ST. PAUL'S HOSPITAL OF ILOILO, INC.

INSTITUTIONAL REVIEW BOARD

2026 | 14th Edition

STANDARD OPERATING PROCEDURES

serving in Excellence

MOVING FORWARD

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

ST. PAUL'S HOSPITAL OF ILOILO, INC.

INSTITUTIONAL REVIEW BOARD

2026 | 14th Edition

STANDARD OPERATING PROCEDURES

Authored by:	**IRB SOP TEAM** *(Based on **Philippine Health Research Ethics Board Standard Operating Procedures Workbook, 2020**)*
Approval Date:	**June 3, 2026**
Approved by:	**Dr. Jaime Manila** *Chair, Institutional Review Board*
Approved by:	**Sr. Arcelita Sarnillo, SPC** *Hospital Administrator*
Effective Date	**June 15, 2026**

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **Table of Contents**

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **Table of Contents**

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

HISTORY:

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

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

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

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

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

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

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

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

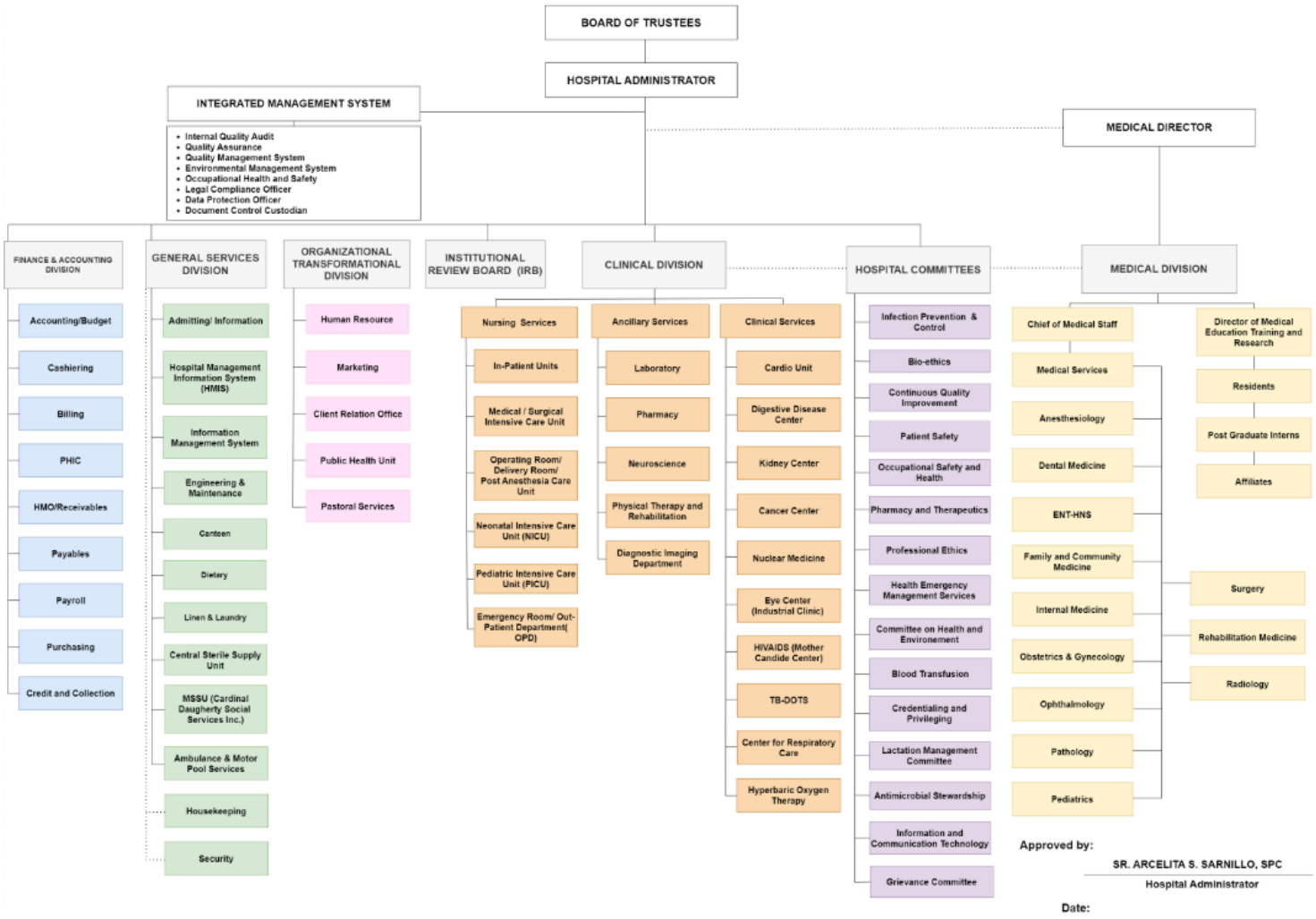
MISSION:
We commit ourselves to:

1. Offer Christ-centered excellent healthcare upholding the bioethical principles and the teaching of the Catholic Church;
2. Innovate & develop competencies of health care professionals through continuing relevant training and research programs;
3. Continually implement and sustain operational and financial excellence through Christian stewardship & good governance.

CORE VALUES: C-A-R-E

1. **C**ompassion – capacity and readiness to suffer with those who suffer; to feel one with the suffering and those in pain, to be moved with one's deepest interiority "may pagmamalasakit".
2. **A**ccountability – the capacity and readiness to accept consequences of one's decision/action and the responsibility of stewardship in caring and serving.
3. **R**espect – showing appreciation towards the value of another person; manifest a differential regard to the values; principles and beliefs of others.
4. **E**xcellence – doing the right thing all the time; error free state; quality of doing things efficiently.

ST. PAUL' S HOSPITAL OF ILOILO. INC
FUNCTIONAL ORGANIZATIONAL CHART



Approved by:

SR. ARCELITA S. SARNILLO, SPC
Hospital Administrator

Date:

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

HISTORY:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In April 2021, Sr. Gertrude Caryls Kuebler, SPC was appointed IRB Office Manager.
By June 2022, she was reappointed as IRB Office Manager.

In January 2023, the accreditation expired, but extensions were granted. From September 18-22, 2023 PHREB conducted an online accreditation.

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

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

In March 23-27, 2026, the PHREB conducted an online accreditation.

In April 2026, Ms. Ana Liza P. Sevillon and Ms Ma. Clarissa T. Columna were appointed as non medical, non scientist, non affiliated regular member. Ms. Ann Dixie Francisco was appointed as part-time Staff Secretary.

In May 2026, Dr. Princi Demaisip was appointed as medical, non-affiliated regular member. Dr. Ken Hilario Lapastora was newly appointed as Medical, affiliate alternate member.

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

IRB Vision and Mission:

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

MISSION:

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

On May 2026, the IRB committed was re-classified as follows:

Name of IRB Members	Membership Regular/Alternate	Role/Position	Affiliation	Highest Educational Attainment	Medical or Non-Medical	Scientist or Non-Scientist	Expertise	May Review	Members since	Expiration of appointment
Dr. Jaime Manila	Regular	Chair, Medical - affiliated	affiliated	Medical Degree; doctor of medicine	M	S	OB-Gyne	Protocol	2007	2027
Dr. Rowena Cosca	Regular	Co-Chair	affiliated	Medical Degree; doctor of medicine	M	S	Clinical Psychiatrist	Protocol	2015	2027
Dr. Ma. Cecilia Florete	Regular	Member-Secretary	affiliated	Medical Degree; doctor of medicine	M	S	Internist-Gastroenterologist	Protocol	2015	2029
Dr. Venerio Gasataya Jr.	Regular Member	Medical-affiliated	affiliated	Medical Degree; doctor of medicine	M	S	General Surgeon	Protocol	2015	2027
Dr. Ronald Latap	Regular	Member, Medical-affiliated	affiliated	Medical Degree; doctor of medicine	M	S	OB-Gyne Gynecologic Oncologist, Colposcopist	Protocol	2024	2027
Atty. Jose Mari Benjamin Tirol	Regular	Member, Non-medical scientist-affiliated	affiliated	Masteral Degree; Master of Law	N	S	Lawyer	Protocol and ICF	2011	2027
Mrs. Maria Thelma Servidad	Regular	Member,Non-medical scientist-affiliated	affiliated	Masteral Degree; Master of Arts in Nursing	N	S	Businesswoman/ Nurse/Teacher	Protocol and ICF	2013	2028
Mr. Christopher Tabsing	Regular	Member, Non-medical scientist-Non-affiliated	affiliated	Masteral Degree; Master in Education	N	S	School Principal II	Protocol and ICF	2015	2028
Mrs. Ma. Romy Alexis Consulta	Regular	Member, Non-medical scientist-Non-affiliated	affiliated	Masteral Degree; Master of Education	N	S	Professor/ Statistician	Protocol and ICF	2019	2028
Sr. Gertrude Caryls Kuebler, SPC	Regular	Member, Non-scientist-affiliated	affiliated	Masteral Degree; Masters in Religious Education	N	S	Religious/ Nurse	Protocol and ICF	2021	2027
Ma. Clarissa T. Columna	Regular	Non-scientist-	non-affiliated	Vocational course	N	N	Embroiderer / Brgy. Official	ICF	2026	2028
Ana Liza P. Sevillon	Regular	Non-scientist-	non-affiliated	Vocational course	N	N	Housewife	ICF	2026	2028

Dr. Princi Demaisip	Regular	Scientist	non-affiliated	Medical Degree; doctor of medicine	M	S	Neurologist	Protocol	2026	2028
Dr. Mark Leonard Flores	Alternate	Medical-affiliated	affiliated	Medical Degree; doctor of medicine	M	S	Pulmonologist/Critical Care	Protocol	2024	2028
Dr. Ken Hilario Lapastora III	Alternate	Medical-affiliated	affiliated	Medical Degree; doctor of medicine	M	S	Surgeon	Protocol	2026	2028
Ms. Imelda Olaguer	Alternate	Non-medical scientist-affiliated	affiliated	Masteral Degree; Masters in Biology	N	S	Professor/Former Research Director	Protocol and ICF	2024	2028

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

SPHI IRB GUIDING PRINCIPLES IN THE ETHICAL EVALUATION OF RESEARCHES:

The St. Paul's Hospital of Iloilo IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents such as the Declaration of Helsinki (2024), CIOMS (2016).

The IRB functions in accordance with national laws, regulations, and guidelines and provides its own standard operating procedures based on:

- Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) by the World Health Organization (WHO);
- National Ethical Guidelines for Research Involving Human Participants (2022);
- WHO 2023 Tool for Benchmarking Ethics oversight of health related research involving human participants
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP 2023)
- Philippine Food and Drug Authority regulations and other relevant laws and regulations.

The IRB will takes the initiative to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research that it has approved.

GENERAL ETHICAL PRINCIPLES:
(Based on CIOMS 2016)

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

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

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

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

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of

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

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

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

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

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

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

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

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

General Principles

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPHI-ADM-04-22-01

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

Peace be with you!

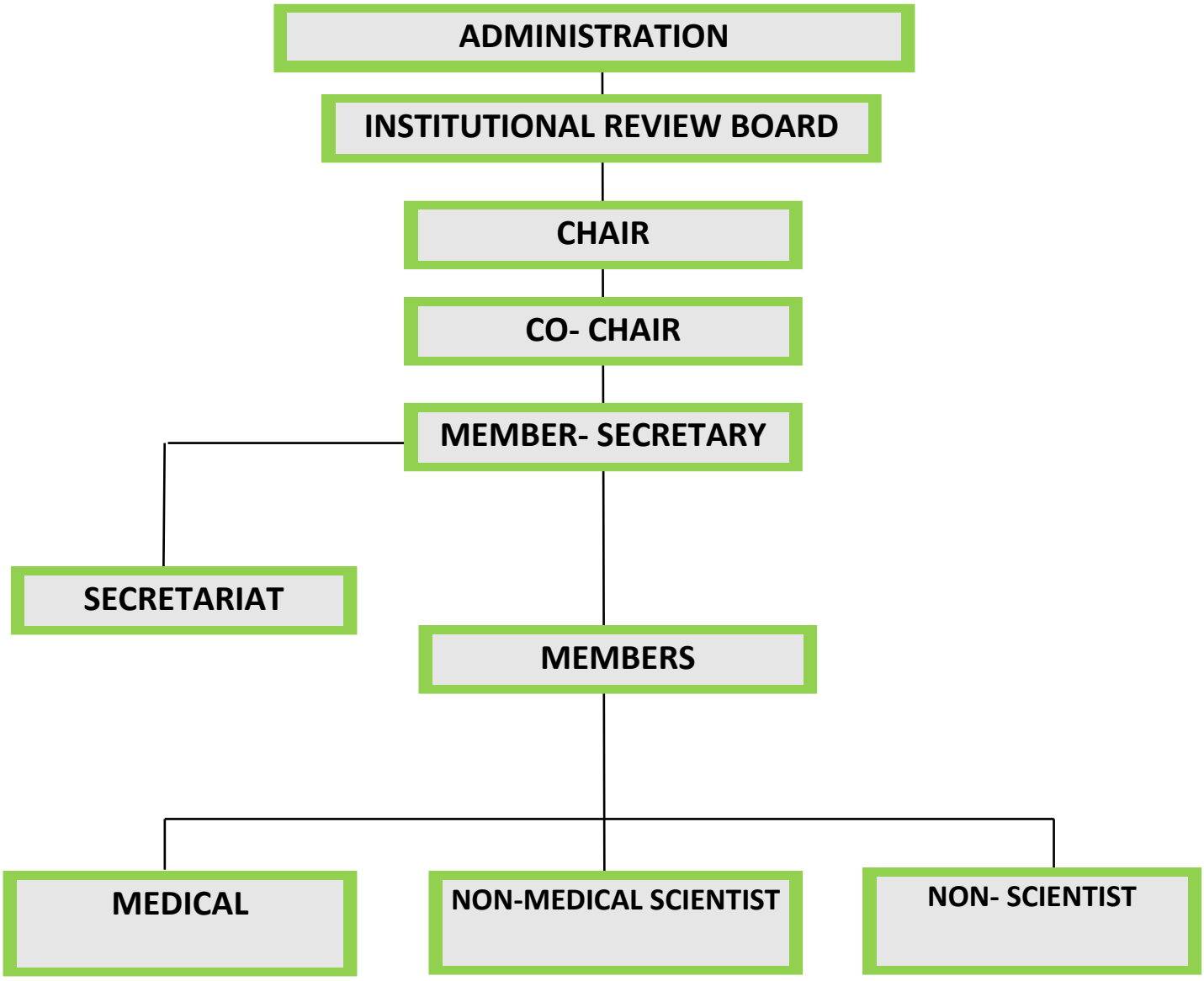
The St. Paul's Hospital of Iloilo- Institutional Review Board (SPHI-IRB) is an independent body created by St. Paul's Hospital of Iloilo, INC under the Office of the Hospital Administrator. The SPHI-IRB plays a crucial role in ensuring that all research involving human subjects is conducted ethically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

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

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

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

SR. ARCELITA S. SARNILLO, SPC
Hospital Administrator


ADMINISTRATION
INSTITUTIONAL REVIEW BOARD
CHAIR
CO- CHAIR
MEMBER- SECRETARY
SECRETARIAT
MEMBERS
MEDICAL
NON-MEDICAL SCIENTIST
NON- SCIENTIST

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 01** **Selection and Appointment of IRB Members**
Effective Date: June 15, 2026	

INSTITUTIONAL REVIEW BOARD
"FLOW CHART OF PROTOCOLS SUBMISSIONS"

Protocol package for Clinical trial or Research –initiated studies:

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

⬇

IRB Staff receives the complete protocol and other documents.
Assigns IRB Protocol Code
Forwards to Chair or Member-Secretary for assessment
(Day 1)

⬇

Chair or Member-Secretary: Determination the type of Review
Full Board, Expedited, SJREB or Exempt from Review.
(Day 1)

⬇

FULL BOARD REVIEW	EXPIDITED REVIEW	SJREB REVIEW	EXEMPT FROM REVIEW
Chair or Member-Secretary: Assigns two (2) Primary Reviewers. (Day 1)	Chair or Member-Secretary: Assigns two (2) Primary Reviewers. (Day 1)	Chair or Member-Secretary: Assigns two (2) Primary Reviewers who will attend SJREB Meeting (Day 1)	Chair or Member-Secretary: assess the protocol based on Exempt from review checklist (Day1)
⬇	⬇	⬇	⬇
The IRB Staff notifies and send electronic copy to primary reviewers ten (10) days before the full board meeting. (Day 2)	The IRB Staff notifies and send electronic copy to Primary reviewers. (Day 2)	The IRB send a letter of notification signed by the IRB Chair to SJREB that the Primary reviewers/ proxy member will participate in the joint review.	Staff prepares Certificate of Exemption (Day 2)

Primary Reviewers: Review and evaluate protocols and other documents (10 working days). (Day 3-12)	Primary Reviewers: Review and evaluate protocols and other documents (5 working days). (Day 3-7)	Primary Reviewers attends SJREB Meeting every 2nd Wednesday of the month.	Issuance of Certificate of Exemption to PI/Researcher. (Day 3)
↓	↓	↓	
IRB REGULAR MEETING (2nd Thursday of the month) Primary reviewers present the evaluation thoroughly by using the evaluation forms. All members discuss technical and ethical issues.	Primary Reviewers returns the evaluation forms five. (Day 8)	The Chair and Member-Secretary consolidates site specific issues and comments, and makes a preliminary decision for reporting to the SJREB during SJREB full board meeting.	
↓	↓	↓	
The Chair summarizes the issues. The board decides the result of the full review by consensus voting. (2nd Thursday of the month) (Day 19)	The Chair consolidates the results of the review and finalizes the decision on the expedited review. (Day 9-10) Result of expedited review is reported by The Chair in the IRB Meeting (Day 19)	The primary reviewers attend the SJREB full board meeting	
↓	↓	↓	
The IRB Staff prepares the communication letter of the IRB Decision (Approval, Notification Letter) (Within three- seven (3-7) days after the full board meeting)	The IRB Staff prepares the communication letter of the IRB Decision (Approval, Notification Letter) (Day 11)	The IRB Staff obtains the SJREB meeting minutes and decision notification from the SJREB secretariat seven days after the SJREB full board meeting. The Chair and Member-Secretary conduct an expedited site-specific review within 7 days of receipt And make a local site decision based on SJREB outcomes.	
↓	↓		
The IRB Staff communicates and released the review result to the PI/Researcher (Within three- seven (3-7) days after the full board meeting) (Day 27)	The IRB Staff communicates and released the review result to the PI/Researcher (Day 12)		
↓			
APPROVAL	**MINOR/MAJOR REVISIONS**	**DISAPPROVAL**	
PI/Researcher may commence with Study upon receipt of the Approval Form signed by the IRB Chair.	PI/Researcher revise the protocol or related documents and resubmit to the IRB.	PI/Researcher receive the Notification of IRB Decision Form (signed by the IRB Chair). They are not allowed to do the Study.	
↓	↓	↓	
SUBMISSION OF POST-APPROVAL REPORTS	**RESUBMISSION**	**APPEAL**	
PI/Researcher required to submit post-approval reports up to final reports.	Revised study Protocol, ICF, and or other study materials: For Major Revision: twenty (20) working days For Minor revision: ten (10) working days after the receipt of the Decision letter	PI/Researcher 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. (Within 20 days)	

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO** **INSTITUTIONAL REVIEW BOARD** **SOP No: 01** **Selection and Appointment of IRB Members**

"FLOW CHART OF POST-APPROVAL SUBMISSIONS"

IRB Staff receives the complete post approval documents. (Day 1)				
↓				
IRB Staff notifies the Chair or Member-Secretary the post-approval reports and other docuemnts (Day 1)				
↓		↓		↓
FULL BOARD REVIEW		**EXPIDITED REVIEW**		**SJREB REVIEW**
The Staff notifies and sends the pertinent protocol file to the previously assigned two (2) Primary Reviewers. (Day 1)		The Staff notifies and sends the pertinent protocol file to and the previously assigned two (2) Primary Reviewers to do the expedited review. (Day 1)		IRB Staff notifies the Chair once protocol received need to be reviewed by the SJREB.
↓		↓		↓
Primary Reviewers: Review and evaluate protocols and other documents (10 working days).		Primary Reviewers: Review and evaluate protocols and other documents (5 working days).		IRB staff notifies the primary reviewers and send the post approval reports from SJREB secretariat.
↓		↓		↓
REVIEW OF POST APPROVAL SUBMISSION (2nd Thursday of the month) Primary reviewers present the evaluation thoroughly by using the evaluation forms.				The primary reviewers will attend the SJREB meeting.
↓		↓		↓
The Chair summarizes the issues. The board decides the result of the full review by voting. (2nd Thursday of the month)		The Chair consolidates the results of the review and finalizes the decision on the expedited review. (Day 12) Approved post-approval reports will be included in the next IRB meeting agenda		The Chair consolidates the result of the IRB review and SJREB meeting and finalize the decision.
↓				
The IRB Staff communicates to the PI/Researcher the review result.				
↓			↓	
Issuance of Notice of IRB action (Protocol amendment, Application for Continuing Review, Final Report, Protocol Deviations, Early Termination Report, Queries & Concern, Serious Adverse Event, RNE, Site Visit			Issuance of Certificate of approval (Protocol Amendment & Application for Continuing Review)	
↓	↓	↓		
MINOR, MAJOR MODIFICATON, REQUEST FURTHER ADDITIONAL INFORMATION, REQUEST FURTHER ADDITIONAL ACTION	**NO FURTHER ACTION NEEDED**	**DISAPPROVE**		
(PA, ACR, SAE, PD, ETR, Q&C, RNE, FR)	(PA, ACR, SAE, PD, ETR, Q&C, RNE, FR)	(PA)		

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 01** **Selection and Appointment of IRB Members**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall select and appoint IRB members through a nomination process that ensures representation of different disciplines (scientists, non-scientists, medical, non-medical), sectors (male and female, older and younger age groups) and affiliation with the institution (affiliated and non-affiliated members). The SPHI-IRB shall have at least seven (7) members, which shall include at least one whose primary concern is in the medical sciences, at least one whose primary concern is in non-medical or non-scientific, at least one with expertise in legal matters, at least one who is not affiliated with SPHI, and at least one who is a Sister of St. Paul of Chartres.

There shall be regular and alternate members with specific roles and responsibilities.

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

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

2. Objective of the Activity

This activity aims to ensure that the members are from diverse backgrounds and sectors as stated above, and of non-scientists who will represent the interest and concern of the communities from which study participants are likely to be drawn from.

3. Scope

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

4. Workflow

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

5. Description of Procedures

Step 1: Nomination of candidates

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

Members are selected based on their:

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

1.2 The Chair shall inform prospective members that they have been nominated for membership in the SPH IRB and inquire if they are interested to become members. If they manifest their interest, the Office Manager and staff shall provide them with the appointment letter specific to their discipline, sector, and affiliation (i.e. scientist/medical member, non- medical/non-scientist, affiliate, non-affiliate member, and alternate member). The said appointment letter shall also contain their specific duties and responsibilities.

1.3 The members shall not be terminated prior to the expiration of their terms except for good cause.

1.4 Senior decision makers shall not serve in the IRB.

1.5 Responsibilities of IRB Regular Member:

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

Responsibilities of an IRB Alternate Member:

a. Attends IRB meetings if appointed to be a primary reviewer or when the regular IRB member with the same expertise is absent
b. Receives, and reviews the same materials that the regular member receives
c. Maintains confidentiality of the documents and deliberations of the IRB meetings
d. Declares any conflict of interest in the review of research proposals

e.Participates in continuing education activities in health research and ethics education
f. Leads the prayer during the meeting
g.Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others
h.Participates in making decisions and is included as part of the quorum
i. Reviews protocols if the topic is along their expertise
j. Commits to submit assessment forms to the IRB

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

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

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

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

Step 3: Preparation of appointment letter of new members

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

3.2 The Office Manager or staff submits the appointment letter to the Hospital Administrator for her signature.

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

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

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

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

4.4 Renewal of appointment of the members shall be made one month prior to the expiration of their appointment.

4.5 Members shall attend PHREB mandated trainings such as Basic Research Ethics Training (BRET), Good Clinical Practice Training (GCP), Standard Operating Procedures (SOP) Training, and Continuing Research Ethics Training (CRET) to maintain good standing. These certifications need to be active and up to date.

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

The Office Manager or Staff files the documents (Appointment letter (Form 1.0, Form 1.1, and Form 1.2), Agreement on Confidentiality and COI (Form 1.8), Curriculum Vitae (Form 1.9), and training certificates of newly appointed member/s in their specific membership file folder.
All of these documents are kept securely in a locked "SPHI IRB Documents" cabinet.

6. Forms

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

7. History of SOP

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

09	2024 Feb. 22	IRB SOP TEAM	Added step 3 in description of procedures. Added timeline in calendar days in the workflow.
10	2025 May 15	Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis Serafin Thomas Dabao III	Revised SOP 01 Selection and Appointment of Members.
11	23 May 2026	IRB SOP TEAM	Revised SOP 01 Selection and Appointment of Members.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 02** **Designation of IRB Officers**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall have a Chair, Co-Chair and a Member Secretary. The Hospital Administrator designates the Chair. The Chair calls for a meeting and selects the Co-Chair and Member-Secretary upon consultation and votation among the IRB members. The Chair recommends to the Hospital Administrator the designation of the officers. The appointment shall be based on competency, expertise, trainings and ethical and/or scientific knowledge upholding the corporate values of the institution and with commitment and willingness to volunteer their necessary time and effort for the IRB's work. The Officers shall continue their term for as long as they are members of the IRB or a new designation will happen. Nominees must be a member of the IRB for at least 2 years, must be affiliated or non-affiliated, and has research experience and research ethics training. The Officers shall not be terminated prior to the expiration of their terms except for good cause.

2. Objective of the Activity

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

3. Scope

This SOP begins with the call for a meeting to select the officers and ends with the filing of appointment documents of the said officers.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Call for a meeting	Chair	1 day
Step 2: Votation of IRB Officers	IRB Members	1 day
Step 3: Endorsement of Officers	Chair	1 day
Step 4: Signing of Appointment letter (Appointment letter and Agreement of Confidentiality and Conflict of Interest (COI)	New Officers	1 day
Step 5: Filing of appointment documents and Curriculum Vitae (CV) in the Membership file	Office Manager or Staff	1 day

5. Description of Procedures

Step 1: Call for a meeting

The Chair calls for a meeting to select officers from the members of the IRB.

Step 2: Votation of IRB officers

2.1 The Chair presides over the nomination and votation of officers.

2.2 The Chair presents details of the roles and responsibilities of the Chair, Co-Chair and Member-Secretary.

Responsibilities of the IRB Chair:

a. Represents the IRB in internal and external meetings and conferences
b. Presides over the IRB meetings, and is accountable to the Hospital Administrator
c. Oversees review of protocols
d. Initially reviews all submitted protocols and other documents to decide which protocols may

be expedited or full board review

e. Assigns primary reviewers for protocols and other documents from among IRB members

f. Reviews Protocol and protocol-related submissions (Protocols for Initial Review of Full Board, Resubmission, Amendments, Progress Reports, Final Reports, Protocol Deviations, Site Visits, etc.)

g. Invites Independent Consultants who are not within the area of competence or expertise of the IRB members

h. Checks and signs provisional agenda, outgoing IRB communications such as approval letter, notification of IRB decision, requests, inquiries and others

i. Maintains confidentiality of the documents and deliberations during IRB meetings

j. Declares any conflict of interest

k. Participates in continuing education activities in health research and ethics

l. Acts on operations-related communications

m. Approves request for access and retrieval of documents

n. Prepares an annual report summarizing IRB activities and decision outcomes to the Hospital Administrator

n. Supervises development and revisions of SOPs.

Responsibilities of Co-Chair:

a. Presides over meetings in the absence of the Chair

b. Performs other duties designated by the Chair in the absence of the latter

c. Participates in IRB meetings

d. Reviews, discusses and considers research proposals submitted for evaluation

e. Reviews protocols and protocol-related reports assigned by the Chair

f. Maintains confidentiality of the documents and deliberations during IRB meetings

g. Declares any conflict of interest

h. Participates in continuing education activities in health research and ethics

i. Makes motion for the approval of the provisional agenda, minutes of the previous meeting and others

Responsibilities of Member-Secretary:

a. Supervises the IRB Office Manager and Staff

b. Assists the Chair in assigning Primary Reviewers

c. Attends IRB meetings

d. Determines the presence of quorum during the meeting

e. Assesses SAE and SUSAR reports submitted to the IRB and Reports SAE/SUSARs during the IRB meeting and Recommends appropriate action

f. Oversees/assists the documentation by real time the conduct of the full board meeting

g. Oversees/assists the office Manager and Staff in the preparation of the draft minutes of regular IRB meetings

h. Oversees the protection and maintenance of IRB documents and ensures filing and archiving procedures are followed

i. Reviews protocols and protocol-related reports and monitor ongoing studies as appropriate

j. Maintains confidentiality of the documents and deliberations during IRB meetings

k. Declares any conflict of interest

l. Participates in continuing education activities in health research and ethics education

2.3 Nominees must be a member of the IRB for at least 2 years, must be affiliated or non-affiliated, and has research experience and research ethics training.

Step 3: Endorsement of Officers

The Chair endorses the elected officers to the Hospital Administrator.

Step 4: Signing of Appointment letter and Agreement on Confidentiality and COI

4.1 The New Officers designated by the Hospital Administrator signs the Appointment letter (Appointment letter of IRB Chair (Form 1.4), Appointment letter of IRB Co-Chair (Form 1.5) and Appointment letter of IRB Member-Secretary (Form 1.6) and Agreement on Confidentiality and COI (Form 1.8).

4.2 Submit the updated CV (Form 1.9), and Certificates of Research Ethics Training

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

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

6. Forms

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

7. History of SOP

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

08	2025 June 5	Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis Serafin Thomas Dabao III	Revised SOP 02 Designations of Officers.
09	23 May 2026	IRB SOP TEAM	Revised SOP 02 Designations of Officers.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 03** **Appointment of Independent Consultants**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall appoint an Independent Consultants (ICs) whose expertise is not within the area of competence or specialization of the IRB members, but is needed in a study under review. He/she may or may not be affiliated with the institution.

2. Objective of the Activity

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

3.Scope

This SOP begins with the selection of the Independent Consultants and ends with the filing of documents of in the Independent Consultants File.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Selection of Independent Consultants	Chair and IRB members	1 day
Step 2: Preparation of appointment letters of new Independent Consultants	Office Manager	1 day
Step 3: Receipt of appointment letters of Independent Consultants and collection of their Curriculum Vitae, and Agreement on Confidentiality and Conflict of Interest (COI)	Office Manager and Staff	1 day
Step 4: Inclusion of the New ICs in the pool of ICs		1 day
Step 5: Filing of documents in the Independent Consultants File		1 day

5. Description of Procedures

Step 1: Selection of Independent Consultants

1.1 The Chair and IRB Members select the Independent Consultants with the necessary expertise to provide relevant technical information for a comprehensive review of a study and whose expertise is not within the area of competence or specialization of the IRB members.

1.2 The Chair informs the selected ICs. If the ICs agrees, the Chair requests the Office Manager and Staff to prepare the appointment letters to be signed by the Hospital Administrator.

Step 2: Preparation of appointment letters of new ICs

2.1 The Office Manager or Staff prepares the Appointment letters (Form 1.7) of the new ICs which shall include their term of office, and duties and responsibilities.

2.1.1 The said appointment letters shall also contain their specific duties and responsibilities.

Responsibilities of IRB Independent Consultants:

a. ICs are asked to give their expert opinion on a protocol for review. They may be available for clarification during the discussion of the protocol in an IRB meeting or maybe consulted by the Primary reviewers before the meeting. They are not given a protocol to review.
b. Declares any Conflict of Interest (COI) in the protocol for review
c. Maintains confidentiality of the documents and deliberations of the IRB meetings

2.2 The Office Manager or staff submits the appointment letters to the Hospital Administrator for her signature.

Step 3: Receipt of appointment letters of Independent Consultants and collection of their Curriculum Vitae, and Agreement on Confidentiality and Conflict of Interest (COI)

3.1 The Office Manager or Staff, upon receipt of the appointment letters that have been signed by the Hospital Administrator, informs the newly appointed ICs and requests them to sign the "Conforme" to manifest their acceptance and signs the Agreement on Confidentiality and COI (Form 1.8).

3.2 New ICs shall submit their signed and dated CVs (Form 1.9), and update the same at least once every two (2) years.

3.3 Renewal of appointment of the ICs shall be made one month prior to the expiration of the appointment.

Step 4: Inclusion of the New ICs in the pool of ICs

The Office Manager or Staff includes the new ICs in the pool of ICs and appropriate database containing their name, expertise, institutional affiliation, and date of appointment.

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

The Office Manager or Staff files the documents: Appointment letter (Form 1.7), Agreement on Confidentiality and COI (Form 1.8), and Curriculum Vitae (Form 1.9) of newly appointed ICs in their specific membership file folder.

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

6. Forms

Appointment Letter of Independent Consultants (Form 1.7)
Agreement on Confidentiality and COI (Form 1.8)
Curriculum Vitae (Form 1.9)

7. History of SOP

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

			the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header. Edited duration of time to report SAE/SUSARs on-site.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early Termination report.
06	2019 Dec. 30	IRB SOP TEAM	Revise sequencing
07	2025 June 5	Dr. Jaime Manila, Atty. Jose Mari Benjamin Tirol, and Dr. Luis Serafin Thomas Dabao III	Revised SOP 03 Appointment of Independent Consultants.
08	26 May 2026	IRB SOP TEAM	Revised SOP 03 Appointment of Independent Consultants.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 04** **Management of Initial Submissions**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall require a set of documents (one (1) hard copy and an electronic copy) listed in a checklist for initial submission. Only complete documents submitted shall be accepted. The Chair shall do a preliminary evaluation to determine whether a research proposal is exempted from review or needs to undergo (Expedited or Full board) ethical review based on the NEGRIHP 2022.

2. Objective of the Activity

This SOP aims to ensure that study documents, which are submitted by the Principal Investigator/Researcher for initial review, are properly received, identified, and recorded.

3.Scope

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

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of protocol and protocol related documents for Initial Review	Office Manager or Staff	1 day
Step 2: Recording of the protocol in the logbook		
Step 3: Coding of the protocol		
Step 4: Determination of the type of review and Assignment of the Primary reviewers a.Exempt from Review b.Expedited Review c.Full Board	Chair or Member-Secretary	1 day
Step 5: Preparation of the protocol file folder	Office Manager or Staff	1 day
Step 6: Entry in the database		1 day

5.Description of Procedures

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

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

1.2 The Checklist for Initial Submission Form (Form 2.0) to be filled up by the Office Manager or Staff includes the following:

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

Researcher Initiated protocol-Researcher and Adviser).

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

1.3 The Application for Ethics Review of a New Protocol Form (Form 2.1) to be filled up by the PI/Researcher includes the following:

- General Information
- Brief Description of the Study
- Checklist of Documents

1.4 The IRB Office Manager or Staff returns the protocol submission package to the PI/Researcher if the documents are incomplete.

Step 2: Recording of the protocol in the logbook

2.1 The Office Manager or Staff records the protocol in the Incoming Communications Logbook.

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

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

Step 3: Coding of the Protocol

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

Wherein:

SPHI- stands for St. Paul's Hospital Iloilo
IRB - stands for Institutional Review Board
yyyy- refers to the year of submission (ex. 2025)

xx - chronological number based on order of Receipt (01, 02, 03, etc.)
Example: SPHI-IRB-2025-01

Step 4: Determination of the type of review and Assignment of the Primary reviewers

4.1 The Chair or Member-Secretary determines the type of review a protocol should undergo.

4.2 The following are the bases for the classification as to type of review:

4.2.1 Exempt from Review- for protocols with negligible or low risk *(when there is no foreseeable risk of harm or discomfort, and any risk is merely an inconvenience.)*

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

- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events
- Research involving large statistical data without identifiers
- Research not involving humans or human data

4.2.2 Expedited Review-for protocols with minimal risk (*when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

The following are the types of protocols that may be expedited:

- About a topic that should not result in causing social stigma
- Does not involve vulnerable populations
- Retrospective studies using anonymized data from medical SPHI records
- Studies using simple questionnaires without identifiers
- Laboratory research that uses anonymized human tissue/specimen

4.2.3 Full Board review- for protocols with more than minimal risk (*when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

The following are the types of protocols that may be reviewed by Full Board:

- Human health research involving medium to high risks to human participants
- Intervention studies involving experimental treatments like clinical trials
- May involve vulnerable populations who should be protected
- Involves private information that may cause stigma

4.3 The Chair or Member-Secretary designates two (2) IRB Members to be the primary reviewers of the protocol regardless of whether the type of review is expedited or full review.

4.4 Primary reviewers are selected on the basis of expertise related to the Clinical research protocol.

4.5 Any medical members can be selected as primary reviewers in a research initiated (Resident/student) protocol.

4.6 The medical/scientific primary reviewer analyses the scientific and ethical aspects of the protocol while the non-medical/non scientific primary reviewer focuses on the informed consent form (ICF).

4.7 The Chair or Member-Secretary chooses from the roster of Independent Consultants for clarification on the protocol if the IRB members do not have the needed expertise on a certain research protocol information.

4.8 An IRB member who is a Chair or training officer of the department cannot be assigned as Primary Reviewer for the particular researcher-initiated protocol coming from their own department.

Step 5: Preparation of the protocol file folder

The Office Manager or Staff prepares the protocol file folder with properly labelled protocol title, protocol code, name of the PI/Researcher, sponsor code (if applicable), and date of approval.
The staff makes a protocol file Index and place the protocol file in the secured active file cabinet with lock and key.

Step 6: Entry in the database

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

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

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

6. Forms

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

7. History of SOP

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

		Luis Serafin Thomas Dabao III	
13	27 May 2026	IRB SOP TEAM	Revised SOP 04 on Management of Initial Submission.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 05** **Exempt from Review**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall classify studies (for protocols with negligible or low risk) that will be exempted from review based on the criteria from the National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), 2022.

2. Objective of the Activity

This activity aims to review protocols that qualify for exempt from review.

3.Scope

This SOP begins with the receipt of the application for initial review (exempt from review) and ends filing of the documents in the protocol file.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1. Receipt of a submitted protocol for initial review	Office Manager or Staff	1 day
Step 2: Determination of the submitted protocol for exempt from review	Chair or Member-Secretary	1 day
Step 3: Preparation of Certificate of Exemption	Office Manager or Staff	1 day
Step 4: Signing of the Certificate of Exemption	Chair	1 day
Step 5: Communication of the Certificate of Exemption to the researcher	Office Manager or Staff	1 day
Step 6: Reporting of Exempt from Review Protocols in the IRB Meeting		1 day
Step 7: Filing of the documents in the protocol file	Staff	1 day

5.Description of Procedures

Step 1: Receipt of a submitted protocol for initial review

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

Step 2: Determination of the submitted protocol for exempt from review

The Chair or Member-Secretary determines if the protocol is exempt from review using the Checklist for Exemption Form (Form 3.4).

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

- Evaluation of public programs by the agency itself
- Quality control studies by the agency itself
- Standard educational tests and curriculum development
- Surveillance functions of DOH
- Historical and cultural events
- Research involving large statistical data without identifiers

☐ Research not involving humans or human data

Step 3: Preparation of Certificate of Exemption

If the protocol qualifies for exempt from review, the Office Manager or Staff prepares the Certificate of Exemption (Form 3.0) which includes the requirement to submit an Amendment Report if there are changes in the protocol that may change the risk benefit ratio, and submission of final report at the end of the study. Any change or alteration in the protocol requires submission of revised protocol for IRB review.

Step 4: Signing of the Certificate of Exemption

The Chair signs the certificate of exemption.

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

5.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Certificate of Exemption (Form 3.0) signed by the Chair, is available for release.

5.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

Step 6: Reporting of Exempt from Review Protocols in the IRB Meeting

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

Step 7: Filing of the documents in the protocol file

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2019 July 26	IRB SOP TEAM	First draft
02	2024 Feb.22	IRB SOP TEAM	Added timeline in calendar days in the workflow.
03	2024 Apr 29	IRB SOP TEAM	Added checklist for Exemption form and Investigators Responsibilities after approval.
04	2025 May 15	Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba	Revised SOP 05 on Exempt from Review.
05	28 May 2026	IRB SOP TEAM	Added step 7

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 06** **Expedited Review**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall conduct an expedited review for study protocols that entails minimal risk to the study participants that neither include vulnerable subjects nor cause social stigma. This includes retrospective studies using anonymized data, studies using simple questionnaires without identifiers, and laboratory research that uses anonymized human tissue/specimen.

This SOP shall also apply to post-approval report submissions of expedited review protocols: resubmissions when the recommendations are minor modifications in the protocol or ICF, post-approval reports/submissions/applications, and off-site SAEs and SUSARs.

2.Objective of the Activity

This activity aims to review protocols that qualify for expedited review while demonstrating due diligence and high standards in the system of protection of human participants.

3.Scope

This SOP begins with the assignment of primary reviewers, and ends with the Inclusion of the approved protocols by expedited review in the agenda.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Assignment of Primary Reviewers	Chair or Member-Secretary	1 day
Step 2: Notification of Primary Reviewers	Office Manager or Staff	1 day
Step 3: Provision of study documents and evaluation forms		
Step 4: Accomplishment and submission of evaluation forms	Primary Reviewers	5 days
Step 5: Finalization of review results	Chair	1-2 days
Step 6: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 7: Filing of documents in the file folder		1 day
Step 8: Inclusion of the approved protocols by expedited review in the agenda		1 day

5.Description of Procedures

Step 1: Assignment of Primary Reviewers

The Chair or Member-Secretary assigns two (2) primary reviewers (one medical/scientist member and one non-medical/non-scientist member) to do the expedited review of the submitted protocols for initial review. The primary reviewers will also review the resubmission and post approval reports.

Step 2: Notification of Primary Reviewers

The Office Manager or Staff notifies the assigned Primary Reviewers. The Reviewers confirm their availability and declare no conflict of interest to do the expedited review.

Step 3: Provision of study documents and evaluation forms

3.1 The Office Manager or Staff sends the documents and evaluation forms (IRB Protocol Evaluation Form (Form 3.1), IRB Informed Consent Evaluation Form (Form 3.2)) via email to the assigned primary reviewers.

3.2 The Office Manager or Staff provides pertinent documents of protocols for initial review and for post-approval report submissions.

Step 4: Accomplishment and submission of evaluation forms

4.1 The two Primary Reviewers accomplish and submit the evaluation forms (IRB Protocol Evaluation Form (Form 3.1), IRB Informed Consent Evaluation Form (Form 3.2)) that has been reviewed and completed in the most comprehensive and informative manner within five (5) working days after receipt of the pertinent documents.

4.2. IRB Decision points for initial submission (Expedited review) are:

- **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 shall be noted in the minutes of meeting and communicated to the PI/Researcher.

4.3 IRB Decision points for resubmission:

- Approval
- Major Revisions
- Minor Revisions
- Disapproval

4.4 IRB Decision points for post-approval submissions:

4.3.1 For the amendments:

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

4.3.2 For progress reports:

- Accepted
- Request further information
- Require specific action

4.3.2 For SAE/SUSAR:

- 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:

4.3.3 For RNE:

- 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

4.3.4 For final reports:

- ☐ To accept
- ☐ To require submission with Corrections

4.3.5 For application for continuing review:

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

4.8 The Primary Reviewers send the Evaluation forms (IRB Protocol Evaluation Form (Form 3.1), IRB Informed Consent Evaluation Form (Form 3.2)) after five (5) working days from the receipt of the documents.

Step 5: Finalization of review results

5.1 The Chair finalizes the review results after the Primary Reviewers discuss and submit their findings.

5.2 If the two primary reviewers considerably differ in opinion about the study, the Chair shall mediate discussions among members to facilitate consensus. For conflicting reviews, mandatory referral to the Full Board IRB Meeting is recommended.

5.3 The Office Manager or Staff prepares the communication to be signed by the Chair.

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

6.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Approval Letter (Form 6.1), and the Notification of IRB Decision (Form 6.2) signed by the Chair, is available for release.

6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

Step 7: **Filing of documents in the file folder**

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

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

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

6. Forms

IRB Protocol Evaluation Form (Form 3.1)
IRB Informed Consent Evaluation Form (Form 3.2)
Approval Letter (Form 6.1)
Notification of IRB Decision (Form 6.2)
Notice of IRB Meeting (Form 5.0)

Index of Files Content (Form 7.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug.18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed management of Expedited Review
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Included in 4.1.3 the post approval submissions. Updating of protocol file index and electronic database. Stated in step 8 the review of expedited procedure.
06	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow.
07	2025 May 15	Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba	Revised SOP 06 on Expedited Review.
08	28 May 2026	IRB SOP TEAM	Revised SOP 06 on Expedited Review.

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 07** **Full Review**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall conduct a full-board review when a proposed study entails more than minimal risk, participants belong to the vulnerable group or when the study generates vulnerability. This includes Intervention protocols involving experimental treatments and devices, collection of identifiable biological specimens from vulnerable groups, protocols including questionnaires and social interventions that are confidential in nature that will cause stigma and social harm. Protocol for resubmission requiring major revision, post-approval reports involving major changes from previously approved protocol or consent form that change the risk/ benefit ratio, protocol deviations/violations, progress reports and continuing review with medium to high risks to human subjects/ participants, onsite SAEs or SUSARs, Final report and Early Termination report shall be reviewed by full board. Only protocols submitted for, at least, ten (10) working days before a scheduled meeting shall be included in the agenda for full review.

2. Objective of the Activity

This activity aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials with more than minimal risk.

3.Scope

This SOP begins with the assignment of Primary Reviewers and ends with the filing of protocol related materials and updating of protocol database.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Assignment of Primary Reviewers	Chair or Member-Secretary	1 day
Step 2: Notification of Primary Reviewers and/or Independent Consultant	Office Manager or Staff	
Step 3: Provision of protocol and protocol-related documents and assessment forms to the Primary Reviewers	Office Manager or Staff	1 day
Step 4: Provision of protocol summary to the rest of the committee members		1 day
Step 5: Presentation of the protocol summary, review findings and recommendations during the IRB regular meeting	Primary Reviewers	1 day
Step 6: Discussion of technical and ethical issues	IRB members	
Step 7: Summary of issues and resolutions	Chair	
Step 8: IRB action	IRB members and Chair	
Step 9: Documentation of the Board deliberation and action	Member-Secretary or Staff	
Step 10: Preparation of the Board action/decision	Office Manager or Staff	1 day
Step 11: Communication of IRB decision/action to PI/Researcher		1 day

Step 12: Filing of protocol related materials and updating of protocol data base	Office Manager or Staff	1 day

5. Description of Procedures

Step 1: Assignment of Primary Reviewers

1.1 The Chair or Member-Secretary assigns two (2) Primary Reviewers ((medical/scientific and a non-medical/non-scientific members) with the necessary expertise to be responsible for the review of the protocol in a comprehensive manner. The primary reviewers will also review the resubmission and post approval reports.

1.2 The Chair invites an Independent consultant whose expertise is not within the area of competence or specialization of the IRB members, but is needed in a study under review. He/she may or may not be affiliated with the institution.

Step 2: Notification of Primary Reviewers and IC

The Office Manager or Staff notifies the assigned Primary Reviewers. The Reviewers confirm their availability and declare no conflict of interest to do the full review.

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

3.1 The Office Manager or Staff sends the documents and evaluation forms (IRB Protocol Evaluation Form (Form 3.1), IRB Informed Consent Evaluation Form (Form 3.2)) via email to the primary reviewers.

3.2 The Office Manager or Staff provides pertinent documents of protocols for initial review and for post-approval report submissions.

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

The Office Manager or Staff provides the rest of the Members of the IRB with the protocol summary within ten (10) working days before the IRB monthly meeting.

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

The Primary Reviewers present their protocol summary, review of findings and recommendations during the IRB regular monthly meeting. If the Primary Reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the Primary Reviewer so that the meeting can proceed.

Step 6: Discussion of technical and ethical issues

6.1 The Chair leads the discussion of the technical and ethical issues using the (Protocol Evaluation Form 3.1, and Informed Consent Evaluation Form 3.2) and the assessment of the Primary Reviewers.

6.2 The Chair may call on the Independent Consultant and/or Principal Investigator/Researcher for clarifications, if needed.

6.3 The Chair asks the IC and/or PI/Researcher to leave the meeting prior to board deliberation and decision-making.

Step 7: Summary of issues and resolutions

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

Step 8: Approval of the IRB Action

8.1 The Chair confirms the quorum before making a decision.

8.2 The IRB board makes a decision by votation.

8.2.1 IRB Decision points for initial review are:

8.2.1.1 Approval (when no further modification is required)

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

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

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

8.3 IRB Decision points for resubmission:

- ☐ Approval
- ☐ Major Revisions
- ☐ Minor Revisions
- ☐ Disapproval

8.4 IRB Decision points for post-approval review:

8.3.2 For the amendments:

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

8.3.3 For progress reports:

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

8.3.4 For on-site SAE/SUSAR reports:

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

8.3.5 For RNE:

- ☐ Recommend suspension of the study until risk is resolved
- ☐ Withdrawal of ethical clearance
- ☐ Submission of a plan to mitigate risk/harm
- ☐ Require an amendment to the protocol
- ☐ Uphold original ethical clearance

8.3.6 For protocol deviations/violations:

- ☐ Submission of additional information

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

8.3.7 For early termination reports:

- ☐ Acceptance of the decision with no further action
- ☐ Request for additional information
- ☐ Requirement for further action

8.3.8 For final reports:

- ☐ To accept
- ☐ To require submission with Corrections

8.3.9 For application for continuing review:

- ☐ Approved
- ☐ Additional information required
- ☐ Submission of an explanation for failure to submit required reports
- ☐ Disapproved

Step 9: Documentation of the Board deliberation and action

The Member-Secretary or Staff documents the Board deliberations and action in real-time. An audio-recorder is also used to ensure the proper and complete documentation of the discussion during the meeting (SOP 26 Preparing the Minutes of the Meeting).

Step 10: Preparation of the Board action/decision

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

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

11.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Approval Letter (Form 6.1), Notification of IRB Decision (Form 6.2) signed by the Chair, is available for release.

11.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

IRB Protocol Evaluation Form (Form 3.1)
IRB Informed Consent Evaluation Form (Form 3.2)
Protocol Amendment Form (Form 4.0)

Progress Report Form (Form 4.1)
Protocol Report Updates (SAE/SUSARS) (Form 4.2)
RNE reports (Form 4.3)
Protocol Deviation/Violation Form (Form 4.4)
Early Termination Report Form (Form 4.5)
Final Report Form (Form 4.6)
Application for Continuing Review Form (Form 4.7)
Approval Letter (Form 6.1)
Notification of the IRB Decision Form (Form 6.2)
Communication Letter (Form 6.3)
Index of Files Content (Form 7.0)

7. History of SOP

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

09	2025 May 15	Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba	Revised SOP 07 on Full Review.
10	28 May 2026	IRB SOP TEAM	Revised SOP 07 on Full Review.

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 08** **Review of SJREB**
Effective Date: June 15, 2026	

1. Policy Statement

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

2.Objective of the Activity

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

3.Scope

This SOP begins with the receipt of management of research protocols qualified for SJREB joint review, the review process, and coordination with SJREB and ends with the submission of on-site SAE/SUSAR and Protocol Deviation reports to the Coordinating Primary Investigator until completion or closure of the study site.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of complete protocol package for Initial Review and determination of SJREB Review	Office Manager or Staff	1 day
Step 2: Notification of Chair		
Step 3: Assignment of the Primary Reviewers	Chair	
Step 4: Coordinates with SJREB regarding primary reviewers	Office Manager or Staff	1 day
Step 5: Conduct full board review	IRB Members	1 day
Step 6: Primary Reviewers attend the SJREB full board meeting	Primary Reviewers	1 day
Step 7: Obtain minutes of the meeting and notification of the SJREB decision	Office Manager or Staff	1 day
Step 8: Communication of decision/action to PI/Researcher		7 days after the SJREB full board meeting
Step 9: Filing of the documents in the protocol file and update protocol database		1 day
Step 10: Submission of on-site SAE/SUSAR and Protocol Deviation reports to the Coordinating Primary Investigator until completion or closure of the study site		1 day

5.Description of Procedures

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

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

Step 2: Notification of Chair

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

2.2 To be eligible for join review, the research protocol must be implemented in a least three (3) sites in the Philippines and in at least one DOH Hospital.

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

2.4 The Chair assigns two (2) primary reviewers who will review the protocol, and will attend and participate in the SJREB joint review.

Step 3: Assignment of the Primary Reviewers

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

Step 4: Coordinates with SJREB regarding primary reviewers

4.1 The Office Manager or Staff informs the IRB Chair the request from SJREB, and coordinates with the SJREB secretariat upon receipt of the request for the attendance of the Primary Reviewers/ representatives during the SJREB full board meeting.

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

Step 5: Conduct full board review

a. The Primary Reviewers report the results of the review during IRB full board meeting and discuss site

specific issues and concerns. (e.g., PI qualifications and conflict of interest, clinical trial sites, types of participant, community-based research, etc.)

b. The Chair and Member-Secretary consolidate site-specific issues and comments, and prepare a

preliminary decision to be reported by the primary reviewers/representatives during the SJREB full board meeting.

Step 6: Primary Reviewers attend the SJREB full board meeting

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

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

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

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

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

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

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

meeting.

Step 8: Communication of decision/action to PI/Researcher

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

- ☐ Approval
- ☐ Minor Modification: The PI/Researcher is granted 15 days to comply with the IRB recommendation
- ☐ Major Modification: The PI/Researcher is granted 60 days to comply with the IRB recommendations
- ☐ Disapproval

8.2 Resubmitted documents shall be referred to the primary reviewers and discussed in the full board meeting before approval.

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

The Office Manager or Staff files the protocol and related documents, excerpt of the minutes of the meeting in the protocol file folder, creates protocol file index (Form 7.0), and updates the protocol database.

Step 10: Submission of on-site SAE/SUSAR and Protocol Deviation reports to the Coordinating Primary Investigator until completion or closure of the study site.

The Office Manager or staff submits on-site SAE/SUSAR and Protocol Deviations reports of the PI to The Coordinating Primary Investigator until completion or closure of the study site as noted by the Chair.

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2024 Feb. 22	IRB SOP TEAM	First draft
02	2024 Apr. 29	IRB SOP TEAM	Revised SJREB
03	2025 June 3	Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba	Revised SOP 08 on Review of SJREB.
04	23 May 2026	IRB SOP TEAM	Added step 10

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 09** **Resubmission**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board (SPHI-IRB) shall require a resubmission of a protocol with an IRB decision for major or minor modifications/revisions of documents (proposal/protocol, and/or ICF) that requires a full board review.

A protocol with major modifications/revisions recommends the revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

A protocol with minor modifications/revisions recommends the revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format).

Failure to resubmit the corrected protocol after three months will be considered as inactive.

2.Objective of the Activity

This activity aims to ensure that the protocols requiring resubmissions will be addressed while demonstrating due diligence and high standards in the system of protection of human participants.

3.Scope

This SOP begins with the receipt of the corrected protocol documents and ends with the filing of protocol related materials and updating of protocol data base.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of resubmission and entry into the logbook	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Primary Reviewers		
Step 4: Review of Resubmission by the Primary Reviewers	Primary Reviewers	10 days
Step 5: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 6: Filing of the documents in the protocol file folder and update the protocol database		1 day

5.Description of Procedures

Step 1: Receipt of resubmission and entry into the logbook

The Office Manager or Staff receives and checks the resubmitted documents (IRB Protocol Resubmission Form (Form 3.3) and logs the protocol documents in the incoming communication logbook.

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair and Primary Reviewers

The Office Manager or Staff notifies the Chair or Member- Secretary and two (2) primary reviewers of the resubmission.

Step 4: Review of Resubmission by expedited review or full board review

4.1 The Primary Reviewers shall conduct diligent assessment of the resubmission and minimize adding new recommendations to avoid additional resubmissions.

4.1.1 In expedited review, the primary reviewers shall review and approve the resubmitted documents if the PI/researcher has substantially complied with the previous recommendations.
If the protocol does not comply with previous recommendations, another resubmission will be recommended until approved.

4.1.2 In full board review,

4.1.2.1 if the protocol undergoes minor modifications/revisions as previously recommended during full board Meeting, it undergoes expedited review. Approved resubmission is included in the agenda of the next meeting.

4.1.2.2 if the protocol undergoes major modifications/revisions as previously recommended during the full board meeting, it undergoes full board review. The primary reviewers may recommend approval if the PI/ researcher has substantially complied with the recommendations.

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

4.3 The IRB discusses the recommendations and make decisions.

4.4 The Chair confirms the quorum before making a decision.

4.5 The IRB board makes a decision by votation.

The Decision points for resubmission review are:

4.5.1 Approval (when no further modification is required)

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

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

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

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

5.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Approval Letter (Form 6.1), Notification of IRB Decision (Form 6.2) signed by the Chair, is available for release.

5.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2019 Jul 25	IRB SOP TEAM	First draft Added SOP 3.4 (Management of Resubmission) Added IRB Checklist for Resubmission (Form 3.4), IRB Protocol Resubmission Form (Form 3.5).
02	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow. Revised scope.
03	2025 June 5	Dr. Jaime Manila, Atty. Jose Mari Benjamin Francisco Tirol, and Dr. Luis Serafin Thomas Dabao III	Revised SOP 09 on Resubmission.
04	29 May 2026	IRB SOP TEAM	Revised SOP 09 on Resubmission.

8.References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 10** **Protocol Review during Emergency Situations**

1. Policy Statement

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

2. Objective of the Activity

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

3.Scope

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

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submitted protocols via electronic means to the official IRB email address	Office Manager or Staff	1 day
Step 2: Notification of Chair		
Step 3: Creation of an Ad hoc committee for the review of emergency situation protocols	Chair	
Step 4: Notify members of the Ad hoc committee	Office Manager or Staff	
Step 5: Call for a special meeting to review emergency protocols	Chair	1 day
Step 6: Discuss the emergency protocol during the special meeting	Ad hoc Committee	1 day
Step 7: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 8: Filing of all related documents to the protocol file and updating database		1 day

5.Description of Procedures

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

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

Step 2: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through Short Message Service (SMS), messenger or email.

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

The Chair creates an Ad hoc committee to review submitted protocols classified as emergency. The Chair Identifies the IRB members who qualify to be members of the ad hoc committee based on Their expertise. The Chair selects the ad hoc committee member secretary to supervise the staff for documentation of the minutes of meetings. Independent Consultants may be invited when necessary. The ad hoc committee shall consist of at least five (5) members or one-third (1/3) of the IRB with the inclusion of a non-scientist and non-affiliated member.

Step 4: Notify members of the Ad hoc committee

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

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

a. The Chair calls for a special meeting to review the emergency related protocols. The special meeting

is conducted virtually, in person, or in mixed platform. The quorum is at least three (3) of the ad hoc committee members including the non-scientist and non-affiliated member.

b. If the pre- identified member of the IRB submits a review but unable to join the special meeting,

they should be considered as part of the quorum requirement.

Step 6: Discuss the emergency protocol during the special meeting

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

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

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

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

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

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

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2024 Jan	IRB SOP TEAM	First draft
02	2025 June 5	Sr. Gertrude Caryls Kuebler, SPC, and Ms. Queenie Crisostomo	Revised SOP 10 on Protocol Review during Emergency Situations.
03	23 May 2026	IRB SOP TEAM	Added 5.2

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 11** **Review of Medical Device Protocol**
Effective Date: June 15, 2026	

1. Policy Statement

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

2. Objective of the Activity

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

3. Scope

This SOP begins with the receipt and documentation of submission of medical device protocols in the logbook/data base and ends with the filing of all related documents and updating of the database.

4. Workflow

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

5. Description of Procedures

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

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

Step 2: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through Short Message Service (SMS), messenger, or email.

Step 3: Determination of type of review and Primary Reviewers

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

CLASSIFICATION OF MEDICAL DEVICES

Medical devices shall be classified into the following four classes

Class Risk Level:

Class A - Low risk
Class B - Low-moderate risk
Class C - Moderate-high risk
Class D - High risk

3.2 The Chair determines the two (2) Primary Reviewers based on their expertise and invites an Independent Consultant with knowledge and expertise on the medical device, if necessary.

Step 4: Review and discuss protocols and make recommendations

4.1 The Primary Reviewers review the submitted documents.

4.1.1 For expedited review protocols, the Primary Reviewers submit their Evaluation forms (Form 3.1 and Form 3.2) to the Office Manager or Staff after five (5) working days from the receipt of the documents.

4.1.2 For full board review protocols, the Primary Reviewers submit their Evaluation Forms (Form 3.1 and Form 3.2) three (3) days before the full board meeting. The protocol and findings are discussed in full board.

4.1.3 The Primary Reviewers consider the following in the review of medical device protocols:

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

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

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

The following are the decision points:

- Approved
- Major Modification
- Minor Modification
- Disapproved

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

5.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Approval Letter (Form 6.1), and the Notification of IRB Decision (Form 6.2) signed by the Chair, is available for release.

5.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2024 Feb. 22	IRB SOP TEAM	First draft
02	2024 Apr 29	IRB SOP TEAM	Revised Medical Device Protocol.
03	2025 May 15	Sr. Gertrude Caryls Kuebler, SPC, and Ms. Queenie Crisostomo	Revised SOP 11 Review of Medical Device Protocol.
04	23 May 2026	IRB SOP TEAM	Revised timeline

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 12** **Review of Amendments**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of proposed amendments for review and approval before their implementation.

Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, changes in study design, addition or deletion of treatment, significant changes in the number of participants) shall be reviewed by Full Board.

2.Objective of the Activity

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such as amendments that has no impact on the safety and welfare of study participants.

3.Scope

This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and ends with updating the protocol database.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and entry into logbook of incoming communications	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Primary Reviewer		
Step 4: Determination of type of review: Expedited or Full Board Review	Chair	
Step 5: Review of Amendment Report	Primary Reviewers	5 day (Expedited) 10 days (Full board)
Step 6: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 7: Filing of Amendments and decision letter and updating of the protocol database		1 day

5.Description of Procedures

Step 1: Receipt and entry into logbook of incoming communications

The Office Manager or Staff receives Application for Review of Amendments (Form 4.0) and enters the date and pertinent information in the logbook of incoming communications.

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of the Chair and Primary Reviewers

The Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned two (2) Primary Reviewers.

Step 4: Determination of type of review

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

4.1 Criteria for Amendment of Expedited Review

4.1.1 Do not impact on study results or scientific soundness,
4.1.2 Do not affect safety and wellbeing of the participants,
4.1.3 No change in the inclusion/exclusion criteria,
4.1.4 Positive benefit/risk ratio,
4.1.5 No vulnerability issues
4.1.6 Deletion of sub-investigator

4.2 Criteria for Amendment of Full Board Review

4.2.1 Change in study design
4.2.2 Significant changes in the number of participants
4.2.3 Increases risk that change the benefit/risk ratio
4.2.4 Additional or deletion of treatment
4.2.5 Addition of new sub-investigator

Step 5: Review of Amendment Report

5.1 For Expedited Review:

5.1.1 The Primary Reviewers submit their Evaluation Form after five (5) working days from the receipt of the Protocol Amendment.
5.1.2 The Chair evaluates the Protocol Amendment Report Form(Form 4.0) submitted by the Primary Reviewers for finalization.

5.2 For Full Board Review:

5.2.1 The Primary Reviewers submit their Evaluation Form three (3) days before the IRB meeting.
5.2.2 The Primary Reviewers presents their findings during the board meeting for discussion.

5.3 The Chair confirms the quorum before making a decision.
5.4 The IRB members make a decision by votation.
5.5 The Office Manager or Staff prepares a draft of the committee decision based on either the expedited review report or minutes of the meeting. The Chair signs the decision letter as follows:

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

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

6.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email the Decision of the IRB (Approval Letter (Form 6.1), Notification of the IRB Decision Form (Form 6.2), signed by the Chair, is available for release.
6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.
06	2019 July 26	IRB SOP TEAM	Separate procedures for review of Protocol amendment.
07	2019 Dec. 30	IRB SOP TEAM	Revise step 3. Delete step 3.2 (except A) in section 4.1.6. Clarify step 4.1.
08	2020 Oct. 20	IRB SOP TEAM	Delete step 3.2.
09	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow. Revise scope, revised description of procedures step 4, 4.3
10	2025 May 15	Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer	Revised SOP 13 on Protocol Amendment.
11	26 May 2026	IRB SOP TEAM	Added specific criteria

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 13** **Review of Progress Report**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of a progress Report. The IRB shall periodically review or monitor the protocols more frequently depending upon the degree of risk to the participants, the nature and duration of the study, and the vulnerability of the study participants. The frequency of the progress report is indicated in the Approval Letter (Form 6.1).

2. Objective of the Activity

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

3.Scope

This SOP begins with the receipt and entry to logbook of incoming documents and ends with updating the protocol database.

4.Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and entry into the incoming logbook of progress reports submissions	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Primary Reviewers		
Step 4: Determination of the type of Review	Chair	
Step 5: Review of the progress report	Primary Reviewers	5 day (Expedited) 10 days (Full board)
Step 6: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 7: Filing of progress report in the appropriate protocol folder and update of the protocol database		1 day

5.Description of Procedures

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

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

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair and Primary Reviewers

3.1 The Office Manager or Staff notifies the Chair and the Primary Reviewers regarding the Progress Report through SMS, messenger, or email.

3.2 The Office Manager of Staff send the Progress report submission to the Chair and Primary Reviewers via email.

Step 4: Determination of type of review

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

Step 5: Review of the progress report

5.1 The Primary Reviewers review the progress report of researcher- initiated protocols for Expedited Review (SOP 6 Expedited Review) for five (5) working days using Progress Report Form (Form 4.1).

5.2 The Primary Reviewers submit the results of the review to the Office Manager or Staff after five (5) working days upon receipt of the report.

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

5.4 The Primary Reviewers review the Progress report of protocols for Full Board Review (SOP 7 Full Board Review) in ten (10) working days.

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

5.6 The IRB members discuss the progress report during the full board meeting.

5.7 The IRB board makes a decision by votation.

The following are the decision points:

- Accepted
- Request Further Information
- Require specific Action

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

6.1 For the decision of the Progress report by expedited review, the Office Manager or Staff prepares the draft decision and the Chair finalizes and signs the decision letter IRB Communication Letter (Form 6.3) before the board meeting.

6.2 For the decision of the Progress report by full board, the Chair finalizes and signs the decision letter IRB Communication Letter (Form 6.3) after the board meeting.

6.3 The Office Manager or Staff informs the Investigator/researcher through Short Message Service (SMS), messenger or email that the decision of IRB Communication Letter (Form 6.3) signed by the Chair, is available for release.

6.4 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

Step 7: Filing of progress report in the appropriate protocol folder and update of the protocol database

The Office Manager or Staff files the Progress report (Form 4.1), IRB Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the protocol database.

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.
06	2019 July 26	IRB SOP TEAM	Separate procedures for review of progress report.
07	2019 Dec 30		Revised sequencing of SOPs on Post-Approval Reviews.
08	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow.
09	2025 May 15	Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer	Revised SOP 14 on Progress Report.
10	26 May 2026	IRB SOP TEAM	Added 5.7 in step 5

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 14** **Review of SAE and SUSAR Reports**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require on-site Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) reports to be submitted by the Principal Investigator (PI)/Researcher. Fatal or life- threatening on-site SAEs shall be reported within 24 hours, and other SAEs within ten (10) working days after the event has come to the attention of the researcher. The Member-Secretary and the Primary Reviewers shall review and analyze the on-site SAEs and SUSARs. The consolidated recommendations of the Member-Secretary and the Primary Reviewers are reported to the IRB during the regular monthly meeting for discussion. Review of SAE and SUSAR shall adhere to the national (NEGRIHP 2022) and international guidelines (ICH GCP).

2. Objective of the Activity

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

3. Scope

This SOP begins with Receipt and documentation of submission of report of SAEs and SUSARs in the logbook and end with the filing of all related documents and update the database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of submitted report of SAEs and SUSARs in the logbook	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Member-Secretary		
Step 4:Submission of report to the Member- Secretary and Primary Reviewers		1 day
Step 5: Submission of the recommendations by the Primary Reviewers and Consolidation of recommendations	Designated SAE Reviewer and Primary Reviewers	1 day
Step 6: Report and discussion and the SAEs and SUSARs during the board meeting	Member- Secretary, IRB	1 day
Step 7: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 8: Filing of all related documents and update of the database		1 day

5. Description of Procedures

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

1.5 The Office Manager or Staff receives the SAE/SUSARs (Form 4.2) from the PI/researcher and records it in the incoming communication logbook and SAE/SUSAR database. The submission date is checked and noted whether they comply with submission timeline.

1.6 The Office Manager or Staff includes the on-site SAE/SUSARs reports in the agenda of the monthly meeting.

1.7 The national and international off-site SAEs/SUSARs reports are included in the agenda every six (6) months.

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair and Member-Secretary

The Office Manager or Staff notifies the Chair and Member-Secretary about the submitted reports through short messaging service (SMS), messenger or email.

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

The Office Manager or Staff submits to the Designated SAE Reviewer (Member-Secretary) and the two primary reviewers the SAEs/SUSARs reports ten (10) working days before the regular meeting.

Step 5: Submission of the recommendations by the Primary Reviewers and Consolidation of recommendations

5.1 The Primary reviewers submit to the Designated SAE Reviewer (Member-Secretary) their evaluation five (5) working days prior to the meeting for the consolidation of their recommendations.

5.2 The Member-Secretary submits the consolidated recommendations to the Office Manager or Staff three (3) working days prior to the IRB monthly meeting.

Step 6: Report and discussion and the SAEs and SUSARs during the board meeting

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

- the number of studies that have on-site SAEs/ SUSARs
- the number of on-site SAEs/ SUSARs
- the number of the type of Safety report: SAEs/SUSARs
- the nature of the report if drug related or study related
- the event that occurred
- the inclusion or exclusion/termination of the subject with on-site SAEs/SUSARs
- the effect of the on-site SAEs/SUSARs to the participant
- the outcome of the on-site SAEs/SUSARs on the participant
- the action of the PI/Researcher

6.2 The Member-Secretary reports the summary of the national and international off-site SAEs/SUSARs/ Line Listing every six (6) months. The report includes:

- the number of studies that have national and international off-site SAEs/ SUSARs/Line Listing
- the number of national and international off-site SAEs/ SUSARs/ Line Listing

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

6.4 The Chair presides over the board for the discussion of the recommendations.

6.5 The IRB members make a decision by votation.
The following are the decision points:

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

Step 7: Communication of IRB decision to PI/Researcher

7.1 The Office Manager or Staff informs the PI/Researcher through Short Message Service (SMS), messenger or email that the decision of the IRB, (Communication Letter (Form 6.3)) signed by the Chair, is available for release.

7.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

The Office Manager or Staff files the SAE/SUSARs, IRB Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the SAE/SUSAR protocol database.

6 Forms

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

7 History of SOP

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

07	2025 May 15	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 15 on SAE /SUSAR reports.
08	26 May 2026	IRB SOP TEAM	Revised SOP 14 on SAE /SUSAR reports.

8 References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 15** **Review of Reportable Negative Events Report**
Effective Date: June 15, 2026	

1. Policy Statement

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

2. Objective of the Activity

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

3. Scope

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

4. Workflow

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

5. Description of Procedures

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

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

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair

The Office Manager or Staff notifies the Chair about the submitted report through Short Message Service (SMS), messenger or email.

Step 4: Call for a special meeting

4.1 The Chair calls for a special meeting.

4.2 The Office Manager or Staff prepares for a special meeting and notifies the IRB members. The IRB members are provided with the RNE report for review.

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

Step 5: Deliberation on the RNE

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

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

- Recommend suspension of the study until risk is resolved.
- withdrawal of ethical clearance
- submission of a plan to mitigate risk/harm
- require an amendment to the protocol
- uphold original ethical clearance

Step 6: Communication of IRB decision to Researcher

6.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS) messenger or email the Decision of the IRB (Communication Letter (Form 6.3) signed by the Chair, is available for release.

6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

The Office Manager or Staff files the RNE report (Form 4.3), excerpt of the minutes of the meeting in the protocol file folder, makes a protocol file index (Form 7.2) and updates the protocol database.

6. Forms

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

7. History of SOP

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

05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early Termination report.
06	2019 Dec. 30	IRB SOP TEAM	Revised sequencing.
07	2025 June 4	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 16 on review RNE report.
08	23 May 2026	IRB SOP TEAM	Revised SOP number

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 16** **Review of Protocol Deviations/Violations**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the Investigators to submit reports on protocol deviation/ violations of the approved researches within five (5) working days after the occurrence of the incident. This includes the statements and proofs of the corrective action and preventive action. The Protocol Deviations/Violations report shall undergo full board review due to its impact of the non-compliance of the protocol on the health and well-being of the participants and/or on the science/study results.

2. Objective of the Activity

This activity aims to ensure that the safety and well-being of the human participants are safeguarded and that the credibility of the data is maintained.

3. Scope

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

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and documentation of report of protocol deviations/violations in the logbook	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of the Chair and Primary Reviewers		
Step 4: Inclusion of the report in the agenda in the IRB Meeting	Chair and Staff	1 day
Step 5: Full Review of Protocol Deviations/violations	Primary Reviewers	1 day
Step 6: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 7: Filing of all related documents to the protocol file		1 day

5. Description of Procedures

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

The Office Manager or Staff receives the report on protocol deviations/violations in the appropriate report form (Form 4.4) and enters the appropriate information into the incoming communication log book and protocol deviation/violation database.

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the relevant protocol file folder and earmarks pertinent Documents.

Step 3: Notification of the Chair and Primary Reviewers

3.1 The Office Manager or Staff notifies and sends via email the Protocol deviations/violations report (Form 4.4) to the Chair and the two (2) Primary Reviewers.

3.2 The Primary Reviewers are given ten (10) working days to review the protocol deviation/violation report prior to the IRB meeting.

3.3 All protocol deviations/violations will be discussed by full board.

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

The Chair includes the report on protocol deviations/violations in the full review of the Agenda of the IRB meeting.

Step 5: Full Review of Protocol Deviations/violations

a. The Primary Reviewers review and discuss in the full board the protocol deviation/violation report

considering the nature of the deviation, detailed description of reported deviation/violation, explanation why it happened, deviations from the approved protocol, explanation for deviation/violation, impact of deviation/violation on participants' risks/harms and integrity of data, and corrective actions and preventive actions.

The Chair confirms the quorum before making a decision.

5.2 The IRB Members make a decision by votation.

5.3 The following are the decision points:

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

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

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

6.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS) messenger or email that the Decision of the IRB (Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3) signed by the Chair, is available for release.

6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

The Office Manager or Staff files the Protocol Deviations/Violations Form (4.4), Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the protocol Deviations/Violations database.

6. Forms

Protocol Deviations/Violations Form (4.4)
IRB Communication Letter (Form 6.3)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed reviews of protocol deviations or violations reports.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.
06	2019 Dec. 20	IRB SOP TEAM	Revise sequencing of SOPs on Post- Approval Reviews.
07	2024 Feb. 22	IRB SOP TEAM	Edited scope. Added timeline in calendar days in the workflow.
08	2024 June 28	IRB SOP TEAM	Revised sequencing of post approval reports
09	2025 May 15	Dr. Rowena Cosca, Mr.C hristopher Tabsing, and Ms.Imelda Olaguer	Revision SOP 17 on Protocol deviations/violations reports.
10	27 May 2026	IRB SOP TEAM	Revision SOP 16 on Protocol Deviations/violations reports.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 17** **Review of Early Termination Reports**

1. Policy Statement

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

2. Objective of the Activity

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

3. Scope

This SOP begins with the receipt and entry to incoming logbook and ends with an update of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of the early termination report and entry into the logbook	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Primary Reviewers		
Step 4: Full review of Early Termination Report	Primary Reviewers	1 day
Step 5: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 6: Filing of the Early Termination report and updating of the protocol database		1 day

5. Description of Procedures

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

The Office Manager or Staff receives the Early Termination report (Form 4.5) and enters the appropriate information into the incoming communication logbook.

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair and Primary Reviewers

3.1 The Office Manager or Staff notifies the Chair and the two (2) Primary reviewers about the early termination report by email or messenger.

3.2 The Office Manager or Staff sends via email the Early Termination Report (Form 4.5) to the Primary Reviewers not later than ten (10) working days before the board meeting.

Step 4: Full review of Early Termination Report

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

4.2 The Chair confirms the quorum before making a decision.

4.3 The IRB Members make a decision by votation.

4.4 The following are the decision points:

- Acceptance of the decision with no further action
- Request for additional information
- Require for further action

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

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

5.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Communication Letter (Form 6.3)), signed by the Chair, is available for release.

5.2 The Office Manager or Staff ensures that the PI/researcher receives the communication letter and signs the Outgoing Communication Logbook.

Step 6: Filing of the Early Termination report and updating of the protocol database

The Office Manager or Staff files the Early Termination Report (Form 4.5), Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the protocol database.

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.

05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.
06	2019 July 26	IRB SOP TEAM	Separate procedures for review of Early Termination report.
07	2019 Dec. 30	IRB SOP TEAM	Revised sequencing of SOPs on Post-Approval Reviews.
08	2024 Feb. 22	IRB SOP TEAM	Edited policy statement, objectives and scope. Added timeline in calendar days in the workflow.
09	2024 June 28	IRB SOP TEAM	Revised sequencing of post approval reports
10	2025 May 15	Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer	Revised SOP 18 on Review of Early Termination Reports.
11	28 May 2026	IRB SOP TEAM	Revised SOP 17 Review of Early Termination Reports

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 18** **Review of Final Report**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the Principal Investigators/Researcher to submit the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full board review.

2. Objective of the Activity

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

3. Scope

This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt of the final report and entry into logbook	Office Manager or Staff	1 day
Step 2: Retrieval of pertinent protocol file		
Step 3: Notification of Chair and Primary Reviewers		
Step 4: Determination of type of review	Chair	
Step 5: Notification of the Primary Reviewers	Office Manager or Staff	
Step 6: Review of Final Report: Expedited or Full Board Review	Chair	1 day
Step 7: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 8: Filing of the Final Report and related documents and updating of the protocol database		1 day

5. Description of Procedures

Step 1: Receipt of final report and entry into logbook

The Office Manager or Staff receives and enters the date of receipt of the final report into the incoming communication logbook. The Office Manager or Staff receives and logs the final report submitted by the Principal Investigator/Researcher.

Step 2: Retrieval of pertinent protocol file

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

Step 3: Notification of Chair and Member-Secretary

3.1 The Office Manager or Staff notifies the Chair or Member-Secretary regarding the final report through Short Message Service (SMS), messenger or email within the day of the receipt of the report.

3.2 The Office Manager or Staff forwards the Final Report (Form 4.6) to the Chair via email.

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

Step 4: Determination of type of review

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

Step 5: Notification of the Primary Reviewers

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

5.2 The Office Manager or Staff sends the Final Report to the Primary Reviewers via email.

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

6.1 The Primary Reviewers review protocols for Expedited Review for five (5) working days (SOP 7 Expedited Review).

6.1.1 The Primary Reviewers submit their Evaluation (Form 4.6) after five 5 working days from receipt of the report.

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

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

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

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

6.5 The Chair confirms the quorum before making a decision.

6.6 The IRB Members make a decision by votation.

The following are the decision points:

- Accept
- Require submission with Corrections

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

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

7.2 The Office Manager or Staff communicates to the PI/Researcher through SMS, messenger or email that the Decision of the IRB (Communication Letter (Form 6.3)), signed by the Chair, is available for release.

7.3 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Provides instructions for the review of progress and final reports, and for the management of the premature or early termination of a protocol and protocol amendments.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Modify sequencing of SOP on Review procedures. Separate procedures for review of progress report, protocol amendment, final report and Early termination report.
06	2019 July 26	IRB SOP TEAM	Separate procedures for review of Final report.
07	2019 Dec. 30	IRB SOP TEAM	Revised sequencing of SOPs on Post-Approval Reviews. Harmonize steps in workflow and description of procedures.
08	2024 Feb. 22	IRB SOP TEAM	Edited policy statement, objectives and scope. Added timeline in calendar days in the workflow.
09	2024 June 28	IRB SOP TEAM	Revised sequencing of post approval reports.
10	2025 June 3	Dr. Rowena Cosca, Mr. Christopher Tabsing and Ms. Imelda Olaguer	Revised SOP 19 on Review of Final Report.
11	26 May 2026	IRB SOP TEAM	Corrected the form reference in step 3.1

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 19** **Management of an Application for Continuing Review**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall require the submission of an application for Continuing Review at least 20 working days before the expiration of the one (1) year ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for continuing review. Similarly, protocols that underwent Expedited review that have no Post-Approval Reports which may reclassify the protocol for full board review, shall undergo Expedited review. The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board retains the discretion to entertain applications that were submitted less than 20 days before the expiration of the clearance.

2. Objective of the Activity

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

3. Scope

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

4. Workflow

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

5. Description of Procedures

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

The Office Manager or Staff receives and logs the application for continuing review submitted by the Principal Investigator/Researcher in the incoming communication logbook.

Step 2: Retrieval of pertinent protocol files

The Office Manager or Staff retrieves the pertinent files as indicated in the continuing review forms and prepares them for the Chair and two (2) Primary Reviewers for review. The files include the approved protocol and Informed Consent Form versions, amendments, related past submissions, progress reports, protocol deviations/violations reports, safety reporting, SAE/SUSAR reports, site visit

(if applicable) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

Step 3: Notification of Chair and Primary Reviewers

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

Step 4: Determination of type of review

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

Step 5: Review of the Application for Continuing Review

a. The Primary Reviewers review the application for Continuing Review of researcher- initiated protocols for Expedited Review (SOP 6 Expedited Review) for five (5) working days using Application for Continuing Review Form(Form 4.7)
   i. The Primary Reviewers submit the results of the review to the Office Manager or Staff after five (5) working days from the receipt of the report.
   ii. The Chair reviews the Evaluation Form of the Primary Reviewers and finalizes the decision.

5.2 The Primary Reviewers review the application for Continuing Review of protocols for Full Board Review (SOP 7 Full Board Review) in ten (10) working days.

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

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

5.2.3 The Chair confirms the quorum before making a decision.

5.2.4 The IRB board makes a decision by votation.

5.3 The following are the decision points:

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

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

6.1 For the decision of the Application for continuing review by expedited review, the Office Manager or Staff prepares the draft decision and the Chair finalizes and signs the decision letter (Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3) before the board meeting.

6.2 For the decision of the Application for continuing review by full board, the Chair finalizes and signs the decision letter (Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3) after the board meeting.

6.3 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Approval Letter (Form 6.1)/IRB Communication Letter (Form 6.3), signed by the Chair, is available for release.

6.4 The Office Manager or Staff ensures that the PI/researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2020 Oct. 20	IRB SOP TEAM	First draft
02	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow.
03	2024 June 28	IRB SOP TEAM	Revise sequencing of post approval reports
04	2025 June 3	Dr. Rowena Cosca, Mr. Christopher Tabsing, and Ms. Imelda Olaguer	Revised SOP 20 on Continuing Review Application.
05	26 May 2026	IRB SOP TEAM	Revised SOP 19 on Continuing Review Application.

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 20** **Conduct of Site Visits**
Effective Date: June 15, 2026	

1. Policy Statement

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

2. Objective of the Activity

This activity aims to monitor the Principal Investigator's compliance with the IRB approved protocols, and the ICF process, and to ensure the continuing protection and promotion of participant's dignity, rights and well-being.

3. Scope

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

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Selection of site to visit	IRB Members	1 day
Step 2: Notification of PI/researcher	Office Manager or Staff	1 day
Step 3: Creation of Site Visit Team	Chair	1 day
Step 4: Conduct of site visit	Site Visit Team (members)	1 day
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team (members)	1 day
Step 6: Communication of IRB decision/action to PI/Researcher	Chair and Staff	1 day
Step 7: Filing of the Final Report and related documents and updating of the protocol database	Staff	1 day

5. Description of Procedures

Step 1: Selection of site to visit

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

The following are the criteria:

1. A routine site visit
   - ☐ Can happen during start of the study
2. For a cause
   - ☐ high risk studies
   - ☐ receipt of significant number of protocol deviations/violations and SAEs,
   - ☐ receipt of complaints from participants and families/complaints raised against the site
   - ☐ non-receipt of required after-approval reports from the PI/Researcher
   - ☐ multiple studies conducted by a PI/Researcher

Step 2: Notification of PI/Researcher

2.1 The Chair signs the communication letter.

2.2 The Office Manager or Staff notifies the PI/Researcher concerning the reason for the planned site visit in the communication letter.

2.3 The Site visit will be done ten (10) working days after the PI/Researcher has received the communication letter.

Step 3: Creation of Site Visit Team

3.1 The Chair creates the site visit team composed of at least two (2), but not more than four (4) of its members to perform the site visit.

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

- Review the appropriate documents for the site visit
- Prepares Site Visit Form (Form 4.8)

Step 4: Conduct of site visit

The IRB Site visit team conducts the Site visit.

During the Site Visit, the team does the following:

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

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

5.1 The Team leader of the Site Visit Team drafts the report using the Site Visit Form (Form 4.8) within five (5) working days and forwards the draft report to the other members of the visit team for concurrence and decision.

5.2 The Office Manager or Staff includes the conduct of the Site Visit under the agenda item on Site Visit in the next board meeting.

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

6.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB (Communication Letter (Form 6.3)), signed by the Chair, is available for release.

6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

The Office Manager or Staff files the Site Visit Form (Form 4.8), Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the protocol database.

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed management of Site Visit.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Indicated in step 1.2 the maximum number of protocols.
06	2019 July 26	IRB SOP TEAM	Only IRB members and Staff cited in the Workflow.
07	2019 Dec. 30	IRB SOP TEAM	Revised sequencing of SOPs on Post- Approval Reviews.
08	2024 Feb. 22	IRB SOP TEAM	Revised scope and added timeline in calendar days in the workflow. Revise description of procedures step 2, 2.1.
09	2025 May 15	Dr. Ronald Latap, Mrs. Maria Thelma Servidad, and Ms. Ma. Luisa Alba	Revised SOP 21 on Conduct of Site Visit.
10	27 May 2026	IRB SOP TEAM	Revised SOP 20 on Conduct of Site Visit.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 21** **Management of Queries and Complaints**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have procedures on the Management of Queries and complaints from PI/Researcher, research participants, third parties and other research stakeholders shall be attended to promptly and appropriately while exercising due diligence.

2. Objective of the Activity

This activity aims 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 to promote public trust and confidence in the Institution, especially the IRB, and to ensure that the rights and well-being of participants are attended to.

3. Scope

This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the IRB meeting.

4. Workflow

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

5. Description of Procedures

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

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

Step 2: Referral of query or complaint to competent authority

The Office Manager or Staff refers queries and complaints to the IRB Chair who determines the level of risk.

2.1 For minimal risk, the queries and complaints are referred to the two (2) Primary Reviewers of the protocol for expedited review.

2.2 For more than minimal risk, the chair presents the queries and complaints to the Committee during

the full board meeting.

2.3 The Chair request the Primary Reviewers to lead the discussion with the provided pertinent materials as reference.

Step 3: Formulation of response

3.1 The Primary Reviewers formulate a response using the Queries and Complaints Form.

3.1.1 For expedited review, the Primary Reviewers accomplish the Queries and Complaints Form (Form4.9) and submits its response to the IRB chair within three (3) working days.

3.1.2 The Chair reviews and approves the response of the Primary Reviewers.

3.1.3 For Full Board (more than minimal risk), the Primary Reviewers lead the discussion with other committee members and arrives at a decision during the board meeting.

3.1.4 The following are the decision points:

- Request for explanation/justification from researcher
- Accept request/demand of participant
- Suspension of further recruitment
- Amendment of protocol and re-consent of participants
- Site visit (Constitute a site visit team to gather more information, verification and clarification regarding the source and cause/s of the complaint for each early resolution)
- Others (Designate the Primary Reviewers to meet with the complainants and the researcher, (preferably separately), for clarification of issues and obtain suggestions for resolution if necessary)

Step 4: Communication of Response

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

4.2 The Chair reviews and signs the communication before forwarding it to the Persons with legitimate interests such as investigators/researcher, sponsors, Institutions, regulatory agencies, etc.

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2016 May 20	IRB SOP TEAM	First draft
02	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at

			the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
03	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
04	2019 June 13	IRB SOP TEAM	Split Step 2 into two separate task.
05	2019 July 26	IRB SOP TEAM	Added management of appeals.
06	2019 Dec. 30	IRB SOP TEAM	Revise sequencing of SOPs on Post- Approval Reviews.
07	2020 Oct. 20	IRB SOP TEAM	Separate Management of Appeals.
08	2024 Feb. 22	IRB SOP TEAM	Added timeline in calendar days in the workflow.
09	2025 May 15	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 22 on Management of Queries and Complaints.
10	28 May 2026	IRB SOP TEAM	Revised SOP 21 on Management of Queries and Complaints.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 22** **Management of Appeal**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have procedures to manage appeals of the Principal Investigator/Researcher, which may include the feasibility and acceptability of IRB recommendations including its disapproval.

2. Objective of the Activity

This activity aims to ensure fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

3. Scope

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

4. Workflow

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

5. Description of Procedures

Step 1: Receipt of an appeal

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

Step 2: Retrieval of pertinent protocol file

The Office Manager or Staff retrieves the corresponding protocol file for reference of the Chair and two (2) Primary Reviewers.

Step 3: Notification of Chair and Primary Reviewers

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

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

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

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

4.2 The Office Manager or Staff informs the PI/Researcher to be available on the scheduled meeting in

case there is a need for further clarification.

Step 5: Discussion of and deliberation on the appeal

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

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

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

d. Based on the deliberations, the Chair summarizes the decision points and instructs the IRB Staff to prepare the draft decision letter, either an Approval Letter (Form 6.1), or Notification of IRB Decision (Form 6.2).

5.4.1 The following are the decision points:

- Approval (when no further modification is required)
- 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)

5.4.2 Reasons for vote of disapproval should be noted in the minutes of meeting and communicated to the PI/Researcher.

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

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

6.1 The Office Manager or Staff communicates to the PI/Researcher through SMS, messenger or email that the Decision of the IRB (Communication Letter (Form 6.3)), signed by the Chair, is available for release.

6.2 The Office Manager or Staff ensures that the PI/Researcher receives the communication letter and signs the Outgoing Communication Logbook.

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

The Office Manager or Staff files the letter of appeal, Communication Letter (Form 6.3), excerpt of the minutes of the meeting in the protocol file folder, updates the protocol file index (Form 7.0), and updates the protocol database.

6.Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2020 Oct. 20	IRB SOP TEAM	First draft
02	2024 Feb. 22	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow.
03	2025 June 4	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 23 on Management of Appeal.
04	23 May 2026	IRB SOP TEAM	Revised SOP 22 on Management of Appeal.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 23** **Preparing for a Meeting**

1. Policy Statement

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

2. Objective of the Activity

This activity aims to contribute a smooth, orderly and efficient conduct of board meetings.

3. Scope

This SOP begins with the preparation of the agenda and ends with the notification of IRB Members and confirmation of attendance.

4. Workflow

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

5. Description of Procedures

Step 1: Preparation of the Agenda

1.8 The Office Manager or Staff checks the submitted documents in the incoming communication logbook and prepares the draft of the Notice of IRB Meeting.

1.9 The Office Manager or Staff forwards the draft of the Notice of IRB Meeting to the Member-Secretary to finalize, review and makes changes if needed.

1.10 The provisional draft of the Notice of IRB Meeting is presented to the IRB Chair for approval.

Step 2: Coordination with the physical plant division

The Office Manager or Staff coordinates with the hospital staff in charge of the Cancer Center conference room fifteen (15) working days before the upcoming IRB meeting, if the attendees cannot accommodate in the IRB office.

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

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

3.2 The Office Manager or Staff sends the documents via email to all IRB members ten (10) working days

prior to the scheduled IRB meeting.

Step 4: Preparation of logistics for the meeting

4.1 The Office Manager or Staff prepares the logistics for the meeting (honoraria, snacks, LCD projector, Laptop, camera) three (3) working days before the meeting.

4.2 The Office Manager or Staff sends a link to those IRB members who will attend the IRB meeting online, two (2) days before the IRB meeting.

4.3 The Staff prepares the IRB Office one (1) day before the IRB regular meeting.

Step 5: Notification of IRB Members and confirmation of attendance

The Office Manager or Staff informs the IRB members of the scheduled meeting through SMS or messenger to confirm their attendance, and the presence of quorum three (3) working days before the meeting.

6. Forms

Notice of IRB Meeting with Agenda Template (Form 5.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Added detailed preparation of the IRB meeting.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2024 Feb. 22	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow. Revise step 3 (3.2) and step 5, (5.4 & 5.6).
06	2024 Apr 29	IRB SOP TEAM	Added statements in the description of procedures.
07	2025 May 15	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 25 on Preparing for a Meeting.
08	28 May 2026	IRB SOP TEAM	Revised SOP 23 on Preparing for a Meeting.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 24** **Preparing the Notice of the Meeting with Agenda**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall prepare the notice of the IRB meeting based on the received submitted documents in the incoming communication logbook at the latest, five (5) working days before the scheduled regular meeting. The provisional agenda shall be included in the Notice of IRB Meeting.

2. Objective of the Activity

This activity aims to ensure a smooth, orderly, inclusive and efficient meetings.

3. Scope

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

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Preparation of the draft of the Notice of Meeting with the Agenda	Office Manager or Staff	2 days
Step 2: Approval of the draft of the Notice of Meeting with the Agenda	Chair	2 days
Step 3: Communication of the Notice of Meeting with the Provisional Agenda	Office Manager or Staff	1 day
Step 4: Approval of the provisional meeting agenda	IRB members	1 day
Step 5: Filing of the final Meeting Agenda	Office Manager or Staff	1 day

5. Description of Procedures

Step 1: Preparation of the draft of the Notice of Meeting with the Agenda

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

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

8.3.5 Review of Reports on Negative Events (RNE)
8.3.6 Protocol Deviations and Violations
8.3.7 Early Termination Reports
8.3.8 Final Reports

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

Step 2: Approval of the draft meeting Agenda

The Chair approves and signs the draft Notice of Meeting with the Agenda. The approved draft Meeting Agenda becomes the Provisional Agenda.

Step 3: Communication of the Notice of Meeting with the Provisional Agenda

The Office Manager or Staff sends the Notice of IRB Meeting with the Provisional Agenda via email to the IRB members three (3) working days before the scheduled meeting.

Step 4: Approval of the Provisional Agenda

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

Step 5: Filing of the final Meeting Agenda

The Office Manager or Staff files the signed final meeting agenda in the file folder and stores in a locked cabinet.

6.Forms

Notice of IRB Meeting (Form 5.0)

7.History of SOP

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

			Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2024 Feb. 22	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow. Revise description of Procedures 5.2.5 step 1.
06	2024 June 28	IRB SOP TEAM	Revise sequencing in the Notice of the IRB Meeting template.
07	2025 May 15	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 25 on Preparing the Notice of the Meeting with Agenda.
08	28 May 2026	IRB SOP TEAM	Revised SOP 24 on Preparing the Notice of the Meeting with Agenda.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 25** **Conduct of Meetings**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall conduct a meeting to be presided by the Chair or a designated substitute. It shall proceed only when a quorum (50% of the total regular members + one (1)) is present. The members must be a representation of different disciplines (scientists, non-scientists, medical, non-medical), sectors (male and female, older and younger age groups) and affiliation with the institution (affiliated and non-affiliated members). The meeting shall be guided by the approved agenda. The presence of the conflict of interest among the members shall be disclosed prior to the discussion of protocol for review.

The Conduct of Meetings shall abide by the national and International guidelines. The meetings shall be conducted either face to face, virtual platform or hybrid.

2. Objective of the Activity

This activity aims to provide an opportunity for the IRB to meet and arrive at a collegial decision regarding the study protocols and the IRB operations, and to be informed of pertinent administrative matters.

3. Scope

This SOP begins with the Communication of the notification of Meeting with the Provisional Agenda, and other meeting materials and ends with the collection, storage, and disposal of meeting materials.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Communication of the Notification of Meeting with the Provisional Agenda, and other meeting materials	Staff	1 day
Step 2: Opening Prayer	IRB Members	1 day
Step 3: Call to Order	Chair	
Step 4: Determination of quorum	Member-Secretary	
Step 5: Approval of the provisional agenda	IRB Members	
Step 6: Approval of minutes of the previous meeting	IRB Members	
Step 7: Discussion of "business arising from the minutes of the previous meeting	IRB Members	
Step 8: Disclosure of conflict of interest (COI)	IRB Members (who have COI)	
Step 9: Review of protocols and protocol-related Submissions	Chair and Members	
Step 10: Site Visit	Site visit team leader	
Step 11: Queries and Complaints/Appeal	Chair	
Step 12: Exempt from Review Protocols		
Step 13: Report of the Approved new protocols by Expedited Review		
Step 14: Report of the Approved post-approval reports by Expedited Review		

Step 14:Notifications	Member-Secretary
Step 16: Discussion of other matters	Chair
Step 17: Adjournment	
Step 18: Collection, storage, and disposal of meeting materials	Staff

5. Description of Procedures

Step 1: Communication of the Notification of Meeting with the Provisional Agenda, and other Meeting Materials

The Staff sends the Notification of meeting with the provisional agenda and other meeting materials three (3) working days prior to the meeting via email.

Step 2: Opening Prayer

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

Step 3: Call to order

The Chair calls the meeting to order.

Step 4: Determination of quorum

4.1 The Member-Secretary determines the quorum by the presence of majority (50% of the total regular members + one (1)). The members must be a representation of different disciplines (scientists, non-scientists, medical, non-medical), sectors (male and female, older and younger age groups) and affiliation with the institution (affiliated and non-affiliated members).

4.2 When the quorum is announced, the formal meeting starts. All the members who are present signs the Attendance Sheet (Form 5.1).

Step 5: Approval of the provisional agenda

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

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

Step 6: Approval of minutes of the previous meeting:

The IRB Members approve the provisional minutes of the previous meeting after corrections are done, and after a motion for approval is made and duly seconded.

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

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

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

Step 8: Disclosure of Conflict of Interest

8.1 The Chair asks the IRB members if there is conflict of interest with any protocol to be discussed. All members declare their Conflict of Interest (COI) or no COI related to any protocol to be discussed/reviewed.

8.2 The Chair manages the conflict of Interest by asking the concerned member to leave the conference room/IRB Office while the protocol is being discussed. Quorum should be maintained when a member with COI leaves the room. The Staff calls back the member with COI after the discussion, and decision has been made.

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

Step 9: Review of protocols and protocol-related submissions

The IRB Members review the new Protocols for Initial Review of Full Board, Resubmission, Review of SJREB Protocols, Post-approval reports (Amendments, Progress Reports, SAE/SUSAR Reports, Review of Reports on Negative Events (RNE), Protocol Deviation/Violation, Early Termination Reports, Final Reports, and Application for Continuing Review) Site Visit, Queries and Complaints/Appeal, Exempt from Review Protocols, Report of the approved new protocols by expedited review, report of the approved post approval reports by expedited review, and Notifications.

9.1 For Initial Review,

9.1.1 The two (2) primary Reviewers present the summary of their findings based on the Protocol Evaluation and ICF Evaluation forms.

9.1.2 The Chair facilitates the discussion on the protocol issues and findings. The presentation and the discussion follow the structure of the Protocol and ICF Evaluation forms.

9.1.3 When an Independent Consultant is invited to give their expert opinion on a protocol for review, the IC clarifies technical issues and answers queries of the IRB members. The IC may be available during the discussion of the protocol in an IRB meeting or maybe consulted by the Primary reviewers before the meeting. The IC is not given a protocol to review and cannot participate in the voting process during the IRB meetings.

If the study involves children, a pediatrician IC must be requested.

9.1.4 The Chair may call on the PI /Researcher for clarifications, if needed. The PI/Researcher is not asked to present the protocol.

9.1.5 The Chair asks the IC and/or PI to leave the meeting prior to board deliberation and decision-making.

9.1.6 The Chair or Member-Secretary summarizes the recommendations before making a decision.

9.1.7.The Chair confirms the quorum before making a decision. The IRB makes a decision by votation. The position which obtains the majority vote prevails. The result of the voting is documented.

IRB Decision points for initial review are:

9.1.7.1 Approval (when no further modification is required)

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

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

9.1.7.4 Disapproval (due to ethical or legal concerns)

9.1.8 Reasons for vote of disapproval should be noted in the minutes of meeting and communicated to the PI/Researcher.

9.2 Resubmission for full review

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

9.2.2 The IRB discusses the recommendations and make decisions.

9.2.3 The Chair confirms the quorum before making a decision.

9.2.4 The IRB board makes a decision by votation.

The following are the decision points:

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

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

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

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

9.3 Amendments for full review

9.3.1 The Primary Reviewers present their assessment and recommendations on the Amendment reports to the IRB

9.3.2 The IRB discusses the recommendations and make decisions.

9.3.3 The chair confirms the quorum before making a decision.

9.3.4 The IRB board makes a decision by votation.

The following are the decision points:

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

9.4 Progress Report for full review

9.4.1 The Primary Reviewers present their assessment and recommendations on the Progress reports to the IRB

9.4.2 The IRB discusses the recommendations and make decisions.

9.4.3 The chair confirms the quorum before making a decision.

9.4.4 The IRB board makes a decision by votation.

The following are the decision points:

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

9.5 SAE/SUSAR Reports for full review

9.5.1 During the meeting, the Member-Secretary (Designated SAE Reviewer) reports and discusses the on-site SAEs/SUSARs.

9.5.2 The Member-Secretary makes recommendations appropriate for the on-site SAEs/SUSARs.

9.5.3 The Chair presides over the board for the discussion of the recommendations.

9.5.4 The IRB members make a decision by votation.

The following are the decision points:

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

9.6 Review of Reports on Negative Events (RNE) by full board

9.6.1 The Primary Reviewers present and discuss the RNE report.

9.6.2 The IRB Members deliberate on the RNE.

9.6.3 The IRB members make a decision by votation.

The following are the decision points:

- ☐ 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

9.7 Protocol Deviation/Violation by full board

9.7.1 The Primary Reviewers review and discuss the protocol deviation/violation report.

9.7.2 The IRB Members make a decision by votation.

9.7.3 The following are the decision points:

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

9.8 Early Termination Reports by full board

9.8.1 The IRB Members review and discuss the Early Termination Report.

9.8.2 The IRB Members make a decision by votation.

9.8.3 The following are the decision points:

- ☐ Acceptance of the decision with no further action
- ☐ Request for additional information
- ☐ Require for further action

9.9 Final Reports by full board

9.9.1 The Primary Reviewers present their findings.

9.9.2 The IRB members discuss the final report and make a decision by votation.

The following are the decision points:

□Accept
□Require submission with Corrections

9.10 Application for Continuing Review by full board

9.10.1 The Primary Reviewers present their findings.

9.10.2 The IRB members discuss the application for continuing review and make a decision by votation. The following are the decision points:

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

Step 10: Site Visit Report

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

Step 11: Queries and Complaints/Appeal

The Primary Reviewers presents and discuss the Queries and Complaints/Appeal report during the full board meeting.

Step 12. Exempt from Review Protocols

The Chair reports the protocols that are exempted from review.

Step 13. Report of the approved new protocols by Expedited Review

The Chair reports the approved new protocols by expedited review.

Step 14. Report of the approved post-approval reports by Expedited Review

The Chair reports approved post-approval reports by Expedited Review.

Step 15: Notifications

15.1 The IRB Member-Secretary presents the notification letters submitted by the PI/Researcher. The Notification letters include notification of IDMC letters, close-out notifications, notification of IB Brochure, End of global trial notification, memos, etc.

15.2 The Member-Secretary notes all the Notification letters.

Step 16. Discussion of Other Matters

16.1 Others

16.1.1 The Chair presents other matters listed for discussion.

16.2 Giving of Honoraria

16.2.1 The Staff gives the honoraria. The Members sign as they received it.

16.3 Schedule of Next IRB Monthly Meeting

16.2.3 The Chair announce the schedule of the next IRB meeting.

Step 17: Adjournment

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

Step 18: Collection, storage, and disposal of meeting materials

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

18.2 A copy of every document shall be filed in its proper study file folder.

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed procedures related to conduct of the meeting.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Stated in step 9 the responsibility of chair or member secretary during IRB review meeting.
06	28 June 2022	IRB SOP TEAM	Added 1.4 in the description of procedures in step 1. Added gender representation in step 4, 4.1.
07	2024 Feb. 22	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow.). Added in the description of procedures step 1 (1.4), step 9 (9.1-9.4 & 9.7).
08	2024 June 28	IRB SOP TEAM	Revised sequencing in step 9.
09	2025 May 15	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 26 on Conduct of Meetings.
10	28 May 2026	IRB SOP TEAM	Revised SOP 25 on Conduct of Meetings.

18. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 26** **Preparing the Minutes of the Meeting**

1. Policy Statement

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

2. Objective of the Activity

This activity aims to ensure the proper documentation of the procedures and decisions in the IRB meeting.

3. Scope

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

4. Workflow

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

5. Description of Procedures

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

The Office Manager or Staff prepares the minute's template by filing it out with preliminary or relevant information of all the protocols submitted using the Minutes of Meeting Template (Form 6.0).

Step 2: Preparation of the draft Minutes

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

2.2 The Member-Secretary drafts the minutes of meeting for protocols as discussed by full board.

2.3 A recorder is played during the meeting to record the proceedings.

The contents of the minutes of the meeting includes the following:

A. Meeting number and form number
B. Date of the meeting
C. Attendance of the IRB Officers and Members (members present & absent)
D. Attendance of the Guest/IC
E. Attendance of the IRB Staff
F. Opening Prayer
G. Call to Order
H. Determination of the Quorum

I. Approval of the Agenda
J. Reading and Approval of the Minutes of the Previous Meeting
K. Business Arising From the Minutes of the Meeting
L. Disclosure of Conflict of Interest among Members
M. The IRB members declares their COI related to any protocol to be discussed/reviewed during the meeting.
N. Protocol Review
O. Application for Continuing Review
P. Site Visit
Q. Queries and Complaints/Appeal
R. Exempt from Review Protocols
S. Report of the Approved new protocols by Expedited Review
T. Report of the Approved post-approval reports by Expedited Review
U. Notifications
V. Other Matters
W. Checking of Quorum
X. Adjournment
Y. Name and signature of the person who prepared the minutes.
Z. Name and signature of the Chair to indicate the contents have been verified and corrected.

Step 3: Notation of the draft Minutes

3.1 The IRB Staff prepares the draft of the Minutes of the meeting and submits it to the Member-Secretary within three (3) working days after the IRB meeting.

3.2 The Member-Secretary checks and makes necessary correction on the draft of the Minutes of Meeting made by the Staff within three (3) working days of receipt from the IRB Staff.

3.3 The Staff finalizes the minutes of the meeting with corrections from the Member-Secretary.

3.4 The IRB Staff sends the provisional minutes of the meeting via email together with the Notice of IRB meeting three (3) days before the IRB Meeting.

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

4.1 During the IRB full board meeting, the IRB Chair asks the IRB members for the approval of the minutes of previous meeting.

4.2 The IRB Members may make corrections on the provisionary minutes of the meeting prior to its approval.

4.3 The IRB Member makes a motion for the approval of the provisional minutes of the meeting and this is duly seconded.

4.4 The Chair and Member-Secretary sign the approved minutes of the previous meeting.

Step 5: Filing of Minutes of the Meeting

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

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

6. Forms

Minutes of the Meeting Template (Form 6.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Revised the preparation of the minutes of the SPHI-IRB full-board meeting to ensure proper documentation of the procedures and decisions during the meeting.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2024 Feb. 22	IRB SOP TEAM	Revised scope and added timeline in calendar days in the workflow.
06	2024 June 28	IRB SOP TEAM	Revised sequencing in the Minutes of Meeting template
07	2025 May 15	Dr. Ma. Cecilia Florete, and Ms. Queenie Crisostomo	Revised SOP 27 on Preparing the Minutes of the Meeting.
08		IRB SOP TEAM	Edit Step 2, 3 and 4

8.References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 27** **Communicating IRB Decisions**

1. Policy Statement

St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall communicate its decisions (Approval Letter (Form 6.1), Notification of IRB Decision (Form 6.2), and Communication letter (Form 6.3) to the PI/Researcher within three to seven (3-7) working days after the meeting.

The Chair shall sign the communication letters/documents.

2. Objective of the Activity

This activity aims to ensure that all Persons with legitimate interest in these files such as PI/Researcher, institutional authorities, regulatory agencies, and sponsors are appropriately, accurately and promptly informed of the results of deliberations of the IRB.

3. Scope

This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Finalization of the IRB recommendations (in case of full review) or Finalization of recommendations of primary reviewers (in case of expedited review)	Chair	1 day
Step 2: Transfer of information from minutes or assessment forms to IRB Communication forms or templates	Member-secretary, Office Manager and Staff	2 days
Step 3: Approval of the IRB Communication Forms decision document	Chair	1 day
Step 4: Communication of IRB decision/action to PI/Researcher	Office Manager or Staff	1 day
Step 5: Filing of the document in the protocol file folder		1 day

5. Description of Procedures

Step 1: Finalization of the IRB recommendations (in case of full review) or Finalization of recommendations of reviewers (in case of expedited review)

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

For expedited reviews, the Chair finalizes the recommendations and decisions upon submission of the two (2) primary reviewers.

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

2.1 The Office Manager or Staff transfers the recommendations and/or decision to the IRB Communication Forms such as Approval Letter (Form 6.1), Notification of the IRB Decision Form (Form 6.2), IRB Communication Letter (Form 6.3). The transfer of information is done within two (2) working days.

2.2 The Member-Secretary checks the correctness of the communication.

Step 3: Approval of the IRB Communication Forms decision document

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

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

4.1 The Office Manager or Staff communicates to the PI/Researcher through Short Message Service (SMS), messenger or email that the Decision of the IRB, signed by the Chair, is available for release.

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

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

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

6. Forms

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

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed instructions related to the preparation and management of IRB communication.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Added Management of Appeals of IRB Decision.
06	2024 Feb. 22	IRB SOP TEAM	Revised scope and added timeline in calendar days in the workflow.
07	2025 May 16	Dr. Venerio Gasataya Jr., Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 28 on Communicating IRB Decision.
08	23 May 2026	IRB SOP TEAM	Revised timeline

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 28** **Managing IRB Incoming and Outgoing Communications**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have procedures in managing all incoming and outgoing communications (protocol, non-protocol, administrative and non-administrative) to and from Persons with legitimate interest such as PI/Researcher, institutional authorities, and regulatory agencies.

2. Objective of the Activity

This activity aims to establish accountability and an efficient and effective tracking system.

3. Scope

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

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Sorting of incoming and outgoing communications	Office Manager or Staff	1 day
Step 2: Recording of incoming and outgoing communications		
Step 3: Acting on communications		1 day
Step 4: Filing of incoming and outgoing communications and Updating of respective databases		1 day
Step 5: Creating protocol file index and updating of databases	Office Manager or Staff	1 day

5. Description of Procedures

Step 1: Sorting of incoming and outgoing communications

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

1.2 This may include either Protocol or non-protocol related, administrative or non-administrative letters, memoranda, or emails coming from PI/researchers, sponsors, other institutions and agencies.

Step 2: Recording of incoming and outgoing communications

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

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

- Date of Receipt
- IRB Protocol Code
- Principal Investigator/Researcher
- Type of Document Submitted
- Name and signature of the submitter

- Name and signature of the Receiver
- Action Taken

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

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

2.4 Contents of Incoming and Outgoing administrative logbook

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

2.5 Contents of Incoming and Outgoing non-protocol related/non-administrative related documents logbook

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

Step 3: Acting on communications

3.1 The Office Manager or Staff refers the communication to the Chair.

3.2 The Chair reviews and finalizes the response to the communication letter.

3.3 The Chair signs the outgoing communication letter.

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

The Office Manager or Staff files all incoming and outgoing communications, after it has been acted upon by the Chair, in the protocol file folder.

Step 5: Creating protocol file index and updating of databases

5.1 The Office Manager or Staff creates the protocol file index (Form 7.0) and updates the protocol database.

5.2 Administrative and non-administrative communications are kept securely in a cabinet labelled as "SPHI IRB Administrative Documents".

6 Forms

Protocol File Index (Form 7.0)

7 History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed management of incoming and outgoing communications
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow.
06	2025 May 15	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 29 on Managing IRB Incoming and Outgoing Communications.
07	23 May 2026	IRB SOP TEAM	Revised SOP 28 on Managing IRB Incoming and Outgoing Communications.

8 References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 29** **Management of Active Files**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have procedures on how to manage active files. It shall be kept in a secured cabinet, arranged in an orderly manner for easy identification and retrieval.

2. Objective of the Activity

The activity aims to ensure accessibility, easy retrieval of current files, and protection of those that require confidentiality.

3. Scope

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

4. Workflow

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

5. Description of Procedures

Step 1: Classification and coding of active files

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

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

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

Step 2: Updating of corresponding protocol folder

2.1 The Office Manager or Staff ensures that the protocol documents are filed properly in a sturdy file folder that is labelled along the spine with the following:

- IRB Protocol Code
- Study Title
- Sponsor protocol code
- PI

- Date of Approval
- Type of reports
- Number indicating the number of folders per report

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

Step 3: Periodic updating of the Protocol File

3.1 The Office Manager or Staff updates the protocol file in each assigned folder in chronological order with the most recent documents on the topmost. These documents include the following:

3.1.1 Protocol (Original and Revised) versions

3.1.2 Informed consent (Original and Revised) versions

3.1.3 Post Approval Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR/RNE, Amendment, Early Termination, Site Visit Reports, Application for Continuing Review and Final Reports

3.1.4 Assessment Forms for each of the submitted and reviewed reports which should be signed and dated by the Primary Reviewers

3.1.5 Excerpts of the Minutes of Meetings when the protocol and reports were included in the agenda

3.1.6 Decision and Approval Letters

3.1.7 Communication Letters

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

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

3.4 Active files are maintained under lock and key, with limited access only to the Member-Secretary, Office Manager and Staff

6. Forms

Index of File Contents (Form 7.0)

7. History of SOP

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

06	2025 May 15	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 30 on Managing Active Files.
07	23 May 2026	IRB SOP TEAM	Revised SOP 29 on Managing Active Files.

8. References

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

Version No: 14	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD**
Approval Date: June 3, 2026	**SOP No: 30** **Archiving**
Effective Date: June 15, 2026	

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall keep the completed, terminated or declared inactive file in an archive room for three years from the archiving date of the study. For Clinical trials, the protocol files shall be kept for five years from the archiving date of the study. The hard copy of the protocol files are shredded and the electronic documents related to the protocol are deleted after the retention period.

2. Objective of the Activity

This activity aims to ensure efficient and effective storing of inactive, terminated, and completed files for retrieval of information and in compliance with national and international guidelines.

3. Scope

This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Acceptance of Final report or Early Termination report or identification of a protocol as inactive	Office Manager or Staff	1 day
Step 2: Updating of corresponding protocol folder and appropriate labels		
Step 3: Transferring the protocol folder in the archives room		1 day
Step 4: Updating the protocol database		

5. Description of Procedures

Step 1: Acceptance of Final report or Early Termination report or identification of a protocol as inactive

1.1 The Office Manager or Staff accepts the Final report (Form 4.6) or Early Termination report (Form 4.5) from the PI/researcher and the office Manager or staff identifies the protocol as inactive. Inactive files are unfinished or incomplete studies that have remained inactive for three (3) years without any follow- up from the investigators/researchers.

1.2 There is no need to PI/Researcher to acknowledge communication letters before archiving.

Step 2: Updating of corresponding protocol folder and appropriate labels

2.1 The Office Manager or Staff updates the corresponding protocol folder and labels it by putting a sticker on the protocol file folder with a word "INACTIVE", archiving date, and archiving year in the existing protocol code on the spine of the folder for easy retrieval and identification of studies.

Step 3: Transferring the protocol folder in the archives room.

4.1 The Office Manager or Staff transfers the protocol folder in the archives room. Inactive, terminated and completed studies are kept and secured in a well- locked IRB Archives Room, with access limited only to the Office Manager or Staff for confidentiality and security purposes.

4.2 All archived protocols (including those of residents and students) are filed in the cabinet in chronological order based on the code.

Step 4: Update of the protocol database

The Office Manager or Staff updates the protocol database.

6. Forms

Early Termination report (Form 4.5)
Final report (Form 4.6)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed management of terminated, inactive, and completed files for archiving.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Added archiving date to the IRB protocol No.
06	2025 May 15	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 31 on Archiving.
07	23 May 2026	IRB SOP TEAM	Revised SOP 30 on Archiving.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 31** **Managing Access to Confidential Files**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall have procedures on how to manage access to the IRB confidential files.

Persons with legitimate interest in these files such as PI/Researcher, institutional authorities, regulatory agencies, and sponsors.

2. Objective of the Activity

This activity aims to help protect the intellectual property rights of researchers/sponsors and uphold data privacy and confidentiality to enhance the credibility and integrity of the IRB.

3. Scope

This SOP begins with the receipt of the request to access to confidential files and ends with the return of the documents to the protocol folder.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Receipt and logging of request for access to confidential files	Office Manager or Staff	1 day
Step 2: Approval of requests for access to confidential files	Chair or Member-Secretary	1 day
Step 3: Retrieval of confidential files	Office Manager or Staff	1 day
Step 4: Supervision in the use of confidential files		
Step 5: Return of confidential files		1 day

5. Description of Procedures

Step 1: Receipt and logging of request for access to confidential files

1.1 The Office Manager or Staff:

a. Receives the request from Persons with legitimate interest to confidential files
b. Logs the request in the incoming protocol logbook
c. Refers to the Chair or Member-Secretary

Step 2: Approval of requests for access to confidential files

The Chair or Member-Secretary:

a. Reviews the justification of the request
b. Approves the request
c. Informs the Office Manager or Staff of the approval

Step 3: Retrieval of confidential files

3.1 The Office Manager or Staff retrieves the requested confidential files and fill up the IRB Request Form (Form 7.1).

3.2 The Office Manager or Staff ensures that:

Only specific documents requested is retrieved and made available in the IRB office for the Persons with legitimate interest.

Step 4: Supervision in the use of confidential files

The Office Manager or Staff supervise the use of the requested confidential files.

Step 5: Return of confidential files

The Office Manager or Staff returns the complete confidential files in the protocol file folder appropriately once the request has been served.

6. Forms

IRB Request Form (Form 7.1)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed management of incoming and outgoing communications.
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History. Changed IRB Forms Header.
05	2019 June 13	IRB SOP TEAM	Revise scope and added timeline in calendar days in the workflow.
06	2025 June 4	Dr. Venerio Gasataya Jr. Sr. Gertrude Caryls Kuebler, SPC, and Dr. Mark Leonard Flores	Revised SOP 32 on Managing Access to Confidential Files.
06	23 May 2026	IRB SOP TEAM	Revised SOP 31 on Managing Access to Confidential Files.

8. References

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

Version No: 14 Approval Date: June 3, 2026 Effective Date: June 15, 2026	**ST. PAUL'S HOSPITAL OF ILOILO INSTITUTIONAL REVIEW BOARD** **SOP No: 32** **Writing and Revising SOP**

1. Policy Statement

The St. Paul's Hospital of Iloilo, Inc. Institutional Review Board shall review/revise the Standard Operating Procedures (SOP) every three years or as necessary by reason of changed circumstances, compliance with government regulations, and others. The REC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

2. Objective of the Activity

Writing and revising SOPs aims to establish quality assurance of IRB functions.

3. Scope

This SOP begins with the proposal and approval for the revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

4. Workflow

ACTIVITY	RESPONSIBLE PERSON/S	TIMELINE (IN WORKING DAYS)
Step 1: Proposal and approval for revision of a new SOP	Chair	1 day
Step 2: Designation of SOP Team		
Step 3:Drafting of the revision of new SOP	IRB SOP Team	10 days
Step 4: Review and finalization of the SOP	IRB Members	5 days
Step 5: Submission of finalized SOP to the Hospital Administrator	Chair	1 day
Step 6: Inclusion of Revised SOP in the SOP Manual and its dissemination	Office Manager or Staff	5 days

5. Description of Procedures

Step 1: Proposal and approval for revision of a new SOP

The Chair proposes the revision of its Standard Operating Procedures to the IRB during a meeting. The IRB identifies, discusses and decides the revision of the SOPs.

Step 2: Designation of SOP Team

The Chair designates members to compose a team for the revision of the SOP. The Team is an ad hoc committee composed of IRB members. The team elects a team leader to supervise the SOP revision.

Step 3: Drafting of the revision of new SOP

The IRB SOP Team drafts the revision basing on the SOP Template consisting of the following:

a. Header that includes the SOP number and title, logo, effectivity and approval date, version number which is descriptive of contents
b. Policy Statement
c. Objective/s of the activity, which defines the purpose and intended outcome
d. Scope, which defines the extent of coverage of the SOP and its limitations
e. Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each steps and timeline
f. Detailed instructions, which elaborates the steps listed in workflow

g. Forms, documents to be accomplished by different parties as required by the SOP
h. History which tabulates the different versions (from draft to finals versions) of the document by author, version, date, and description of main changes
i. References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies.

Step 4: Review and finalization of the SOP

4.1 The SOP Team submits their draft to the IRB Chair who initiates the finalization process by presenting the draft to the IRB during a board meeting for its review, with the assistance of the Office Manager or Staff.

4.2 The IRB Team approves the revised SOP.

Step 5: Submission of finalized SOP to the Hospital Administrator

5.1 The Chair submits through the Office Manager the final version of the revised SOP to the Hospital Administrator for final approval. The Hospital Administrator approves the revised SOP, she shall affix her signature in the appropriate section in the cover.

5.2 The Approved revised SOP will be implemented seven days from the date of approval of the Hospital Administrator.

Step 6: Inclusion of Revised SOP in the SOP Manual and its dissemination

6.1 The Office Manager or Staff sends electronic copies of the approved SOPs to the IRB members upon approval by the Hospital Administrator.

6.2 The Office Manager or Staff maintains the original hard copy in the office and electronic copy of the revised SOP. The newly revised SOP is made available in the IRB Website. The old version of the SOP is kept in the Administrative Inactive Files.

6. Forms

IRB SOP Template (Form 8.0)

7. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
01	2015 Aug. 18	IRB SOP TEAM	First draft
02	2016 May 20	IRB SOP TEAM	Detailed procedures of the revision of the SOP
03	2016 Oct. 26	IRB SOP TEAM	Changed the Declaration of Helsinki to 2013 at the History of IRB. Edited the definition of the Expedited Review, Assent and Quorum at the Glossary. Labelling of all IRB Forms. Edited the SOP of Full Review.
04	2018 Dec. 07	IRB SOP TEAM	Edited the SPHI-IRB History, Changed IRB Forms Header. Selection and tenure of appointment of the Board.
05	2019 June 13	IRB SOP TEAM	Added in step 6 the Retrieval of Obsolete/Superseded SOPs.

06	2019 July 26	IRB SOP TEAM	Only IRB members and Staff cited in the Workflow.
07	2019 Dec. 30	IRB SOP TEAM	Harmonized Workflow and description of procedures. Delete step 3.2 in Protocol 4.1. Revised sequencing of SOPs on Post-Approval Reviews.
08	2020 Oct. 20	IRB SOP TEAM	Separate Management of Appeals. Added definition and responsibilities of IRB Office Manager. Edited Approval Letter, Resubmission form and Informed Consent. Corrected numbering of steps in the description of procedures. Added in the SOP 1.2 the responsibilities of IRB chair, co-chair and Member secretary. Edited SOP forms. Added Management of Application for Continuing Review. Edited IRB forms.
09	2022 June 28	IRB SOP TEAM	Edited SPH-IRB History. Edited IRB Checklist for Initial Submission. Added 1.4 in the description of procedures in step 1. Added gender representation in step 4, 4.1.
10	2024 Feb. 22	IRB SOP TEAM	Revised scope and added timeline in calendar days in the workflow.
11	2025 June 5	Sr. Gertrude Carys Kuebler, SPC, and Ms. Queenie Crisostomo	Revised SOP 33 on Writing and Revising SOP.
12	23 May 2026	IRB SOP TEAM	Revised SOP 32 on Writing and Revising SOP.

8. References

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