers- refer to the members of the IRB assigned by the Chair or Member-Secretary to review and present the findings and recommendations on the study protocol for review during the IRB full-board meeting.

Principal Investigator - the chief or person primarily responsible for the implementation of a research project. (*See also investigator)*

Privacy- is the right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively; it is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others. (*See also Confidentiality)*

Progress Report – report required by SPHI IRB to be submitted by the Principal Investigator to monitor the safety of participants enrolled in a study.

Protocol - a document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22); a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. (International Conference on Harmonisation (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.44). (*See also research protocol)*

Protocol Amendment - A written description of a change/s to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun.

Protocol Deviation/Violation - failure to comply with the procedures in the approved protocol or to comply with national/international guidelines in the conduct of human research.

Protocol Package Acknowledgment Receipt - a letter or information sent to signify that the package containing protocol-related documents has been received by the IRB Staff.

Query- the act of asking for information or clarification about a study.

Quorum- Presence of at least five members, including at least one lay or non-scientific member, one non-affiliated member and with gender representation, to make decisions about the proposed research.

Randomization, Random Assignment -process of assigning research participants to treatment or control groups using an element of chance to determine the assignments to reduce bias (ICH-GCP).

Real Time Recording – Recording of data or information that take place instantaneously or in the same timeframe as it is happening.

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.

Regulatory and Accrediting Authorities- person/s appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for

verification of data (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

Research participants or subjects - An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22).

Research protocol - a document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. (*See also protocol)*

Risk - the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated benefits to the subjects or to society. The investigator(s) and IRB must assess the risks and benefits of proposed research. (*See also minimal risk)*

Resubmission – study protocols/documents returned after having minor or major revisions.

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.

Serious adverse Event - or serious adverse drug reaction is an adverse event that results to death, life-threatening incident or causes immediate risk of death from the event; results to in-patient or prolongation of hospitalization, causes significant disability, incapacity, and congenital anomaly or another episode which is considered a significant hazard to the participant. See also adverse event or unexpected adverse event. Also, any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires in-patient hospitalization or prolongation of existing hospitalization, -results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect (International Conference on Harmonisation (ICH) - Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.50) (*See adverse event)*

Side Effect- undesired effect of a treatment which is either immediate or long-term.

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

Sponsor- an individual, company, institution, or organization that takes responsibility for initiating, managing, and financing a clinical trial.

Standard of Care or Treatment -healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care.

Site Visit – any visit made in the study site to check compliance with GCP and IRB approved protocol and related documents.

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

SPHI Institutional Review Board - ethics review committee organized by the St. Paul's Hospital of Iloilo, Inc. to ensure that health research is conducted according to international ethical principles, national and institutional guidelines. This is an independent body constituted of medical, scientific, and lay members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. [ICH E6 1.31].

Standard Operating Procedure (SOP) – detailed written instruction in a certain format describing the activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function.

SOP Team – an ad hoc committee composed of IRB members designated to rewrite/revise the IRB SOP.

Study Documents - All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Study Protocol Related Document – refers to all records, accounts, notes, report, data and ethics communications (submission, approval and progress reports) collected, generated or used in connection with the Study, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and construction of the Study. (*See also study document*)

Surrogate Assent – surrogate assent – Necessary when an adult is not able to provide consent for themselves to participate in research due to: cognitive impairment, lacking capacity, or suffering from a serious or life-threatening disease. This is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB (Retrieved from http://www.virginia.edu/vpr/irb/hsr/surrogate_assent.html). (*See also assent and child's assent)*

Suspected Unexpected Serious Adverse Reaction - is an adverse reaction that has not been anticipated, nor previously experienced, or observed, and is not consistent with the informed consent, information sheets or applicable product information in the investigator's protocol or brochure, product or package insert or summary of product characteristic. (*See also adverse event and serious adverse event)*

Submission – all protocols submitted to the SPHI IRB for ethical review.

Term of Office- the specified length of time that a person serves in a particular designation/rule.

Voluntary - free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. (IRB Guidebook, US DHHS)

Vulnerability - refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, General Ethical Principles)

Vulnerable persons/groups - are individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. (International Conference on Harmonisation (ICH) – Guideline for Good Clinical Practice (GCP) E6 (R1), art. 1.61) Vulnerable persons are those who are relatively incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, Commentary on Guideline 9) These are also classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare; these are "persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority"(http://www.pre.ethics.gc.ca.engish/tutorial/glossary.cfm#cdownloaded on July 9, 2010)

VI. References

A Workbook for Developing Standard Operating Procedures, 2020 by Philippine Health Research Ethics Board. Retrieved from file:///C:/Users/SPHI/Downloads/2020%20PHREB%20SOP%20Workbook-%20PDF%20(3).pdf

Revised SJREB SOP version 04.

National Ethical Guidelines for Research Involving Human Participants 2022. Retrieved from https://www.pchrd.dost.gov.ph/wp-content/uploads/2023/05/2022-NEGRIHP_Official-Gazatte_Ver-5-1.pdf

Philippine Heart Center Institutional Review Board Request to Waive Written and Verbal ICF Retrieved from ICF Waiver Form FM-E-IRB-2019-041 Rev. 04.pdf

September-2015-ASEAN-Medical-Device-Directive. Retrieved from https://asean.org/wp-content/uploads/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf

International Ethical Guidelines for Health-related Research Involving Humans. CIOMS 2016. Retrieved from https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

WHO 2023 Tool for Benchmarking Ethics oversight of health related research involving human participants. Retrieved from https://iris.who.int/bitstream/handle/10665/372984/9789240076426-eng.pdf?sequence=1

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, 2024

ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6 (R3). Retrieved from https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf