| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 1.1**<br>**Selection and Appointment of Members** |
| Effective Date: July 1, 2024 | |

**1.1.1. Policy Statement**

The selection and appointment of the members of the St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) shall ensure to maintain its independence and make its composition multidisciplinary and multisectoral, with good representation of male and female members and a fair age distribution.

The board shall have at least seven members. The members shall include at least one member whose primary concern is in the medical sciences, at least one member whose primary concern is in non-medical or non-scientific, at least one with expertise in legal matters, at least one member who is not with the institution and at least one Sister of St. Paul of Chartres member.

The members are 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. To ensure the continuity, development and maintenance of the IRB work, a staggered term of tenure is also established.

The process of selection and appointment 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.

**1.1.2. Objective of the Activity**

The appointment process aims to ensure that the selection of members are from diverse background and sectors including, but are not limited to the following: individuals with expertise in medical or scientific area, law, non-medical or non-scientific, and lay people who will represent the interest and concerns of the communities from which participants are likely to be drawn.

**1.1.3. Scope**

This SOP applies specifically to the selection of members of the IRB. This SOP begins with the call for nominations and ends with the filing of appointment documents and CVs of IRB members in the membership file.

**1.1.4. Responsibilities**

1.1.4.1. In case of vacancy or need for another member/s, the current IRB members, headed by the Chair or a designated substitute, nominate candidates who have the necessary qualifications for the position. The Chair submits the list to the Hospital Administrator for the selection and appointment.

1.1.4.2. The Hospital Administrator of St. Paul's Hospital of Iloilo, Inc. is responsible to formally appoint board members, from the list of nominees given by the Chair or any person/s whom she believes qualified for the vacant position. The appointment is based on their competency, 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 participating in health research and ethics education activities.

1.1.4.3. The new member/s signs the appointment letter, Agreement on Confidentiality and Conflict of Interest (COI) and submits his/her/their updated Curriculum Vitae (CV) using the IRB Form.

1.1.4.4. The Staff Secretary is responsible for filing the documents of newly appointed member/s. She keeps it in locked "SPHI IRB Documents" cabinet.

### 1.1.5. Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Nomination of candidates in case of vacancy or need for another member/s* | *IRB members* | *1 day* |
| *Step 2: Submission of the list of nominees to the Hospital Administrator* | *Chair* | *1 day* |
| *Step 3: Facilitate appointment of new members* | *Chair/ Office Manager* | *1 day* |
| *Step 4: Receipt of Appointment of IRB Regular and Alternate Members* | *Chair* | *1 day* |
| *Step 5: Signing of important documents (Appointment Letter, COI, CV)* | *New IRB member/s* | *1-2 days* |
| *Step 6: Filing of appointment documents and CVs in the membership file* | *Staff Secretary* | *1 day* |
| *Step 7: Resignation, Disqualification, and Replacement Members* | *IRB members* | *7 days* |

### 1.1.6. Description of Procedures

**Step 1: Nomination of candidates in case of vacancy or need for another member/s:**

The current IRB members, headed by a Chair or a designated substitute, nominate candidates who have the necessary qualifications for the position:

**1.1.** Members are selected based on their:

- Good moral character
- Personal capacities
- Ethical and/or scientific knowledge and expertise
- Willingness to volunteer their time and effort to perform their functions in the IRB

**1.2.** Members have prior training in Good Clinical Practice, research methodology and research ethics, or should be willing to undergo such training during their membership.

**1.3.** Members discloses in writing any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.

**1.4.** Members submits their curriculum vitae, properly signed and dated and update them at least once every two (2) years.

**1.5.** Members sign a confidentiality/conflict of interest agreement at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The Office Manager and Staff Secretary are likewise expected to sign a similar document.

**1.6.** The Chair discusses 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: Submission of the list of nominees to the Hospital Administrator:**

The Chair submits to the Hospital Administrator the list of possible individual/s to fill the vacant position.

**Step 3: Facilitate appointment of new members:**

Provide TOR specific to the position of the member (i.e. scientist/medical member, non-medical/non-scientist member, alternate member, independent consultant)

**3.1.** The Chair and Office Manager facilitate the appointment of new board members, from the list of nominees whom he/she believes qualified for the vacant position.

**3.2.** The Office Manager facilitate appointment letter to the new members that includes the term of office and their duties and responsibilities.

**IRB Regular Member Responsibilities:**

a. Participates in IRB meetings
b. Reviews, discusses and considers research proposals submitted for evaluation
c. Reviews protocols and protocol-related reports and monitor on-going studies as appropriate
d. Evaluates 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. Lay members extensively reviews the informed consent forms of research protocols submitted for review
j. Leads prayer during the meeting
k. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others

l. Review with an external perspective to ensure the IRB independence. (*for member who is non-affiliated only*)

**IRB Alternate Member Responsibilities:**

a. Participates in 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 in the votation.

**Step 4: Receipt of Appointment of IRB Regular and Alternate Members**

Designation letter that was signed by the Hospital Administrator and received by the IRB Chair.

**Step 5: Signing of important documents (Appointment Letter, COI, CV):**

The new member/s sign the appointment letter (Form 1.1- Form 1.4), Agreement on Confidentiality and COI (Form 1.7) and Curriculum Vitae (Form 1.8)

**Step 6: Filing of appointment documents and CVs in the membership file:**

**6.1.** The Staff Secretary files the documents of newly appointed member/s in their specific membership file folder (Appointment letter with COI, training certificates and curriculum vitae).

**6.2.** All of these documents are kept securely in locked "SPHI IRB Documents" cabinet.

**Step 7: Resignation, Disqualification, and Replacement of Members**

**7.1.** Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Hospital Administrator.

**7.2** Members may be separated from the Board by disqualification for valid reasons as determined by majority vote of the IRB members.

**7.2.1** Refusal to sign the Confidentiality and Conflict of Interest Agreement.

**7.2.2** Failure to comply with the Confidentiality and Conflict of Interest Agreement.

**7.2.3** Non-compliance of duties and responsibilities stated in the St. Paul's Hospital Of Iloilo, Inc Institutional Review Board (SPHI- IRB) Standard Operating Procedures (SOPs).

**7.3** Members that have resigned or have been disqualified may be replaced by following the selection and appointment procedures previously stated.

**7.4** The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

**1.1.7. Forms**

Appointment Letter for Regular IRB Medical-affiliated Members (Form 1.1)
Appointment Letter for Regular IRB Medical non-affiliated Member (Form 1.2)
Appointment Letter for Regular IRB non-medical affiliated Member (Form 1.3)
Appointment Letter for Regular IRB non-medical non-affiliated Member (Form 1.4)
Agreement on Confidentiality and COI (Form 1.7)
CV (Form 1.8)

**1.1.8. 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 specific Appointment Letter for 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* | *Description of the qualification of chair, co-chair and secretary Harmonizing tenure of members 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* | *Harmonize 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* | *Removes 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* |

### 1.1.9. References


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 1.2**<br>**Designation of Officers** |
| Effective Date: July 1, 2024 | |

**1.2.1. Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have a chair, co-chair, and member-secretary who shall be appointed among the members by the Hospital Administrator. The appointment shall be based on their competency, 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 participating in health research and ethics education activities.

**1.2.2. Objective of the Activity**

This SOP aims to designate the duties and responsibilities of IRB officers, members and staff.

**1.2.3. Scope**

The scope of this SOP includes the selection of Chair, Co-Chair and Member- Secretary. It starts with the call for a special meeting to elect the concerned officers and ends with the filing of appointment documents of the officers.

**1.2.4. Responsibilities**

1.2.4.1 **Hospital Administrator**

a. Appoints the IRB officers, (Chair, Co-Chair, Member-Secretary, members and staff based on their personal capacities, interest, competency, 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 participating in health research and ethics education activities.

1.2.4.2 **Chair**

The following are the responsibilities of the IRB Chair:

a. Presides over the IRB meetings and is accountable to the Hospital Administrator
b. Initially reviews all submitted protocols and other documents to decide which protocols may be expedited or full board review
c. Assigns primary reviewers for protocols and other documents from among IRB members
d. Reviews Protocol and protocol-related submissions (Protocols for Initial Review of Full Board, Resubmission, Amendments, Progress Reports, Final Reports, SAE/SUSARs reports, Protocol Deviations, Site Visits, etc.)
e. Invites independent consultants for the protocols for review that are not within the area of competence or expertise of the IRB members
f. Checks and signs provisional agenda, outgoing IRB communications such as approval letter, notification of IRB decision, requests, inquiries and others
g. Maintains confidentiality of the documents and deliberations during IRB meetings
h. Declares any conflict of interest
i. Participates in continuing education activities in health research and ethics
j. Acts on operations-related communications
k. Approves request for access and retrieval of documents
l. Prepares an annual report summarizing IRB activities and decision outcomes to the Hospital Administrator

1.2.4.3 **Co- Chair**

The following are the responsibilities of an IRB Co-Chair*:*

a. Presides over meetings in the absence of the Chair
b. Performs other duties in the absence or as designated by the Chair
c. Participates in IRB meetings
d. Reviews, discusses and considers research proposals submitted for evaluation
e. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate
f. Evaluates final reports
g. Maintains confidentiality of the documents and deliberations during IRB meetings
h. Declares any conflict of interest
i. Participates in continuing education activities in health research and ethics
j. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others.

**1.2.4.4 Member- Secretary**

The following are the responsibilities of the IRB *Member-Secretary:*

a. Supervises the IRB staff (Office Manager & Staff Secretary)
b. Decides which protocols may be expedited or full board review and assigns primary reviewers
c. Participates in IRB meetings
d. Determines the presence of quorum during the meeting
e. Assesses serious adverse event and suspected unexpected serious adverse reactions reports submitted to the IRB
f. Reports SAE/SUSARs during the IRB meeting and Recommends appropriate action
g. Documents the conduct of the full board meeting
h. Prepares minutes of regular IRB meeting
i. Maintains good IRB documentation and archiving procedures
j. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate
k. Evaluates final reports
l. Maintains confidentiality of the documents and deliberations during IRB meetings
m. Declares any conflict of interest
n. Participates in continuing education activities in health research and ethics

**1.2.4.5: Designation and Appointment of IRB Office Manager.**

The administrator selects/ designates/appoints the IRB office manager. He/She may not be a member of the IRB

Responsibilities of the 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. Organizes protocol file folders
f. Maintains confidentiality of the documents of the IRB and deliberations during IRB meetings
g. Maintains the cleanliness and orderliness of the Office.
h. Responsible for IRB accounts

i. Maintains good IRB documentation and archives.
j. Accountable for all documents and office files and secures all files under lock and key.

**1.2.4.6: Responsibilities of the IRB Staff Secretary:**

a. Updates logbooks for incoming and outgoing communications and IRB database.
b. Receives research proposals and documents for review and other important documents for IRB.
c. Organizes an effective and efficient tracking procedure for each proposal Received
d. Prepares two (2) weeks before the scheduled meeting, organizes the logistics for the meeting and assembles the needed documents.
e. Collects, stores, and disposes materials after IRB meeting
f. Assists in communicating with the IRB members and Investigators.
g. Communicates with researchers, employees, and other individuals to answer questions, disseminate or explain information, and Receive inquiries.
h. Answers telephone and take messages to obtain information and to respond to requests.
i. Compiles, copies, sorts, and organizes IRB documents, communications, records, and other IRB files.
j. Maintains and updates filing of studies, inventory, and database systems manually and through the use of computer.
k. Delivers confidential documents for review and other important documents to the IRB members.
l. Maintains confidentiality of the documents of the IRB and deliberations during IRB meetings.
m. Maintains the cleanliness and orderliness of the Office.
n. Requests supplies and follow-up repairs.
o. Does other responsibilities assigned by the IRB Chair, Member-Secretary and Office Manager.
p. Archives studies with approved final report or early study termination report
q. Retrieves and returns document to the files
r. Supervises the use of retrieved document
s. Maintains IRB documentation and archives.
t. Accountable for all documents and office files and secures all files under lock and key.

**1.2.5. Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Facilitate the appointment of IRB officers and staff* | *IRB Chair* | *1 day* |
| *Step 2: Signing of important documents (Appointment Letter, COI, CV)* | *New IRB Officers, Office Manager and Staff Secretary* | *1 day* |
| *Step 3: Filing of appointment documents and CVs in the membership file* | *Staff Secretary* | *1 day* |

**1.2.6. Description of Procedures**

**Step 1: Facilitate the appointment of IRB officers and staff:**

The IRB Chair facilitate the appointment of the IRB officers and staff based on their competency, 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 participating in health research and ethics education activities.

**Step 2: Signing of important documents (Appointment Letter, COI, CV):**

The newly appointed IRB Chair, Co-Chair, Member-Secretary, Members, Office Manager and Staff Secretary sign the appointment letter, Agreement on Confidentiality and COI (Form 1.6) and CV (Form 1.7)

**Step 3: Filing of appointment documents and CVs in the membership file**:

The Staff secretary files the documents in their own membership file folders that are kept securely in "SPHI IRB Documents" cabinet. (Appointment letter with COI, training certificates and curriculum vitae).

**1.2.7. Forms**

Agreement on Confidentiality and COI (Form 1.6)
CV (Form 1.7)

**1.2.8. 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* | *Added the responsibilities of IRB Chair, Co-chair, and Member-secretary* |
| *07* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow* |

**1.2.9. References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board; "**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 1.3**<br>**Appointment of Independent Consultants** |
| Effective Date: July 1, 2024 | |

**1.3.1 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.

**1.3.2 Objectives**

This SOP describes the selection and appointment process of Independent Consultants (IC).

**1.3.3 Scope**

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

**1.3.4 Responsibilities**

1.3.4.1 The Chair identifies the study that requires an independent consultant. He/she seeks the Recommendation of IRB members for possible qualified consultants. He/she submits to the Hospital Administrator the list of probable IC based on their expertise, and availability.

1.3.4.2 The Hospital Administrator approves the appointment of IC.

1.3.4.3 An IC reviews the research protocols and answers the inquiries of primary reviewer before the scheduled IRB meeting. He/she may be invited to attend full board meetings to share his/her inputs and Recommendations. However, he/she cannot participate in the voting process during the IRB meetings.

**1.3.5 Workflow**

| ***ACTIVITY*** | ***RESPONSIBILITY*** | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Identification of the study that requires an IC* | *Chair* | *1 day* |
| *Step 2: Recommends names of potential consultants* | *IRB Members* | *1 day* |
| *Step 3: Submit names of probable consultants to the Hospital Administrator* | *Chair* | *1 day* |
| *Step 4: Facilitate appointment of IC* | *Chair/ Office Manager* | *1 day* |
| *Step 5: Signing of Appointment letter and Agreement on Confidentiality and COI* | *Office Manager/ Staff Secretary* | *2 days* |
| *Step 6: Inclusion in the pool of IC* | *Office Manager* | *1 day* |
| *Step 7: Filing of appointment documents and CVs in the membership file* | *Staff secretary* | *1 day* |

### 1.3.6 Description of Procedures

**Step 1: Identification of the study that requires an IC:**

If the IRB Chair determines that a study involves procedure/s that are not within the area of competence or expertise of the IRB members, the IRB may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IRB.

**Step 2: Recommends names of potential consultants:**

The Chair asks IRB members for possible qualified IC. The IRB members Recommend names of potential Consultants.

**Step 3: Submit names of probable consultants to the Hospital Administrator:**

The Chair endorses the names of probable Consultants to the Hospital Administrator for approval.

**Step 4: Facilitate appointment of Independent Consultant:**

**4.1.** The Chair and Office Manager facilitate the appointment of the Independent Consultant. The Chair submit the list of names whom he/she believes qualified as IC.

**4.2.** The Administrator issues appointment letter (Forms 1.6) to the new IC which includes the term of office and their duties and responsibilities.

**Step 5: Signing of Appointment letter and Agreement on Confidentiality and Conflict of Interest:**

The Office Manager or Staff Secretary will facilitate the signing of agreement on Confidentiality and COI (Form 1.7) and fill-up IRB CV (Form 1.8).

**Step 6: Inclusion in the pool of IC:**

The Staff Secretary adds the newly appointed IC in the pool of existing consultants of IRB in the electronic database of IC.

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

The Staff Secretary files the documents (Appointment letter with COI, training certificates and curriculum vitae) of newly appointed consultant/s. All of these documents are kept securely in locked "SPHI IRB Documents".

### 1.3.7 Forms

Appointment Letter for IRB IC (Form 1.6)
Agreement on Confidentiality and COI (Form 1.7)
Curriculum Vitae (Form 1.8)

### 1.3.8 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* | *Deleted non-relevant forms (form 1.1-1.6)*<br>*Deleted SOP 1.5* |
| *05* | *2019 July 26* | *IRB SOP TEAM* | *Only IRB members and Staff cited in the Workflow* |
| *06* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow* |

**1.3.9 Reference**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 1.4**<br>**Training of IRB Officers, members, Consultants and Staff** |
| Effective Date: July 1, 2024 | |

**1.4.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board officers, members, consultants and staff shall regularly attend seminars, trainings and workshops to develop and enhance their competence, skills and knowledge.

**1.4.2 Objectives**

This SOP ensures to develop and enhance the competence, skills and knowledge of IRB officers, members, consultant and staff in research ethics and guidelines and in the review of different types of protocols.

**1.4.3 Scope**

This SOP describes the training requirements of St. Paul's Hospital of Iloilo IRB officers, members, consultants and staff from initial training to continuing education to maintain and update IRB competence in the review of different types of protocols.

**1.4.4 Responsibilities**

1.4.4.1. The Chair identifies officers, members of the IRB, consultants, office manager and staff secretary who will attend the seminars, trainings and workshops and submit their names together with the letter of request to the Hospital Administrator.

1.4.4.2. The Hospital Administrator approves the letter of request upon her evaluation.

1.4.4.3. The Officers, Members, Consultants, Office Manager and staff secretary who attend the seminars, trainings, and workshops submit their certificate to the Secretariat for filing. The Office Manager identifies schedule of available seminars, trainings and workshops on basic and advance ethics, research practice, and other relevant topics and keeps track of the training needs of all members, office manager and staff secretary.

1.4.4.4. The Staff Secretary files the certificates to the IRB Membership File.

**1.4.5 Workflow**

| ***ACTIVITY*** | ***RESPONSIBILITY*** | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Identification of the available seminar, trainings and workshops for IRB Members, Staff and Independent Consultants* | *Office Manager* | *1 day* |
| *Step 2: Identification of the IRB members and staff to attend the seminar, trainings and workshops* | *Chair* | *1 day* |
| *Step 3: Submit letter of request which includes the names of members and staff to the Hospital Administrator* | *Chair* | *1 day* |

| | | |
|---|---|---|
| *Step 4: Seek approval of the request for seminar, training or workshop* | *Chair/Office Manager* | *1-2 days* |
| *Step 5: Attendance in Seminars, trainings or workshops* | *IRB Members and Staff* | *1 day* |
| *Step 6: Filing of Training certificates* | *Staff Secretary* | *1 day* |

**1.4.6 Description of Procedures**

**Step 1: Identification of the available seminar, trainings or workshops for IRB Members, Staff and Independent Consultants:**

**1.1** There should be a training needs assessment among the IRB members. The Office Manager obtains information and identifies the schedule of available seminars, trainings and workshops on basic and continuing advanced trainings on ethics, research practice, and other relevant topics and presents it to the Chair, together with the IRB Seminar, Training and Workshop Monitoring Sheet (Form 1.10).

**1.2** Initial research ethics seminars, training and workshops consist of basic training in research ethics principles, GCP, and in-house mentoring in IRB Standard Operating Procedures.

- Basic Research Ethics Training (BRET)
- SOP training (PHREB for officers, staff) and some members; in-house for other members, office manager)
- Good Clinical Practice (GCP) training (including national laws, policies and guidelines)
- Quality review of protocols including Risk/Benefit Assessment, Vulnerability issues in Research, and review of ICF
- Post approval review
- Training for Office Manager and Staff on research ethics office procedures (e.g. filing, management of database, etc.)

**1.3** Continuing advanced training on research, good research practice training and other relevant topics.

**Step 2: Identification of the IRB members and staff to attend the seminar, trainings and workshops:**

The Chair assigns the probable officers, members, consultants, office manager or staff secretary who will attend the available seminars, trainings or workshop upon evaluation of the Monitoring Sheet.

**Step 3: Submit letter of request which includes the names of members and staff to the Hospital Administrator:**

The Chair makes a letter of request and Recommends names of the IRB Officers, Members, Consultants, Office Manager or Staff secretary to the Hospital Administrator for the approval.

**Step 4: Seek approval of the request for seminar, training or workshop:**

The Chair and Office Manager facilitate approval of the request for seminar, training or workshop.

**Step 5: Attendance in Seminars, trainings or workshops:**

IRB Members, Office Manager and Staff secretary attend the available seminar, training or workshop to enhance their knowledge, skills and competence on research, ethics and on other relevant topics.

**Step 6: Filing of Training certificates:**

The Staff Secretary files the certificates to the IRB Membership File and logs the training, seminar or workshop in the Monitoring Sheet. All of these documents are kept securely in locked "SPHI IRB Documents"

### 1.4.7 Form

IRB Seminar, Training and Workshop Monitoring Sheet (Form 1.10)

### 1.4.8 History of SOP

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2015 Aug. 18* | *IRB SOP TEAM* | *First draft* |
| *02* | *2016 July 15* | *IRB SOP TEAM* | *Included in the revised 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.* |
| *05* | *2019 June 13* | *IRB SOP TEAM* | *Included the identification of training of all IRB members and secretariat. 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* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow. Added step 1 (1.2)* |

### 1.4.9 Reference


"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 2**<br>**Management of Initial Submissions** |

**2.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require a set of documents (hard copies and electronic copies) listed in a checklist for initial submission, and resubmission. Only the complete documents submitted shall be accepted.

**2.2 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.

**2.3. Scope**

This SOP covers the management of all initial submissions and resubmissions to the St. Paul's Hospital of Iloilo, Inc. Institutional Review Board.

The Institutional Review Board, headed by the Chair, shall accepts the following protocols for review:
1) St. Paul's Hospital of Iloilo funded researches
2) Protocol submitted by the faculty, staff, students, and residents of institution
3) Researches to be done at St. Paul's Hospital of Iloilo
4) Researches referred from the Philippine National Health Research System (PNHRS), Philippine Health Research Ethics Board (PHREB), Department of Health (DOH), industry organizations, etc.

This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database.

**2.4. Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Acceptance of documents for Initial review and declaration of no conflict of interest* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Receipt of study documents for initial review and determination of completeness of submission* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 3: Coding of the research studies Received* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 4: Entry into logbook/database* | *Staff Secretary* | *1 day* |
| *Step 5: Determination of type of review/action*<br>*a) Exempt from Review*<br>*b) Expedited Review*<br>*c) Full Board*<br>*d.) SJREB Review* | *Chair, Member-Secretary* | *1 day* |

| | | |
|---|---|---|
| *Step 6: Use of Study Assessment Forms* | *Primary Reviewers* | *7-14 days* |

**2.5. Description of Procedures**

**Step 1: Acceptance of documents for Initial review and declaration of no conflict of interest:**

The Principal Investigator submitted the protocol for initial review. The IRB required hard copies and electronic copies. Upon submission both hard and electronic copy, the PI will sign the Declaration of No Conflict of Interest Form (Form 2.1).

**Step 2: Receipt of study documents for initial review and determination of completeness of submission:**

The IRB Office Manager or Staff Secretary checks the documents being submitted based on the IRB Checklist for Initial Submission (Form 2.2).

**2.1.** The protocol package for clinical trial and/or sponsor-initiated studies has to include the following:

- ☐ Letter of Application & Complete Protocol
- ☐ Protocol Summary
- ☐ Investigator's Brochure
- ☐ Data collection form/s
- ☐ Informed Consent Forms (English, Tagalog, and local dialect (Hiligaynon))
- ☐ CV of the Principal Investigator and his/her co-investigators
- ☐ GCP Certificate of the Principal Investigator (PI) and his/her co-investigators
- ☐ Declaration of No Conflict of Interest for Principal Investigators/Researchers (Form 2.1)
- ☐ Valid PRC License
- ☐ No Conflict of Interest Form
- ☐ GANTT Chart (as necessary)
- ☐ Advertisement, Diary card and other related documents
- ☐ Case report form/s
- ☐ Certificate of Technical Review (as necessary)
- ☐ Budget- Draft is acceptable
- ☐ Clinical Trial Agreement- Draft is acceptable
- ☐ Material Trial Agreement-Draft is acceptable

Three (3) copies of this protocol package should be submitted to the IRB.

**2.2.** The protocol package for researcher-initiated studies (residents, staff, students, government sector and private sector, etc.) has to include the following:

- ☐ Letter of Application & Complete protocol (Chapter 1-3) A4 Bond Paper
- ☐ Executive summary that follows research project proposal format
- ☐ Data collection form/s
- ☐ Informed Consent form (English/Tagalog, and local dialect (Hiligaynon))
- ☐ Budget (as necessary)
- ☐ CV of the PI and co-investigators (with 2x2 picture)
- ☐ Declaration of No Conflict of Interest for Investigators/Researchers (Form 2.1)

- ☐ Valid PRC License
- ☐ GCP Certificate (for interventional study only)
- ☐ GANTT Chart (as necessary)
- ☐ Certificate of Technical Review
- ☐ Letter of Approval from Hospital Administrator and Data Protection Officer

For submission, the Principal investigator/researcher may submit their application letter at SPH-IRB located at 4th Floor Cancer Center Building and look for IRB secretariat.

**2.3.** The Office Manager or Staff Secretary issues the "Protocol Package Acknowledgment Receipt" (Form 2.3) upon the Receipt of the complete package. The Contents of the Protocol package acknowledgement Receipt is as follows:

- ☐ IRB Protocol No.
- ☐ Protocol Title
- ☐ Date
- ☐ Sponsor
- ☐ Type of Submission
- ☐ PI
- ☐ Contact No. of PI
- ☐ Type of Research
- ☐ List of the Documents Submitted
- ☐ Name and signature of the person who submitted the protocol
- ☐ Name and signature of the person who Received the protocol

**2.4.** The Office Manager or Staff Secretary will communicate with the Principal Investigator if documents submitted are incomplete.

**Step 3: Coding of the research studies Received:**

The Office Manager and Staff Secretary assigns an IRB protocol number upon the Receipt of complete protocol package. The study files are coded as follows:

**SPHI-__-0_-1_**

Wherein:

**SPHI** - stands for St. Paul's Hospital Iloilo

-__ - refers to the type of research.
**CT**- for Clinical Trial;
**RR** for Resident Research;
**StR** for Student Research (undergraduate and graduate research studies);
**SR** for Staff Research or any study from the staff of this Institution;
**HR** for those researches initiated or with partnership with St. Paul's Hospital Iloilo; and

**OR** for other kind of researches.

**-0_** - chronological number based on order of Receipt (01, 02, 03, etc.)

**-1_** - refers to the year of submission (ex. 15 for 2015, 16 for 2016)

Examples:

**SPHI-CT-01-15**
**SPHI-RR-01-15**
**SPHI-StR-02-16**
**SPHI-SR-02-16**
**SPHI-HR-03-17**
**SPHI-OR-03-17**

**Step 4: Entry into logbook/database:**

**4.1.** The Staff Secretary writes/logs the documents Received in Incoming Communications Logbook. She also updates the Initial Submissions Electronic Database (Form 2.4) for effective and efficient monitoring of the IRB.

**4.2.** The contents of the Initial Submissions Electronic Database are the following:

- ☐ Protocol Title
- ☐ IRB Protocol Number
- ☐ Sponsor Code
- ☐ Principal Investigator
- ☐ Sponsor
- ☐ Type of Research
- ☐ Date Received
- ☐ Type of Review (Exempt, Expedited, Full Board, and SJREB)
- ☐ Date of IRB Meeting where Protocol is discussed
- ☐ Primary Reviewer
- ☐ IRB Decision
- ☐ Date of Action of Letter to PI/Researcher
- ☐ Revision 1 (Document submitted, Date of submission, Date of Review, Review Decision)
- ☐ Revision 2 (Document submitted, Date of submission, Date of Review, Review Decision)
- ☐ Date of IRB Approval
- ☐ Status
- ☐ Date of Expiration of Approval
- ☐ 1st Amendment (Document, date of submission and review, Review decision, date of Approval)
- ☐ 2nd Amendment (Document, date of submission and review, Review decision, date of Approval)
- ☐ 3rd Amendment (Document, date of submission and review, Review decision, date of Approval)
- ☐ 4th Amendment (Document, date of submission and review, Review decision, date of Approval)
- ☐ 5th Amendment (Document, date of submission and review, Review decision, date of Approval)
- ☐ Progress Report (Due date of PR, Date of submission, Date of Review and IRB Action/Recommendation)

- ☐ SAE Submissions (Date of Submission, Date of Review, IRB Action/Recommendation)
- ☐ SUSAR Submission
- ☐ Protocol Deviation (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 Archiving)
- ☐ Date of Shredding (Date of Shreeding)

**Step 5: Determination of type of review/action (Expedited Review, Full Board)**

**The Chair determine the type of review a protocol should undergo.**

Please see Chapter 3 Types of Review:

SOP 3.1 Exempt from Review
SOP 3.2 Expedited Review and
SOP 3.3 Full Board Review
SOP 3.4 SJREB Review

**Step 6: Use of Study Assessment Forms**

**6.1** The IRB primary reviewer checks the two (2) Study Assessment forms. (Form 3.2 Protocol Evaluation Form and Form 3.3 Informed Consent Evaluation Form)
Use appropriately filled protocol and ICF assessment forms as guides in the review of protocol and ICF.

**6.2** The primary reviewer reads the protocol and related documents and individually fills up the form for each protocol. All the items in the study assessment forms are filled up including the area where comments are made. Do a systematic and quality, meaningful review of the protocol and ICF – review first the Scientific soundness, followed by Ethical issues, and then the ICF.

**6.3** The primary medical reviewer accomplishes the Protocol Evaluation Form while the primary non-medical reviewer focuses on the Informed Consent Form only.

**6.4** The Study Assessment Forms ensure assessment of the scientific and ethical aspect of the protocol.

a. The following will be considered as applicable:
   - Appropriateness of the study design in relation to the objective of the study.
   - Statistical methodology (including sample size calculation) and the potential for reaching sound conclusion with the smallest number of research participants.
   - Justification of predictable risk and inconvenience weighed against the anticipated benefits for the research participants and concerned communities.
   - Risks for the use of control arm (placebo) if any.
   - Criteria for withdrawal of research participants
   - The adequacy of the site, including the support staff, available facilities and emergency

procedures.
- Adequacy of other protocol related documents, including advertisements.
- Look for disclosure or declaration of potential conflict of interest.

b. Recruitment of Research Participants
- Characteristic of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
- Means by which initial contact and Recruitment is to be conducted.
- Inclusion criteria for research participants
- Exclusion criteria for research participants

c. Care and Protection of Research Participants
- Suitability of investigators qualification and experience for the proposed study. Check the Curriculum Vitae and information about the investigators, including Good Clinical Practice (GCP) training for clinical trials.
  Consider whether education and training background are related to the study.
- Medical care to be provided to research participants during and after the course of the research.
- Adequacy of medical supervision and psychosocial support.
- Steps to be taken if research participants voluntarily withdraw during the research.
- Arrangement, if appropriate for informing the research participants attending physician or family doctor, including procedures for seeking the participants consent to do so.
- Description of any plans to make the study product available to the research participants.
- Description of any financial cost to research participants.
- Compensation for research participants for transportation allowance and lost days at work or school.
- Provision for compensation/ treatment in the case of injury/ disability or death of a research participant attributable to participation in the research.
- Insurance and indemnity arrangements.

d. Protection of Research Participant Confidentiality
- A description of who will have access to research participant's data, including medical records and biological sample.
- Measure taken to ensure the confidentiality and security of research participants personal information.
- Ensure to request PI/Researcher to include waiver of informed consent if it is review of records.

e. Informed Consent Process
- Full description of the process of obtaining informed consent including those responsible for obtaining it.
- Adequacy, completeness and comprehension of written and oral information to be given to

the research participants and when appropriate, their legally acceptable representative (LAR).

- Use of understandable language for better comprehension, translate into local language or dialect.
- Assurances that research participants will receive information that becomes available during the research relevant to their participation including their rights, safety and well-being.
- Provisions made for Receiving and responding to queries and complaints from research participants by indicating the names and contact information of the research team and the IRB.

f. Vulnerability

- Review of involvement of vulnerable study populations. Evaluation of mechanism, to protect the vulnerable subject below 18 years of age needing assent
- Subjects who are mentally incapacitated needs legal representative.
- Elderly subjects may have cognitive problems also need legal representative.
  Assent
- The feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:
  0-under 7: No need for assent
  7-under 12: Verbal Assent
  12-under15: Simplified written assent
  15-under18: the minor can co-sign the consent signed by the parents

g. Risk

- The 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 use of placebo as detailed in the Declaration of Helsinki (as applicable)

h. Benefits

- The 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

i. Incentives or compensation

- The amount and method of compensations, financial incentives, or reimbursement of study-related expenses

j. Community Considerations

- The impact of the research on the local 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.

- The extent to which the research contributes expected benefits to the community or to society, or contributions to scientific knowledge.

k. Discuss the potential COI of the PI as investigator/IRB member and as the attending physician; consistently document the management of the COI in the minutes of meeting

l. Discuss the process of recruitment particularly if PI is also the health care provider of the potential participant

m. Review Ethical Considerations

- Discuss ethical issues and their impact on the safety and well-being of participants
- Discuss vulnerability – identify vulnerable participants – Provide mechanisms to ensure safety and well-being of participants
- Discuss risk vs benefit
- identify risks (physical, psychological, etc.)
- Mitigate risks by requiring referral for care for participants who may develop adverse events
- Approve only if benefit is more than the risk

n. Comment on the comprehensibility of the ICF language with the perspective of a study participant.

o. Ensure to require PI to have ICF translated in Hiligaynon.

p. Discuss the process of getting the informed consent considering the potential COI of PI as concurrent attending physician of the participant

q. Justify any Recommendation for an increase in honorarium for participants Ensure that compensation, re-imbursements are given right after the visit of the participant

**2.6. Forms**

Declaration of No Conflict of Interest of Investigators/Researchers (Form 2.1)
IRB Checklist for Initial Submission (Form 2.2)
Protocol Package Acknowledgement Receipt (Form 2.3)
Initial Submissions and Resubmissions Electronic Database (Form 2.4)

**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 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* |

**2.8. References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 3.1**<br>**Exempt from Review** |

### 3.1.1 Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) may have studies that are exempt from review. Protocols with negligible to not more than minimal risk maybe exempted from regular review.

### 3.1.2 Objective of the Activity

This exempt from review aims to describe the protocols for review that qualify for exemption.

### 3.1.3 Scope

This SOP applies to initial submission qualified for the exempt of review.

1. The following are 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

   Investigator/Researcher Responsibilities after Approval:
2. A final report shall be submitted at the end of the study.
3. Any change or alteration in the exempted protocol shall invalidate the exemption granted.
4. A revised protocol shall be submitted to IRB for review if it still qualifies for exemption.

### 3.1.4 Workflow

| ***ACTIVITY*** | ***RESPONSIBILITY*** | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Review of submitted protocol applying for exemption from review* | *The Chair or Member-Secretary* | *7 days* |
| *Step 2: Furnish Certificate of Exemption or Recommend for full board or expedited review (form 3.1)* | *Chair* | *1 day* |
| *Step 3: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 4: Filing of the documents to the protocol file* | *Staff Secretary* | *1 day* |

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.1**<br>**Exempt from Review** |
| Effective Date: July 1, 2024 | |

**3.1.5 Description of Procedures**

**Step 1: Review of submitted protocol applying for exemption from review**

The chair or member secretary shall evaluate and review the submitted protocol applying for review of exemption using Checklist for Exemption Form (Form 3.6)

**Step 2: Furnish Certificate of Exemption or Recommend for full board or expedited review**

**2.1** The chair or member secretary submit the result of the assessment. The certificate of exempt signed by the IRB will be issued to protocol that qualify for exempt from review.

**2.2** If the protocol does not meet the criteria for exemption, the reviewer shall recommend the protocol either for full board or expedited review.

**2.3** The staff secretary prepare a report of all protocol exempted from review and will be presented by the reviewer during the full board meeting.

**Step 3: Communication of the IRB decision/Action to the Principal Investigator/Researcher**

**3.1** The Office Manager or Staff Secretary prepare the certificate of exempt from review (form 3.1) signed by the chair.

**3.2** Office Manager or Staff Secretary will communicate to the PI via phone calls or text message and will issue the certificate of exemption.

**Step 4: Filing of the documents to the protocol file**

**4.1** The staff secretary file the copy of the document in the protocol file and keep in the locked cabinet.

**3.1.6 Form**

Certificate of Exempt from Review (Form 3.1)
Checklist for Exemption Form (Form 3.6)

**3.1.7 History of SOP**

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2019 July 26* | *IRB SOP TEAM* | *First draft*<br>*Added SOP 3.1 Exempt from Review*<br>*Added Form 3.1 (Certificate of Exempt from Review)* |
| *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.* |

**3.1.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board; "**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition. **"Standard Operating Procedures of Lung Center of the Philippines-Institutional Ethics Review Board"**, 2018, Version 04.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.2**<br>**Expedited Review** |
| Effective Date: July 1, 2024 | |

**3.2.1 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 and when the study participants do not belong to a vulnerable group. The results of the initial review shall be released to the principal investigator within four weeks after the submission of all the required documents

**3.2.2 Objective of the Activity**

Review of studies that do not entail more than minimal risk to study participants and those involving participants not belonging to a vulnerable group aims to demonstrate due diligence and high standards in the system of protection of human participants.

**3.2.3 Scope**

This SOP applies to initial and post-approval submissions on protocols which have been classified as not involving more than minimal risk to study participants and whose participants do not belong to vulnerable groups.

The following are types of protocols that can be subjected to expedited review:

- ☐ Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.

- ☐ Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).

- ☐ Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood (e.g., body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

- ☐ Research involving data, documents or specimens that have been already collected or will be collected for on-going medical treatment or diagnosis.

- ☐ Administrative revisions, such as correction of typing errors.

- ☐ Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.

**3.2.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Assignment of Reviewers or IC/s (SOP on Appointment of IC (SOP#1.3))* | *Chair* | *1 day* |
| *Step 2: Notification of Reviewers or IC/s* | *Staff Secretary* | *1 day* |
| *Step 3: Provision of study documents and evaluation form (Protocol Evaluation Form and Informed Consent Evaluation Form) to reviewers* | *Staff Secretary* | *1 day* |
| *Step 4: Accomplishment and submission of evaluation forms* | *Primary Reviewers* | *7 days* |
| *Step 5: Consolidation and Finalization of review results* | *Chair* | *1-2 days* |
| *Step 6: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 7: Updating of Protocol File index and Electronic data base: (SOP on Management of Active Files (SOP#7.2))* | *Staff Secretary* | *1 day* |
| *Step 8: Inclusion of the Review in the Agenda of the next meeting (SOP on Preparing the Notice of IRB Meeting with Agenda (SOP#5.2))* | *Chair and Staff Secretary* | *1 day* |

**3.2.5 Description of Procedures**

**Step 1: Assignment of Reviewers or Independent Consultant/s:**

**1.1** The Chair or Member-Secretary assigns one medical member and one lay member to do the expedited review of the submitted protocols.

**1.2** If the Chair determines that a study involves procedure/s that are not within the area of competence or expertise of the IRB members, the Chair may invite the individual with expertise in special areas from the pool of existing IC in order to assist in the review of the protocol in addition to those available within the IRB.

**1.3** In case there is a need for an additional consultant, the Chair asks IRB members for possible qualified IC and Reviewers.

**1.4** The IRB members Recommend names of potential Consultants.

**1.5** The Chair endorses the names of probable Consultants to the Hospital Administrator for approval.

**1.6** The Hospital Administrator formally appoints IC and issues appointment letter to the new IC which includes their terms of office and duties and responsibilities.

**Step 2: Notification of Reviewers or Independent Consultant/s:**

**2.1** The Staff Secretary informs the assigned Reviewers through SMS (text) or phone call once the Chair has decided to whom he will give the protocols for review.

**2.2** The Reviewers confirm their availability and suitability to do the expedited review.

**Step 3: Provision of documents and evaluation forms to Reviewers:**

**3.1** The Staff Secretary delivers the documents and evaluation forms to the offices of the assigned reviewers.

**3.2** He/she provides pertinent documents (complete protocol package for initial submission; for post-approval submissions, pertinent information from the retrieved protocol and the report itself) and the evaluation forms (Protocol Evaluation Form and Informed Consent Evaluation Form) to the reviewers.

**Step 4: Accomplishment and Submission of Evaluation forms:**

**4.1** The assigned reviewers accomplish and submit the evaluation forms that has been reviewed and completed in the most comprehensive and informative manner within seven (7) days after receipt thereof.

**4.2** They may bring all the documents and evaluation forms to the IRB Office or inform the Staff or Staff Secretary to pick-up the pertinent documents from their Offices.

**Step 5: Consolidation and Finalization of the review results:**

**5.1** The two assigned reviewers confer about their findings and submit their decision to the Chair.

**5.2** If the decision is approved and the Chair agrees, then the decision is communicated to the researcher immediately without waiting for the IRB meeting.

**5.3** This is only reported in the next IRB meeting by the Member secretary.

**5.4** There is no discussion on Expedited review protocol unless an issue is raised when it is reported during the IRB meeting.

**5.5** If there is disagreement between the two reviewers, the Chair reviews and may decide to approve it or bring the protocol to full board meeting.

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

**6.1** Once the communication form has been approved by the Chair, the Staff Secretary informs the Investigators through SMS (text) or phone call that the decision of the IRB is available.

**6.2** He/she also informs the Investigator to pick up the official document from the IRB Office.

**6.3** The Office Manager or Staff Secretary releases the Notification of IRB Decision or Approval Letter after 10 days.

**Step 7: Updating of Protocol File index and Electronic data base:**

The Staff Secretary updates the index of file contents, the electronic and the manual database of the specific protocol file and keeps the document/s in the protocol file folder for easy monitoring and reference of the IRB.

**Step 8: Inclusion of the Review in the Agenda of the next IRB regular meeting:**

**8.1** Using the Notice of the Meeting with Agenda Template, the Staff Secretary prepares the draft of the agenda.

**8.2** He/she includes the report of the result of the expedited review to be presented by the assigned reviewers.

**8.3** The contents of the item are the following information: IRB Protocol number, Sponsor Protocol number, Protocol Title, Principal Investigator, Sponsor, Documents, Issue and the Decision.

**8.4** Only Approved protocols reviewed by expedited procedures are included in the meeting agenda and are reported to full board meeting.

### 3.2.6 Forms

IRB Protocol Evaluation Form (Form 3.2)
IRB Informed Consent Evaluation Form (Form 3.3)

### 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 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.*<br>*Updating of protocol file index and electronic database.*<br>*Stated in step 8 the review of expedited procedure.* |
| *06* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow.* |

**3.2.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition

**3.3.1 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 to study participants or when study participants belong to vulnerable groups. Such a protocol shall be deliberated and decided upon during IRB regular meeting, preferably within six (6) weeks after submission of the required documents. Full review shall be conducted through a primary reviewer system.

**3.3.2 Objective of the Activity**

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

**3.3.3 Scope**

This SOP applies to initial, revisions and post-approval submissions on protocols which have been classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups.

The following are types of protocols that should undergo full board review:

- ☐ Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3).
- ☐ Phase 4 intervention research involving drugs, biologics or device.
- ☐ Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm.
- ☐ Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review.
- ☐ Protocols that involve collection of identifiable biological specimens for research.
- ☐ Major revisions of the protocol and informed consent after initial review.
- ☐ Annual Progress report, On-site SAE, SUSAR report, Review of Negative Events (RNE), Protocol Deviation, Early Termination report, Final report, Application for Continuing review, Site visit, and Review of Appeal.

### 3.3.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of IC (SOP#1.3))* | *Chair or Member-Secretary* | *1 day* |
| *Step 2: Notification of Primary Reviewers or IC* | *Staff Secretary* | *1 day* |
| *Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers and to the rest of the IRB members* | *Staff Secretary* | *1 day* |
| *Step 4: Presentation of review findings and Recommendations during IRB regular meeting (SOP on Conduct of Meeting (SOP#5.3))* | *Chair and Primary Reviewers* | *1 day* |
| *Step 5: Discussion of technical and ethical issues* | *IRB members* | *1 day* |
| *Step 6: Summary of issues and resolutions* | *Chair* | *1 day* |
| *Step 7: IRB action* | *All IRB members* | *1 day* |
| *Step 8: Documentation of the Board deliberation and action(SOP on Preparing the Minutes of the Meeting (SOP#6.1))* | *Member -Secretary and Staff Secretary* | *1 day* |
| *Step 9: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 10: Updating of Protocol File index and Electronic data base* | *Office Manager or Staff Secretary* | *1 day* |

### 3.3.5 Description of Procedures

**Step 1: Assignment of primary reviewers or Independent Consultants:**

**1.1** The Chair or Member-Secretary assigns primary reviewers who will be responsible in presenting the evaluation in a comprehensive manner during the regular meeting.

**1.2** If the Chair determines that a study involves procedure/s that are not within the area of competence or expertise of the IRB members, the Chair may invite the individual with expertise in special areas from the pool of existing IC in order to assist in the review of the protocol in addition to those available within the IRB. Invite an independent consultant (expert) to add in the review of the protocol (methodology, benefits, risks, new information about the intervention) if the primary protocol review lacks the expertise.

**Step 2: Notification of primary reviewers and independent consultants:**

The Staff Secretary informs the Members and the IC through SMS (text) or phone call once the Chair has decided who will be the primary reviewers and if there is a need for IC.

**Step 3: Provision of protocol and protocol-related documents and assessment forms to Reviewers and to the rest of the IRB members:** (i.e. the distribution of protocol, ICF and related documents to all members 1 month before the meeting)

**3.1** Fifteen (15) days before the IRB meeting, all the members are provided with the complete protocol and the evaluation forms (IRB Protocol Evaluation Form (Form 3.1) and the Informed Consent Evaluation Form (Form 3.2)).

**3.2** Principal Investigator and/or proponents are to be invited in the meeting, upon the Recommendation of the Chair, to be scheduled for the purpose.

**Step 4: Presentation of review findings and Recommendations during IRB regular meeting:**

**4.1** The presence of the Primary Reviewers is required during the conduct of the review and on its presentation.

**4.2** Should they be absent during the scheduled meeting, the chair will invite the Alternate member as the primary reviewer with same expertise.

**4.3** The presentation is guided by the use of IRB evaluation forms. Recommendations are comprehensive and organized.

**Step 5: Discussion of technical and ethical issues:**

The IRB discusses technical and ethical issues such as the study design, vulnerability Subject who, risk/benefits assessment, language of informed consent form, description of risks/benefits in the ICF, provision for treatment of study related injuries and provision for compensation. *(Please see SOP #2, Management of Initial Submission).*

**Step 6: Summary of issues and resolutions:**

**6.1** The Chair asks the members their evaluation on each item based on the forms provided.

**6.2** He/she also summarizes the issues and Recommendations on the protocol based on the deliberation.

**6.3** The members approve by consensus. The approval is done through a motion from any member of the board and seconded accordingly.

**6.4** If there are no objections, the motion is carried.

**Step 7: IRB actions:**

The Chairman or the Member-Secretary will summarize the issues raised during the discussion before decision making. IRB actions may either be:

- 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.

**7.1** Communication of IRB decision/action:
The IRB discusses the reports, the amendments and the Recommendations of the reviewers.

**7.1.1** The action of the IRB for Initial submission and resubmission may be one of the following:

- ☐ Approval
- ☐ Minor Revision
- ☐ Major Revision/ Resubmission
- ☐ Disapproval

**7.1.2** For the amendments, the decision will be:

- ☐ Approved
- ☐ Major revision
- ☐ Minor revision
- ☐ Disapproved

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

- ☐ Accepted
- ☐ Request further information
- ☐ Require specific action from researcher
- ☐ Take Note and No Further Action needed

7.1.4 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: _____

**7.1.5** For the RNE, 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: _____

**7.1.6** For the protocol deviation/violation, the decision will be:
- ☐ Submission of additional information
- ☐ Submission of corrective action/Preventive actions
- ☐ Clarificatory interview with the Principal Investigator
- ☐ Site visit
- ☐ Suspension of recruitment
- ☐ Suspension of the study
- ☐ Others**:**

**7.1.7** For early termination reports given by the Principal Investigator and/or the Sponsor, the IRB decision may be to:
- ☐ accept, or
- ☐ request further additional information or action

**7.1.8** For the final reports, the decision will be:
- ☐ to accept, or
- ☐ to require submission with Corrections

**7.1.9** For the application for continuing review, the decision will be:
- ☐ Approved
- ☐ Request additional information
- ☐ Submission of an explanation for failure to submit required reports
- ☐ Disapproval

**Step 8: Communication of IRB action to the Principal Investigator:**

**8.1** The Staff Secretary fills-up the IRB Communication Forms template (Approval Letter, Notification of the IRB Decision Form, Communication Letter) using the information from the Minutes of the Meeting for the full-board review.

**8.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**8.3** The Staff Secretary informs the Investigators/Researcher through SMS (text)/phone call or email that the decision of the IRB is available.

**8.4** He/she also informs the Investigator to pick up the official document from the IRB Office.

**8.5** The Office Manager or Staff Secretary releases the Notification of IRB Decision or Approval Letter ten (10) days after the IRB meeting.

**Step 9: Updating of Protocol File index and Electronic data base:**

**9.1** The Staff Secretary updates the index of file contents and keeps the document/s in the protocol file folder for easy monitoring and reference of the IRB.

**9.2** He/she also updates the active files using electronic and paper-based database once a week and updates the back-up system of all active files and documents twice a month.

### 3.3.6 Forms

IRB Protocol Evaluation Form (Form 3.2)
IRB Informed Consent Evaluation Form (Form 3.3)

### 3.3.7 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 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.* |

**3.3.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**,

| | |
|---|---|
| Version No: 03 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.4**<br>**Review of SJREB** |
| Effective Date: July 1, 2024 | |

**3.4.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) shall require the submission of research protocol and the review process of researches that are qualified for Single Joint Ethics Review Board (SJREB) joint review.

**3.4.2 Objective of the Activity**

Review of SJREB aims to streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines. To harmonize the results of ethics review among various site IRBs through joint review. To strengthen the ethics review capacity of PHREB Level 3 IRBs to review different types of protocols that are conducted at their sites and to shorten the turn-around time of ethics review of multi-site protocols.

**3.4.3 Scope**

This SOP applies to the management of research protocols qualified for SJREB joint review, the review process and coordination with SJREB.

**3.4.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt of complete protocol package for SJREB join review* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Notification of Chair* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 3: Send the protocol package to the primary reviewers.* | *Staff Secretary* | *1 day* |
| *Step 4: Coordinates with SJREB regarding primary reviewers* | *Staff Secretary* | *1 day* |
| *Step 5: Conduct Preliminary review* | *IRB Members* | *2nd Thursday of the month* |
| *Step 6: Primary Reviewers attend SJREB full board meeting* | *Primary Reviewers* | *1 day* |
| *Step 7: Obtain minutes of meeting and notification of decision from SJREB* | *Staff Secretary* | *7 days after the SJREB full board meeting* |
| *Step 8: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 9: Filing of all related documents and update the protocol database* | *Staff Secretary* | *1 day* |

**3.4.5 Description of Procedures**

**Step 1: Receipt of complete protocol package for SJREB join review**

**1.1** The Office Manager of Staff Secretary receives and check the completeness of the initial protocol package submission from the PI.

**1.2** Research protocols classified under joint review must be submitted to IRB at least one (1) month prior to submission to SJREB.

**Step 2: Notification of Chair**

**2.1** The Chair is notified by the Staff Secretary regarding the new protocol submission.

**2.2** The IRB chair verifies whether the research protocol is for joint review. To be eligible for joint review, the research protocol must be implemented in a least three (3) sites in the Philippines in at least one (1) DOH Hospital.

**2.3** The Chair informs the staff secretary 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 (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.

**Step 3: Send the protocol package to the primary reviewers.**

The IRB send a letter of notification signed by the IRB chair to SJREB that the Primary reviewers/ representative will participate in the joint review.

**Step 4: Coordinates with SJREB regarding primary reviewers**

**4.1** The staff secretary informs the IRB chair regarding the request from SJREB. The staff secretary coordinates with the SJREB secretariat upon receipt of request for primary reviewers/ representatives from IRB.

**4.2** The staff secretary in coordination with the chair gives the names of the assigned reviewers/representatives who will attend the SJREB full board meeting. The staff secretary asks the details regarding the SJREB full board meeting to be communicated to the reviewers.

**Step 5: Conduct Preliminary Review**

5.1 The Primary reviewers report the results of the review during IRB full board meetings and discuss site-specific issues and concerns. (i.e., PI qualifications and COI, site of the clinical trials, type of participants, community-based research, etc.)

**5.2** The chair and member secretary consolidates site specific issues and comments, and makes a preliminary decision to be reported by the primary reviewers/representatives to the SJREB during SJREB full board meeting.

**Step 6: Primary Reviewers attend SJREB full board meeting**

**6.1** The primary reviewers accomplish 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 discussion of the protocol documents, and vote on specific items to arrive at a decision.

**Step 7: Obtain minutes of meeting and notification of decision from SJREB**

**7.1** The decision of the SJREB precedes the decision of the IRB.

**7.2** The IRB staff secretary obtains the minutes of the meeting and notification of decision from the SJREB secretariat seven (7) days after the SJREB full board meeting.

**7.3** Within seven (7) days after receiving the minutes and the decision of the SJREB, the chair and member secretary make a site decision in an expedited meeting taking into consideration the decisions made by the SJREB and to address site specific concerns.

**7.4** The consolidated decisions of the IRB and SJREB will be presented during the next IRB full board meeting.

**Step 8: Communication of IRB decision/action to the PI/researcher**

The IRB staff secretary notifies the PI regarding the outcome of the IRB review and the SJREB review as follows:

- ☐ Approval
- ☐ Minor Modification

PI shall be given fifteen (15) days to comply with the IRB recommendation.

- ☐ Major Modification

The PI shall be given sixty (60) days to comply with the IRB recommendations. The resubmitted documents shall be referred to the primary reviewers and discussed at full board once again before approval is granted.

- ☐ Disapproval

**Step 10: Filing of all related documents and update the protocol database**

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

**3.4.6 Form**

SJREB Form 3.1 (COI)

SJREB Form 2 (Protocol Assessment Form)
SJREB Form 3 (Informed Consent Assessment Form)

**3.4.7 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* | *Revise SJREB* |

**3.4.8 Reference**


**Lung Center of the Philippines-Institutional Review Board SOP**, 2023.
**Revised SJREB SOP** version 04.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.5**<br>**Review of Resubmission** |
| Effective Date: July 1, 2024 | |

### 3.5.1 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 sixty (60) days for the major revisions and within two (2) weeks for minor revisions. Major revisions will be discussed by the full board and expedited review will be reported by the primary reviewers during the regular meeting.

### 3.5.2 Objective of the Activity

A review of resubmission aims to ensure the compliance of the protocol that needs revision for the safety and beneficial effect of the study participants.

### 3.5.3 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.

### 3.5.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receive and manage the resubmitted protocol package* | *Staff Secretary* | *1 day* |
| *Step 2: Review the resubmission* | *Primary Reviewers* | *7 days* |
| *Step 3: Return documents with a decision/Recommendation* | *Primary Reviewers* | *7 days* |
| *Step 4: Presentation of review findings and Recommendations during IRB regular meeting:* | *IRB members* | *1 days* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: Filing of the documents in the protocol file folder and update the protocol database* | *Staff Secretary* | *1 day* |

### 3.5.5 Description of Procedures

**Step 1: Receive and manage the resubmitted protocol package**

The Office Manager or Staff secretary receives and checks the documents being submitted based on the IRB Checklist for Resubmission (Form 3.4)

**1.1.** Three (3) copies of resubmitted protocol for clinical trial and/or sponsor-initiated studies has to include the following:

- ☐ Letter of Resubmission
- ☐ Items Revised
- ☐ Major
- ☐ Minor
- ☐ Protocol Resubmission Form

**1.2** The Staff secretary logs the protocol documents in the incoming communication logbook.

**1.3** The Staff secretary sends the resubmitted initial protocol package to the same primary reviewers who did the initial review.

**Step 2: Review the resubmission**

The primary reviewers review the resubmitted documents and assess whether the PI complied with the IRB requirements for modification as summarized in IRB Protocol Resubmission Form (Form 3.5)

**Step 3: Return documents with a decision/Recommendation**

**3.1** The primary reviewers return the resubmission package to the secretariat staff indicating their Recommendation.

**3.2** In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the previous Recommendations set forth by the IRB during full board meeting.

**3.2** Minor modifications as previously Recommended during full board meeting shall go to expedited review.

**3.4** For major modifications for full board discussion, the primary reviewers may Recommend approval if the PI has substantially complied with the Recommendations during the previous full board meeting.

**Step 4: Presentation of review findings and Recommendations during IRB regular meeting:**

**4.1** The primary reviewers present their assessment and Recommendations on the resubmitted documents to full board.

**4.2** The IRB discusses technical and ethical issues such as the study design, vulnerability, risk/benefits assessment, language of informed consent form, description of risks/benefits in the ICF, provision for treatment of study related injuries and provision for compensation.

**4.3** The IRB members shall deliberate on the Recommendations by the primary reviewers and decide on appropriate actions to be taken.

**4.4** Decision can be any of the following:
a) Approve
b) Minor modification
c) Major modification
d) Disapprove

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

The Chair formulated a letter to the PI regarding the decision of the IRB. The Staff secretary transfers the Recommendations and/or decision to the IRB Communication forms template (Approval letter, Notification of IRB Decision)

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

**6.1** The Staff secretary files copy of the approved protocol documents in the protocol file folder and keep in the lock cabinets. She/he also updates the electronic database.

**3.5.6 Forms**

IRB Checklist for Resubmission (Form 3.4)
IRB Protocol Resubmission Form (Form 3.5)

**3.5.7 History of SOP**

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2019 Jul 25* | *IRB SOP TEAM* | *First draft*<br>*Added SOP 3.4 (Management of Resubmission)*<br>*Added IRB Checklist for Resubmission (Form 3.4)*<br>*IRB Protocol Resubmission Form (Form 3.5)* |
| *02* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow. Revise scope.* |

**3.5.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;
**"Standard Operating Procedures of Lung Center of the Philippines-Institutional Ethics Review Board"**, 2018, Version 04;
**PHREB Standard Operating Procedures**, 202

| | |
|---|---|
| Version No: 02 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.6**<br>**Protocol Review during emergency situations** |
| Effective Date: July 1, 2024 | |

### 3.6.1 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.

### 3.6.2 Objective of the Activity

To provide guidelines for conduct of research ethics review through electronic means during emergency situations.

### 3.6.3 Scope

This SOP provides instructions for review and approval of protocol review during emergency situations. This SOP includes the process from online submission of protocols to the review of the post-approval submissions.

### 3.6.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of submission of protocols via electronic means to the official IRB email address.* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Notification of Chair.* | *Staff Secretary* | *1 day* |
| *Step 3: Determine type of review and identify primary reviewers. (SOP on Expedited Review (SOP #3.1) or full review (SOP on full review (SOP#3.2)).* | *IRB Chair/Member-Secretary* | *1 day* |
| *Step 4: Request an Independent Consultant* | *Chair* | *1 day* |
| *Step 5: Review protocols sent via email and make Recommendations.* | *Primary Reviewers* | *7 days* |
| *Step 6: Discuss the results of the review during full board meeting via zoom.* | *Primary Reviewers* | *1 day* |
| *Step 7: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 8: Filing of all related documents and update the protocol database.* | *Staff Secretary* | *1 day* |

### 3.6.5 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 Secretary 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 Chair is notified by the Staff Secretary about the submitted report through SMS (text) or phone.

**Step 3: Determine type of review and identify primary reviewers.**

**3.1** The IRB Chair or Member Secretary identifies the primary reviewers of the protocol.

**3.2** The Chair/Member-secretary reviews the protocol package to determine whether the protocol is for full board or expedited review.

**Step 4: Request an Independent Consultant**

The Chair will invite an expert or independent consultant to review the said protocol. The IC will be given the complete protocol and will attend the full board meeting.

**Step 5: Review of protocols sent via email and make Recommendations.**

**5.1** The primary reviewers check the submitted documents.

When reviewing a protocol during emergency situations, the reviewer should also consider the following:

a. Social value
b. Scientific soundness
c. Fair selection of participants
d. Informed Consent Forms
e. Overall risk-benefit
f. Feasibility of the study in the site
g. Qualifications and COI of the Principal Investigator
h. Community Involvement

**Step 6: Discuss the results of the review during full board meeting via zoom.**

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

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

**Step 7: Communication of IRB decision/action to PI/researcher**:

**7.1** The Staff Secretary fills-up the IRB Communication Forms template using the information from the Minutes of the Meeting of the full-board review.

**7.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**7.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 8: Filing of related documents:**

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

**3.6.6 Form**

**3.6.7 History of SOP**

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2024 Jan* | *IRB SOP TEAM* | *First draft* |

**3.6.8 Reference**

**Makati Medical Center Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 03 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.7**<br>**Review of Medical Device Protocol** |
| Effective Date: July 1, 2024 | |

**3.7.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) requires the review of medical device protocols in full board or expedited review depending on the level of risk involved in the study.

**3.7.2 Objective of the Activity**

Review of medical device protocols aims to ensure the safety and welfare of human participants.

**3.7.3 Scope**

This SOP provides instructions for review and approval of protocols on medical devices intended for human participants.

**3.7.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of submission of medical device protocols in the logbook/data base* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Notification of Chair.* | *Staff Secretary* | *1 day* |
| *Step 3: Determine type of review and identify primary reviewers. (SOP on Expedited Review (SOP #3.1) or full review (SOP on full review (SOP#3.2)).* | *IRB Chair/Member-Secretary* | *1 day* |
| *Step 4: Review protocols and make Recommendations.* | *Primary Reviewers* | *7 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 on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 7: Filing of all related documents and update the protocol database.* | *Staff Secretary* | *1 day* |

**3.7.5 Description of Procedures**

**Step 1: Receipt and documentation of submission of Medical Device protocol in the logbook/database:**

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

**Step 2: Notification of Chair:**

The Chair is notified by the Staff Secretary about the submitted protocol through SMS (text) or phone.

**Step 3: Determine type of review and identify primary reviewers.**

**3.1** The IRB Chair or Member Secretary identifies the primary reviewers of the protocol. If the study is multicenter *(Please see SOP 3.4 on review of SJREB).*

**3.2** The Chair/Member-secretary reviews the medical device protocol package to determine whether it is for full board or expedited review.

**3.3** The Chair may invites Independent Consultant who has necessary expertise on the protocol.

**Step 4: Review protocols and make Recommendations.**

**4.1** The primary reviewers and IC check the submitted documents.

When reviewing a medical device protocol, the reviewer should also consider the following:

i. Proposed investigational plan (use of the device in the study)
j. Informed Consent Form/s
k. Description of the device/ Product information including handling and storage requirements.
l. Description of study participant selection criteria
m. Safety monitoring procedures
d. Reports of prior investigations conducted with the device
e. Principal Investigator's curriculum vitae
f. Risk assessment determination for new investigational device
g. Statistical plan and analysis
h. Copies of all labelling for investigational use
i. FDA approval of the medical device, if applicable

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

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

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

The reviewer's assessment will be presented and discussed during the full board meeting. If the protocol is SJREB, the result during the SJREB meeting will be presented during full board meeting.

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

**6.1** The Staff Secretary fills-up the IRB Communication Forms template using the

information from the Minutes of the Meeting of the full-board review.

**6.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**6.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 7: Filing of related documents:**

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

**3.7.6 Form**

Protocol Evaluation Form (Form 3.1)
Informed Consent Evaluation Form (Form 3.2)

**3.7.7 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* |

**3.7.8 Reference**

**Makati Medical Center Standard Operating Procedures,** 2020.
**Lung Center of the Philippines-Institutional Review Board SOP**, 2023.

| | |
|---|---|
| Version No: 02 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 3.8**<br>**Review of Public Health Protocols** |
| Effective Date: July 1, 2024 | |

### 3.8.1 Policy Statement

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

### 3.8.2 Objective of the Activity

Review of public health protocols aims to ensure the safety and welfare of human participants.

### 3.8.3 Scope

This SOP provides instructions for review and approval of protocols on public health intended for human participants.

### 3.8.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of submission of public health protocols in the logbook/data base* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Notification of Chair.* | *Staff Secretary* | *1 day* |
| *Step 3: Determine type of review and identify primary reviewers. (SOP on Expedited Review (SOP #3.1) or full review (SOP on full review (SOP#3.2)).* | *IRB Chair/Member-Secretary* | *1 day* |
| *Step 4: Review public health protocols and make Recommendations.* | *Primary Reviewers* | *1 day* |
| *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 on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 7: Filing of all related documents and update the protocol database.* | *Staff Secretary* | *1 day* |

### 3.8.5 Description of Procedures

**Step 1: Receipt and documentation of submission of report of Public Health protocol in the logbook/database:**

The Office Manager or Staff Secretary receives the complete documents from the

PI/Sponsor and records it in the logbook and in a protocol Database.

**Step 2: Notification of Chair:**

The Chair is notified by the Staff Secretary about the submitted protocol through SMS (text) or phone.

**Step 3: Determine type of review and identify primary reviewers.**

**3.1** The IRB Chair or Member Secretary identifies the primary reviewers of the protocol.

**3.2** The Chair/Member-secretary reviews the protocol to determine whether the protocol is for full board or expedited review.

**Step 4: Review protocols public health 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?
g 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**:

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

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

**Step 5: Communication of IRB decision/action to the PI/researcher**:

**5.1** The Staff Secretary fills-up the IRB Communication Forms template using the information from the Minutes of the Meeting of the full-board review.

**5.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**5.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 6:** Filing of related documents:
The Staff Secretary files all reports, makes a copy of all related documents in the protocol file and update the protocol database.

**3.8.6 Form**

Review of Public Health Protocol (Form 3.7)

**3.8.7 History of SOP**

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2024 Apr. 29* | *IRB SOP TEAM* | *First draft* |
| *02* | *2024 June 20* | *IRB SOP TEAM* | |

**3.8.8 Reference**


**https://ahpsr.who.int/publications/i/item/2019-12-02-ethical-considerations-for-health-policy-and-systems-research.**
**Ethical considerations for health policy and systems research A publication from the Alliance for Health Policy and Systems Research (WHO) with the Global Health Ethics Unit (WHO),** 2019

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.1**<br>**Review of Protocol Amendment** |
| Effective Date: July 1, 2024 | |

**4.1.1 Policy Statement**

The St. Paul's Hospital of Iloilo Institutional Review Board shall require the submission of an application for the amendment of previously approved study protocols and related documents prior to the implementation of these changes.

**4.1.2 Objectives of the Activity**

This activity aims to determine the compliance of the approved protocol, its safety and beneficial effects to the study participants.

**4.1.3 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.

**4.1.4. Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and entry to the incoming logbook and in the electronic database of the protocol amendment applications for review* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Determine type of review and identify primary reviewers. (SOP on Expedited Review (SOP #3.1) or full review (SOP on full review (SOP#3.2)).* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 3: Review amendments and make Recommendations.* | *Primary Reviewers* | *2nd day from the time of submission to not < 2 weeks before the IRB meeting* |
| *Step 4: Discuss the amendment or report the result of the review during full board meeting.* | *Primary Reviewers* | *Not >4 weeks from the time of submission* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: File documents and update electronic database.* | *Staff Secretary* | *1 week after the IRB meeting* |

**4.1.5. Description of Procedures**

**Step 1: Receipt and entry to the incoming logbook and in the electronic database of the protocol**

**amendment applications for review:**

The Office Manager or Staff Secretary receives the reports and makes an entry on the specified reports or amendment application on the logbook and electronic database using the Excel format.

**Step 2: Determine type of review and identify primary reviewers:**

**2.1** The IRB Office Manager or Staff Secretary identifies the initial primary reviewers of the protocol and refers the amendment package to them for review.

**2.2** The Chair/Member-secretary reviews the amendment package to determine whether the amendment is for full board or expedited review.

A. Major protocol amendments involve changes that may increase the risk to study participants or alters risk - benefit balance. These amendments are referred for full board review. These protocol amendments include, but are not limited to the following:

a) A change in study design
b) Additional treatments or the deletion of treatments
c) Any change in the inclusion/exclusion criteria
d) Change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
e) Significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
f) Significant decrease or increase in dosage amount
g) Any other changes that will entail more than minimal risk

B. Minor protocol amendments are those that are unlikely to compromise the integrity of the research or the welfare and rights of the participants and presents no new ethical issues, and are administrative in nature. The review of these amendments is thru expedited process.

**2.3** If the primary reviewers are not available to do the review, the chair or member-secretary shall do the review provided they do not have Conflict of Interest. Otherwise, the Chair designates qualified members to review the amendments.

**Step 3: Review amendments and make Recommendations:**

**3.1.** The primary reviewers check the amended documents and compare them with the previously IRB approved documents in the protocol files. The primary reviewers assess if the proposed amendments would alter the risk/ benefit balance of the study, if the study is feasible, and if the safety and well-being of the participants are being uphold. The primary reviewers make appropriate Recommendations using IRB Protocol Amendment Form (Form 4.1).

**3.2.** If an amendment is minor, as assessed by the primary reviewers, it is reviewed under expedited process at the level of the Chair.

**3.3.** If an amendment is deemed major or disapproved, as assessed by the reviewers, it is referred to full board review.

**3.4.** The primary reviewers must complete and submit the results of review to the Chair/member-secretary within seven (7) days prior to the full board meeting.

**3.3** The primary reviewer has to assess if there is a change in risk and benefit ratio.

**Step 4: Discuss the amendment or report the result of the review during full board meeting.**

**4.1** The primary reviewers present the results of the review to the board and together with the IRB members, discuss the issues related to the amendments to arrive at a decision.

**4.2** The board may decide whether there's a need for the PI to clarify, elaborate or explain further the amendments.

**4.3** For the amendments, the decision will be:

- ☐ approved
- ☐ additional justification/information required
- ☐ reconsent required
- ☐ disapproved

**Step 5: Communication of IRB decision/action to PI/researcher**

The Chair formulates a letter to the PI regarding the decision of the IRB. The Staff Secretary transfers the Recommendations and/or decision to the IRB Communication Forms template (Approval Letter, Notification of the IRB Decision Form, Communication Letter)

**Step 6: File documents and update electronic database.**

The Staff Secretary ensures that the investigator receives the IRB communication form signed by the Chair. The Staff Secretary files all reports, which include the amendment and committee decision, and makes a copy of all amendment related documents in the protocol file index and electronic data base.

**4.1.6. Forms**

Protocol Amendment Form (Form 4.1)

**4.1.7. 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* | *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.*<br>*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.*<br>*Delete step 3.2 (except A) in section 4.1.6*<br>*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* |

**4.1.8. References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition;

**"Standard Operating Procedures of Lung Center of the Philippines-Institutional Ethics Review Board",** 2018, Version 04.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.2**<br>**Review of Progress Report** |
| Effective Date: July 1, 2024 | |

**4.2.1 Policy Statement**

The St. Paul's Hospital of Iloilo Institutional Review Board shall require the submission of progress reports at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB shall choose to review or monitor the protocols more frequently.

**4.2.2 Objectives of the Activity**

This activity aims to determine the compliance of the approved protocol, its safety and beneficial effects to the study participants.

**4.2.3 Scope**

This SOP applies to the management and review of progress submitted by the proponent while the study is on-going or has ended.

The annual progress report becomes the basis for continuing review of protocols whose approval needs to be renewed every year.

**4.2.4. Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and entry to the incoming logbook and in the electronic database of progress reports submissions for continuing review* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: The Staff Secretary forwards the progress report to the IRB Members* | *Staff Secretary* | *1 day* |
| *Step 3: Review of progress reports* | *IRB Members* | *14 days* |
| *Step 4: Discuss the progress report during full board Meeting* | *IRB Members* | *1 day* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: File progress report and update protocol file index and protocol database* | *Staff Secretary* | *1 day* |

**4.2.5. Description of Procedures**

**Step 1: Receipt and entry to the incoming logbook and in the electronic database of progress reports submissions for continuing review:**

**1.1** Checks monthly (set at the beginning of the month) the database and tracks due dates of progress reports of Research Protocols previously approved by IRB.

**1.2** Prepares and sends reminder letter to the PI one (1) month before the due date of expiration of approval.

**1.3** All required documents must be submitted on or before the expiration date. The progress report should be received within the cut off period of one (1) month before the full board review meeting to be included in the agenda for the months' full board meeting.

**1.4** Records the date of submission in the Logbook of Submitted documents and in the Electronic Database.

**Step 2: The Staff Secretary forwards the progress report to the IRB Members:**

**2.1** The Staff Secretary forwards to the IRB members the progress report and relevant documents of previous reviews such as protocol amendments/deviations and on-site SAEs/SUSARS since the last continuing review at least two (2) weeks before the full board review meeting.

**2.2** The Staff Secretary shall ensure that the reviewers will have the complete relevant documents to facilitate review and assessment of the progress report.

**Step 3: Review of progress reports:**

**3.1** The IRB members conduct review of the progress report if they are in accordance with the original protocol and related documents approved by the IRB.

**3.2** The IRB members refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of amendments.

**3.3** The following are the key evaluation points in the review of progress reports:

A. Risk Assessment:

a) The risks to the study participants are minimized.

b) The risks - benefit balance is reasonable, if any. What is important, is the knowledge that may be gained from the study.

c) Adequacy of Informed Consent Forms. The different types of informed consent form should be provided, if applicable. It should be the most recently approved or currently in use.

d) Appropriate and new significant findings should be provided to the study participants since these may be related to willingness to continue participation in the study (e.g. important toxicity or adverse event information).

B. Local issues such as the following:

a) Changes in the PIs circumstances (e.g. suspension of hospital privileges or medical license, involvement in numerous clinical trials).

b) Evaluation, investigation and resolution of complaints related to the research, if any.

c) Changes in the acceptability of the research protocol in terms of institutional

commitments such as personnel and financial resources, and adequacy of facilities. Changes in regulations, applicable national law or standards of professional conduct of practice.

d) PI concerns about trial conduct at the site such as study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent documents required by institutional policies, if any.

C. Progress of the study:

a) Start date of the study and expected duration

b) Total subject enrollment:

- ☐ Expected enrollment
- ☐ Actual enrollment
- ☐ Enrollment issues
- ☐ Withdrawal of participants:
  -number of participants who withdrew
  - lost to follow-up
  - Summary of reasons for withdrawal at local site

D. The IRB members shall give Recommendations as follows:

a) Acceptance of the progress report

b) PI to provide further information or submit additional documents.

c) Requires specific action from researcher (e.g. Request modifications of the protocol or informed consent form if there is any change in the original risk-benefit assessment or any significant issues that may change risk-benefit balance.)

d) Take note and no further action needed

e) Others

E. The IRB Members must complete the review and accomplish Progress Report Form (Form 4.3) and shall be submitted to the secretariat within 7 days prior to the full board meeting.

F. The Recommendations and significant issues identified by the IRB members shall be included in the agenda for discussion during the full board meeting to arrive at a final decision and appropriate action.

G. For review of protocol progress reports under expedited review, IRB action is finalized at the level of the Chair and should be completed within two (2) weeks.

**Step 4: Discuss the progress report to during full board Meeting:**

**4.1.** The IRB members present the results of the review, their Recommendations and any significant issues identified in relation to the progress of the study.

**4.2.** The board deliberates and determines the need for the PI to elaborate, clarify or explain further any aspect of the progress report.

**4.3.** The action of the IRB for progress reports may be one of the following:

- ☐ Accept
- ☐ Request further information
- ☐ Requires specific action from the researcher
- ☐ Take note and no further action needed
- ☐ Others

**Step 5: Communication of IRB decision/action to PI/researcher:**

**5.1** The Office Manager and Staff Secretary take note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.

**5.2.** The Staff Secretary prepares the notification of IRB decision and sends the notification to the PI.

**Step 6. File progress report and update protocol file index and protocol database**

**6.1** The Staff Secretary keeps a copy of the progress report package together with the comments of the IRB members in the protocol file folder and update the protocol file index.

**6.2.** The Staff Secretary files the protocol file folder in the active study file section of the cabinet under lock and key and updates the electronic database.

**4.2.6. Forms**

Progress Report Form (Form 4.2)

**4.2.7. 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* | *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.*<br>*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* | *IRB SOP TEAM* | *Revise sequencing of SOPs on Post- Approval Reviews.* |
| *08* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow.* |

**4.2.8. References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition.

**"Standard Operating Procedures of Lung Center of the Philippines-Institutional Ethics Review Board",** 2018, Version 04.

### 4.3.1 Policy Statement

This SOP applies to the review of Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs), DSUR, Line Listing, PSLL report submitted by the Principal Investigator (PI) and sponsor to the St. Paul's Hospital of Iloilo IRB to comply with ICH GCP. The IRB shall require the submission of reports of SAEs and SUSARS which are fatal or life-threatening as soon as possible or within 24 hours when the on-site SAEs occurred, and those which are not life-threatening within two (2) weeks after the event has come to the attention of the researcher. The Member-Secretary is assigned to analyze the SAEs and SUSARs. The Recommendations of the Member-Secretary are reported to the IRB during the regular monthly meeting for final action. This focus of review is for onsite SAEs. It explains the relatedness and expectedness assessment that the reviewer will do based on the effects and outcome of the SAE on the participant.

### 4.3.2 Objectives 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 the information submitted and to safeguard its contents.

### 4.3.3 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, local site and off site.

ICH-GCP E6 defines a Serious Adverse Event (SAE) or a Serious Adverse Drug Reaction (ARD) as any untoward medical occurrence that at any dose:

- Results in death,
- Is life threatening,
- Requires hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability or incapacity, or
- Results in a congenital anomaly or birth defect

A Suspected Unexpected Serious Adverse Reaction (SUSAR) 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.

### 4.3.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/data base* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol file* | *Office Manager or Staff Secretary* | *1 day* |

| | | |
|---|---|---|
| *Step 3: Notification of Chair* | *Staff Secretary* | *1 day* |
| *Step 4: Delivery of report to the member-secretary* | *Staff Secretary* | *1 day* |
| *Step 5: Inclusion of the report of the assigned reviewer in the agenda of the next regular IRB meeting* | *Chair and Staff Secretary* | *1-2 days* |
| *Step 6: Report on the SAEs and SUSARs & Recommendations* | *Member- Secretary, IRB* | *1 day* |
| *Step 7: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 8: Filing of all related documents and update the electronic data base (SOP on Management of Active Files(SOP#7.2))* | *Staff Secretary* | *1 day* |

**4.3.5 Description of Procedures**

**Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database:**

The Office Manager or Staff Secretary receives the Protocol Report Updates Form (SUSARs) (Form 4.3) from the PI/Sponsor and records it in the logbook and in an Excel file database.

**Step 2: Retrieval of pertinent protocol file:**

Pertinent information about the protocol, such as the earlier reports on SAEs and SUSARs, will be retrieved by the Office Manager or Staff Secretary.

**Step 3: Notification of Chair:**

The Chair is notified by the Staff Secretary about the submitted report through SMS (text) or phone.

**Step 4: Delivery of report to the member-secretary:**

**4.1** The Staff Secretary informs the Member-Secretary, or the Member assigned by the Chair, about the submission of the SAEs/SUSARs through phone or SMS.

**4.2** The Staff Secretary delivers the report to the Office of the Member-Secretary or the assigned Member two (2) weeks before the regular meeting to review and give Recommendations on the reports.

**Step 5: Inclusion of the report of the assigned reviewer in the agenda of the next regular IRB meeting:**

The Chair Recommends the inclusion of the report in the agenda of the next meeting and the Staff Secretary includes it in the agenda.

**Step 6: Report on the SAEs and SUSARs & Recommendations:**

**6.1** During the meeting, the Member-Secretary reports on the summary of the SAEs. The report includes:

- ☐ the number of studies that have SAES and SUSARs,
- ☐ the number of SAEs that occurred on-site, local site and off sites(foreign),
- ☐ the number of the type of SAE: SUSAR or No SUSAR,
- ☐ 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

**6.2** The Member-Secretary Recommends appropriate action by filling up the Section 2 of the Protocol Report Updates Form submitted by the investigator.

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

- ☐ For multicenter, international studies, note the trend of occurrence of SAE/ SUSAR in study sites in foreign counties and other local sites.
- ☐ For multicenter, national studies, note the nature (related or expected) of the SAE/ SUSAR
- ☐ 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. The Member-Secretary informs the Chair and other members about the Recommendation for appropriate IRB action.

**6.4** After reviewing the report and the Recommendation by Member-Secretary, the Chair presides over the board discussion of the SAEs and similar adverse experiences or advisories.

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

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action is needed.

**6.6** The Member-Secretary, then, fills up the final action taken by the IRB in the SAE/SUSAR report.

**Step 7: Communication of IRB decision/action to PI/researcher**:

**7.1** The Staff Secretary fills-up the IRB Communication Forms template using the information from the Minutes of the Meeting of the full-board review.

**7.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**7.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 8: Filing of all related documents and update the electronic database:**

The Staff Secretary files all reports, makes a copy of all related documents in the protocol file and update the electronic data base.

**4.3.6 Form**

Protocol Report Update Form (SUSAR) (Form 4.3)

**4.3.7 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* | *Revise sequencing of* |

| | | | |
|---|---|---|---|
| | | | *SOPs on Post- Approval Reviews.* |
| *07* | *2024 Feb. 22* | *IRB SOP TEAM* | *Added timeline in calendar days in the workflow. Edited description of procedures Step 6, 6.1.* |
| *08* | *2024 June 28* | *IRB SOP TEAM* | *Revise sequencing of post approval reports* |

**4.3.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition;

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 03 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.4**<br>**Review of Reportable Negative Events Reports** |
| Effective Date: July 1, 2024 | |

**4.4.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) requires the submission of Review of Reportable Negative Events (RNE) reports, at the latest three (3) days after the event has come to the attention of the researcher. Reportable Negative events are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported to the IRB as essential to the continuing concern for a favorable balance of risks and benefits from the study. An example of a policy statement is as follows: *"The IRB shall require the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.*

*Example of RNE reports includes but not limited to the following: Enrolling an ineligible subjects without prior acknowledgment from IRB and Sponsors, Breach of confidentiality, etc.*

**4.4.2 Objective of the Activity**

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

**4.4.3 Scope**

This SOP applies to the review of RNE reports. This SOP begins with the receipt and documentation of submission of RNE reports in the logbook and ends with the filling of all related documents and update of the protocol database.

**4.4.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of submission of report of RNEs in the logbook/data base* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol file* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 3: Notification of Chair* | *Staff Secretary* | *1 day* |
| *Step 4: Call for a Special Meeting.* | *IRB Chair* | *1-3 days* |
| *Step 5: Conduct of the Special Meeting.* | *IRB Members* | *1 day* |
| *Step 6: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |

| | | |
|---|---|---|
| *Step 7: Filing of all related documents and update the protocol database* | *Staff Secretary* | *1 day* |

**4.4.5 Description of Procedures**

**Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database:**

The Office Manager or Staff Secretary receives the accomplished RNE report form (Form 4.4) from the PI/Sponsor and records it in the logbook and in an protocol Database. The staff noted whether the submission is within the required timeline.

**Step 2: Retrieval of pertinent protocol file:**

Pertinent information about the protocol will be retrieved by the Office Manager or Staff Secretary.

**Step 3: Notification of Chair:**

The Chair is notified by the Staff Secretary about the submitted report through SMS (text) or phone.

**Step 4: Call for a Special Meeting.**

The Office Manager or staff secretary prepares for a special meeting. The researcher and other members of the study team may be invited for a clarificatory meeting.

**Step 5: Conduct of the Special Meeting.**

The Chair leads the discussion of the special meeting, summarizes the RNE report and informs the IRB members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The Research team is excused and the IRB members deliberate on possible options, 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 Recommendation to the PI/researcher**:

**6.1** The Staff Secretary fills-up the IRB Communication Forms template using the information from the Minutes of the Meeting of the full-board review.

**6.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**6.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 7: Filing of related documents:**

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

**4.4.6 Form**

Reportable Negative Events Reports (Form 4.4)

**4.4.7 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* | *Added example in the policy statement* |
| *03* | *2024 June 28* | *IRB SOP TEAM* | *Revise sequencing of post approval reports* |

**4.4.8 Reference**

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.5**<br>**Review of Protocol Deviation/ Violation** |
| Effective Date: July 1, 2024 | |

**4.5.1 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 three (3) days after the occurrence of the incident.

**4.5.2 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.

**4.5.3 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.

**4.5.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and documentation of report of protocol deviation/violation in the logbook and in the data base* | *Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol file* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 3: Notification of the Chair* | *Staff Secretary* | *1 day* |
| *Step 4: Inclusion of the report in the agenda of the next IRB meeting(SOP on Preparing the Meeting Agenda(SOP#5.2); SOP on Conduct of Meeting(SOP#5.3))* | *Chair and Staff Secretary* | *1-2 days* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6:Filing of all related documents to the protocol file(SOP on Managing Active Files(SOP#7.2))* | *Staff Secretary* | *1 day* |

**4.5.5 Description of Procedures**

**Step 1: Receipt and documentation of report of protocol deviation/violation in the logbook and in the data base:**

**1.1** The Investigator submits the protocol deviation/violation report (Include submission of corrective/preventive actions (CAPA) as Recommendation to PI) to the IRB Secretariat within three (3) days after the occurrence of the incident.

**1.2** If in case this happens during a weekend or within official holidays of the year, notifications through phone or email must be accomplished and communications followed through on the first day of the working week thereafter.

**1.3** The Staff Secretary receives and documents the report of the protocol deviation/violation in the logbook and data base in an Excel file.

**Step 2: Retrieval of pertinent protocol file:**

The protocol and the previous reports related to protocol deviations/violations are retrieved by Office Manager or Staff Secretary.

**Step 3: Notification of the Chair:**

The Staff Secretary notifies the Chair by phone and by SMS regarding the submission of the report on protocol deviation/violation.

**Step 4: Inclusion of the report in the agenda of the next IRB meeting:**

The Chair decides on the inclusion of the report in the agenda of the next meeting.

**Step 5: Communication of decision/action to PI/researcher:**

**5.1** The IRB members are given the report for review two (2) weeks prior to the meeting.

**5.2** Individual Recommendations are discussed during the meeting and a final decision is made.

**5.3** Possible decisions include one or several of the following:

- ☐ Submission of additional information
- ☐ Submission of corrective/Preventive actions
- ☐ Clarificatory interview with the Principal Investigator
- ☐ Site visit
- ☐ Suspension of recruitment
- ☐ Suspension of the study

**5.4** The Staff Secretary sends a letter of notification, signed by the Chair, to the investigator regarding the decision of the IRB.

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

The Staff Secretary files all the related documents in the protocol file.

**4.5.6 Forms**

Protocol Deviation/Violation Form (4.5)

**4.5.7 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. 30* | *IRB SOP TEAM* | *Revise sequencing of SOPs on Post- Approval Reviews.* |
| *08* | *2024 Feb. 22* | *IRB SOP TEAM* | *Edited scope. Added timeline in calendar days in the workflow.* |
| *09* | *2024 June 28* | *IRB SOP TEAM* | *Revise sequencing of post approval reports* |

**4.5.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition;

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 4.6**<br>**Review of Early Termination Report** |

### 4.6.1 Policy Statement

The St. Paul's Hospital of Iloilo Institutional Review Board shall require PI to inform it, and to submit an early termination report, whenever it is determined that the continuation of a study/protocol shall or has the potential to affect or threaten the rights, safety and welfare of participants are threatened, or for any other reason.

### 4.6.2 Objectives of the Activity

The objective of this activity is to establish the procedures for the reporting of the early termination of studies/protocols, the reason/s therefor, and its effects, if any on the study participants.

### 4.6.3 Scope

This procedure describes how the IRB proceeds and manages the premature or early termination of a protocol, i.e. its discontinuation before its scheduled end. Protocols are usually terminated at the Recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, Sponsor, Pl, by the IRB itself or other authorized bodies. This is done when the safety of the study participants is doubtful or at risk. It begins with the PI's submission to the IRB of the Early Termination Report to formally inform the IRB of his and/or the sponsor's decision to discontinue/pre-terminate the study, and ends with the PI's receipt of the IRB's action concerning the same, and the updating of the protocol database.

### 4.6.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receive application or Recommendation for early study termination* | *PI and Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol file* | *Office Manager or Staff Secretary* | *0 (same day as above)* |
| *Step 3: Review the submission* | *IRB Members* | *1 day* |
| *Step 4: Discuss the early termination result to the IRB during full board meeting* | *IRB Members* | *30 days or less (depends on when the report is submitted in relation to the schedule of the next full board meeting of the IRB)* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: File documents and update protocol file index and electronic database* | *Staff Secretary* | *0 (same day as above)* |

**4.6.5 Description of Procedures**

**Step 1: Receive application or Recommendation for early study termination.**

**1.1** An application for early study termination is submitted when an IRB approved study protocol is being recommended for termination before its scheduled completion. This is done when the rights, safety and welfare of participants are threatened or upon the request of the PI or sponsor due to operational problems.

**1.2.** Receive Recommendation and comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.

**1.3.** Inform the PI to prepare and submit a protocol termination package**.**

**1.4.** The Office Manager or Staff Secretary receives the study protocol termination package submitted by the PI and checks the submission for completeness, including the IRB Early Study Termination (Form 4.6).

**1.5.** The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data**.**

**1.6.** Check approval given by the IRB from the protocol files and type of review from the protocol database.

**1.7**. Staff Secretary logs the date of submission in the Logbook and IRB Electronic Database

**Step 2: Retrieval of pertinent protocol file:**

The Office Manager or Staff Secretary retrieves the pertinent documents in relation to the report submitted by the PI.

**Step 3: Review the submission:**

**3.1** The IRB Members assess the termination issues, review the safety data and make Recommendation. * It is important to note if the Termination Package contains a plan of how the participants who are still active in the study will be followed up. If no plan is noted, the IRB should Recommended to the PI that such plan should be included.

**3.2.** The Office Manager or Staff Secretary shall include the submission for early termination in the agenda for full board review.

**Step 4: Discuss the early termination result to the IRB during full board meeting:**

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

- ☐ accept, or

☐ request further additional information or action

**Step 5: Communication of IRB decision/action to PI/researcher:**

**5.1** The Chair formulates a letter to the PI regarding the decision of the IRB. The Staff Secretary transfers the Recommendations and/or decision to the IRB Communication Form template (Communication Letter)

**5.2** The Staff Secretary ensures that the investigator receives the IRB communication form signed by the Chair. The Staff Secretary files all reports and makes a copy of all related documents in the protocol file index and electronic data base.

**Step 6. File documents and update protocol file index and electronic database**

**6.1** The Staff Secretary keeps a copy of the early termination report package together with the review comments of the IRB members in the protocol file folder and update the protocol file index.

**6.2.** The Staff Secretary files the protocol file folder in the active study file section of the cabinet under lock and key and updates the protocol electronic database.

**4.6.6 Forms**

Early Termination Report Form (Form 4.6)

**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* | *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.*<br>*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* | *Revise 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* | *Revise sequencing of post approval reports* |

**4.6.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board", 2015**, First Edition.

**"Standard Operating Procedures of Lung Center of the Philippines Institutional Ethics Review Board",** 2018, Version 04.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 4.7**<br>**Review of Final Report** |

### 4.7.1 Policy Statement

The St. Paul's Hospital of Iloilo Institutional Review Board shall require the PI to submit a final report not more than one (1) month after completion of the research, for its review and information.

### 4.7.2 Objectives of the Activity

The objective of this activity is to establish the procedures for the reporting by the PIs of their final report, for the review and information of the IRB.

### 4.7.3 Scope

This activity establishes the process or procedure for the submission to the IRB by the study proponents of their final reports, at the end of their study, for the information of the former. It begins with the PI's submission to the IRB of the Final Report, and ends with the PI's receipt of the IRB's action concerning the same, and the updating of the protocol database.

### 4.7.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt and entry to the incoming logbook and in the electronic database of the final report* | *PI and Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol file* | *Office Manager or Staff Secretary* | *0 (same day as above)* |
| *Step 3: Notification of the Chair or Member-Secretary and Forward final or closure report to primary reviewers for review* | *Staff Secretary and Chair* | *1 day* |
| *Step 4: Review of Final report:* | *IRB Members* | *30 days or less (depends on when the report is submitted in relation to the schedule of the next full board meeting of the IRB)* |
| *Step 5: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: File documents and update protocol file index and electronic database* | *Staff Secretary* | *0 (same day as above)* |

### 4.7.5 Description of Procedures

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.7**<br>**Review of Final Report** |
| Effective Date: July 1, 2024 | |

**Step 1: Receipt and entry to the incoming logbook and in the electronic database of the final report:**

**1.1** The Office Manager or Staff Secretary receives the reports and makes an entry on the specified electronic database using the Excel format.

**1.2** End of study reporting is facilitated through submission of the Final Report Form using IRB Final Report Form (Form 4.7) together with the documents deemed relevant by the PI. This comprises the final report package.

**1.3** The Office Manager or Staff Secretary reviews the completeness of submitted report.

**1.4** The Office Manager or Staff Secretary logs the report in the electronic database using the Excel format.

**Step 2: Retrieval of pertinent protocol file:**

The Office Manager or Staff Secretary retrieves the pertinent documents in relation to the report submitted by the PI.

**Step 3: Notification of the Chair or Member-Secretary and forward final or closure report to primary reviewers for review:**

**3.1** The Staff Secretary notifies the Chair or Member-Secretary regarding the reports and the protocol to be amended through phone or SMS within the day of the receipt of the report.

**3.2** The Staff Secretary forwards the Final report to the IRB members.

**3.3** The Staff Secretary includes the final report submission on the agenda for the next IRB monthly meeting for discussion and final decision.

**Step 4. Review of Final report:**

**4.1** The IRB members discusses the final reports during the full board meeting.

**4.1.1.** For the final reports, the decision will be:

- ☐ to accept, or
- ☐ to require submission with Corrections

**Step 5. Communication of IRB decision/action:**

**5.1** The Chair formulates a letter to the PI regarding the decision of the IRB. The Staff Secretary transfers the Recommendations and/or decision to the IRB Communication Form template (Communication Letter)

**5.2** PI may be requested to provide additional information or submit additional documents, in which case the final report maybe accepted, but action regarding archiving maybe deferred depending on the submission of requested additional information.

**5.2** If the final report is approved, the PI is informed of the following:

- ☐ The study protocol is now classified as INACTIVE
- ☐ Ethical clearance is deemed expired effective on the day of the IERB meeting.
- ☐ Study protocol record will be made available for three (3) years in the archives after the expiration date.

**Step 6. File documents and update protocol file index and electronic database:**

**6.1** The Staff Secretary stores the signed Final Report documents in the study protocol file folder upon approval of the final report, and when no further action is expected from the PI.

**6.2** The Staff Secretary enters relevant study protocol data into the study protocol Database to signify the end of the study.

**6.3** The Staff Secretary transfers the study protocol folder to the Inactive Files.

**4.7.6 Forms**

Final Report Form (Form 4.7)

**4.7.7 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.*<br>*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* | *Revise 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* | *Revise sequencing of post approval reports* |

**4.7.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition;

**"Standard Operating Procedures of Lung Center of the Philippines Institutional Ethics Review Board",** 2018, Version 04.

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 11 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.8**<br>**Management of an Application for Continuing Review** |
| Effective Date: July 1, 2024 | |

### 4.8.1 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 six (6) weeks 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 shall undergo Expedited review in its application for continuing review.

### 4.8.2 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.

### 4.8.3 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 to logbook and protocol database.

### 4.8.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt of the application for continuing review and entry to logbook* | *Staff Secretary* | *1 day* |
| *Step 2: Retrieval of pertinent protocol files* | *Staff Secretary* | *1 day* |
| *Step 3: Notification of Chair and Primary Reviewers* | *Staff Secretary* | *1 day* |
| *Step 4: Determination of type of review* | *Chair or Member-secretary* | *1 day* |
| *Step 5: Communication of the IRB Decision/action to the PI/researcher* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: Logging and filling of documents* | *Staff Secretary* | *1 day* |

### 4.8.5 Description of Procedures

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

The Office Manager or Staff Secretary receives, logs and enters in the protocol database the information included in the application for continuing review.

**Step 2: Retrieval of pertinent protocol files**

The staff secretary 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 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 secretary staff notifies the Chair and primary reviewers about the submission of application for continuing review and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.

**Step 4: Determination of type of review:**

The Chair 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 3.3 Expedited Review and SOP 4.2 Full Review).

**Step 5: Communication of the IRB Decision/action to PI/researcher:**

The Staff secretary 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 (Form 6.4).Possible decisions include the following: Approval, Additional information required, Submission of an explanation for failure to submit required reports or Disapproval.

**Step 6: Logging and filling of documents:**

The Staff files the application for Continuing review, the Recommendations of the reviewers and decision letter in the appropriate protocol folder.

**4.8.6 Forms**

Application for Continuing Review (Form 4.8)

**4.8.7 History**

| *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* |

**4.8.8 Reference**


**"A Workbook for Developing Standard Operating Procedures"** 2020 by Philippine Health Research Ethics Board. **PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 4.9**<br>**Site Visits** |

### 4.9.1 Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall designate a site visit team to conduct visits of selected sites of approved protocols that fall within the established criteria.

### 4.9.2 Objective of the Activity

This activity establishes the procedure for the IRB to determine the necessity of monitoring/ visiting a study site, of designating a site visit team for this purpose, and of informing the PI of its conduct, schedule, and other particulars, and thereafter, of its results.

### 4.9.3 Scope

This SOP applies to any site visit made in any study site to check compliance with GCP and IRB approved protocol and related documents.

### 4.9.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Determination of necessity of site visit* | *IRB members* | *1 day* |
| *Step 2: Creation of Site Visit Team* | *IRB Members* | *0 (same day as above)* |
| *Step 3:Notification to the Principal Investigator about the planned visit study site* | *Staff Secretary* | *1 one day later* |
| *Step 4: Conduct of on-site visit* | *IRB Site Visit Team* | *0-5 days from notification* |
| *Step 5: Drafting of the report and Recommendation* | *Head of the IRB Site Visit Team* | *0-7 days from site visit* |
| *Step 6: Presentation of the findings to the Board* | *Head of the IRB Site Visit Team* | *30 days or less (depends on when the report is submitted in relation to the schedule of the next full board meeting of the IRB)* |
| *Step 7: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 8: Monitoring the implementation of board Recommendation and reports action to the board* | *IRB Site Visit Team* | *0-5 (days after informing PI)* |

**4.9.5 Description of Procedures**

**Step 1: Determination of site to visit:**

**1.1** The IRB Members review periodically the database files of the submitted/approved study protocols and determine the study sites needed to be monitored/site visit.

**1.2** The following are the criteria:

- ☐ Frequent protocol violations/deviations
- ☐ Reports of remarkable serious adverse events
- ☐ New Principal Investigator (for the clinical trial)
- ☐ Failure to submit final report
- ☐ Maximum number of protocols the PI can manage

**Step 2: Creation of Site Visit Team:**

**2.1** During the board meeting, the IRB designates at least two, but not more than four of its members to perform on its behalf an on-site visit of the research projects it has approved.

**2.2** 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 St. Paul's Hospital of Iloilo IRB files for the study and site,
- ☐ Make appropriate notes, and
- ☐ Copy some parts of the files for comparison with the site files.

**Step 3: Notification to the Principal Investigator about the planned visit study site:**

**3.1** The Staff Secretary prepares the IRB Communication Letter concerning the planned study site visit.

**3.2** The Chair checks and signs the Communication Letter before it is forwarded to the PI.

**3.3** The site visit will be done two (2) weeks after the PI has received the communication letter.

**Step 4: Conduct of on-site visit:**

During the Site Visit: The team does the following:

- ☐ Uses the Site Visit Form (Form 4.9)
- ☐ Reviews the informed consent document to make sure that the site is using the most recent version
- ☐ Reviews randomly the subject files to ensure that subjects have signed the informed consent form
- ☐ Checks study protocol
- ☐ Checks documents and verify if these have been approved
- ☐ Checks if the files are orderly and confidentiality is maintained
- ☐ Checks the on-site facilities
- ☐ Determines the over-all protection of the rights, safety, and welfare of human participants in the study
- ☐ Debriefs the PI about on-site visit findings and comments
- ☐ Gets immediate feedback

**Step 5: Drafting of the report and Recommendation:**

After the Visit, the Head of the Site Visit Team writes a report/comment using the Site Visit Form (Form 4.9) within one (1) week describing the findings during the audit and forwards a copy of the site visit results to the IRB Staff for inclusion in the next board meeting.

**Step 6: Presentation of the findings to the Board:**

**6.1** The Head of the Site Visit Team presents the site visit report during the board meeting.

**6.2** The Board makes a decision about appropriate action.

- ☐ Uphold original approval with no further action
- ☐ Request further information from the principal investigator (specify)
- ☐ Recommend further action: (specify)

**Step 7: Communication of board decision to the Principal Investigator:**

The Staff Secretary prepares the communication letter about the decision of the board signed by the Chair and he/she sends the letter to the PI for appropriate action.

**Step 8: Monitoring the implementation of board Recommendation and reports action to the board:**

**8.1** The Site Visit Team will monitor implementation of board Recommendation and reports action to the board.

**8.2** The Principal Investigator follows the Recommendations of the board and submits a report of their actions to the Office Manager/Staff Secretary through a formal letter addressed to the Chair two (2) weeks upon receipt of the Recommendation of the Board.

**8.3** The Head of the Study Site Visit Team reports to the board the response of the Principal Investigator's action during the IRB meeting.

**8.4** The Staff Secretary keeps all the on-site visit documents in the protocol file folder.

**4.8.7 Form**

Site Visit Form (Form 4.9)

**4.8.8. 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* | *Revise sequencing of SOPs on Post- Approval Reviews.* |
| *08* | *2024 Feb. 22* | *IRB SOP TEAM* | *Revise scope and added timeline in calendar days in the workflow. Revise description of procedures step 2, 2.1* |

**4.8.9 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.10**<br>**Queries and complaints** |
| Effective Date: July 1, 2024 | |

### 4.10.1 Policy Statement

Queries and complaints may come from various stakeholders but the responsibility of the St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (IRB) is highest for those coming from research participants. Nevertheless, all queries and complaints shall be addressed as promptly, diligently, adequately, and appropriately as possible, while exercising due diligence.

### 4.10.2 Objective of the Activity

There are two intended outcomes in managing 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; and (2) to promote trust and confidence in the Hospital, especially the IRB, among research participants, study sponsors, researchers, and the general public.

### 4.10.3 Scope

This activity establishes the IRB's the processes and procedures for the management of queries and complaints from the various stakeholders, concerning the studies and protocols submitted to it for review. It commences with the receipt, logging, and acknowledgement of the said query or complaint, and ends with the IRB furnishing the author of the query/ complaint with a copy of its response/action taken. This SOP is limited to entertaining and addressing queries and complaints from research participants, or their families, in studies for which it has issued an ethical approval.

### 4.10.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt, logging and acknowledgement of queries and complaints; Notification of Chair* | *Author of query/ complaint and Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Determination whether or not it is within the scope of the IRB's authority and resolving/addressing the complaints* | *Chair* | *0 (same day as above)* |
| *Step 2a: Endorsement of the query/complaint of it is outside the scope of the IRB* | *Chair, proper office, Hospital Administrator* | *0 (same day as above)* |
| *Step 2b: Convening of the IRB (in a special meeting, if necessary) if the query/complaint is within the scope of the IRB* | *Chair, IRB, Hospital Administrator* | *0 (same day as above)* |
| *Step 3: Communication of Response* | *Staff Secretary* | *1 (day after determination)* |

| | | |
|---|---|---|
| *Step 4: Logging of the response and inclusion in the Agenda of the IRB Meeting* | *Office Manager or Staff Secretary* | *0 (same day as above)* |

**4.10.5 Description of Procedures**

**Step 1: Receipt, logging and acknowledgement of queries and complaints; Notification of Chair:**

**1.1** Determination whether or not it is within the scope of the IRB's authority to resolve or Address.

**1.1** All queries and complaints shall be in writing and signed by the complainant and shall be filed with the IRB through the Office Manager or Staff Secretary which shall record the same in a Queries and Complaints Forms and Log.

**Step 2: Determination whether or not it is within the scope of the IRB's authority to resolve or address the complaints:**

**2.2** Within the day from its receipt of the complaint, the Office Manager or Staff Secretary informs the Chair, who shall determine whether or not it is within the scope of the IRB's authority to resolve or address.

**2.3** If the query or complaint is outside the scope of coverage of the IRB's authority under this SOP, then the Chair endorses the same to the proper authority or office, and advises the Hospital Administrator accordingly.

**Step 2a: Determination to resolve or address the complaints:**

**2a.1** If the Queries and Complaints is within the scope or authority of the IRB, then the Chair informs the Hospital Administrator, and convenes the IRB (in a special meeting if necessary) to investigate the same. The Hospital administrator will give her advice and opinion regarding the matter and will coordinate with the IRB regarding her decision.

**2a.2** The investigation is summary in nature and technical rules shall not apply.

**2a.3** The IRB resolves the query or complaint within seven (7) days from its receipt for its comments and Recommendations.

**Step 3: Communication of Response:**

**3.1** The Staff Secretary transfers the Recommendations and/or decisions of the board to the IRB Communication Letter template.

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

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

**5.1** The Staff Secretary logs the documents to be signed by the receiving party on the Queries and Complaints Log.

**5.2** The Staff secretary includes it in the meeting agenda.

**4.9.7 Form**

Queries and Complaints Form (Form 4.10)
Queries and Complaints Logbook

**4.9.8 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.* |

**4.8.9 Reference**

**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board.

| | |
|---|---|
| | **INSTITUTIONAL REVIEW BOARD** |
| Version No: 11<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **SOP No: 4.11**<br>**Management of Appeals** |

### 4.11.1 Policy Statement

It is the policy of the SPHI that a research that has been disapproved by the IRB cannot be conducted at SPHI. However, investigators may appeal the decisions made by IRB by writing a letter to the IRB Chair requesting for re-review and provide the supporting information/material for consideration.

### 4.11.2 Objective of the Activity

There are two intended outcomes in the management of appeals: (1) to promptly, diligently, adequately, and appropriately managed the appeals for the reconsideration of disapproved study protocols; and (2) to promote trust and confidence in the Hospital, especially the IRB, among research participants, study sponsors, researchers, and the general public.

### 4.11.3 Scope

This activity establishes the procedures for the management of appeals that may be filed by investigators whose researches/studies were disapproved by IRB. It begins with the receipt of the appeal, the IRB's action, and the notification of the PI of the decision of the IRB. This SOP applies to study protocols disapproved by the IRB and addressing appeals from Principal Investigators, research participants, or their families and sponsors.

### 4.11.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Receipt, logging and acknowledgement of appeals; Notification of Chair* | *PI and Office Manager or Staff Secretary* | *20 days or less from the PI's receipt of the IRB's decision disapproving the research* |
| *Step 2: Evaluation of the Appeal and includes in the next IRB meeting agenda* | *Chair* | *1 day* |
| *Step 3: Review of the Appeal* | *Chair and reviewers, if the appeal is granted; Chair only if appeal is denied* | *30 days if appeal is granted; 5 days if appeal is denied* |
| *Step 4: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 5: Logging and filling of documents* | *Office Manager or Staff Secretary* | *0 (same day as above)* |

**4.11.5 Description of Procedures**

**Step 1: Receipt, logging and acknowledgement of appeals; Notification of Chair:**

**1.1** The Principal Investigator who disagree with the disapproved decision of the IRB may submit a written letter of appeal for reconsideration within twenty (20) days after receipt of the latter. The Investigator will provide a supporting information or materials that will aid the IRB in the review of appeal.

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

**1.3** The Staff secretary will inform and forward the letter of Appeal to the IRB Chair.

**Step 2: Evaluation of the Appeal and includes in the next IRB meeting agenda:**

**2.2** The IRB chair will review and evaluate the appeal together with the supporting information or materials and the previous minutes of the meeting where the disapproved decision was made.

**2.3** If there is a merit in the appeal, the IRB chair will assign primary reviewers of the study protocol.

**2.4** The appeal will be included in the agenda of the next IRB monthly meeting.

**2.5** Investigators will be given the opportunity to attend the next scheduled IRB meeting to discuss their appeal and answer any questions posed by IRB.

**2.6** In case of Conflict, the Chair will forward the appeal to the hospital administrator who upon review of the case shall decide.

**Step 3: Review of the Appeal:**

**3.1** The primary reviewers present their assessment and Recommendations on the resubmitted documents to full board.

**3.2** The IRB members shall deliberate on the Recommendations by the primary reviewers and decide on appropriate actions to be taken.

**Step 4: Communication of the IRB Decision/action to PI/Researcher:**

**4.2** If the IRB's decision is to consider the protocol for review, the Staff Secretary transfers the Recommendations and/or decisions of the board to the IRB Communication Letter template informing the Principal Investigators of the IRB decision.

**4.3** If the IRB's decision is to sustain the disapproval, the Staff secretary will inform the

**4.4** Principal Investigator through the Communication Letter regarding the reason of the final disapproval.

**4.5** If the Principal investigator is given the decision of final disapproval, the said decision will no longer be appealed again.

**Step 5: Logging and filling of documents:**

The Staff Secretary files the documents including the minutes of the meeting in the IRB cabinets.

**4.11.6 Form**

Appeals Logbook

**4.11.7 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.* |

**4.11.8 Reference**

**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board.

| | |
|---|---|
| Version No: 01 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 4.12**<br>**Non-Compliance to SPHI IRB Administrative Protocol** |
| Effective Date: July 1, 2024 | |

### 4.12.1 Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) requires the review of erring investigators who fail to comply with the procedures set by St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB).

### 4.12.2 Objective of the Activity

To describe the IRB process of erring investigators who fail to comply with the procedures set by St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB).

### 4.12.3 Scope

This SOP applies to all SPHI-affiliated investigators/researcher with protocols conducted in and outside St. Paul's Hospital of Iloilo, Inc. This specifies appropriate actions to ensure compliance.

Initiation and/or implementation of any non-approved study protocol shall be considered a VIOLATION of the standard operating procedures of the SPHI-IRB.

Any ongoing non-registered or non-approved study shall be suspended until the study proponents fully comply with the IRB requirements.

### 4.12.4 Responsibilities

It is the responsibility of the IRB Secretariat to monitor compliance to SPHI IRB Standard Operating Procedures and Protocol.

It is the responsibility or the board members or designated members to take action related to non compliance to SPHI IRB Protocol.

It is responsibility of the SPHI- IRB is to ensure all investigators comply with SPHI-IRB administrative protocols.

### 4.12.5 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Monitor or receive report of non-compliance with the SPHI IRB SOP.* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Notification of concern to the Member-Secretary and Chair.* | *Staff Secretary* | *1 day* |
| *Step 3: Review non-compliance report and determine the urgency and appropriate action* | *IRB Chair/Member-Secretary* | *1 day* |

| | | |
|---|---|---|
| *Step 4: Discuss during full board meeting and make a decision.* | *Members/ Chair* | *1 day* |
| *Step 5: Communication of IRB Recommendation to the PI/researcher (SOP on Communicating IRB Decisions(SOP #6.2))* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 6: Filing of all related documents and update the protocol database.* | *Staff Secretary* | *1 day* |
| *Step 7: Follow up the recommended action after a reasonable time.* | *Staff Secretary* | *1 day* |

**4.12.6 Description of Procedures**

**Step 1: Secretariat monitors compliance or any IRB member may receive noncompliance reports**

The Secretariat receives the report of non-compliance with the SPHI IRB SOP and ensures the completeness of the information.

**Step 2: Notification of Chair and Member Secretary:**

2.1 The Chair and Member Secretary is notified by the Staff Secretary about the submitted report through SMS (text) or phone for appropriate assessment of the urgency of the concern and action needed.

2.2 Issues as well as the details of non-compliance involving research investigators are included in the agenda of the IRB meeting for Board recommendation and decision.

**Step 3: Review Non-Compliance to SPHI IRB Administrative Protocol and make Recommendations.**

**3.1** The Board Members check the submitted documents.

**Criteria for Non-Compliance**

If a non-registered study has been completed, the following sanction/s will be imposed:

**A. For the 1st offense:**

1) Prohibition from citing SPHI IRB as the study location or institutional review center.
2) Non-inclusion of the study in the investigator's list of reference or bibliography.

**B. For the next offense:**

• Prohibition from participation of the investigator(s) in any other institutional research in SPHI IRB.

**Criteria for Withdrawal of Approval**

Approval may be withdrawn by the SPHI IRB for the following reasons:

A. Breach of previously approved conduct of the research.
B. Failure to respond to SPHI IRB's request for information/ action.

**Step 4: Discuss during full board meeting and make a decision.**

**Board Decision**

A. Continue study and monitor compliance
B. Request for further information
C. For site visit
D. Suspend the study
E. Suspend enrollment of new patients
(NB.* until the following are met:
1) Additional information is made available.
2) SPHI IRB recommendations are implemented by the Principal Investigator and considered satisfactory by the SPHI IRB.)
F. Terminate approval of current study**

(NB** Termination is based on one or more of the following:
1) SAE reports that indicate significant and study related harm to participants
2) Fraudulent violations and major breach of previously approved protocols that affects scientific integrity and safety of participants
3) Implementation of major amendments with implications to participant safety and scientific integrity without approval by the SPHI IRB
4) Failure to respond to SPHI IRB's request for information/action
Research proposal of an involved Principal Investigator or co-investigator are held in abeyance as determined by the Chair.

Principal investigator may be invited during the full board meeting for clarification about the issue.
For reports of non-compliance to the SOP, the chair is informed of such report and calls for a special meeting when needed to deliberate on the incident.
Board members discuss and recommend the appropriate sanction. The Chair gives the final decision of the board.

**Step 5: Communication of IRB decision/action to PI/researcher**:

**7.1** The Staff Secretary fills-up the IRB Communication Forms template using the information from the Minutes of the Meeting of the full-board review.

**7.2** The IRB Chair checks and signs the IRB Communication form before the Office Manager or Staff Secretary forwards it to the investigator, institutions, agencies, etc.

**7.3** The Office Manager or Staff Secretary gives the communication letter to the Investigator/Sponsor regarding their Recommendations whenever it is necessary. The Office Manager or Staff Secretary ensures that the investigator receives the letter signed by the Chair.

**Step 7: Filing of related documents:**

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

**Step 8: Follow up the recommended action**

The Staff Secretary follows up the action after a reasonable time as stipulated in the letter to the principal investigator.

### 4.12.7 Form

### 4.12.8 History of SOP

| *Version No.* | *Date* | *Authors* | *Main Change* |
|---|---|---|---|
| *01* | *2024 June 28* | *IRB SOP TEAM* | *First draft* |

### 4.12.9 Reference

**Makati Medical Center Institutional Review Board – Standard Operating Procedure**

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 5.1**<br>**Preparing for a Meeting** |
| Effective Date: July 1, 2024 | |

**5.1.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct regular meetings every second Thursday of the month. Special meetings shall be held any day should there be a need to resolve issues that need immediate attention. All meetings shall be held at the SPH IRB Office.

**5.1.2 Objective of the Activity**

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

**5.1.3 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.

**5.1.5 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Compilation of all IRB documents* | *Staff Secretary* | *1-2 days* |
| *Step 2: Preparation of the Agenda* | *Chair, Staff Secretary* | *1 day* |
| *Step 3: Assembly of materials and documents needed for the meeting* | *Office Manager and Staff Secretary* | *1 day* |
| *Step 4: Preparation of logistics for the meeting* | *Staff Secretary* | *1-2 days* |
| *Step 5: Notification of IRB Members and confirmation of attendance* | *Staff Secretary* | *1 day* |

**5.1.6 Description of Procedures**

**Step 1: Compilation of all IRB documents:**

The Staff Secretary compiles all documents/ information submitted to the IRB within a given period (two (2) weeks prior to the last IRB meeting until two weeks before the next meeting) to include them in the next full board meeting agenda for discussion or information of the IRB members.

**Step 2: Preparation of the agenda:**

The Staff Secretary prepares the draft of the Notice of IRB Meeting with Agenda (Form 5.1) for checking of IRB Chair.

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

**3.1** The Office Manager and Staff Secretary prepares all the materials for the meeting which includes, but not limited to the meeting agenda, minutes of the previous meeting, documents for review, SAE/SUSARs report, photocopies of all progress reports, protocol deviations, administrative documents, etc.

**3.2** They ensure that all members will have their own copies for review. Members who prefer to review electronic copies of documents shall be provided with links while hard copies of documents shall be provided for those who prefer to review hard copies of the protocol.

**3.3** All documents are delivered by the Staff Secretary to the offices of the members two (2) weeks prior to the schedule of the IRB meeting.

**Step 4: Preparation of logistics for the meeting:**

**4.1** Three (3) days before the meeting, the Staff Secretary fills up the Administrator Office Borrower's Form to borrow the LCD projector and laptop from the Administration.

**4.2** He/ She also forwards the request for snacks to the SPHI canteen. The IRB Staff prepares the IRB Office for the IRB regular meeting.

**4.3** The Office Manager ensures to request honoraria of the members who attended the previous IRB regular meeting from the Hospital Administrator, which will be given during the next meeting.

**Step 5: Notification of IRB Members and confirmation of attendance:**

**5.1** Before the end of the IRB regular meeting, the Chair announces the schedule of the next meeting.

**5.2** Prior to the delivery of the documents, the Staff Secretary informs the IRB members of the schedule of the meeting through SMS (text) to confirm their attendance and the presence of quorum.

**5.3** The members confirm their attendance through SMS (text) or phone call to the IRB Office.

**5. 4** The staff secretary to check the attendance at least 10 days before the meeting date to ensure that quorum will be met.

**5.6** If quorum will not be met, invite an alternate member. Provide a copy of the protocol package to the alternate member for his/her review.

**5.7** Once the primary reviewer is absent, the alternate member with the same expertise will be invited to attend the IRB meeting and reviewed the assigned protocol.

**5.1.7 Forms**

Notice of IRB Meeting with Agenda Template (Form 5.1)

**5.1.8 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* | *2024 June 28* | *IRB SOP TEAM* | *Added step 5.7* |

**5.1.9 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition.

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 5.2**<br>**Preparing the Notice of the Meeting with Agenda** |
| Effective Date: July 1, 2024 | |

**5.2.1 Policy Statement**

The meeting agenda of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall be based on the submissions two (2) weeks prior to the last meeting up to two (2) weeks before the scheduled regular meeting. It shall follow the established template for Notice of IRB Meeting with Agenda.

**5.2.2 Objective of the Activity**

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

**5.2.3 Scope**

This SOP describes how the IRB determines what items are 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.

**5.2.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Preparation of the draft of the meeting agenda* | *Staff Secretary* | *1-2 days* |
| *Step 2: Preparation of the provisional meeting agenda* | *Chair* | *1-2 days* |
| *Step 3: Distribution of the Notice of the Meeting with Provisional Agenda* | *Staff Secretary* | *1 day* |
| *Step 4: Approval of the provisional meeting agenda* | *IRB members* | *1 day* |
| *Step 5: Filing of the Notice of the Meeting with Final Agenda* | *Staff Secretary* | *1 day* |

**5.2.5 Description of Procedures**

**Step 1: Preparation of the draft of the meeting agenda**:

**1.1** Using the Notice of the Meeting with Agenda Template (Form 5.1) and the report of the Staff Secretary regarding the compiled documents he/she has received (two weeks prior to the last IRB meeting until two weeks before the next meeting), the Office Manager or the Staff Secretary prepares the draft of the agenda. The contents of the agenda of the regular meeting are as follows:

I. Opening Prayer
II. Call to Order
III. Determination of a Quorum
IV. Approval of the Agenda
V. Reading and Approval of the Minutes of the Previous Meeting
VI. Business Arising from the Minutes of the Previous Meeting
VII. Disclosure of Conflict of Interest among Members

VIII. Protocol Review
- A. New Protocols for Initial Review of Full Board
- B. Resubmission
- C. Review of SJREB Protocols
- D. Appeal
- E. Amendments
- F. Progress Reports
- G. SAE/SUSAR Reports
- H. Review of Reports on Negative Events (RNE)
- I. Protocol Deviations and Violations
- J. Early Termination Reports
- K. Final Reports
- L. Application for Continuing Review
- M. Site Visit
- N. Queries and Complaints
- O. Report on the Results of the Expedited Review
- P. Reports of Exempt from Review Protocols
- Q. Other Reports/Notification

IX. Other Matters

X. Checking of Quorum

XI. Adjournment

**1.2** The contents of the items under the protocol review are the following information:

- ☐ IRB Protocol #
- ☐ Sponsor code
- ☐ Protocol Title
- ☐ Principal Investigator
- ☐ Primary Reviewers
- ☐ Sponsor
- ☐ Documents
- ☐ Discussion

**Step 2: Preparation of the provisional meeting agenda:**

**2.1** The Chair checks the draft of the Agenda. He/she then, signs the Notice of the Meeting with Provisional Agenda and gives to the Staff Secretary for the distribution to the IRB members.

**2.2** The process shall end two (2) weeks before the scheduled meeting.

**Step 3: Distribution of the Notice of the Meeting with Provisional Agenda:**

The Staff Secretary distributes the Notice of IRB Meeting with Provisional Agenda together with other documents to the offices of the IRB members two weeks before the scheduled meeting.

**Step 4: Approval of the provisional meeting agenda:**

**4.1** At the start of the meeting, the provisional agenda is approved by the IRB members present.

**4.2** If there are other specific matters to be discussed, they are included in the final agenda

**Step 5: Filing of the Notice of IRB Meeting with Final Agenda:**

**5.1** The Staff Secretary files the Notice of IRB Meeting with Final Agenda in its specific folder that is kept securely in SPHI IRB Documents Cabinet.

**5.2** Extra copies are brought to the Shredding Room for proper disposal.

### 5.2.6 Forms

Notice of IRB Meeting with Agenda Template (Form 5.1)

### 5.2.7 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 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 procedures5.2.5 step 1.* |
| *06* | *2024 June 28* | *IRB SOP TEAM* | *Revise sequencing in the Notice of the IRB Meeting template* |

### 5.2.8 References


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board; "**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition; **PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 5.3**<br>**Conduct of Meetings** |
| Effective Date: July 1, 2024 | |

**5.3.1 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. There shall be a quorum of at least five members that shall include medical, non-medical and non-affiliate members. The meeting shall be guided by the approved agenda. Disclosure of conflict of interest shall be done prior to discussion of protocols for review.

**5.3.2 Objective of the Activity**

Meetings are aimed at arriving at collegial decision regarding study protocols and IRB operations.

**5.3.3 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.

**5.3.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Distribution of meeting materials* | *Staff Secretary* | *1 day* |
| *Step 2: Opening Prayer* | *Member* | *1 day (IRB Meeting)* |
| *Step 3: Call to Order* | *Chair* | *1 day (IRB Meeting)* |
| *Step 4: Determination of quorum* | *Member-Secretary* | *1 day (IRB Meeting)* |
| *Step 5: Approval of the provisional agenda* | *IRB Members* | *1 day (IRB Meeting)* |
| *Step 6: Approval of minutes of the previous meeting* | *IRB Members* | *1 day (IRB Meeting)* |
| *Step 7: Discussion of "business arising from the minutes"* | *IRB Members* | *1 day (IRB Meeting)* |
| *Step 8: Disclosure of conflict of interest (COI)* | *IRB Members (who have COI)* | *1 day (IRB Meeting)* |
| *Step 9: Review of protocols and protocol-related Submissions (Protocols for Initial Review of Full Board, Resubmission, Appeal, Amendments, Progress Reports, SAE/SUSARs reports, RNE reports, Protocol Deviation/Violation, Early Termination, Final Report, Application for Continuing Review, Site Visits, Queries and Complaints, etc)* | *Chair and Members* | *1 day (IRB Meeting)* |
| *Step 10: Report of results of expedited review* | *Assigned Reviewers* | *1 day (IRB Meeting)* |
| *Step 11: Discussion of Other Matters* | *Chair and Members* | *1 day (IRB Meeting)* |

| | | |
|---|---|---|
| *Step 12: Adjournment* | *Chair* | *1 day (IRB Meeting)* |
| *Step 13: Collection, storage, and disposal of meeting materials* | *Staff Secretary* | *1 day (IRB Meeting)* |

**5.3.5 Description of Procedures**

**Step 1: Distribution of meeting materials:**

**1.1** The Office Manager and Staff Secretary prepares all the materials fifteen days prior to the IRB regular meeting. These include, but are not limited to the meeting agenda, minutes of the previous meeting, documents for review, SAE/SUSARs report, photocopies of all progress reports, protocol deviations, administrative documents, etc.

**1.2** Three (3) copies are prepared for this purpose.

**1.3** Two (2) weeks prior to the meeting, the above materials and documents are distributed by the Staff Secretary to the offices of the members.

**1.4** Due to COVID restriction. Face to face, virtual or hybrid meeting is allowed.

**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 number of members present (50% + 1) classified as to medical, non-medical, non-affiliate, and gender representation.

**4.2** Presence of a quorum is announced and the formal meeting starts. The members present sign the Attendance Sheet (Form 5.2)

**Step 5: Approval of the provisional agenda**:

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

**5.2** Provisional agenda is approved by a motion from any member of the board and seconded accordingly.

**Step 6: Approval of minutes of previous meeting:**

**6.1** After making Corrections if there are any, the approval of the minutes is done through a formal motion from any member of the board and seconded accordingly.

**6.2** The Member-Secretary cannot make a motion for the approval of the minutes.

**Step 7: Discussion of "business arising from the minutes":**

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

**7.2** Follow up of previous issues are made by any of the members and the matters are resolved.

**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 and document in the minutes each time before reviewing a new protocol and before making a decision

**8.2** If there is no COI, members sign the COI form. If there is any member who has COI with any protocol, the Chair manages the conflict by asking the concerned member to leave the conference room while the protocol is being discussed.

**8.3** He/she is called back after a decision has been made.

**8.4** The Member-Secretary determines the quorum every time a member leaves the room.

**Step 9: Review of protocols and protocol-related submissions (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** Primary reviewers present issues for discussion during the review of protocols. Medical members discuss the protocol evaluation and lay/ non-medical members present the evaluation of the informed consent form prior to the decision of the IRB. Primary protocol reviewer should present a summary or synopsis of the protocol before presenting the results of his/her review.

**9.2** They review, discuss and evaluate research proposals, protocol-related reports and monitor on-going studies as appropriate. Discuss the potential COI of the PI as investigator/IRB member and as the attending physician; consistently document the management of the COI in the minutes of meeting

**9.3** All IRB members participate actively in IRB meetings. Ensure that all members read and review the protocol (synopsis) and participate in the discussion.

**9.4** The Principal Investigator need not be present in the meeting but shall be available if there are questions from any of the members. Invite the PI only if there are unsettled issues in the protocol reviewed by the primary reviewer. Clearly describe in the procedure the clarificatory interview of the PI (Avoid asking PI to present the protocol)

**9.5** An Independent Consultant is invited to review the research protocols, answer the queries of the primary reviewer and to share his/her inputs and Recommendations. However, he/she cannot participate in the voting process during the IRB meetings.

**9.6** The Chair or member-secretary summarize the discussion points before decision-making

**9.7** The members approve by consensus. Clearly document the decision making process of the IRB (consensus) Project the real time minutes taking for IRB members to provide immediate feedback on items that are being discussed

**9.8** The Chair asks the members their evaluation on each item based on the forms provided.

**9.9** A member makes a motion for approval of a decision and seconded accordingly.

**9.10** If there are no objections, the motion is carried.

**9.11** The IRB discusses the issues and Recommendations related to resubmissions, amendments progress/final reports, early termination reports protocol deviations, etc. submitted by the Principal Investigator to the IRB.

**9.12** The assigned members also discuss the result of the site visits, if there are any.

**9.13** The Member-Secretary or the member appointed by the Chair reviews, analyzes and makes Recommendations on the SAE/SUSAR report.

**9.14** During the meeting, the Chair together with the other IRB members give the final Recommendations on the SAEs and SUSARs.

**Step 10: Report on results of expedited review:**

If there are protocols assigned for expedited review, the assigned reviewers present the evaluation report and Recommendations.

**Step 11: Discussion of Other Matters:**

The IRB Chair presents other matters listed for discussion.

**Step 12: Adjournment:**

If there are no other matters to be discussed, the Chair adjourns the meeting.

**Step 13: Collection, storage, and disposal of meeting materials:**

**13.1** The Staff Secretary is tasked to collect all the documents used during the meeting.

**13.2** 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.

**13.3** The Office Manager or Staff Secretary Shreds the extra copies every third Friday of the month before disposing it properly.

**5.3.6 Form**

Attendance Sheet (Form 5.2)

**5.3.7 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 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.*<br>*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.).*<br>*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* | *Revise sequencing in step 9* |

**5.3.8 References**

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 5.3**<br>**Conduct of Meetings** |
| Effective Date: July 1, 2024 | |

**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board; "**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition; **PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 6.1**<br>**Preparing the Minutes of the Meeting** |
| Effective Date: July 1, 2024 | |

**6.1.1 Policy Statement**

The minutes of the meeting of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall be based on the approved agenda and the proceedings of the IRB meeting shall be the basis of the decision letter on protocols.

**6.1.2 Objective of the Activity**

The preparation and approval of the minutes of the SPHI-IRB full-board meeting ensures proper documentation of the procedures and decisions during the meeting.

**6.1.3 Scope**

This SOP includes IRB actions related to the documentation of the proceedings of a meeting, the final output of which is the SPHI-IRB Minutes of the Meeting. This SOP begins with the entry of preliminary information on the minute's template and ends with the filing of the approved minutes.

**6.1.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Entry of preliminary information on the template of Minutes of the Meeting* | *Staff Secretary* | *1 day* |
| *Step 2: Preparation of the draft of the Minutes of the Meeting* | *Member-Secretary and Staff Secretary* | *1-3 day* |
| *Step 3: Attestation of the draft of Minutes of the Meeting* | *Chair* | *1 day* |
| *Step 4: Approval of the minutes in the next IRB meeting* | *Chair and Members* | *1 day* |
| *Step 5: Filing of Minutes of the Meeting* | *Staff Secretary* | *1 day* |

**6.1.5 Description of Procedures**

**Step 1: Entry of preliminary information on the template of Minutes of the Meeting:**

The Staff Secretary prepares the Minutes of the Meeting Template (Form 6.1) by filling it out with preliminary or relevant information using the SPHI-IRB Agenda, three (3) days before the IRB meeting.

**Step 2: Preparation of the draft of the minutes:**

**2.1** During the IRB meeting, the Member-Secretary and Staff Secretary document the proceedings in accordance with the agenda.

The Member-Secretary takes down notes of the proceedings as the meeting progresses by writing directly into the printed minutes of the meeting template.

**2.3** The Staff Secretary does the real-time note-taking by projecting the template on screen.

**2.4** An audio-recorder is also used to ensure the proper documentation of the discussion during the meeting.

**2.5** The Member-Secretary and Staff Secretary organize the minutes of the meeting on the following day for proper documentation.

**Step 3: Attestation of the draft of the minutes:**

**3.1** The Member-Secretary, assisted by the Staff Secretary, prepares the complete, corIRBt, and final draft of the minutes of the meeting three days after the IRB meeting for attestation by the Chair.

**3.2** The Staff Secretary reproduces the minutes of the meeting to be forwarded to all IRB members two (2) weeks before the next IRB meeting for Corrections and comments.

**3.3** The minutes of the meeting consist of, but are not limited to the following items:

- ☐ Date and venue of the IRB meeting
- ☐ Members attendance (members present and absent)
- ☐ Independent Consultants, Primary Investigators, guests, and observers attendance (if any)
- ☐ Opening Prayer
- ☐ Time when the meeting was called to order
- ☐ Determination of quorum by the Member-Secretary
- ☐ Approval of the Agenda
- ☐ Reading and Approval of the Minutes of the Last Meeting
- ☐ Business Arising From the Previous Meeting
- ☐ Disclosure of Conflict of Interest (COI) among Members
- ☐ Protocol Review
  - A. New Protocols for Initial Review of Full Board
  - B. Resubmission
  - C. Review of SJREB Protocols
  - D. Appeal
  - E. Amendments
  - F. Progress Reports
  - G. SAE/SUSAR Reports
  - H. Review of Reports on Negative Events (RNE)
  - I. Protocol Deviation/Violation
  - J. Early Termination Reports
  - K. Final Reports
  - L. Application for Continuing Review
  - M. Site Visit
  - N. Queries and Complaints
  - O. Report on the Results of the Expedited Review
  - P. Reports of Exempt from Review Protocols

Q. Other Reports/Notification

- ☐ Other Matters
- ☐ Checking of Quorum
- ☐ Schedule of the Next meeting
- ☐ Time adjourned
- ☐ Name and signature of the person who prepared the minutes
- ☐ Name and signature of the Chair with the date of attestation

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

The approval of the minutes is done through a formal motion from any member of the board and seconded accordingly

**Step 5: Storage of the approved minutes:**

**5.1** The Staff Secretary keeps a copy of the minutes in the Minutes of the Meeting file in a cabinet labelled as "SPHI IRB Documents" in the IRB office of St. Paul's Hospital Iloilo.

**5.2** The Staff Secretary maintains a central file of all meeting minutes by year to facilitate retrieval.

**6.1.6 Form**

Minutes of the Meeting Template (Form 6.1)

**6.1.7 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* | *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* | *Revise scope and added timeline in calendar days in the workflow.* |
| *06* | *2024 June 28* | *IRB SOP TEAM* | *Revise sequencing in the Minutes of Meeting template* |

**6.1.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 6.2**<br>**Communicating IRB Decisions** |

**6.2.1 Policy Statement**

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall communicate its decisions to the researcher within six (6) weeks after the receipt of complete set of documents or within two (2) weeks after the IRB monthly meeting. The communication document shall include clear instructions/Recommendations for guidance of the researcher and shall be written on an official paper of the SPHI-IRB signed by the IRB Chair.

**6.2.2 Objective of the Activity**

The purpose of this SOP is to provide instructions related to the preparation and management of IRB communication to ensure that all stakeholders are appropriately informed of the decisions of the IRB.

**6.2.3 Scope**

This SOP covers IRB actions related to the communicating IRB decisions using the official IRB Communication Forms (Forms 6.3- 6.5).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.

**6.2.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Attestation of the minutes of the meeting (in case of full review) or Finalization of Recommendations of reviewers (in case of expedited review)* | *Chair/Assigned reviewers* | *1-2 days* |
| *Step 2: Transfer of information from minutes or assessment forms to IRB Communication forms templates* | *Staff Secretary* | *1 day* |
| *Step 3: Approval of the IRB Communication Forms decision document* | *Chair* | *1 day* |
| *Step 4: Communication of IRB decision/action to PI/Researcher (SOP on Communication IRB Decisions (SOP #6.2)).* | *Chair, Office Manager or Staff Secretary* | *10 days* |
| *Step 5: Filing of the document in the protocol file folder* | *Staff Secretary* | *1 day* |

**6.2.5 Description of Procedures**

**Step 1: Attestation of the minutes of the meeting (in case of full review) or finalization of Recommendations of reviewers (in case of expedited review):**

The Member-Secretary prepares the complete, correct, and final draft of the minutes of the full-board meeting for attestation of the Chair. For expedited review, the Chair consolidates and finalizes the Recommendations and/or decisions of the assigned reviewers.

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

The Staff Secretary transfers the Recommendations and/or decision to the IRB Communication Forms template (Approval Letter (Form 6.2), Notification of the IRB Decision Form (Form 6.3), Communication Letter (Form 6.4)) the day after the attestation of the Chair in the minutes, or finalization of the reviewers' Recommendations.

**Step 3: Approval of the IRB decision document:**

Once a week, the Chair visits the IRB Office to review and approve the IRB Communication forms by signing the documents before forwarding them to the investigators, sponsors, institutions, agencies, etc.

**Step 4: Informing of the availability of IRB Communication:**

**4.1** Once the document has been approved by the Chair, the Staff Secretary informs the Investigators through SMS (text) or phone call that the decision of the IRB is available.

**4.2** She also informs the Investigator to pick up the official document from the IRB Office.

**4.3** The Staff Secretary logs the documents to be signed by the receiving party on the Out-going Communications Logbook.

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

The Staff Secretary updates the protocol file index, electronic and the manual database of the specific protocol file and keeps the document/s in the protocol file folder.

**6.2.6 Forms**

Approval Letter (Form 6.2)
Notification of the IRB Decision Form (Form 6.3)
Communication Letter (Form 6.4)

**6.2.7 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 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* | *Revise scope and added timeline in calendar days in the workflow.* |

**6.2.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 7.1**<br>**Managing IRB Incoming and Outgoing Communications** |
| Effective Date: July 1, 2024 | |

**7.1.1. Policy Statement**

The incoming and outgoing communications of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall be recorded promptly and accurately in "Incoming Logbook", "Outgoing Logbook", and in hard-copy and electronic database for monitoring and tracking purposes.

**7.1.2. Objective of the Activity**

The purpose of this SOP is to ensure proper, efficient and effective management of IRB incoming and outgoing communications for easy monitoring of the IRB.

**7.1.3. Scope**

This SOP covers IRB actions related to organizing incoming and outgoing documents and ensuring an appropriate IRB response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

**7.1.4. Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Sorting of incoming/outgoing communications* | *Office Manager and Staff Secretary* | *1 day* |
| *Step 2: Recording of incoming/outgoing communications* | *Staff Secretary* | *1 day* |
| *Step 3: Acting on communications* | *Chair/Member-Secretary* | *1-2 days* |
| *Step 4: Storing or filing of incoming/outgoing communications* | *Staff Secretary* | *1 day* |

**7.1.5. Description of Procedures**

**Step 1: Sorting of incoming/outgoing communications:**

**1.1** The Office Manager and Staff Secretary, under the supervision of the Member-Secretary, organizes 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;
- ☐ memorandum;
- ☐ others

**Step 2: Recording of incoming/outgoing communications**:

**2.1** The Staff Secretary records the incoming and outgoing communications in its specific logbook.

**2.2** The Contents of the Incoming Communications Logbook are:

- ☐ Date of the Letter
- ☐ IRB Protocol #
- ☐ Principal Investigator
- ☐ Document Submitted
- ☐ Name of the person who endorsed the document
- ☐ Date Received
- ☐ Name and signature of the person who Received the communication
- ☐ Action Needed
- ☐ Remarks

**2.3** The Contents of the Outgoing Communications Logbook are:

- ☐ Date of the Letter
- ☐ IRB Protocol #
- ☐ IRB Communication
- ☐ Principal Investigator
- ☐ Name of the person who endorsed the document
- ☐ Date Received
- ☐ Name and signature of the person who Received the communication
- ☐ Action Taken
- ☐ Remarks

**Step 3: Acting on communications:**

**3.1** The Staff Secretary presents all communications to the IRB Chair, who in turn, initially reviews all submitted protocols and other documents to decide which protocols may be expedited or full board review and assigns primary reviewers among IRB members.

**3.2** He/she also acts on operations-related and/or administrative communications.

**3.3** The Chair reviews and approves the IRB outgoing communications before forwarding them to the investigators, sponsors, institutions, agencies.

**Step 4: Storing or filing of incoming/outgoing communication:**

**4.1** All protocol-related communications are filed in the study protocol file. Those that are not protocol-related are kept securely in a cabinet labelled as “SPHI IRB Documents Cabinet”.

**4.2** The Staff Secretary makes sure to log the incoming and outgoing communication in protocol file index for easy monitoring and reference of the IRB.

**7.1.6. Forms**

Incoming Communications Logbook
Outgoing Communications Logbook

**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* | *2024 Feb. 22* | *IRB SOP TEAM* | *Revise scope and added timeline in calendar days in the workflow.* |

**7.1.8. References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 7.2**<br>**Managing Active Files** |
| Effective Date: July 1, 2024 | |

**7.2.1 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 to allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP#7.4)

**7.2.2 Objective of the Activity**

The management of active files ensures proper, effective and easy retrieval of current files, and protection of their confidentiality.

**7.2.3 Scope**

This SOP covers the procedures done related to protocols accepted for review, undergoing review, or has been approved by the IRB (management of all active study files originating from protocol submissions and includes all documents that reflect all actions taken by the IRB before its completion, withdrawal or termination). It also applies to the management of other IRB documents and records such as IRB monthly meeting file; communications; IRB documents; finance; and membership file that are kept securely in a separate cabinet. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

**7.2.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Classification and coding of active files* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 2: Entry in the active file logbook* | *Staff Secretary* | *1 day* |
| *Step 3: Entry in the active file database* | *Staff Secretary* | *1 day* |
| *Step 4: Organization of the study file folder and administrative documents* | *Office Manager or Staff Secretary* | *1 day* |
| *Step 5: Maintenance of file* | *Office Manager or Staff Secretary* | *3 years* |

**7.2.5 Description of Procedures**

**Step 1: Classification and coding of active files**:

**1.1** The IRB uses a coding system for efficient and effective classification of the documents.

**1.2** The Office Manager or Staff Secretary assigns an IRB protocol number upon initial submission of protocol.

**1.3** Folders of the protocol files are labelled and numbered using sticker paper for proper identification. It contains the following details:

- ☐ IRB Protocol #

- ☐ Sponsor protocol code
- ☐ Protocol Title
- ☐ Principal Investigator
- ☐ Approval date
- ☐ Number of folder

**Step 2: Entry in the active file logbook**:

Upon recording the documents in the incoming or outgoing communications logbook

**2.1** The Contents of the Incoming Communications Logbook are:

- ☐ Date of the Letter
- ☐ IRB Protocol #
- ☐ Principal Investigator
- ☐ Document Submitted
- ☐ Name of the person who endorsed the document
- ☐ Date Received
- ☐ Name and signature of the person who Received the communication
- ☐ Action Needed
- ☐ Remarks

**2.2** The Contents of the Outgoing Communications Logbook are:

- ☐ Date of the Letter
- ☐ IRB Protocol #
- ☐ IRB Communication
- ☐ Principal Investigator
- ☐ Name of the person who endorsed the document
- ☐ Date Received
- ☐ Name and signature of the person who Received the communication
- ☐ Action Taken
- ☐ Remarks

**Step 3: Entry in the Active file database**

The Staff Secretary enters the data of the documents in its specific Active File Database (Form 7.1) with the following information:

- ☐ IRB Protocol #
- ☐ Sponsor code
- ☐ Title
- ☐ Principal Investigator
- ☐ Sponsor
- ☐ Type of Research
- ☐ Submission Date
- ☐ Primary Reviewer
- ☐ IRB Decision
- ☐ Approval Date

- ☐ Due Annual Update Report
- ☐ Status

**Step 4: Organization of the study file folder and administrative documents**:

**4.1** The Office Manager or Staff Secretary ensure that the protocol documents are filed properly in a sturdy file folder (one (1) folder per study protocol) and are logged in Index of File Contents (Form 7.2) for easy monitoring and reference of the IRB.

**4.2** A labelled paper/divider is used to separate the documents in the protocol file folders.

**4.3** Administrative and operations-related documents are also filed in labelled folders that are kept securely in well-locked cabinets.

**4.4** A chronological method of filing of all documents is being used, which means, from the oldest (bottom) to the newest document (up), for easy access and retrieval.

**4.5** The study file folder may contain the following documents depending on the kind of study:

- ☐ Application letter to conduct the study
- ☐ Study Protocol
- ☐ Related documents that came with the study protocol
- ☐ Resubmissions(as necessary)
- ☐ Investigator's brochure ( for Clinical trial)
- ☐ Informed Consent Forms
- ☐ Budget (as necessary)
- ☐ Certificate of Technical Review
- ☐ Curriculum Vitae of the Principal Investigator or Researcher and his or her co-investigators
- ☐ Declaration of No Conflict of Interest of Investigators/ Researchers
- ☐ Valid PRC License
- ☐ GCP Training Certificate (for Clinical trial)
- ☐ GANTT Chart (as necessary)
- ☐ Protocol Evaluation and Informed Consent Evaluation forms
- ☐ Notifications of IRB Decision
- ☐ Approval letters
- ☐ Excerpt of the Minutes of the Meetings when the protocol was discussed
- ☐ Amendment reports
- ☐ Continuing review applications
- ☐ Continuing review evaluation forms
- ☐ Serious Adverse Event Reports/Suspected Unexpected Serious Adverse Reactions
- ☐ Deviations or Violation Reports
- ☐ Progress Reports
- ☐ Protocol Report Updates Forms
- ☐ Site Visit reports

- ☐ Miscellaneous Communications
- ☐ Other reports
- ☐ Final Reports

**Step 5: Maintenance of file:**

**4.1** Protocol folders are kept in secured and well-identified locked cabinets, with access limited only to Office Manager and Staff Secretary for confidentiality and security purposes.

**4.2** The protocol files are arranged in chronological order according to protocol number.

**4.3** The Staff Secretary updates the active files using electronic (Microsoft Excel Software; files are password protected) and paper-based database (Active file Database kept in a locked cabinet) once a week.

**4.4** The Office Manager and Staff Secretary keeps the administrative documents and records such as IRB monthly meeting file, communications, IRB documents, finance, membership file, etc. in a locked cabinet labelled as "Confidential Files SPHI IRB Documents".

**4.5** There is a separate cabinet for IRB members that are also locked to compile the documents for review and for sending to the offices of the members.

**4.6** Another locked cabinet is used to keep all the IRB documents for the IRB meeting which consists of, but are not limited to, the following documents: folders of minutes of the meeting for each IRB member; attendance of the meetings; honoraria for IRB members folder; other documents needed for the meeting; and audio recorder

**4.7** A back-up system (in the form of portable hard-drive) of all active files and documents are also updated by the Staff Secretary twice a month.

**4.8** The back-up system is kept in a secured cabinet at the Office of the SPC member of the IRB, located in a separate building.

### 7.2.6 Forms

Active file Database (Form 7.1)
Index of File Contents (Form 7.2)
IRB Membership Database
Independent Consultants Database

### 7.2.7 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 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 Electronic database.* |
| *05* | *2024 Feb. 22* | *IRB SOP TEAM* | *Revise scope and added timeline in calendar days in the workflow.* |

**7.2.8 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

"**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.

**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12<br>Approval Date: June 28, 2024<br>Effective Date: July 1, 2024 | **INSTITUTIONAL REVIEW BOARD**<br><br>**SOP No: 7.3**<br>**Archiving and Terminated, Inactive and Completed Files** |

**7.3.1 Policy Statement**

Archived study files of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board refer to protocols that are completed, inactive, terminated or withdrawn. They shall be retained for at least three years and in compliance with the provisions of the WHO Operational Guidelines, CIOMS Guidelines ICH-GCP and the National Ethical Guidelines for Health Research.

**7.3.2 Objective of the Activity**

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

**7.3.3 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.

**7.3.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Approval of Final or Early Termination Reports* | *IRB Members* | *30 days* |
| *Step 2: Reclassification of the documents for archiving.* | *Office Manager and Staff Secretary* | *1 day* |
| *Step 3: Archiving of studies with approved final report or early study termination report.* | *Staff Secretary* | *1 day* |
| *Step 4: Maintenance of Archives* | *Staff Secretary* | *3 years* |

**7.3.5 Description of Procedures**

**Step 1: Approval of Final or Early Termination Reports**:

The IRB members approves the final or early termination report of the study protocol during the IRB meeting.

**Step 2: Reclassification of the documents for archiving:**

**2.1** The Office Manager and Staff Secretary reclassifies the protocols for archiving by adding an archiving code sticker on the protocol file folder with the "INACTIVE" on it word and adding archiving date in the IRB protocol labels for easy retrieval and identification of studies.

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

**Step 3: Archiving of studies with approved final report or early study termination report:**

**3.1** The Staff Secretary organizes the protocol for archiving.

**3.2** With the assistance of the Office Manager, he/she reviews the contents of the protocol file before transferring the file folders from the active study cabinet to the IRB Archives.

**3.3** The Staff Secretary enters the archiving data in the electronic and paper-based inactive protocol database (Form 7.3).

**Step 4: Maintenance of Archives:**

**4.1** Protocol folders of the inactive, terminated and completed studies are kept in secured and well-locked IRB Archives, with access limited only to Office Manager and Staff Secretary for confidentiality and security purposes.

**4.2** The protocol files are arranged in chronological order according to IRB protocol number.

**4.3** Protocol files in the Archives are kept for three years for retrieval of information and in compliance with national and international guidelines before shredding proper disposal.

**7.3.6 Forms**

Inactive Protocol Database (Form 7.3)

**7.3.7 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 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.* |

| | | | |
|---|---|---|---|
| *05* | *2024 Feb. 22* | *IRB SOP TEAM* | *Revise scope and added timeline in calendar days in the workflow.* |

**7.3.8 Reference**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**"Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board",** 2015, First Edition;

**PHREB Standard Operating Procedures,** 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 7.4**<br>**Managing Access to Confidential Files** |
| Effective Date: July 1, 2024 | |

### 7.4.1 Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board files which consist of, but are not limited to study protocols, study protocol-related documents, operations-related documents, membership files, Minutes of the Meeting, Agenda, all IRB communications and documents shall be considered confidential.

Access shall be allowed to IRB members and staff, regulatory and accrediting authorities only. Non-members may have access to confidential files upon the approval of the Chair once a formal letter of request and signing of the confidentiality agreement are accomplished.

### 7.4.2 Objective of the Activity

This SOP describes the management of all IRB study files and documents, requests for access and its retrieval to maintain its confidentiality and the integrity of IRB.

### 7.4.3 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.

### 7.4.4 Workflow

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Maintenance of confidentiality of IRB files* | *IRB members, Office Manager and Staff Secretary* | *3 years* |
| *Step 2: Access to confidential files* | *IRB members, Office Manager and Staff Secretary* | *1 day* |
| *Step 3: Approval of requests for access and retrieval of documents* | *Chair* | *1 day* |
| *Step 4: Supervision of use of retrieved document* | *Staff Secretary* | *1 day* |
| *Step 5: Return of document to the files* | *Staff Secretary* | *1 day* |

### 7.4.5 Description of Procedures

**Step 1: Maintenance of the confidentiality of IRB files:**

**1.1** All documents in the IRB are considered confidential.

**1.2** The documents are kept in locked cabinets with keys available only to the Staff and Clerk Secretaries.

**1.3** Electronic files are also protected with a password accessible to all IRB members, Office Manager and Staff secretary only.

**1.4** Proper handling of original documents and copies of these documents are also ensured during the day-to-day operations of the IRB to protect the confidentiality of study files and related documents.

**Step 2: Access to confidential files:**

**2.1** Only the St. Paul's Hospital of Iloilo IRB Members, Office Manager and Staff Secretary, regulatory and accrediting authorities (with a signed Confidentiality Agreement and Conflict of Interest Disclosure) are authorized to access confidential files.

**2.2** Investigators and researchers may have access to confidential files upon the approval of the Chair once a formal letter of request and signing of IRB Request Form (Form 7.4) and confidentiality agreement.

**Step 3: Approval of requests for access and retrieval of documents:**

Once the Chair approves and gives permission to have access to confidential files, the requesting individual is allowed access to such documents.

**Step 4: Supervision of the use of the retrieved documents:**

**4.1** The Staff Secretary logs the retrieved document in the Borrowers' Logbook before releasing to the requesting party.

**4.2** Access to IRB document is generally for office use only. Copies can be accommodated on a case to case basis upon the approval of IRB Chair.

**4.3** The Staff Secretary makes only the exact number of copies requested.

**4.4** The recipient signs for the copies requested in the Logbook upon receipt of the copies.

**4.5** IRB Borrower's Logbook contains the following fields of information:

- ☐ 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
- ☐ Name and Signature of St. Paul's Hospital of Iloilo IRB Secretariat who retrieved the document
- ☐ Name and Signature of borrower upon retrieval
- ☐ Name and Signature of SPHI- IRB Secretariat upon return of document copied
- ☐ Number of copies made/signature of IRB Secretariat
- ☐ Number of copies Received/signature of IRB Secretariat

**Step 5: Return of document to the files:**

The Staff Secretary returns the borrowed documents to ensure that it is returned to the proper file folder.

### 7.4.6 Forms

IRB Request Form (Form 7.4)
IRB Borrower's Logbook

### 7.4.7 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 handling, distribution and retrieving confidential files of IRB.* |
| *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.* |

### 7.4.8 References


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board; "**Standard Operating Procedures of St. Paul's Hospital of Iloilo Institutional Review Board"**, 2015, First Edition.
**PHREB Standard Operating Procedures**, 2020.

| | |
|---|---|
| Version No: 12 | **INSTITUTIONAL REVIEW BOARD** |
| Approval Date: June 28, 2024 | **SOP No: 8**<br>**Writing and Revising SOP** |
| Effective Date: July 1, 2024 | |

**8.1 Policy Statement**

It may be necessary or appropriate to rewrite or revise the Standard Operating Procedures (SOP) of St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI IRB) every three years or as necessary by reason of changed circumstances, compliance with government regulations, and others.

**8.2 Objective of the Activity**

Writing and revising SOPs establishes quality assurance of IRB functions.

**8.3 Scope**

This SOP applies to all IRB activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

**8.4 Workflow**

| *ACTIVITY* | *RESPONSIBILITY* | *TIMELINE IN CALENDAR DAYS* |
|---|---|---|
| *Step 1: Proposal and approval for revision* | *IRB members* | *1 days* |
| *Step 2: Designation of SOP Team* | *Chair* | *1 day* |
| *Step 3:Drafting of the revision/s* | *IRB SOP Team* | *7 days* |
| *Step 4: Review and approval of Revised SOP* | *IRB Members* | *1-2 days* |
| *Step 5: Submission to and Approval by Hospital Administrator* | *Chair* | *1-2 days* |
| *Step 5: Inclusion of Revised SOP in the SOP Manual and its dissemination* | *Office Manager and Staff Secretary* | *30 days* |
| *Step 6: Retrieval of Obsolete/Superseded SOPs* | *Office Manager and Staff Secretary* | *1 days* |
| *Step 7: Inclusion of Revised SOP in the SOP Manual and its dissemination* | *IRB SOP Team* | *30 days* |

**8.5 Description of Procedures**

**Step 1: Proposal and approval for revision:**

The IRB, upon a majority vote of its members, may propose the revision of its Standard Operating Procedures to the Hospital Administrator stating the reasons therefore.

**Step 2: Designation of SOP Team:**

**2.1** The Chair designates members for the Re-writing/Revising Team (SOP IRB Team).

**2.2** The Team is an ad hoc committee composed of IRB members.

**2.3** They choose from among themselves their Head and assisted by the Office Manager and Staff Secretary. They may invite resource person/s to assist them in their task.

**Step 3: Drafting of the revision/s:**

The SOP IRB Team drafts the revision basing on the SOP template consisting of the following:

- ☐ Number and version
- ☐ Title
- ☐ Policy Statement
- ☐ Objectives
- ☐ Scope
- ☐ Responsibilities
- ☐ Workflow
- ☐ Detailed Instructions
- ☐ Forms
- ☐ Documents History
- ☐ References
- ☐ Appendices attachment including the glossary

**Step 4: Review and approval of Revised SOP:**

**4.1** Once the SOP Team has finished its task, they submit their draft to the Chair of the IRB who initiates the finalization process by presenting the draft to the entire IRB during a board meeting for its review, with the assistance of the Office Manager and Staff Secretary.

**4.2** Once the draft is finalized at the IRB level, the Office Manager and Staff Secretary submits the same for final approval.

**Step 5: Submission for Approval of Revised SOP**

**5.1.** The Office Manager/Staff secretary submits the final version of the revised SOP to the Hospital Administrator for final approval.

**5.2** The Hospital Administrator approves the revised SOP, she shall affix her signature in the appropriate section in the cover.

**5.3** The Approved revised SOP will be implemented from date of approval of the Hospital Administrator.

**Step 6: Retrieval of Obsolete/Superseded SOPs**

**6.1.** To prevent misuse, the Staff Secretary marks "OBSOLETE" all the pages of the superseded SOP

**Step 7: Inclusion of Revised SOP in the SOP Manual and its dissemination:**

**7.1** Within thirty (30) days upon approval by the Hospital Administrator, the Office Manager and Staff Secretary distributes printed and electronic copies of the approved SOPs to the IRB members and staff.

**7.2** The newly revised SOP is available in the IRB Website. The Office Manager and Staff Secretary maintains the original hard and electronic copy of the revised SOP in the Active Files.

**7.3** The old version of the SOP is kept in the Administrative Inactive Files.

**2.4 Form**

IRB SOP Template

**2.5 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. 7* | *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* | *Harmonize Workflow and description of procedures. Delete step 3.2 in Protocol 4.1. Revise* |

| | | | |
|---|---|---|---|
| | | | *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.*<br>*Added Management of Application for Continuing Review. Edited IRB forms* |
| *09* | *2022 June 28* | *IRB SOP TEAM* | *Edited SPH-IRB History.*<br>*Edited IRB Checklist for Initial Submission.*<br>*Added 1.4 in the description of procedures in step 1.*<br>*Added gender representation in step 4, 4.1.* |
| *05* | *2024 Feb. 22* | *IRB SOP TEAM* | *Revise scope and added timeline in calendar days in the workflow.* |

**2.6 References**


**"A Workbook for Developing Standard Operating Procedures"** 2015 by Philippine Health Research Ethics Board;

**PHREB Standard Operating Procedures**, 2020.