



Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)

STANDARD OPERATING PROCEDURE

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INTRODUCTION

The Chinese General Hospital and Medical Center (CGHMC RERB) started last 2004 as an Ethics Committee headed by Dr. Antonio Periquet. In 2011, Chinese General Hospital and Medical Center Institutional Review Board (CGHMC IRB) was established and chaired by Dr. Leonor Cabral-Lim. It functioned to review and document approvals of all clinical researches conducted at the Chinese General Hospital and Medical Center. Four years later, the IRB was renamed to Chinese General Hospital and Medical Center (CGHMC RERB).

The CGHMC RERB reviews researches conducted by hospital and medical staff, residents, fellows-in training of the Chinese General Hospital and Medical Center (CGHMC) and also industry-sponsored clinical trials by principal investigators who are consultants of CGHMC. The CGHMC RERB is an independent body under the Department of Medical Education and Research (DMER). Its main responsibility is to safeguard the rights, safety, and well-being of human participants involved in health-related research and to provide public assurance of that protection. It functions in full compliance with national/local and international human research ethical guidelines including the principles of ICH Harmonized Tripartite Guidelines for Good Clinical Practice.

The CGHMC has been granted the highest level of accreditation - Level III Ethics Review Committee Accreditation effective February 2016 until 2019 and has been re-accredited and granted Level III Ethics Review Committee last June and recently re-accredited from January 1, 2025 until December 31, 2027 by the Philippine Health Research Ethics Board (PHREB).

The CGHMC RERB has been granted international recognition by the Strategic Initiative for Developing Capacity in Ethical Review – Forum for Ethical Review Committees in the Asian and Western Pacific Region (SIDCER-FERCAP) on November 24, 2015 in Nagasaki, Japan, November 21, 2018 at Chang Gung Memorial Hospital, Taoyuan, Taiwan and recently at Kathmandu, Nepal last November 2024. The CGHMC RERB is also one of the members of the Philippine Health Research Ethics Network (PHREN) since 2017.

Table of Contents

INTRODUCTION.....	1
1. RERB STRUCTURE AND COMPOSITION.....	4
1.1. ETHICAL FRAMEWORK AND COMPOSITION OF THE RERB.....	4
1.2. APPOINTMENT AND DUTIES AND RESPONSIBILITIES OF RERB MEMBERS.....	8
1.3. SELECTION OF INDEPENDENT CONSULTANTS	13
1.4. TRAINING OF RERB MEMBERS	16
1.5. INCENTIVES FOR THE RERB MEMBERS AND INDEPENDENT CONSULTANTS.....	18
2. MANAGEMENT OF PROTOCOL SUBMISSION	20
2.1. MANAGEMENT OF INITIAL PROTOCOL SUBMISSION	20
2.2. DESIGNATION OF PRIMARY REVIEWERS.....	26
2.3. USE OF STUDY ASSESSMENT FORMS	28
2.4. MANAGEMENT OF EXEMPT FROM REVIEW	31
2.5. MANAGEMENT OF EXPEDITED REVIEW.....	34
2.6. FULL BOARD REVIEW OF SUBMITTED PROTOCOL	37
2.7. REVIEW OF A MEDICAL DEVICE PROTOCOL	43
2.8. REVIEW OF RESUBMITTED PROTOCOLS.....	46
2.9. WITHDRAWAL OF STUDY PROTOCOL SUBMISSION	49
2.10. MANAGEMENT OF PROTOCOLS FOR SINGLE JOINT ETHICAL REVIEW BOARD (SJREB) REVIEW	51
3. POST-APPROVAL PROCEDURES	55
3.1. REVIEW OF PROTOCOL AMENDMENTS	55
3.2. CONTINUING REVIEW OF APPROVED PROTOCOLS	58
3.3. REVIEW OF SERIOUS ADVERSE EVENTS AND SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION REPORTS	63
3.4. REVIEW OF PROTOCOL VIOLATION/PROTOCOL DEVIATION/ NON-COMPLIANCE	66
3.5. RESPONDING TO PARTICIPANT’S REQUEST/ QUERIES	69
3.6. SITE VISITS	71
3.7. EARLY PROTOCOL TERMINATION.....	75
3.8. MANAGEMENT OF APPEALS	78
3.9. REVIEW OF FINAL REPORT.....	80
4. MEETING PROCEDURES	83
4.1. PREPARATION AND DISTRIBUTION OF MEETING AGENDA.....	83
4.2. PREPARATION OF MEETING MINUTES.....	86
4.3. CONDUCT OF FULL BOARD MEETING (REGULAR)	89
4.4. CONDUCT OF SPECIAL/ EMERGENCY MEETING	94
5. DOCUMENTATION AND ARCHIVING	96
5.1. COMMUNICATING RERB DECISIONS	96
5.2. MANAGEMENT OF ACTIVE STUDY FILES, DOCUMENTS, AND RECORDS	98
5.3. ARCHIVING OF TERMINATED, INACTIVE OR COMPLETED STUDIES.....	101
5.4. MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND RERB DOCUMENT.....	103

6. WRITING AND REVISING SOPS.....	106
6.1. WRITING SOPS.....	106
6.2. REVISING SOPS	109
APPENDICES.....	112
GLOSSARY	112
REFERENCES.....	114
FORMS.....	115
2025 UPDATED BUSINESS SYSTEMS AND PROCEDURES CGHMC RESEARCH ETHICS REVIEW BOARD (RERB) ...	197
FEEDBACK FORM	203
CGHMC RERB MEMBERS SELF-EVALUATION FORM	204
STATEMENT OF FUNCTIONAL INDEPENDENCE OF CGHMC RERB	205
SJREB SOP	206

1. RERB Structure and Composition

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	1.1. Ethical Framework and Composition of the RERB	

1. Purpose

To describe the composition and structure of the CGHMC Research Ethics Review Board (RERB) in compliance with national and international guidelines in ethical research

2. Scope

The CGHMC RERB is an independent body created by the Chinese General Hospital and Medical Center under the Department of Medical Education and Research (DMER). This Standard Operating Procedures (SOP) provide the Terms of Reference (TOR) that describes the framework for the constitution of the CGHMC RERB, the responsibilities and activities of its officers, members, staff and consultants.

The CGHMC RERB reviews and monitors the following protocols: CGHMC funded researches, researches done in CGHMC by medical house staff, research proposals submitted by CGHMC personnel for thesis defense and industry sponsored researches to be conducted by CGHMC active/visiting medical staff to be conducted off-site (in the event that institution does not have an ethics review board in place).

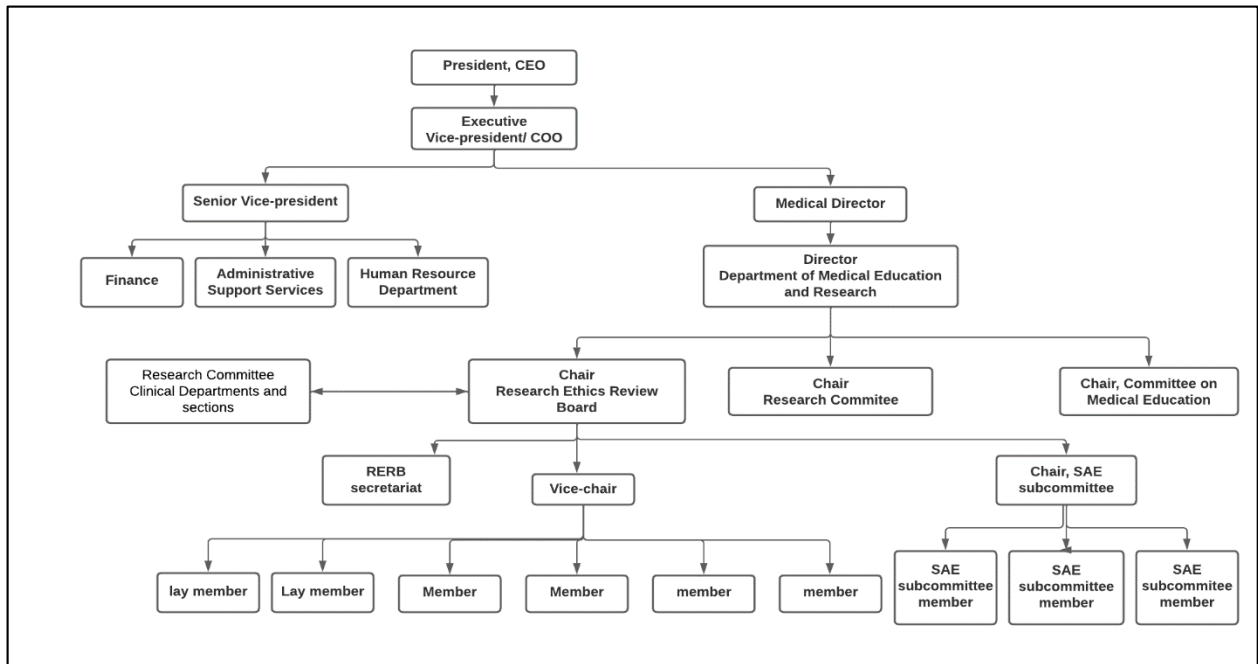
3. Responsibility

Its main responsibility is to safeguard the rights, safety, and well-being of human participants involved in health-related research and to provide public assurance of that protection. In accordance to provisions set forth in the national/international regulations, the CGHMC RERB has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant policies and procedures after research is given approval.

It is the responsibility of the RERB Members, Officers, and Secretariat to understand and implement the SOP of the RERB in the conduct of its functions.

4. Organizational Structure

The Medical Director and DMER Chairman appoints the CGHMC RERB Chair, Vice Chair, Member - Secretary and RERB members to facilitate the discharge of functions of the CGHMC RERB along the line of authority indicated by the following organizational chart:



CGHMC RERB is established by the authority of the Medical Director and DMER and exercises its mandate through the following structure:

1. CGHMC DMER Chair, as the appointing officer.
2. CGHMC RERB Chair, as the recommending officer.
3. CGHMC RERB, as the implementing office with the following members Chair, Vice-Chair, Member-Secretary, Members and Secretariat staff

The CGHMC RERB collaborates and coordinates with the research committees of the different Clinical Departments and sections of the institution with the support of the RERB Secretariat staff. The research committee reviews the technical aspect of the research protocols submitted by the residents, fellows and interns. The research committee head or research adviser endorses the protocols to CGHMC RERB for ethical review and approval. For other protocols, CGHMC RERB reviews both the technical and ethical aspects. Only the Medical Director has the authority to dissolve the CGHMC RERB after due process. At any point in time, should the CGHMC IRB cease to exist, any subcommittee is automatically dissolved.

5. Ethical Framework

5.1. The CGHMC RERB is guided by the ethical principles and procedures expressed in the following international guidelines and documents:

- World Medical Association Declaration of Helsinki (2008 and subsequent revisions)
- **Council for International Organizations of Medical Sciences (CIOMS) 2016**
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2 **2017**
- **WHO Global Benchmarking Tool (GBT) Kit 2023.**
- Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)

5.2. The RERB will function in accordance with national laws, regulations, and guidelines. The RERB provides its own standard operating procedures based on:

- **National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022**
- Philippine Food and Drug Authority regulations and other relevant laws and regulations

5.3. The RERB adheres to national and international ethical standards and recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities. In evaluating protocols and ethical issues, the RERB is cognizant of the diversity of laws, cultures, and practices governing health research in various countries around the world. The RERB strives to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a research proposal is being considered. The RERB will take the initiative to be informed, as appropriate, by national/local ethics committees and researches of the impact of the research that it has approved.

5.4. The RERB is also responsible for the research ethics training of the investigators by providing GCP workshop annually

5.5. The RERB obtains feedback about its performance from researchers and participants (Appendix – Feedback Form)

5.6. Conducts self-evaluation of its performance and maintains transparency about its procedures and decisions

6. Composition

6.1. The CGHMC RERB is comprised of at least 8 regular members including a pediatrician/child development specialist. All members including alternates will be invited to attend monthly meeting. The pediatrician/child development specialist will be invited to specifically review studies pertaining to children.

6.2. For each meeting, all regular members, including alternate members will be invited with a quorum requirement of 50%+1. Moreover, at least 1 member whose primary area of interest is non-medical and at least 1 member who is independent of the institution (who can be represented by the non-medical as the case may be) must be present. **For research ethics committees (REC) with 5–9 members, a quorum requires five members, including at least one non-institutional and one non-medical member.**

6.3. The RERB membership shall allow for multidisciplinary and multisectoral representation. Members should come from diverse background and experiences. This is to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations.

6.4. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the RERB should include a person who will represent the interest and concerns of the community.

- 6.5. One of the members in attendance should be a non-medical (lay member) who is not a practicing medical doctor, but may be an allied health professional, or non-scientific, or not institutionally related.
- 6.6. The RERB shall aim for gender balance in its membership with equal representation of men and women members in order to promote gender sensitivity in its review procedures.
- 6.7. The RERB shall have representatives from both the older and younger generations.
- 6.8. Members with conflict of interest shall not be present during deliberations and decision making.

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 5, 2024	Dr. Bernice Ong-Dela Cruz	Updated organizational structure
7	July 5, 2024	Dr. Bernice Ong-Dela Cruz	Updated the following international guidelines: Sec 5.1. Council for International Organizations of Medical Sciences (CIOMS) 2016 International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2 2017 WHO Global Benchmarking Tool (GBT) Kit 2023. Sec 5.2 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022
7	July 5, 2024	Dr. Bernice Ong-Dela Cruz	Added new responsibilities of RERB Section 5.4 – 5.6 The RERB is also responsible for the research ethics training of the investigators by providing GCP workshop annually The RERB obtains feedback about its performance from researchers and participants Conducts self-evaluation of its performance and maintains transparency about its procedures and decisions
7	July 5, 2024	Dr. Bernice Ong-Dela Cruz	Clarify definition for quorum - sec 6.2 For research ethics committee (REC) with 5 – 9 members, a quorum requires five members only with the required presence of a non-institutional member and non-medical member
7	July 5, 2024	Dr. Bernice Ong-Dela Cruz	Added section on conflict of interest- sec 6.8 Members with conflict of interest shall not be present during deliberations and decision making

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	1.2. Appointment and Duties and Responsibilities of RERB Members	

1. Policy Statement

The selection of REC members shall be through a nomination process that ensures representation of different disciplines and sectors, designated as regular members for an initial period of 2 years and renewable thereafter and shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.

2. Purpose

To describe the appointment procedures of the members of the RERB and to identify the roles and responsibilities of its officers and members

3. Scope

This SOP begins with the recommendation of potential RERB members, and ends with the filing of appointment documents and CVs of REC members in the membership file.

4. Workflow

NO	ACTIVITIES	PERSON/S RESPONSIBLE
1	Recommends list of potential RERB members	Chair of RERB
2	Appoints new RERB members	Chairman of DMER
3	Receives appointment letter and signs conflict of interest Agreement	New RERB member
4	Filing of appointment documents and CVs in membership file.	RERB staff

5. Detailed Instructions

5.1. Recommends a list of potential RERB members.

5.1.1. The RERB Chair recommends list of potential RERB members

5.1.2. Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to volunteer their time and effort and commitment to perform their functions in the RERB.

5.2. Appointment of new RERB members

5.2.1. The DMER Chairman is responsible for appointing RERB members upon the recommendation of the RERB Chair.

5.3. Receives appointment letter and signs conflict of interest Agreement

5.3.1. The Secretariat staff shall provide a copy of the appointment letter with conform signature (Form 1.2D) to each member of the RERB.

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

5.3.3. Members shall sign the confidentiality and conflict of interest agreement form (Form 1.2F) regarding meeting deliberations, applications, information on research participants, and related matters. They should read the text carefully, fill in their names, sign, and date the forms. The members keep a copy for their records

5.3.4. Members shall submit their curriculum vitae (Form 1.2G), properly signed and dated and update them at least once every two (2) years.

5.4. Filing of appointment documents and CVs in membership file.

5.4.1. The Secretariat keeps a copy of the signed Agreement in the membership files. Any member may ask questions, or clarifications from the Chair or Secretariat in relation to the contents of the document.

5.5. Terms of Office

5.5.1. Members, including Chair, Vice-Chair, and Member secretary are appointed for a maximum of two (2) years on the initial appointment. The appointment is renewable every three (3) years by the Appointing Authority.

5.6. Resignation, Disqualification, and Replacement of Members

5.6.1. Members may resign from their positions by submitting a letter of resignation to the DMER Chairman.

5.6.2. Disqualification criteria considered, but not limited to:

- 5.6.2.1. through the conduct of his/her duties blatantly disrespects the RERB in any form
- 5.6.2.2. over-utilizes resources or make unnecessary referrals of goods or service for his own personal financial benefit
- 5.6.2.3. consistently shows biased judgment and viewpoints contrary to the ethical principles of human research

5.6.3. Resignation

5.6.3.1. Members who resigned or were disqualified maybe replaced by following the appointment procedures previously stated.

5.6.3.2. The terms of replacement shall be limited to the remaining term of the member who shall be replaced.

5.7. Duties and Responsibilities RERB Officers

The Chair shall

- Be appointed by the DMER Chairman
- Finalize and approve the agenda and preside in all RERB meetings.
- Conduct a preliminary review of all protocols and decide on the nature of review – expedite, exempt or full board
- Assign primary reviewers to initial protocols submitted

- Ensure that a final decision on all protocols reviewed is made and break a tie whenever a deadlock in RERB voting occurs
- Sign the following communications: Notice of Meetings, Notice of Action to Principal Investigators and Sponsors
- Represent Chinese General Hospital and Medical Center in ethics-related symposia or meetings that require institutional participation
- Ensure that appropriate decisions/actions are made by the RERB on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator, etc.
- Submit annual reports on the accomplishments of the RERB to PHREB, FERCAP and DMER
- Communicate decisions of the RERB to research proponents
- Ensures that all RERB members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter
- Prepares budget plan for the RERB

The Vice Chair shall

- Be appointed by the Chair and selected based on experience and expertise from among the current RERB members
- Have the authority to perform all the duties of the Chair when the latter is unavailable or unable to perform them
- Serve as Chair of SAE subcommittee
- Perform other tasks as delegated by the Chair

The member secretary shall

- Be appointed by the Chair
- Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
- Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting
- Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submission
- Supervises the RERB Secretariat staff in the preparation of the agenda and minutes
- Review minutes of the meeting
- Accurately record (real-time) minutes of the meeting of the RERB

The Secretariat staff shall

- Organize an effective tracking procedure for each proposal received
- Prepare, maintain, and distribute study files
- Organize RERB meetings regularly
- Prepare and maintain meeting agenda and minutes of meeting
- Maintain good RERB documentation and archiving procedures
- Communicate with the RERB members and investigators
- Arrange training for personnel and RERB members
- Organize the preparation, reviews, revision, and distribution of SOPs and guidelines

- Provide the necessary administrative support for RERB related activities to the Chair of the RERB
- Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the RERB members
- Maintain a library of relevant resource materials and references
- Ensure that all relevant documents are kept in order, maintained locked and secured in the cabinets

RERB Member

- The role of the scientific and/or medical member is to review both the study protocol and informed consent forms, while the role of the non-medical or lay member is to focus on the review of the informed consent process and form
- Attend RERB meetings regularly
- Makes a timely and thorough review and decision regarding protocols given to him/her for evaluation
- Familiarizes him/herself with the CGHMC RERB SOP, his/her terms of reference, and the international and national guidelines on research ethics.
- Review, discuss and participate in the evaluation and approval of research protocols
- Assess serious adverse event reports and recommend appropriate action
- Review progress reports and monitor ongoing studies as appropriate
- Evaluate final reports
- Maintain confidentiality of the documents and deliberations during RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in health research and ethics

Serious Adverse Events (SAE) Subcommittee

- The CGHMC Chair creates and designates the SAE Subcommittee to review all types of serious adverse events (SAEs), including unsuspected serious adverse reactions (SUSARs) occurring on or off site and give recommendations to the RERB about the appropriate action to full board to ensure safety of patients
- The SAE Subcommittee consists of one (1) Subcommittee Chair and two (2) members, as appointed by the CGHMC Chair. The RERB Vice-chair is assigned as the Subcommittee Chair and presides over SAE Subcommittee meetings. A member of the subcommittee should have a strong background on pharmacology/ clinical pharmacy.
- The subcommittee members hold quarterly meetings or as scheduled by the subcommittee chair.

6. Forms

FORM NO	FORMS
1.2A	Letter of Appointment of RERB Chair
1.2B	Letter of Appointment of RERB Vice-Chair
1.2C	Letter of Appointment of RERB Member Secretary
1.2D	Letter of Appointment of RERB Member
1.2E	Letter of Appointment of SAE Subcommittee member

1.2F	Letter of Appointment of Alternate Member
1.3A	Confidentiality and Conflict of Interest Agreement
1.3B	Curriculum Vitae

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Role and responsibilities of RERB officers were revised Flowcharts
6	Sep 19, 2018	RERB Members	Added the ff as functions of the Chair Approves the agenda Prepares budget plan for the RERB Ensures that RERB members receive orientation and undergo basic research ethics training immediately after their appointment and continuing education thereafter
6	Sep 19, 2018	RERB Members	Removed from the Chair and officers the responsibility of sourcing funds
7	Oct 20, 2024	Dr. Bernice Ong-Dela Cruz	Added table of applicable forms after each SOP
7	Oct 20, 2024	Dr. Bernice Ong-Dela Cruz	Added function of Chair - Submit annual reports on the accomplishments of the RERB to PHREB, FERCAP and DMER
7	Oct 20, 2024	Dr. Bernice Ong-Dela Cruz	Added composition and functions of SAE sub-committee

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	1.3. Selection of Independent Consultants	

1. Policy Statement

The RERB shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/she need not be affiliated with the institution.

2. Purpose

To describe the procedures for the appointment of RERB independent consultants

3. Scope

This SOP begins with the recommendation of potential independent consultants, and ends with the filing of appointment documents and CVs of independent consultants in the membership file.

4. Process Flow

NO	ACTIVITIES	PERSON/S RESPONSIBLE
1	Recommends list of potential independent consultants	Chair of RERB / RERB members
2	Approves and appoint new independent consultant	Chairman of DMER
3	Receives appointment letter and signs confidentiality and conflict of interest Agreement	New independent consultant
4	Stores documents in RERB files under "Independent Consultants"	RERB secretariat staff

5. Detailed Instructions

5.1. Recommends list of potential independent consultants

5.1.1. The RERB Chair and Board members recommends independent consultants to help review research where the RERB lacks expertise.

5.1.2. The Chair finalizes and approves a list based on expertise and availability criteria and submits them to the Chairman of DMER.

5.2. Approves and appoint new independent consultant

5.2.1. The DMER Chairman shall approve and appoint independent consultants to help the RERB in protocol review.

5.2.2. Initial appointment will be two (2) years, and renewable every two (2) years by Appointing Authority.

5.3. Receives appointment letter (Form 1.3) and signs confidentiality and conflict of interest Agreement

5.3.1.Independent Consultant signs agreements

- 5.3.1.1. A signed Confidentiality/Conflict of Interest (Form 1.2F)
- 5.3.1.2. An updated curriculum vitae (Form 1.2G)
- 5.3.1.3. A signed Terms of Reference (Form 1.2H. See Appendix)

5.3.2.Independent Consultants render services

- 5.3.2.1. The RERB Secretariat provides study protocol documents to the concerned independent consultant for review, after the latter has signed the Terms of Reference and the Confidentiality/Conflict of Interest Agreement.
- 5.3.2.2. The independent consultant must complete the assessment form to be reviewed by the RERB at the time the study is reviewed.
- 5.3.2.3. The independent consultant shall attend the RERB meeting, present his/her assessment, and participate in the discussion but without voting rights. The report becomes a permanent part of the study file.

5.3.3.Termination of Services

- 5.3.3.1. Independent consultant's services may be terminated by either the consultant or by the DMER Chairman upon recommendation of the Board.
- 5.3.3.2. Upon termination of the independent consultant's services, the Secretariat shall ensure that all the necessary documentation is filed with the other administrative documents.

5.4. Filing of documents

- 5.4.1.The Secretariat keeps the pertinent documents in an independent consultant's file. S/He prepares and files a roster of independent consultants and the areas of their expertise Store documents in the RERB folder under **Independent Consultants File** in alphabetical order.

FORM NO	FORMS
1.2G	Letter of Appointment of Independent Consultant
1.3A	Confidentiality and Conflict of Interest Agreement
1.3B	Curriculum Vitae
1.5B	Independent Consultant Terms of Reference

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 16, 2024	Dr. Bernice Ong-Dela Cruz	Number of forms harmonized with the SOPs where they are used

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	1.4. Training of RERB Members	

1. Policy Statement

CGHMC RERB recognizes the importance of training and continuing professional development. RERB shall provide training requirements of RERB officers, members and secretariat staff from initial training to continuing education in order to maintain and update RERRB competence in the review of different types of protocols

2. Purpose

To properly describe CGHMC RERB procedures in order to ensure initial and continuing training of RERB members and staff

3. Scope

This SOP begins with the requirement of basic research ethics training of all members and staff and ends in the tracking and keeping of their training records

4. Process Flow

NO	ACTIVITIES	PERSON/S RESPONSIBLE
1	Require basic research ethics training for all members and staff	Chair of RERB
2	Identify schedules of trainings / workshops	Secretariat staff
3	Attend in-house or external trainings	Members / secretariat staff
4	Tracks and keeps training records of the RERB members	secretariat staff

5. Detailed Instructions

5.1. RERB members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Issues
- Relevant laws

- Development in relevant science, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws, regulations and related documents

5.2. Initial Training of RERB Members

5.2.1. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in CGHMC RERB standard operating procedures.

5.3. Continuing Ethical Education of RERB Members

5.3.1. Members should have training in RERB SOPs. In addition, they should be provided with external training opportunities at least once a year.

5.3.2. The secretariat shall regularly obtain information on the availability and schedule of training courses, workshops or conferences on ethics

5.3.3. The RERB Chair shall identify members of the RERB who will attend seminars/ training/ workshop or conferences

5.4. Keeping the Training Records

5.4.1. The RERB Secretariat shall

Prepare attendance sheet of in-house training with relevant information about the topic, duration, date and venue.

Ask member attendees to sign the attendance sheet and keep a copy in the membership files.

Keep copies of Training Records (Form 5. See Appendix) of RERB members and staff in the membership and staff files.

Update the CV of individual member/staff to reflect attendance of training activities

6. Forms

FORM NO	FORMS
1.4	Training Record of RERB Member

7. History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	1.5. Incentives for the RERB members and Independent Consultants	

1. Policy Statement

The RERB shall provide incentives/ honorarium for the attendance of full board meeting and review of protocols

2. Purpose

To ensure that members of the RERB and independent consultants are granted honoraria for their work in the RERB

3. Scope

This SOP begins with the creation of annual budget for incentives of RERB members and independent consultants, and ends with the acknowledgement of honorarium by RERB members and independent consultants.

4. Process Flow

NO	ACTIVITIES	PERSON/S RESPONSIBLE
1	Create annual budget recommendation for grant of honoraria of RERB members and independent consultants	Chair of RERB
2	Approval / Disapproval	Chairman of DMER
3	Dispensation of honorarium	RERB secretariat staff
4	Acknowledgment of honorarium	RERB members / independent reviewers

5. Detailed Instructions

5.1. The Chair shall create an annual budget for RERB operation including the honorarium and other expenses.

5.1.1. Chair shall recommend to the DMER Chairman the granting of honorarium to the RERB members and independent consultants for their work in the RERB. The honorarium shall cover attendance and review of protocols

5.2. The DMER Chairman may approve or disapprove the budget and recommendation.

5.3. The secretariat shall dispense the honorarium.

5.4. The RERB members or independent consultants shall sign a voucher upon receipt of honorarium

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

2. Management of Protocol Submission

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.1. Management of Initial Protocol Submission	

1. Policy Statement

The RERB shall require the submission of pertinent documents two (2) hard copies and a soft copy for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGRHP 2022 - Research Ethics Review Process Guideline.

2. Purpose

To describe the initial review procedures of the Research Ethics Review Board (RERB) from the time the RERB Secretariat receives the protocol and related documents until the approval letter is sent by the RERB to the Principal Investigator

3. Scope

This SOP begins with the submission of protocol and its related documents by the PI and ends with the entry of protocol package into the database and filing in the active study file

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Receives and checks for completeness of protocol package	Secretariat staff	4 days
2	Assigns permanent code to the protocol package	Secretariat staff	
3	Logs the received protocol in the RERB database	Secretariat staff	
4	Determines the type of review Exempt (SOP) Expedite (SOP) Full Board (SOP)	RERB Chair	
5	Assign primary reviewers	RERB Chair	
6	Prepare protocol package for distribution to the reviewers	Secretariat staff	
7	Review the study protocol and accomplish the assessment forms	Primary reviewers	7 days

8	Entry into database and filing to Active Study File	Secretariat staff	1 day
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5. Detailed Instructions

5.1. Receives and checks for completeness of protocol package

5.1.1. The CGHMC RERB Office is open from 9:00 AM to 5:00 PM from Monday to Friday, during which the secretariat staff accepts study documents and checks the completeness of the documents based on the checklist included in the Application for Initial Review Form (Form 2.1A and 2.1B). The secretariat staff informs the investigator of the missing documents and returns to the researcher the set of documents if the documents are incomplete

*Important Reminders

Researches of trainees done in relation to completion of training requirements will not be subject to institutional/review fees, unless these are externally funded (in whatever manner). For industry/sponsor initiated clinical trials, Corresponding review fees need to be settled by the investigator/sponsor prior to RERB board review. For institutional fees, refer to Appendix -

All protocols of CGHMC trainees to be conducted in the hospital need to be approved and signed by the respective Department's research technical review committee prior to submission to RERB for review. Co-authors need to affix their signatures in the cover letter stating they have read and likewise approved the conduct/content of the said study.

*Upon submission of the initial protocol for RERB review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains the following REC forms :

Form 2.1A – Application for Initial Review

Form 2.1B – Checklist of Documents Submitted for Protocol Review

Form 2.2 – Protocol Summary Sheet

5.1.2. A protocol package has to include the following:

- Accomplished initial protocol submission form
- Electronic copy of study protocol, Forms
- Full protocol
- Executive summary that follows research project proposal format
- Declaration of conflict of interest (if applicable)
- Data collection form/s
- Informed Consent form (English and Tagalog Version)
- Full study Budget
- CV of the trial team (incl. PI, co-investigators, research assistants/coordinators, etc.) and their updated (actual) GCP Certificate (Co-investigator should at least be in the same basic field of practice/specialization as the principal investigator)
- GANTT Chart (as necessary)

- Ads for recruitment, if applicable
- Case report forms
- Questionnaires (English and Tagalog version)
- Subject Worksheets/Patient Diary/Alert Cards (English and Tagalog versions)
- Technical approval document (for trainee-initiated research)
- For multi-center trial, list of all the trial sites (local and/or international) together with their respective PIs
- Phil FDA approval to conduct the trial (clinical trials)
- Investigator's Brochure (if applicable)
- Certificate of Insurance (if applicable)
- Certificate of Product Registration in the Philippines for Post Marketing Surveillance Studies (PMSS)

5.1.3. For protocols only awaiting approval from the FDA, the RERB can conduct a parallel review; however, the issuance of approval letter shall be withheld until completion of said requirement.

5.1.4. Only protocols with complete requirements (and payments as applicable) will be accepted and received by the Secretariat for RERB review.

5.2. Assigns permanent code to the protocol package

5.2.1. If the package is complete, the Secretariat staff assigns a permanent code to the protocol package. All subsequent communications in relation to the protocol will utilize the code assigned.

5.2.2. A unique code shall be used to identify a specific protocol for efficient file management. The unique code known as CGHMC RERB Code shall be assigned to a specific protocol and shall bear the following:

CGHMC RERB					-		-		
Year				Classification				Series No	

Classification: **R** - resident; **F** – fellows; **C** – consultant; **CT**- clinical trials/ sponsor-initiated protocol; **N** - nurse

For example, the code CGHMC RERB 2018-F-03 shall mean “Third (03) protocol received in 2018 is a resident submitted protocol.

5.3. Logs the received protocol in the RERB database

5.3.1. The Secretariat logs the protocol in the RERB database.

5.4. The Chair shall determine the type of review – full board, expedited or exempt from review

5.4.1. Exemption from Ethical Review (NEGRIHP 2022)

- Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.
- Provided that protocols do not involve more than minimal risks or harms, the following may be considered for exemption from review:
 - Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
 - Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; and

The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
- Protocols that involve the use of publicly available data or information

5.4.2.Criteria for Expedited Review

- Does not involve more than minimal risks or harm but does not qualify for exemption
- About a topic that should not result in causing social stigma
- Does not involve vulnerable populations
- Retrospective studies using anonymized data from medical records
- Studies using simple questionnaires without identifiers
- Proposals such as:
 - Chart review
 - Survey of non-sensitive nature
 - Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data
- Continuing review of clinical trials that do not involve further recruitment of participants.
- Continuing review of studies previously classified under expedited review.
- Study protocol amendments that are administrative in nature and do not affect the study protocol.
- Study protocol amendments that do not change the overall risk profile of the study.
- Review of protocols approved with recommendations in previous submission can be expedited only with minor revisions of the protocol

5.4.3.Full Board

- More than minimal risk protocols and that do not meet the criteria for expedited review or exemption

5.5. Assign primary reviewers

5.5.1. The Chair shall assign two (2) RERB members to the primary reviewers of the protocol regardless of the type of review.

5.6. Prepare protocol package and distribute to primary reviewers

5.6.1. The secretariat prepares the copies of protocol package for distribution to the primary reviewers.

5.6.2. The timeline from receipt of complete package to distribution to primary reviewers within 4 calendar days

5.7. Review the study protocol and accomplish the assessment forms

5.7.1. The primary reviewers shall review the protocol and its related documents and accomplish the assessment form 2.6 and form 2.7 (SOP 2.3) within 7 calendar days

5.8. Filing of initial protocol package in a properly labelled protocol file folder and place in the Active Study File Cabinet.

5.8.1. Put the code of the protocol on the side of the file folder and filing shall be done within 1 calendar day

5.8.2. File the folder in the Active Study Files cabinet under lock and key.

FORM NO	FORMS
2.1A	Application Form for Protocol Review
2.1B	Checklist of Documents Submitted for Protocol Review
2.1C	Protocol Summary Sheet
2.3	Waiver of Informed Consent
2.2	Assent Form
2.4	Notification of RERB Decision
2.5	Approval Letter

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Added the following sections 2. Exempt from review 3. Designation of primary reviewers 4. Management of protocol withdrawal 5. Assent evaluation for researched involving minors 6. History of SOP

			Management of protocol resubmission was transferred from chapter 4 to this chapter Flowcharts were revised to have uniformity
7	July 18, 2022	SOP Team	Added N - nurse for coding of protocol - section 2.1.7.1
7	Oct 4, 2023	SOP Team	Revise process flow with numbers and timeline
7	July 5, 2023	Dr. Bernice Ong-Dela Cruz	Harmonize the step number in the workflow and procedures in the detailed instructions
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.2. Designation of Primary Reviewers	

1. Policy Statement

For the review of protocols (full board or expedited), two (2) primary reviewers shall be assign to review the protocol and related documents on the basis of their expertise

2. Purpose

To describe the process of designating primary reviewers to study protocol

3. Scope

This SOP begins with the designation of primary reviewers and ends with the review of the protocol and its related documents and accomplishment of the forms by the primary reviewers

4. Process Flow

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Assigns the primary reviewers	RERB Chair	3 days
2	Send the protocol package to the assigned primary reviewers	Secretariat staff	
3	Review the protocol and related document and accomplish study assessment forms	Primary reviewers	7 days

5. Detailed Instructions

5.1. Assigns primary reviewer

5.1.1.The RERB Chair assigns one (1) scientific/ medical reviewer and one (1) non-medical as primary reviewers of the study protocol. Reviewers are selected on the basis of their expertise.

5.2. Send protocol package to assigned primary reviewers

5.2.1.The secretariat sends the study protocol package to the assigned primary reviewers.

5.2.2.The timeline from assigning of primary reviewers to distribution of complete package to primary reviewers - within 3 calendar days

5.3. Review protocol and related documents and accomplish study assessment forms

5.3.1.The scientific/medical reviewer is tasked to review technical soundness and related ethical issues while the non-medical reviewer is tasked to review the informed consent process and forms. In the case of clinical trials, a non-medical reviewer can be represented by a member who is not a medical doctor.

5.3.2. After reviewing, primary reviewers are tasked to accomplish study assessment forms and return to secretariat staff.

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.3. Use of Study Assessment Forms	

1. Policy Statement

The RERB uses two study assessment forms. The two assessment forms are accomplished by individual primary reviewers. Any comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two forms. These study assessment forms are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents.

2. Purpose

To describe the procedures related to the use of study assessment forms in ethics review

3. Scope

This SOP begins in the filling up of the Study Assessment Forms in the review of protocols and related documents submitted to RERB for initial review and approval and ends with filing of the accomplished forms in the protocol file

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Fill up study assessment forms during review of the protocol and its related documents	Primary reviewers	7 days
2	Submit accomplished forms to secretariat staff	Primary reviewers	1 day
3	Reviews the accomplished forms and include in the agenda for the meeting	Chair/ secretariat staff	1 day
4	Files duly accomplished forms in the Protocol File Folder of the protocol	Secretariat staff	1 day

5. Detailed Instruction

5.1. Fill up study assessment forms during review of the protocol and its related documents

5.1.1. The CGHMC RERB primary reviewers checks if the two study assessment forms - Protocol Evaluation Form (Form 2.6) and Informed Consent Evaluation Form (Form 2.7) are attached with each protocol package received for review.

5.1.2. The RERB primary reviewers read the protocol and related documents and individually fill up both forms for each protocol. Complete all relevant items in the study assessment forms and make comments.

5.1.3. The primary medical reviewer accomplishes the Protocol Document Evaluation Form (Form 2.6) and Informed Consent Evaluation Form (Form 2.7) while the primary non-medical reviewer focuses on the ICF only.

5.1.4. The study Protocol Evaluation Forms ensure assessment of the scientific and ethical aspects of the protocol.

- Rationale and significance of the study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria
- Vulnerability determination
- Risk/benefit assessment
- Full disclosure of information, including risks
- Benefits and risks that may be derived from the study
- Use of understandable language
- Voluntary participation
- Remuneration
- Confidentiality
- Legally Authorized representative to sign the consent form
- Contact details of RERB Chair and office for ethical concerns and those of the principal proponent and his/her team for protocol related issues

5.2. Submit accomplished forms to secretariat staff

5.2.1. The primary reviewer signs and submits the evaluation forms together with the reviewed protocol back to the Secretariat within 7 days after the receipt of documents

5.3. Reviews the accomplished forms and include in the agenda for the meeting within 1 day

5.3.1. The Secretariat staff checks whether the forms are complete, compiles the assessment forms and submits these to the Member-Secretary and/or Chair

5.3.2. The member-Secretary and/or Chair reviews the complied assessment forms and includes the recommendation and action of the primary reviewers and include them in the agenda in the next full board meeting.

5.4. Files duly accomplished forms in the Protocol File Folder of the protocol

5.4.1. The Secretariat files the accomplished forms in the Protocol File Folder of the protocol

6. Forms

FORM NO	FORMS
2.1D	Reviewer's Protocol Evaluation Form
2.1E	Informed Consent Evaluation Form

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	Oct 4, 2023	SOP Team	Revise process flow with numbers and timeline
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.4. Management of Exempt from Review	

1. Policy Statement

Study protocols may be exempted from ethical review based on the criteria listed in the (NEGHIRP 2022) The Research Ethics Review Process Guideline 3.1. The decision to exempt from review rests on the RERB Chair for efficiency and in the interest of time.

Study protocols that may be exempted are (1) Research about public behavior (voting trends, opinion surveys, etc.), (2) Evaluation of public programs and Quality control studies by the agency itself, (3) Standard educational tests and curriculum development, (4) Surveillance functions of DOH and Historical and cultural events, (5) Research involving large statistical data without identifiers, Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review. Any alteration in exempted protocols shall invalidate the approval of the protocol. The results of the review shall be released to the principal investigator within seven (7) days after the submission of all the required documents a final report shall be submitted to RERB at end of the exempted study.

2. Purpose

To describe the procedure for the review of protocols that qualify for exemption from review

3. Scope

This SOP applies to a study protocol submitted that qualifies the criteria for exemption from review. This SOP begins with the receipt and management of application of exempt Chair decides that the protocol is exempted from review and ends with the filing of documents in the protocol file folder and updating of the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt and management of protocol package	Secretariat staff	5 days
2	Assessment of the protocol using Checklist for Exemption from Full Ethical Review to determine if it meets the exemption criteria	Chair	
3	Communicates RERB decision to PI Issuance certificate of exempt	Secretariat staff	
4	Inclusion of exempt from review in the agenda on the next regular RERB meeting	Secretariat staff	1 day

5	File copy of the documents in the protocol binder and update protocol database – exemption from review	Secretariat staff	1 day
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5. Detailed Instructions

5.1. Receipt and management of protocol package

5.1.1. Secretariat Staff ensures completeness of submitted forms (Form 2.6) and documents

5.1.2. The Secretariat Staff accepts complete protocol submissions and application for exempt from review and returns incomplete or incorrect submissions.

5.2. Assessment of the protocol using Checklist for Exemption

5.2.1. The Chair shall review and evaluate the study protocol applying for review exemption if it meets the criteria for exemption by using the Checklist for Exemption from Full Review (Form 2.7) within 3 days from receipt of the application to determine if it meets exemption criteria

5.2.2. If the protocol does not meet the criteria for exemption, the protocol shall be recommended for full board or expedited review.

5.2.3. Protocols are reviewed to ensure it is technically sound before granting exemption

5.3. Communicates RERB decision to PI and issuance of certificate of exempt

5.3.1. The secretariat shall communicate RERB decision to the principal investigator by preparing the Certificate of Exemption from Review (Form 2.8) duly signed and dated by the Chair and issues the certificate to the principal investigator

5.3.2. The RERB must be notified for any amendment on exempted protocols are not allowed and shall invalidate the approval of the protocol in which case it may be submitted as new protocol for initial review.

5.3.3. Submission of final report at the end of exempted study are required

5.3.4. Any amendment to the protocol that may affect safety of participants should be submitted to RERB for re-evaluation of exemption

5.3.5. The timeline from the receipt of the package to communicating and issuance of certificate to PI - within 5 calendar days

5.4. Inclusion of the exempt from review in the Agenda of the next RERB regular Meeting

5.4.1. The secretariat shall prepare a report of all protocols exempted from review and this will be reported during full-board meeting for the information of the board.

5.5. File copy of the documents in the protocol binder and update protocol database – exemption from review

5.5.1. The secretariat shall file copy of the documents in the protocol file binder and update protocol database for exemption

FORM NO	FORMS
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2.6	Application for exemption of review
2.7	Checklist for exemption of review
2.8	Certificate of Exemption

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Added section - Exempt from review - History of SOP Flowcharts were revised to have uniformity
7	Oct 4, 2023	SOP Team	Revise process flow with numbers and timeline
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added line - sec 6.3.2 –Protocols are reviewed to ensure it is technically sound before granting exemption
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Revise forms – added the following statements Submission of final report at the end of exempted study are required Any amendment to the protocol that may affect safety of participants should be submitted to RERB for re-evaluation of exemption
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.5. Management of Expedited Review	

1. Policy Statement

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to the principal investigator within fourteen (14) days after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular full board meeting.

2. Purpose

To describe the procedures for the review of protocols that qualify for expedited review

3. Scope

This SOP begins with the determination of qualified protocols for expedited review and ends with filing of protocol and related documents.

4. Process/ Flow steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Determines the protocol for expedited review	RERB Chair	4 days
2	Assigns primary reviewers	RERB Chair	
3	Distribute protocol package to primary reviewers	Secretariat staff	
4	Review the protocol using study assessment forms and returns duly accomplished forms to RERB secretariat staff	Primary reviewer	7 days
5	Communicate decision to principal investigator	Secretariat staff	Within 14 days
6	Report expedited reviews during full board meeting	Primary reviewer	1 day
7	File copies of the documents in the protocol folder and update protocol database	Secretariat staff	1 day

5. Detailed Instruction

- 5.1. Determines the protocol for expedited review
 - 5.1.1. The Chair determines if the protocol checks if the submitted protocol qualifies for expedited review. (Section 5.5.2.)
- 5.2. Assigns primary reviewers
 - 5.2.1. The Chair assigns two (2) RERB members as primary reviewers. This will consist of one (1) medical and one (1) non- medical member.
- 5.3. Distribute protocol package to primary reviewers
 - 5.3.1. The secretariat staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated primary reviewers within 4 days after receipt of complete documents.
- 5.4. Review the protocol using study assessment forms and returns duly accomplished forms to RERB secretariat
 - 5.4.1. Primary reviewers review the protocol and return duly accomplished assessment forms study protocol and informed consent assessment form within 7 days upon the receipt of the documents from secretariat staff
 - 5.4.2. The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms. Decision points are: **APPROVED, MAJOR REVISION, MINOR REVISION and DISAPPROVED**. The decision is submitted to the Secretariat staff.
 - 5.4.3. If decision is reached by both primary reviewers, this will be reported during next full board meeting.
 - 5.4.4. Disagreements between primary reviewers will first be resolved by the Chair and may be elevated later to full board
 - 5.4.5. Expedited Review that are disapproved will be elevated to Full Board
 - 5.4.6. The RERB may request information from the Principal Investigator or invite the Principal Investigator for clarificatory interview.
- 5.5. Communicates decision to PI
 - 5.5.1. The Secretariat staff shall prepare the decision letter based on the returned review forms and have it approved and signed by the Chair within 14 days
 - 5.5.2. The Principal Investigator will be notified of the decision through a notification letter (Form 2.4).
- 5.6. Report expedited reviews during full board meeting
 - 5.6.1. Approved protocols on expedited review will be reported on the agenda of the next full board meeting for information of other members
- 5.7. File copies of the documents in the protocol folder and update protocol database
 - 5.7.1. The Secretariat Staff files copies of the approved documents in the protocol file folder.

5.7.2.He/she updates the protocol file index of the protocol file folder and updates the protocol database.

Note: The whole expedited review process should be done within 14 days

6. Forms

FORM NO	FORMS
2.1A	Application Form for Protocol Review
2.1B	Checklist of Documents Submitted for Protocol Review
2.1C	Protocol Summary Sheet
2.3	Waiver of Informed Consent
2.4	Notification of RERB Decision
2.5	Approval Letter

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 18, 2022	SOP Team	Deleted section 2.3.9
7	Oct 4, 2023	SOP Team	Revise process flow with numbers and timeline
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 16, 2024	Dr. Bernice Ong-Dela Cruz	Updated form numbers aligned to SOP numbers where they are used

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.6. Full Board Review of Submitted Protocol	

1. Policy Statement

A full board review shall be conducted when a protocol entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Only protocols submitted within the first week of the month before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and/or the Principal Investigator shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the Principal Investigator within forty- two (42) days after submission of required documents.

2. Purpose

To describe the procedures when protocol submissions are classified for full board review

3. Scope

This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

4. Process/ Flow Step

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Determine the protocols for full board review	RERB Chair	4 days
2	Assigning of primary reviewers	RERB Chair	
3	Distribute protocol package to primary reviewers	Secretariat staff	
4	Review the protocol using the 2 study assessment forms and return the duly accomplished forms to the secretariat	Primary reviewers	7 days
5	Discuss and deliberation the protocol and related documents during full board meeting	RERB members	1 day
6	Communicates decision to PI	Secretariat staff	1 day

7	File copies of the documents in the protocol file folder and update protocol database	Secretariat staff	1 day
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5. Detailed Instructions

5.1. Determine the type of review and assign primary reviewers

5.1.1. The Chair determines if the submitted protocols should undergo full board review.

5.1.2. The following are types of protocols that should undergo full board review after initial submission:

- Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1,2,3 and 4)
- Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
- Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the RERB during review
- Protocols that involve collection of identifiable biological specimens for research

5.2. Assigning of primary reviewers

5.2.1. The Chair designate primary reviewers to review the protocol with appropriate qualifications (medical member with expertise related to the protocol and a non-medical member to review the consent form. An independent consultant may be invited to provide expert opinion.

5.3. Distribute protocol package to primary reviewers

5.3.1. The secretariat staff sends the protocol files together with the assessment forms to the primary reviewers within 4 days after receipt of complete documents

5.4. Review of the Protocol by the primary reviewers and return the duly accomplished forms to the secretariat within 7 days upon the receipt of the complete documents

5.4.1. Use the Protocol Evaluation Form (Form 2.7) and the Informed Consent Evaluation Form (Form 2.8) to review the protocol and the consent form and write relevant comments

5.4.2. Check the CV or information about the investigators (including actual GCP training), the study sites and other protocol related documents, including advertisements.

5.4.3. Consider whether study and training background of the principal and/or sub-investigator/s are related to the study.

5.4.4. Look for disclosure or declaration of potential conflicts of interest.

5.4.5. Determine if the facilities and infrastructure at study sites can accommodate the study.

5.4.6. Check the “Child Assent Form” (Form 2.4) if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

- Children age under 7 years need not have a signed assent form,
- age 7 and under 12 need verbal assent,
- age 12 and under 15 need to sign a simplified child assent form,
- age 15 and under 18 should co-sign in the informed consent form with parents.

5.4.7. The primary reviewers are advised to note the following Review Guidelines:

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
- In assessing the degree of risks against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized.
- Study participants are selected equitably especially if randomization is not to be used. Study participant’s information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants.
- The informed consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure for getting the Informed Consent is clear and unbiased.
- The persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
- There is provision for compensation to study participants. There should be reasonable provision for medical/ psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- There are provisions on steps to be taken when participants voluntarily withdraw during the course of study/trial, where appropriate.
- Contact persons (Principal Investigator and RERB Chair) with address and phone numbers are included in the Informed Consent.

- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- Where applicable, provisions may be made when investigational products will be made available to research participants after the trial at a reduced price.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.
- Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:
 - Community consultation
 - Involvement of local researches and institution in the protocol design, analysis and publication of the results
 - Contribution to development of local capacity for research and treatment in benefit to local communities
 - Sharing of study results with the participants/community

5.4.8. After reviewing the protocol and the documents, the reviewer

- Recommends a decision.
- Records the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision or Disapproved
- Includes comments and reasons for disapproval.
- Checks the completeness and correctness of marked items in the assessment forms.
- Indicates the date and affix his/her signature in the decision form.
- Returns the completed assessment forms to the Secretariat together with the protocol documents.

5.4.9. The secretariat checks the assessment forms for completeness and forwards them to the Chair to be included in the agenda for the next full board meeting.

5.5. Conduct a full board meeting to discuss and make decisions through majority vote about the protocol and related documents.

5.5.1. The members of the RERB attending the full board meeting shall arrive at a decision through majority vote on each issue in the protocol, with a final overall decision for: **APPROVED, MINOR REVISIONS, MAJOR REVISIONS or DISAPPROVED.**

Approval: (when no further modification is required)

Minor Revision : (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, legal or scientific concerns). Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

5.5.2. Principal Investigator will be notified of the schedule of the review. If necessary, the investigator may be invited for clarificatory interview.

5.6. Communicating the CGHMC RERB decision to the principal investigator

5.6.1. All CGHMC decisions are communicated to the PI using Form 2.5 – Notification of RERB Decision and Form 2.6 – Approval Letter.

5.6.2. The secretariat prepares the notification letter to inform the PI of the RERB decision with the reasons for disapproval clearly stated.

5.6.3. Investigators may appeal the decision of the RERB by writing a letter requesting for reconsideration with reasons clearly stated and submission of a new protocol. Any appeal shall be taken up at full board meeting.

5.7. File copies of the documents in the protocol file folder and update protocol database

5.7.1. The RERB Secretariat Staff files the protocol file folder in the active study file section of the cabinet under lock and key and updates the protocol database.

6. Forms

FORM NO	FORMS
2.1A	Application Form for Protocol Review
2.1B	Checklist of Documents Submitted for Protocol Review
2.1C	Protocol Summary Sheet
2.2	Assent Form
2.4	Notification of RERB Decision
2.5	Approval Letter
2.1D	Reviewer's Protocol Evaluation Form
2.1E	Informed Consent Evaluation Form

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Added the following sections Exempt from review

			• Designation of primary reviewers • Management of protocol withdrawal • Assent evaluation for researched involving minors • History of SOP Management of protocol resubmission was transferred from chapter 4 to this chapter Flowcharts were revised to have uniformity
7	July 18, 2022	SOP Team	Removed low and high risk studies
7	July 18, 2022	SOP Team	Remove observer during RERB meeting and transfer to conduct of meeting section
7	Oct 4, 2023	SOP Team	Revise process flow with numbers and timeline
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.7. Review of a Medical Device Protocol	

1. Policy Statement

Medical Device Protocols are reviewed through the same expedited (SOP 5) or full board (SOP 6) procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the REC. The NCMH-REC should have provision to minimize the risks to human participants during review of the protocol and related documents. This activity is in preparation for the capacitation of REC to achieve its purpose

2. Purpose

To provide instructions for review and approval of medical device protocols intended for human participants submitted to CGHMC RERB

3. Scope

This SOP begins with the receipt and management of medical device protocol and ends with the filing of the protocol and updating of database

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Receipt and management of protocol submission	Secretariat staff	4 days
2	Determines type of review and assigns appropriate primary reviewers	RERB Chair	
3	Distribute protocol package to primary reviewers	Secretariat Staff	

4	Reviews the protocol and its related documents by filling up the study assessment forms	Primary reviewers	7 days
5	Discuss and decide on the protocol and related documents during full board meeting	RERB members	1 day
6	Communicate RERB decision to PI	Secretariat staff	1 day
7	Update RERB database and file protocol documents	Secretariat staff	1 day

5. Detailed Instructions

5.1. Receipt and management of protocol submission

5.1.1. The same procedures are followed when the protocol is submitted for initial review.

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

- Proposed investigational plan
- Informed consent form
- Description of the device/Product information
- Description of study participant selection criteria
- Safety monitoring procedures
- Reports of prior investigations conducted with the device
- Principal investigator's curriculum vitae
- Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk)
- Statistical plan and analysis
- Copies of all labeling for investigational use

5.1.2. The Secretariat staff checks the information/communication from the principal investigator related to the Significant Risk (SR) or Non Significant Risk (NSR) determination by regulators (FDA) from the sponsor country.

5.2. Determines type of review and assigns appropriate primary reviewers

5.2.1. The Chair assigns primary reviewers with appropriate expertise are assigned to review the protocol related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a lay person/ non -medical member reviews the consent form.

5.3. Distribute protocol package to primary reviewers

5.3.1. The secretariat staff sends the protocol files together with the assessment forms to the primary reviewers within 4 days after receipt of complete documents

5.4. Reviews the protocol and its related documents by filling up the study assessment forms and return duly accomplished forms to secretariat staff within 7 days upon the receipt of the complete package

5.4.1. The same RERB assessment forms are used for review and the primary reviewers make a decision in expedited review or make a recommendation for discussion during the next full board meeting.

5.5. Discuss and decide on the protocol and related documents during full board meeting

5.5.1. For full board review, a decision is made after discussion.

5.5.2. If the protocols are for revision, they are sent back to the principal investigator for modification. The documents are resubmitted and reviewed through expedited channel for minor revision and sent to full board for review of major revisions.

5.6. Communicate RERB decision to PI

5.6.1. Once an approval decision is reached, the approval letter is prepared, signed by the Chair and communicated to the principal investigator. The frequency of continuing review is indicated in the approval letter.

5.7. Update RERB database and file protocol documents

5.7.1. The relevant documents are kept in the protocol file and the RERB entry about the protocol is updated.

6. Forms

FORM NO	FORMS
2.1A	Application Form for Protocol Review
2.1B	Checklist of Documents Submitted for Protocol Review
2.1C	Protocol Summary Sheet
2.3	Waiver of Informed Consent
2.4	Notification of RERB Decision
2.5	Approval Letter

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.8. Review of Resubmitted Protocols	

1. Policy Statement

The REC shall require resubmission of a protocol that requires either minor or major modification/s 30 days after receipt of the Decision Letter. Minor revisions shall undergo expedited review, while major revisions shall undergo full board review. Protocol shall be reviewed by the same original primary reviewers.

2. Purpose

To describe the review procedures of the CGHMC RERB in relation to resubmission of protocols with revisions after initial review.

3. Scope

This SOP begins with the receipt of the revised protocol documents. It ends with the filing of the documents in the protocol file and the entry of the submission in the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt and management of protocol resubmission package	Secretariat staff	4 days
2	Notification of primary reviewers	Secretariat staff	
3	Distribute protocol package to primary reviewers	Secretariat staff	
4	Review of resubmitted protocol: expedited (SOP 2.5) or full review (SOP 2.6)	RERB Chair and Primary Reviewers	7 days
5	Communicates decision to PI	Secretariat staff	Within 14 days
6	Files duly accomplished form in the protocol file	Secretariat staff	

5. Detailed Instructions

5.1. Receipt and management of protocol resubmission package

5.1.1. The secretariat receives the resubmitted protocol package and checks the completeness of the resubmitted protocol package

- resubmitted protocol form (Form 2.11) addressing the revisions
- revised version of the protocol and related documents
- revisions made to the documents should be highlighted or underlined

5.2. Notification of primary reviewers

5.2.1. Within four (4 days) after the receipt of the Protocol Amendment Application, the Secretariat Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers via email.

5.3. Distribute protocol package to primary reviewers

5.3.1. The secretariat staff sends the protocol files together with the assessment forms to the primary reviewers within 4 days after receipt of complete documents

5.4. Review of resubmitted protocol: expedited (SOP 2.5) or full review (SOP 2.6): expedited (SOP 2.5) or full review (SOP 2.6)

5.4.1. The primary reviewers examine and review the resubmitted protocol by referring to the resubmission form, noting the recommendations the RERB gave, and determining whether these were satisfactorily answered in the resubmitted protocol within 7 days upon the receipt of the complete documents

5.4.2. The report is submitted to the Chair for inclusion in the next regular meeting by the reviewers

5.5. Communicates decision to PI

5.5.1. For approved resubmitted protocols, the secretariat staff prepares the Approval Form that the Chair should sign within 14 days.

5.5.2. If the review decision is after expedited or full board review is still not approval, the secretariat staff prepares the Notification Letter and send this to the PI after this is signed and dated by the chair

5.6. File pertinent documents and update protocol file

5.6.1. The Secretariat Staff files copies of the approved documents in the protocol file folder. He/she updates the protocol file index of the protocol file folder and updates the protocol database.

Note: The whole resubmission process should be done within 14 days

6. Forms

FORM NO	FORMS
2.9	Resubmitted Protocol Form
2.4	Notification of RERB Decision

2.5	Approval Letter
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REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 25, 2024	Dr. Bernice Ong-Dela Cruz	Added step 2 notification of primary reviewers and Step 3 added the type of review and cited the pertinent SOP number

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.9. Withdrawal of Study Protocol Submission	

1. Policy Statement

The CGHMC RERB shall require principal investigators to submit withdrawal of study protocol submission once PI decided to withdraw their study protocol review application and state the reason for its withdrawal

2. Purpose

To describe the RERB procedures related to withdrawal of study protocol submission

3. Scope

This SOP begins with the receipt of the withdrawal of protocol submission, and ends with the filing of the documents in the protocol file and the entry of the submission in the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Receipt and management of protocol withdrawal submission	Secretariat staff	4 days
2	Forward application to assigned original primary reviewers	Secretariat staff	
3	Review the withdrawal and make appropriate actions	Primary reviewers	5 days
4	Present and discuss during full board meeting on appropriate action	Primary reviewers	1 day
5	File copy of the documents in the protocol binder and update database	Secretariat staff	1 day

5. Detailed Instructions

- 5.1. Receipt and management of protocol withdrawal submission
 - 5.1.1. The secretariat staff receives application of withdrawal for study protocol submission (Form 2.12) submitted by the principal investigator
 - 5.1.2. Checks the completeness of the contents of the package to include the application for withdrawal of protocol submission. The request for the withdrawal should contain a brief written summary of the reason for the withdrawal of the protocol submission
- 5.2. Forward application to assigned original primary reviewers
 - 5.2.1. The secretariat shall forward the withdrawal of protocol application to original assigned primary reviewers within 4 days upon the receipt of the complete package
- 5.3. Review the withdrawal application and make appropriate action
 - 5.3.1. RERB Primary reviewers review and evaluates the reason for the withdrawal of the protocol submission and make appropriate action within 5 days upon the receipt of complete documents from the secretariat staff
- 5.4. Present and discuss during full board meeting
 - 5.4.1. The RERB members deliberates on the reason for the withdrawal of protocol submission.
 - 5.4.2. Final decision of the application are as follows:
 - APPROVAL/ NO FURTHER ACTION
 - FURTHER INFORMATION REQUIRED/ CLARIFICATION FROM PI
- 5.5. Communicates the RERB decision to PI
 - 5.5.1. The RERB secretariat prepares letter of notification signed and dated by the Chair within 14 days
- 5.6. File pertinent documents and update protocol database
 - 5.6.1. The secretariat files the pertinent documents, excerpt of the minutes of the meeting when it was discussed, and the Notification Letter, including the response from the PI, if any, in the protocol file folder and update the protocol file index.
 - 5.6.2. Upon approval of the withdrawal of protocol submission Application, the study protocol is classified as inactive, the protocol code no. is updated and the protocol file folder re-labelled and transferred to storage for inactive files.
 - 5.6.3. The secretariat staff updates the protocol database and labels the protocol "inactive-protocol withdrawal."

6. Forms

FORM NO	FORMS
2.10	Application for Withdrawal of Protocol Submission
2.4	Letter of Notification

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2.10. Management of Protocols for Single Joint Ethical Review Board (SJREB) Review	

1. Policy Statement

SJREB is a joint review mechanism for research protocols that will be conducted in at least three (3) sites in the Philippines. SJREB review is required for Philippine Health Research Ethics Board (PHREB) accredited Research Ethics Committees (RECs) of DOH hospitals. It is also applicable to non-DOH Research Ethics Committees (RECs) that will accept the results of the SJREB review and will agree and abide with the procedures that the SJREB follows. Refer to *Standard Operating Procedures for Single Joint Research Ethics Board (SJREB)*, “SOP 1 Authority, Composition and Structure of SJREB.” Appendix

2. Purpose

To describe the procedures in the management of research protocol submissions and the review process of researches that are qualified for Single Joint Research Ethics Board (SJREB) joint review.

3. Scope

This SOP begins with the receipt of parallel submission to CGHMC RERB and SJREB for protocol review and ends with the filing of copies of the protocol and its related documents and updating of the protocol file.

4. Process Flow/ Steps

NO	ACTIVITIES	PERSON(S) RESPONSIBLE	TIMELINE
1	Receipt and management of parallel submission of protocol to SJREB and CGHMC RERB.	Secretariat staff	7 days
2	Receives invite from SJREB for the joint review of the submitted protocol and informs RERB Chair.	Secretariat staff	

3	Provides a letter of intent to SJREB to specify the RERB's interest in participating in the joint review of the submitted protocol.	CGHMC RERB	
4	Assigns primary reviewer	RERB Chair	
5	Distribute the protocol package to the reviewers	Secretariat staff	
6	Reviews the protocol and returns the accomplished assessment forms to the secretariat staff	Primary reviewers	7 days
7	Conduct a preliminary review of the protocol prior to SJREB review meeting	Primary reviewers CGHMC RERB members	7-14 days
8	Primary reviewers attend SJREB meeting	Primary reviewers	1 day
9	Obtain minutes of meeting and notification of decision from SJREB	Secretariat staff	7 days
10	Review of protocol with decision from SJREB and report during the next Full Board meeting	Primary reviewers	3 days
11	Communicate the decision of the review to the Principal Investigator	Secretariat staff	1 day
12	File copies of the protocol and protocol-related documents including SJREB meeting minutes and update database	Secretariat staff	

5. Detailed Instructions

5.1. Parallel submission of protocol documents to SJREB and CGHMC RERB is done.

5.1.1. The secretariat staff receives the initial protocol package submission from the PI and manages the initial protocol submission by following the SOP on Management of Protocol Submissions for initial review

5.1.2. The secretariat staff checks the completeness of protocol package and assigns protocol number in database.

5.1.3. Files the documents in the active protocol folder and prepares corresponding index and tracker.

5.2. Receives invite from SJREB for the joint review of the submitted protocol and informs RERB Chair.

5.2.1. Sites that are selected by the sponsor for the conduct of multi-site researches are invited to send a representative to participate in the review during the SJREB meeting.

5.2.2. The secretariat staff informs the Chair once invitation from SJREB to participate is received

5.3. Provides a letter of intent to SJREB to specify the RERB's interest in participating in the joint review of the submitted protocol.

5.3.1. CGHMC RERB shall submit a letter of intent to SJREB to join in the deliberation by the SJREB. A membership list with Curriculum Vitae (CV) is submitted to SJREB. The Chair identifies the representative (primary reviewers) qualified to do scientific and ethical review for various types of protocols.

5.4. Assigns primary reviewers

- 5.4.1. RERB Chair assigns primary reviewers. Refer to SOP section 2.2
- 5.5. Distribute the protocol package to the reviewers
- 5.5.1. The secretariat staff notifies the assigned reviewers sends the complete CGHMC and SJREB protocol package (if already available) upon acceptance of the initial protocol package submission. The initial protocol package should be distributed within seven (7) calendar days from receipt of protocol submission.
- 5.6. Reviews the protocol and returns the accomplished assessment forms to the secretariat staff
- 5.6.1. The primary reviewers review and assess the research protocol, informed consent forms and related research documents, and accomplish the study assessment forms: Protocol Evaluation Review Form and Informed Consent Evaluation Form.
- 5.6.2. The primary reviewers send the accomplished assessments forms signed and dated to the secretariat staff through e-mail or return the printed assessment forms within seven (7) calendar days from receipt of review package.
- 5.7. Conducts preliminary review
- 5.7.1. All protocols for Single Joint Review undergo preliminary review by the assigned primary reviewer and RERB members during full board review. An Independent Consultant may be request to join at the discretion of the RERB Chair.
- 5.7.2. The RERB members and primary reviewers consolidate site specific issues and comments, and makes a preliminary decision for reporting to the SJREB full board meeting.
- 5.7.3. The secretariat staff submits the accomplished SJREB forms signed and dated by the primary reviewers to SJREB secretariat within seven (7) calendar days before the SJREB full board meeting through SJREB e-mail
- 5.8. Primary Reviewers attend the SJREB Full Board meeting
- 5.8.1. All issues identified are presented by the primary reviewer in the SJREB meeting.
- 5.9. Obtains minutes of meeting and notification of decision from SJREB
- 5.9.1. The secretariat staff obtains the minutes of the meeting and notification of decision from the SJREB Secretariat.
- 5.10. Review of protocol and decision of SJREB and report during the next Full Board meeting
- 5.10.1. The Chair and primary reviewers make a site decision in an expedited meeting taking into consideration the decisions made by SJREB and to address site specific concerns.
- 5.10.2. Primary reviewers report the decision during the next full board meeting
- 5.11. Communicates the decision to the PI
- 5.11.1. The PI will be notified of the outcome of the SJREB review and the RERB review as follows:
Approval: The secretariat sends Approval Letter to the Study Protocol (Form 2.5) to the PI through email, properly signed and dated by the Chair.

Minor Revision: The secretariat prepares the notification letter to inform the PI of the required revisions in the protocol and/or ICF (Form Notification of Decision. PI shall be given fourteen (14) days to comply with the RERB recommendations.

Major Modification: The secretariat prepares the notification letter (Form 2.4) to inform the PI of the required revisions in the protocol and/or ICF. The PI shall be given 30 days to comply with the IERB recommendations.

5.11.2. The RERB Chair signs the communication

5.12. File copies of the protocol and protocol-related documents

5.12.1. The Secretariat staff keeps the protocol and all protocol-related documents in the protocol file.

5.12.2. The Secretariat staff updates the RERB database and protocol tracker and index.

6. Forms

FORM NO	FORMS
2.1A	Application Form for Protocol Review
2.1B	Checklist of Documents Submitted for Protocol Review
2.1C	Protocol Summary Sheet
2.3	Waiver of Informed Consent
2.4	Notification of RERB Decision
2.5	Approval Letter

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	Oct 4, 2023	SOP Team	Added section on management of protocols from SJREB
7	July 15, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement, scope and revise flow and detailed instruction

3. Post-Approval Procedures

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.1. Review of Protocol Amendments	

1. Policy Statement

The RERB shall require the submission of proposed amendments for review and approval before their implementation based on the level of risk of the study. This requirement shall be explicitly stated in the Approval Letter

2. Purpose

To describe the RERB review procedures for amendments of the protocol and related documents

3. Scope

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

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Receipt and management of protocol amendment submission	Secretariat staff	4 days
2	Determines the type of review – full board (SOP 3.4) or expedited (SOP 3.5) and assigns primary reviewers	RERB Chair	
3	Distribute protocol amendment package to primary reviewers	Secretariat staff	
4	Review the protocol amendment and its related documents	Primary reviewers	7 days

5	Discuss protocol amendment and present actions/ recommendations during meeting or report expedited review during meeting	Primary reviewers	1 day
6	Communicate RERB decision to PI	Secretariat staff	1 day
7	File documents and update protocol file index and protocol database	Secretariat staff	

5. Detailed Instructions

5.1. Receipt and management of protocol amendment submission

5.1.1. The RERB Secretariat checks the completeness of the amendment package submitted by the Investigator using the Form 3.10

5.2. Determines the type of review

5.2.1. The Chair determines the type of review of the amendment

5.2.1.1. A full board review is necessary if the proposed study protocol amendment that may change the favorable risk/benefit ratio are classified as Major amendment which includes but not limited to the following:

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

5.2.1.2. Study protocol amendments that do not change the risk profile of study participants (minor amendments) are classified for expedited review.

5.2.2. The original (initial) primary reviewers will be assigned to review the amendment and its related documents. If the initial reviewers are not available or have already resigned to do the review, the Chair designates qualified members to review the continuing review application and progress report.

5.3. Distribute protocol amendment package to primary reviewers

5.3.1. The secretariat staff sends the protocol amendment files together with the assessment forms to the primary reviewers within 4 days after receipt of complete documents

5.4. Review the protocol amendment and its related documents within 7 days upon the receipt of the complete documents

5.4.1. The RERB Secretariat staff will forward to the Primary Reviewers, together with the originally approved protocol for the reviewer to determine whether the amendment will change the original risk-benefit assessment, via email or hard copy.

5.4.2. The primary reviewers check the amended documents and compare them with the previously RERB approved documents in the protocol files. They will check if the amendments would alter the risk/benefit ratio of the study to make appropriate recommendations using Form 3.10.

5.5. Discuss protocol amendment and present actions/ recommendations during meeting or report expedited review during meeting

5.5.1.The Primary Reviewer presents their assessment of the proposed amendment/s to the RERB during full board meeting.

5.5.2.The following are possible decision points of the Board:

- Approved – The amendment is approved and can be implemented as written
- Need for additional information – The RERB finds that the amendment requires justification.
- Require specific actions – e.g. revision of the consent form and/or reconsent of participants or revision of protocol
- Disapproved

5.6. Communication of Decision to PI

5.6.1.The RERB Secretariat prepares a communication letter (Form 3.10) to inform the investigators about the board decision. Decisions could be:

- approved
- additional information required
- specific action/s required from the researcher
- disapproved

5.7. File documents and update protocol file index and protocol database

5.7.1.The RERB Secretariat staff keeps a copy of all amendment related documents in the protocol files and update protocol file index

*Note: Review of protocol amendments should be completed within 14 days when done through expedited review of minor protocol amendments but It may take longer for major amendments depending on the schedule of full board meeting

6. Forms

FORM NO	FORMS
3.1	Protocol Amendment Review Form
3.10	Action Letter to protocol amendment/ final report/ early termination/ SAE/continuing review/ withdrawal of protocol

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 18, 2024	Dr. Bernice Ong-Dela Cruz	Section 5.5.1 added decision point – require specific action/s

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.2. Continuing Review of Approved Protocols	

1. Policy Statement

The RERB shall require the submission of an application for Continuing Review at least two (2) months before the expiration of the approved protocol. Depending upon the degree of risk to the participants, conduct of continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not more than once a year

2. Purpose

To describe the RERB procedures for the continuing review of approved protocols. This post-approval 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 validity and up to the end of the study.

3. Scope

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

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Reminds PI to submit progress report/ continuing report two (2) months prior to due date	Secretariat staff	
2	Submit continuing review application and annual progress report	Principal Investigator	60 days before expiration
3	Receipt and management of document package and check for completeness	Secretariat staff	4 days

4	Determine type of review and assign primary reviewers	RERB Chair	
5	Distribute continuing review package to primary reviewers	Secretariat staff	
6	Review of continuing review application and annual progress report	Primary Reviewers	7 days
7	Discuss the continuing review during full board meeting or report expedited review during full board meeting	RERB Members	1 day
8	Communicate RERB decision to PI	Secretariat staff	1 day
9	File documents and update protocol file index and protocol database	Secretariat staff	1 day

5. Detailed Instruction

5.1. Reminds PI to submit progress report/ continuing report two (2) months prior to due date

5.1.1. The Secretariat checks the database and tracks due dates of continuing and annual progress reports of study protocols approved by the RERB.

5.1.2. The Secretariat prepares and sends reminder letter (Form 3.2) addressed to the PI two (2) months before the due date of the report.

5.2. Submit continuing review application and annual progress report

5.2.1. The PI shall submit application for continuing review sixty (60) days before the expiration of the approved protocol using Form 3.3 and 3.4

5.3. Receipt and management of document package and check for completeness

5.3.1. The Secretariat checks the completeness of submitted report based on the submission of the following:

- Accomplished Progress Report (Form 3.3) and Continuing Review Application Form (Form 3.4)
- copies of the recently approved Informed Consent Form/ Assent Form, if applicable, with the revisions underlined and Bold- Faced to highlight changes.
- Updated Good Clinical Practice (GCP) Training Certificate of the PI and the rest of the research team for studies of long term duration (more than 3 years); and forwards the report to the Chair.

5.4. Determines the type of review and assign primary reviewers

5.4.1. The Chair shall determine the type of review the progress report/ continuing review application should undergo and identify the primary reviewers.

5.4.2. Generally, classification of the type of review of progress report/ continuing review is based on the initial review classification. For example, research protocol initially reviewed at full board shall again be reviewed at full board

5.4.3. If the reviewers are not available to do the review, the Chair designates qualified members to review the continuing review application and progress report.

5.5. Distribute continuing review package to primary reviewers

5.5.1. The secretariat staff sends the protocol amendment files together with the assessment forms to the primary reviewers within 4 days after receipt of complete documents

5.6. Continuing Review of Approved Protocols

5.6.1. The primary reviewers conduct review of continuing/annual reports if they are in accordance with the protocol and related documents approved by the RERB.

5.6.1.1. The primary reviewers refer to the protocol file to check compliance with approval given by the RERB during initial review and upon submission of amendments.

5.6.1.2. The following are the key evaluation points in the review of progress report/ continuing review application:

- Risk assessment

The risks to the study participants are minimized

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

Adequacy of Informed Consent Forms. The different types of informed consent form should be provided, if applicable. It should be the most recently approved or currently in use. d) Appropriate and new significant findings should be provided to the study participants since these may be related to willingness to continue participation in the study (e.g. important toxicity or adverse event information).

- Local issues such as the following:

Changes in the PI's circumstances (e.g. suspension of hospital privileges or medical license, involvement in numerous clinical trials). Evaluation, investigation and resolution of complaints related to the research, if any.

Changes in the acceptability of the research protocol in terms of institutional commitments such as personnel and financial resources, and adequacy of facilities.

Changes in regulations, applicable national law or standards of professional conduct of practice. d) PI concerns about trial conduct at the site such as study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent documents required by institutional policies, if any.

- Progress of the study:

Start date of the study and expected duration

Total subject enrollment

Expected enrollment

Actual enrollment

Enrollment issues

Withdrawal of participants:

- number of participants who withdrew
- lost to follow-up
- Summary of reasons for withdrawal at local site

5.6.1.3. The primary reviewers shall give recommendations as follows:

- **RENEW APPROVAL:** if assessment of the above evaluation points is satisfactory.

Approval of the progress report is necessary to renew approval of the protocol and allow the investigator to continue the conduct of research.

- **Additional information required.**

- **Request modifications** of the protocol or informed consent form if there is any change in the original risk-benefit assessment or any significant issues that may change risk-benefit balance.
 - **SUSPEND**
 - enrollment of new participants
 - research procedures in currently enrolled participants
 - entire study
 - **DISAPPROVE** the renewal of continuing review
- 5.6.1.4. The primary reviewers must complete the review and accomplish Continuing Review Application/Progress Report Form, Section 2 (part to be filled-up by the reviewer) and shall be submitted to the secretariat
- 5.6.1.5. The recommendations and significant issues identified by the primary reviewers shall be included in the agenda for discussion during the full board meeting to arrive at a final decision and appropriate action.
- 5.6.1.6. For review of protocol progress reports and continuing review under expedited review, RERB action is finalized at the level of the Chair and should be completed within fourteen (14) days
- 5.7. Discuss the continuing review/ progress report or report expedited review results to the RERB members during full board meeting.
- 5.7.1. The primary reviewers present to full board the results of the review, their recommendations and any significant issues identified in relation to the progress of the study.
- 5.7.2. The board deliberates and determines the need for the PI to elaborate, clarify or explain further any aspect of the progress report.
- 5.7.2.1. The following are possible review decisions of the board
- Renew approval
 - Request additional information
 - Recommend further actions (i.e. modification in protocol/ICF, suspend study)
 - Disapprove renewal
- 5.7.2.2. For progress reports approved under expedited review, approval is reported to the board by the Chair or Member-Secretary.
- 5.8. Communicate CGHMC RERB decisions to PI
- 5.8.1. The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.
- 5.8.2. The RERB Secretariat prepares the notification of IERB decision and sends the notification to the PI.
- 5.9. File documents and update protocol file index and protocol database
- 5.9.1. The RERB Secretariat keeps a copy of the progress report package together with the review comments of the primary reviewers in the protocol file folder and update the protocol file index.
- 5.9.2. The RERB Secretariat Staff files the protocol file folder in the active study file section of the cabinet under lock and key and updates the protocol database.

6. Forms

FORM NO	FORMS
3.2	Reminder Letter for Continuing Review
3.3A	Progress report form
3.3B	Continuing Review Application Form
3.10	Action Letter to protocol amendment/ final report/ early termination/ SAE/continuing review

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Decision was clarified – voting
6	Sep 19, 2018	RERB Members	History of changes/ revisions was added
7	June 18, 2022	RERB members	Secretariat to remind PIs 2 months instead of 1 month before the expiration to submit continuing review
7	June 18, 2022	RERB members	Updated the requirements of continuing review package to be submitted by PIs to include 1. Most recent approved ICF 2. List of site staff with validated GCP
7	June 18, 2022	RERB members	Revised the duration of approval of continuing review
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.3. Review of Serious Adverse Events and Suspected Unexpected Serious Adverse Reaction Reports	

1. Policy Statement

The CGHMC RERB shall require the submission of reports of SAEs and SUSARs by Sponsor/Principal Investigator. For on-site SAEs and SUSARs, the PI/study team should report the incident within 72 hours from the knowledge of the event and a complete report is submitted within 14 days. For off-site SUSARs, sponsors/ PI are required to submit a cumulative notification to RERB quarterly. Onsite SAE/SUSARs shall be reviewed in the full board review while trending of offsite SAEs/SUSARs shall be reported every quarter.

2. Purpose

To describe the RERB review procedures for serious adverse events (SAE) and suspected unexpected serious adverse reaction (SUSAR) reports and to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

3. Scope

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the RERB to comply with ICH GCP. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the related documents and update of the protocol database

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
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1	Receipt and management of SAE/ SUSAR report submissions	Secretariat staff	4 days
2	Forwards onsite SAE/ SUSAR report to SAE subcommittee Chair	Secretariat staff	
3	Review on-site and off-site SAEs/SUSARs	SAE subcommittee members	14 days
4	Present and discuss on-site SAE/SUSAR reports at full board to ensure patient safety	RERB members SAE subcommittee	2 day
5	Communicates results to PI	Secretariat staff	1 day
6	File documents to protocol file folder and update SAE database (on-site and off-site)	Secretariat staff	1 day

5. Detailed Instructions

5.1. Receipt and management of SAE/ SUSAR report submissions

- 5.1.1.** The Secretariat Staff receives SAE report (Form 3.4) and checks submitted documents for completeness and whether protocol code number and form used are correct.
- 5.1.2.** The IRB requires both hard and soft copies of the submission. Hard copies are required for the filing in the physical file folder, and for the Primary Reviewers who prefer physical documents in the review. Soft copies are required in cases of online reviews and deliberations during IRB full board meetings. These may be submitted via online.
- 5.1.3.** The Secretariat Staff classifies the SAE/SUSAR reports according to their origin or sites where they happened: on-site or off-site (within or outside the country).

5.2. Forwards onsite SAE/ SUSAR report to SAE subcommittee Chair

- 5.2.1.** The Secretariat Staff shall forward the SAE/ SUSAR Report to the SAE subcommittee Chair within 4 days from the receipt of the report

5.3. Review on-site and off-site SAEs/SUSARs

- 5.3.1.** The SAE Subcommittee Chair assigns an SAE Subcommittee primary reviewer who will assess the report and schedule a meeting of the SAE subcommittee within two weeks of the receipt of the report.
- 5.3.2.** The SAE Subcommittee primary reviewer accomplishes the review and returns the signed Serious adverse Event Report Form (Form 3.4) to the Secretariat staff and the Secretariat staff forwards the reviewed forms to the SAE Subcommittee Chair and members.
- 5.3.3.** The SAE subcommittee analyzes the SAE report of the PI about the
 - Seriousness
 - Relatedness
 - Expectedness of the SAE

5.3.4. SAE subcommittee reviews and summarizes off-site SAEs for trending purposes

5.4. Discuss SAE/ SUSARS reports and recommendations of SAE subcommittee to full board

- 5.4.1.** The SAE subcommittee Chair/ primary reviewer shall present the results of on-site SAE/SUSARs subcommittee's review and recommendation to full board.

5.4.2.The full board discusses on-site SAEs and their impact on patient safety.

5.4.3.After deliberation, RERB decides on the appropriate actions as follows:

- No further action is required
- Request further information from the PI
- Conduct site visit
- Request an amendment to the protocol or the informed consent form
- Suspend enrolment of new research participants until further review of the RERB
- Suspend all trial related procedures (except those intended for the safety and well-being of the participant) until further review by the RERB
- Termination of the study

5.4.4. Designated SAE subcommittee member reports trends in off-site SAEs on a quarterly basis to the full board

5.5. Communicate CGHMC RERB decision to PI

5.5.1.The RERB Secretariat notifies the investigator of the action taken by the RERB (Form 3.10)

5.5.2.The RERB Member Secretary drafts a formal letter duly signed and dated by the Chair to the investigator to notify them of the action they should take according to the RERB decision.

5.6. File documents in protocol file folder and update SAE database

5.6.1.The secretariat files the documents in the protocol file folder and update protocol file index.

5.6.2.Summary listing of off-site SAE and SUSAR reports are filed in the study protocol and serve as reference when reviewing onsite SAE/SUSAR reports.

5.6.3.The secretariat updates the SAE database (on-site and off-site)

6. Forms

FORM NO	FORMS
3.4	Serious Adverse Event Report Form
3.10	Notification Letter protocol amendment/ final report/ early termination/ SAE/continuing review

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Off-site SAEs/ SUSARs are added in the process flow
6	Sep 19, 2018	RERB Members	SAE subcommittee was added to specify who reviews the SAE/ SUSARs
6	Sep 19, 2018	RERB Members	Decision was clarified – voting
6	Sep 19, 2018	RERB Members	History of changes/ revisions was added
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

7	July 18, 2024	Dr. Bernice Ong-Dela Cruz	Revised workflow and detailed instructions - harmonizaed
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	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.4. Review of Protocol Violation/Protocol Deviation/ non-compliance	

1. Policy Statement

Principal Investigator shall report protocol deviations or violations in the conduct of approved researches within 1 week from the detection of the protocol violation/deviation. All protocol violations shall undergo full review.

2. Purpose

To describe the RERB review procedures for protocol violation/ deviation

3. Scope

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

4. Process Flow/ Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt and management of protocol deviation report	Secretariat staff	3 days
2	Forward protocol deviation report to primary reviewers	Secretariat staff	
3	Review of protocol deviation reports	Primary reviewers	7 days

4	Discuss and report to full board the decision and information for appropriate action	Primary reviewers	1 day
5	Communicate RERB decision to PI	Secretariat staff	1 day
6	File documents and update protocol file index and protocol database	Secretariat staff	

5. Detailed instructions

5.1. Receipt and management of protocol Noncompliance / violation / deviation reports.

- 5.1.1.** Reports of protocol noncompliance/violation/deviation may come from the investigators and other parties related to any event in the site that is not in compliance with the previous approved protocol and related documents. (Form 3.5)
- 5.1.2.** The PI should document, explain and report to CGHMC RERB any deviation from approved protocol whether minor or major and submit the report within one (1) week from the detection of the deviation
- 5.1.3.** The Secretariat Staff receives the protocol violation/ deviation report (Form 3.5) and checks submitted documents for completeness and whether protocol code number and form used are correct.
- 5.1.4.** The Secretariat Staff records the report in the database.

5.2. Forward protocol deviation report to primary reviewers

- 5.2.1. The Secretariat staff forwards the protocol non-compliance report to the primary reviewers within 3 days after the receipt of the report

5.3. Review of noncompliance / violation / deviation reports by primary reviewers

- 5.3.1. The primary reviewer assesses the reports. Assessment shall focus on whether the protocol violation/deviation impacts on the safety and rights of the participants. Primary reviewers should also analyze the effects of the deviation on the scientific integrity of the data. They shall recommend corrective and preventive actions depending on the degree of seriousness of the noncompliance/violation/deviation.
- 5.3.2. Major protocol deviations are deviations with significant impact and changes on the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that may increase potential risks/harms to participants and on the integrity of the research.
- 5.3.3. Minor protocol deviations applying to protocols found to have no effects on its study or related document and that do not increase potential risks/harms to participants and on the integrity of the research
- 5.3.4. The assigned Primary Reviewers complete their review and recommendations within 7 days after receipt and forward assessment to the Secretariat Staff.

5.4. Discuss or report to full board the information for appropriate action.

- 5.4.1. The Primary Reviewers present the result of their assessment to full board that deliberates on the effects of the protocol violation/ deviation on the rights and safety or research participants or integrity of data.

5.4.2. After reviewing and discussing the report, possible decision points are as follows:

- Acknowledged - no further information or action required - Protocol deviations/ violations are minor and there is no negative impact on the risk-benefit ratio and integrity of data
- Request additional information from the PI to properly evaluate the noncompliance - The details of the deviation/ violation are inadequate of there is a need for an explanation of why and how the deviation/ violation happened
- Corrective actions required - The RERB requires the PI to implement corrective action so that the deviation/ violation will not be repeated, well-being of the participant is promoted, and integrity of data is protected
- Site visit needed

5.5. Communicate RERB's decision to the PI

5.5.1. The RERB Secretariat notifies the PI of RERB decision (Form 3.10): Action letter to Continuing Review Application /Non-compliance/SAE/Site Visit signed and dated by the Chair and sends to the PI. With the following decision points

- 5.5.1.1. Acknowledged (no further action needed)
- 5.5.1.2. Request additional information
- 5.5.1.3. Corrective actions required
- 5.5.1.4. Site visit needed

5.5.2. If corrections or corrective actions are required from the PI, the PI shall provide the information within two weeks from the receipt of the communication

5.6. File documents and update protocol file index and protocol database

5.6.1. Secretariat Staff checks if Protocol Violation/Deviation Report is completely accomplished, signed and dated by Primary Reviewers. He/she files the document in the protocol file folder and updates the protocol file index.

5.6.2. Filed documents should also include the Study Site Monitoring Visit Report, if a post- review study site visit was conducted.

5.6.3. Record the protocol violation/deviation in the protocol violation/deviation database to facilitate tracking of repetitive violations/deviations of the same nature.

6. Forms

FORM NO	FORMS
3.5	Protocol Deviation/ Non-compliance/ Violation Form
3.10	Action Letter to protocol amendment/ final report/ early termination/ SAE/continuing review

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
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6	Sep 19, 2018	RERB Members	Removed section on protocol deviation – sending of PD to national regulatory authorities and sponsor
6	Sep 19, 2018	RERB Members	Classification of the type of review and assigning of primary reviewers are added in all the management of post-approval submission, (also included in the flowchart)
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope Revised form number with SOP
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
	July 15, 2024	Dr. Bernice Ong-Dela Cruz	Revised workflow and detailed instructions – removed classifying of review Revised decision points Harmonized detailed instructions with workflow

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.5. Responding to Participant's Request/Queries	

1. Policy Statement

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the RERB staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion

2. Purpose

To describe the RERB procedures related to participant requests to promote public trust and confidence in the institution, especially in the REC and to ensure that the rights and well-being of participants are attended to.

3. Scope

This SOP 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 REC meeting.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Receives the request or query	Secretariat staff	1 day
2	Assess the nature of the request and refer to appropriate person	Chair/ vice-chair	1 days
3	Take action or refer to board if necessary	Chair/ vice-chair	3 days
4	Communicate the decision to the person who made query	Secretariat staff	1 day
5	File the documents	Secretariat staff	1 day

5. Detailed Instructions

5.1. Receive the request or query.

5.1.1. The RERB Secretariat receives the inquiry or requests from research participants/patients or the community through various forms of communication (email, telephone call, letter, etc.)

5.2. Assess the nature of request and refer to appropriate person

5.2.1. Reply to the request or query and refer to the Chair or RERB member for appropriate action.

5.2.2. Record the request and information in the Request Record Form (Form 3.6) and keep a copy in the files.

5.3. Take action or refer to board if necessary

5.3.1. A designated RERB member takes appropriate action.

- Investigate the fact
- Record information and any action or follow-up taken in the Form 3.6
- Sign and date the form and forward to the Secretariat for filing.
- Report to the RERB about the action taken and the outcomes.

5.4. Communicate the decision to the person who made query

5.5. File the request document

5.5.1. Keep the record form in the “response” file.

5.5.2. Keep a copy in the study file.

5.5.3. Store the file in the appropriately labeled shelf

6. Forms

FORM NO	FORMS
3.6	Request/ Query Record

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 15, 2024	Dr. Bernice Ong-Dela Cruz	Revise detailed instructions to harmonize with flowchart

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.6. Site Visits	

1. Policy Statement

The CGHMC RERB shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: Site visits are part of CGHMC RERB oversight functions in the following conditions: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from participants and families, (d) non- receipt of required after-approval reports from the and (e) multiple studies conducted by a researcher.

2. Purpose

To describe the RERB procedures related to the conduct of site visits

3. Scope

This SOP includes the steps in conducting visits to study sites for reasons set by the Research Ethics Review Board. It begins with the selection of the study site to be visited and ends with filing of Site Visit Reports in the protocol folder and updating of the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Selection of study	RERB members	7 days

2	Create study site visit team	Chair	
3	Prepare study site visit plan	Study site visit team	
4	Notify PI of the site visit	Secretariat staff	
5	Conduct site visit and debrief study team	Study site visit team	
6	Present site findings during full board meeting and recommends appropriate action	Study site visit team and RERB members	14 days
7	Communicate site visit result RERB decision to PI	Secretariat staff	
8	File copies of document	Secretariat staff	

5. Detailed Instructions

5.1. Selection of study

5.1.1. Review periodically the database files of the submitted/approved study protocols.

5.1.2. Select study needed to be monitored based on the following criteria:

- New study or new PIs
- Reports of remarkable serious adverse events
- Big number of studies carried out by the same PI
- Frequent protocol submission for IRB review
- Non-compliance or suspicious conduct
- Frequently fail to submit final reports
- Frequent protocol violations

5.2. Create study site visit team

5.2.1. The Chair shall select members of the study site visit team and designates the team leader. Members should include the primary reviewers. The Site Visit Team members are informed of their assignment.

5.3. The secretariat staff prepares the study site visit package consisting of the following:

5.3.1. Latest version of the approved protocol and informed consent documents

5.3.2. Other relevant documents such as: protocol deviation reports, on-site SAEs/SUSAR reports

5.3.3. Copy of Site Visit Report Form

5.3.4. Prepare Study Site Visit Plan

5.3.4.1. The Study Site Visit Team prepares the study site visit plan that includes the following:

- Date and time of the planned visit
- Members of the study site visit team
- Objectives of the visit
- Documents to be reviewed
- Persons to be interviewed

5.3.5. The study site visit team, in consultation with the Chair, is given access to documents in the protocol file folder of a study for monitoring. The team may also photocopy some parts of

the files (like advertisement materials, the informed consent form (ICF), case report form) for comparison with the documents used in the study sites.

5.4. Notify PI of date of site visit

5.4.1. The secretariat staff contacts the study site or PI and coordinate the date and time for the site visit.

5.4.2. The PI shall be given at least four (4) weeks' notice to ensure their active participation.

5.4.3. The secretariat staff prepares and sends letter to the PI, formally informing them of the planned study site visit. Attach to the letter the study site visit plan and report form

5.4.4. PI shall be notified within 7 days after the selection of the study and creation of site visit team

5.5. Conduct site visit and debrief study team

5.5.1. The study site visit team conducts the site visit as per the study site visit plan and additional guidance from Site Visit Report Form (Form 3.7).

5.5.2. The CGHMC RERB study site visit team will:

- Review filled up informed consent documents to make sure that the site is using the most recent version.
- Review randomly the subject files to ensure that subjects are signing the correct informed consent.
- Observe consent process, if possible.
- Check if the files are orderly and confidentiality is maintained.
- Interview members of the research team.
- Debrief the PI about site visit findings and comments.
- Get immediate feedback.

5.5.3. After the visit, the CGHMC RERB study site visit team will :

5.5.3.1. Write a report using Site Visit Report Form within 2 weeks, describing the findings during the audit

5.5.3.2. Forward a copy of the site visit report to the secretariat for inclusion in the next board meeting.

5.5.3.3. Send a copy of the report to the study site for their file.

File the site visit report in the protocol file.

5.6. Present the site visit findings during the Full Board meeting.

5.6.1. The study site visit team presents the report during the full board meeting.

5.6.2. The Board decides whether the rights, safety and welfare of the research participants are compromised and recommends appropriate action.

5.6.3. Decision/Recommended action of the board can be any of the following:

- NO FURTHER ACTION
- REQUEST ADDITIONAL INFORMATION
- RECOMMEND FURTHER ACTION

5.7. Communicate results of site visit and the recommended actions, if any to the PI.

5.7.1. The secretariat staff communicates the board decision to the PI as follows:

5.7.1.1. If no further action is required, notify PI

5.7.1.2. If additional information or further action is required, notify the PI. The PI must comply with the recommendations and submits response to the RERB.

5.7.1.3. Secretariat staff prepares the report of action taken by the PI and the member-secretary reports it to the board.

5.8. File copies of documents

5.8.1. The secretariat staff files the study site visit report, excerpt of the minutes of the meeting when report was discussed and the notification letter (including the response of the PI, if any) in the protocol file folder and update the protocol file index and protocol database.

6. Forms

FORM NO	FORMS
3.7	Site Visit Report

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Qualified representatives for site visit was removed – changed to Site Visit Team assigned by Chair
6	Sep 19, 2018	RERB Members	“secretariat” was removed as the authority responsible to initiate on-site evaluation of a study visit
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.7. Early Protocol Termination	

1. Policy Statement

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

2. Purpose

This procedure describes how the RERB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. It aims to ensure that the decision takes into consideration the safety and welfare of study participants that have been already recruited and that there is adherence to the principle of fairness for all concerned.

3. Scope

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

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Receives the application or recommendation for early study termination	Secretariat staff	4 days
2	Forward notice of early termination to primary reviewers	Secretariat staff	
3	Review the termination package or termination issues and make recommendation	Primary reviewer	7 days
4	Discuss and report during full board for appropriate action	Primary reviewer	1 day
5	Communicate RERB decision to PI	Secretariat staff	1 day
6	File copies of documents	Secretariat staff	1 day

5. Detailed Instructions

5.1. The secretariat receives application or recommendation for early study termination.

5.1.1. Receives recommendation and comments from the Sponsor, DSMB, RERB members, Scientific Director, or other authorized bodies for study protocol termination.

5.1.2. Informs the principal investigator to prepare and submit a protocol termination package.

5.1.3. Receives the study protocol termination package prepared and submitted by the principal investigator.

5.1.4. Checks the completeness of the contents of the package to include the Study Termination (Form 3.8). The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.

5.2. Forward notice of early termination to primary reviewers

5.2.1. The secretariat staff forwards the notice of early termination to assigned primary reviewers within 4 days upon the receipt of the package

5.3. Review the submission package

5.3.1. The primary reviewers assess the termination issue, review safety data and make recommendation within 7 days upon the receipt of the document

5.3.2. It is important to note if the Termination Package contains a plan of how the participants who are still active in the study will be followed up. If no plan is noted, the CGHMC RERB should recommend to the PI that such plan should be included.

5.3.3. The secretariat shall include the submission for early termination in the agenda for full board review.

5.4. Discuss at full board for appropriate action

5.4.1. The RERB deliberates on the effects of early study termination on the safety and welfare of study participants.

5.4.2. Final decision of the application are as follows:

- APPROVAL/ NO FURTHER ACTION
- RECOMMEND FURTHER ACTION

- FURTHER INFORMATION REQUIRED/ CLARIFICATION FROM PI

5.5. Communicates the RERB decision to PI

5.5.1.The RERB secretariat prepares letter of notification signed and dated by the Chair.

5.5.2.The PI may be requested to provide additional information or documents or implemented actions to ensure the safety and welfare of subjects still active in the study.

5.6. File pertinent documents and update protocol database

5.6.1.The secretariat files the pertinent documents, excerpt of the minutes of the meeting when it was discussed, and the Notification Letter (Form 3.10), including the response from the PI, if any, in the protocol file folder and update the protocol file index.

5.6.2.Upon approval of the Early Study Termination Application, the study protocol is classified as inactive, the protocol code no. is updated and the protocol file folder re-labelled and transferred to storage for inactive files.

5.6.3.The secretariat staff updates the protocol database and labels the protocol “inactive-early termination.”

6. Forms

FORM NO	FORMS
3.8	Study Termination Form
3.10	Action Letter to protocol amendment/ final report/ early termination/ SAE/continuing review

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Basis for decision for termination of study was included
6	Sep 19, 2018	RERB Members	History of changes/ revisions was added
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.8. Management of Appeals	

1. Policy Statement

The CGHMC RERB shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval. Appeals of investigators shall undergo full review and shall be resolved within thirty (30) working days upon receipt of the fully documented appeal.

2. Purpose

To describe the procedures for the review of appeal of CGHMC RERB decision on its review of a study protocol to ensure fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the Researcher/Principal Investigator (PI).

3. Scope

The SOP starts with the receipt of the letter of appeal and ends with the filing of the letter of appeal and related documents and the updating of the protocol file index.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
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1	Receives the letter of appeal	Secretariat staff	4 days
2	Identify the Primary Reviewers and forward the letter of appeal and other relevant documents to the Primary Reviewers	Secretariat staff	
3	Review the appeal and other relevant documents	Primary reviewer	7 days
4	Include the appeal in the agenda of the forthcoming full board meeting	Secretariat staff	1 day
5	Discussion and deliberation of the appeal	RERB members	1 day
6	Communicate RERB decision to PI	Secretariat staff	5 days
7	File the letter of appeal and related documents in the protocol file folder, and update the protocol file index	Secretariat staff	1 day

5. Detailed Instructions

5.1 Receives the letter of appeal

5.1.1. If the Principal Investigator (PI) disagrees with the recommended revisions or the review decision made by the RERB he or she may submit a written appeal for reconsideration of the decision addressed to the Chair. The appeal should include the reason for requesting reconsideration and should contain supplemental documentation in support of the arguments made in the appeal.

5.1.2. The Secretariat staff receives the letter of appeal and records the submission and pertinent information in the logbook.

5.2. Identify the Primary Reviewers and forward the letter of appeal and other relevant documents to the Primary Reviewers within 4 days upon the receipt of the appeal

5.2.1. The Secretariat staff identifies the primary reviewers who did the initial review of the study protocol and forwards by e-mail to the Primary Reviewers letter of appeal and related documents related to the last review.

5.3. Review the appeal

5.3.1 The Primary Reviewers assess the document package whether there is sufficient basis to consider the appeal within 7 days upon the receipt of the complete document

5.4. Include the appeal in the agenda of the forthcoming meeting

5.4.1. The secretariat staff shall include the appeal in the agenda of the forthcoming full board meeting

5.5. Discussion and deliberation of the appeal

5.5.1. The Primary Reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal.

5.5.2. The Chair presents the contents of the appeal and leads discussion.

5.5.3. The PI may be called in for further clarification of issues and will be asked to step out after the board has taken up the issues for clarification

5.5.4. The committee then decides (by voting) whether to accept any or all of the points raised in the appeal.

5.6. Communicate RERB decision to PI

5.6.1. The Secretariat staff prepares the Notification of RERB Decision based on the minutes of the meeting.

5.7. File the letter of appeal and related documents in the protocol file folder, and update the protocol file index and the protocol database

5.7.1. The Secretariat staff files the letter of appeal and its attachments (if any), completed assessment checklist, excerpt of the minutes of the meeting, and duplicate copy of the Notification of RERB decision in the protocol file folder and updates the protocol file index and the protocol data base if the appeal is related to an initial review, review of resubmission, review of application for protocol amendment, continuing review, or review of final report.

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 3, 2024	Dr. Bernice Ong-Dela Cruz	Added new section on Management of Appeals

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	3.9. Review of Final Report	

1. Policy Statement

The CGHMC RERB shall require the submission of the final report to not more than sixty (60) days from end or close out of the study. Final reports shall follow the initial type of review. Submission and review of final reports signal the completion of the study and its acceptance by the research ethics board. Review of final reports should be within 14 days.

2. Purpose

To describe the RERB review procedures for follow-up and review of final reports for any study previously approved by the RERB

3. Scope

This policy applies to the management and review of final reports submitted by the investigators at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	Timeline
1	Receives the final report package	Secretariat staff	4 days

2	Determine the type of review and assigns primary reviewer	RERB Chair	
3	Forward final report to primary reviewers for review	Secretariat staff	
4	Review final reports	Primary reviewer	7 days
5	Present final report during full board meeting	Primary reviewers RERB members	1 day
6	Communicate RERB decision to PI	Secretariat staff	1 day
7	File copies of document	Secretariat staff	1 day

5. Detailed Instructions

5.1. Receipt of final report package

5.1.1.The Secretariat checks the database

5.1.2.The Secretariat reviews the completeness of submitted report based on the items in Final Report Form (Form 3.9) and forwards the report to the primary reviewers for review.

5.1.3.Final reports should contain the summary of events that happened to participants in the site and summary of findings in the site

5.2. Determination of type of review

5.2.1.The Chair determines the type of review the final report should undergo and identify the primary reviewers.

5.2.2.Generally, the review of a final report is based on the type of review (expedited or full board review) of the initial review of the protocol, unless otherwise indicated by the specific details of the submitted information.

5.2.3.The secretariat shall identify the initial primary reviewers of the protocol and forward the protocol package to them.

5.2.4.If the reviewers are not available to do the review, the Chair designates qualified members to review the continuing review application and progress report.

5.3. Forward final report to primary reviewers

5.3.1.The secretariat staff shall forward the Final report or Closure report package to the primary reviewers within 4 days upon the receipt of the package

5.3.2.The secretariat includes the final report submission on the agenda for the next RERB meeting for discussion and final decision.

5.4. Review of Final Reports, render decision and report to full board

5.4.1.The Primary Reviewers accomplish the review by commenting and recommending appropriate action on the Final Report form.

5.4.2.The RERB decision can be any of the following:

- Accepted - The report is accepted and found satisfactory e.g., report submitted on time, title and objectives of the study is consistent with the original proposal unless with prior approved amendment/s, reported adverse events resolved appropriately with summary of results
- Need for additional formation - The report needs additional information regarding issues identified by the RERB
- Action required - The RERB decides that the researcher needs to act on certain issues identified by the board in order to protect participants

- Not accepted - The RERB finds certain aspects of the report that have implications on veracity and consistency. The committee requires submission of the corrected report)

5.5. Communicate result of RERB decision to PI

5.5.1.PI is notified by the secretariat staff of the RERB decision

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

5.5.3.If the final report is approved, the PI is informed of the following:

5.5.3.1. The study protocol is now classified as INACTIVE; Study protocol record will be made available for three (3) years in the archives after the expiration date.

5.6. File copies of document

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

5.6.2.The secretariat staff enters relevant study protocol data into the study protocol Database to signify the end of the study.

5.6.3.The secretariat Staff transfers the study protocol folder to the Inactive Files.

6. Forms

FORM NO	FORMS
3.9	Final Report Form
3.10	Action Letter to protocol amendment/ final report/ early termination/ SAE/continuing review

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	History of changes/ revisions was added
7	Oct 23, 2023	Dr. Bernice Ong-Dela Cruz	Added section 5.1.3 Final reports should contain the summary of events that happened to participants in the site and summary of findings in the site
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revise scope

7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 16, 2024	Dr. Bernice Ong-Dela Cruz	Revised decision points and updated forms

4. Meeting Procedures

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: Effective Date:
	4.1. Preparation and Distribution of Meeting Agenda	

1. Policy Statement

The CGHMC RERB shall have a regular schedule of meetings every third or fourth Thursday of the month. All meetings shall be held within the premises of the institution. Online or hybrid meetings can be held if face to face meetings are not possible. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity.

2. Purpose

To describe procedures for the preparation and distribution of the RERB meeting agenda such that a smooth, orderly, and efficient conduct of meetings will be achieved

3. Scope

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

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Prepare and finalize meeting agenda	Secretariat staff	Within 7 days
2	Approve the meeting agenda and distribute notice of meeting	Chair/ secretariat	
3	Make arrangements for the meeting	Secretariat staff	
4	File notice of meeting and agenda	Secretariat staff	

5. Detailed Instructions

5.1. Collect all documents submitted to the RERB within a given period and put them in the full board meeting agenda for discussion or information of the RERB members.

5.1.1. The standard notice of meeting or agenda contains the ff: (Form 4.1)

- Date of preparation
- Date, time and venue of meeting
- Agenda items
- New protocols for initial review of full board
- Resubmission
- Amendments
- Progress reports
- Continuing Review
- Final reports
- SAE reports
- Protocol violation/deviation
- Site Visit Reports
- Expedited Meeting Reports
- Others matters

5.1.2. Recommendations on protocols requiring clarifications from the principal Investigator during an RERB full board meeting are made by CGHMC RERB primary reviewers, who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the RERB meeting is communicated to them.

5.2. The Secretariat informs and consults the Chair about the agenda items. Soft copies of the agenda of meeting and minutes of previous meeting are sent to all RERB members through email at least a week before the scheduled meeting.

5.3. The Secretariat arranges the venue and other logistics for the meeting at least one week before the scheduled meeting prior to preparation of the notice of meeting.

5.4. The Secretariat makes copies of the notice of meeting containing the approved agenda to the CGHMC RERB members, at least one week before the meeting.

5.5. The Secretariat communicates with the RERB members to confirm their attendance and ensure quorum will be reached for the next board meeting.

5.6. The Secretariat files a copy of the agenda in the Agenda and Minutes folder

6. Forms

FORM NO	FORMS
4.1	Agenda of the Meeting

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Sections preparation and distribution of meeting agenda and preparation meeting minutes transferred from Chapter 5 to this chapter 4
6	Sep 26, 2018	RERB Members	Added 2 new sections Conduct of full board meeting Conduct of special/emergency meeting
7	July 18, 2022	RERB members	Change the process flow of meeting minutes
7	July 18, 2022	RERB Members	Change secretariat to member secretary in the documentation of minutes during the meeting
7	July 18, 2022	RERB Members	Added criteria – determination of quorum in the minutes section
7	Oct 24, 2023	RERB Members	Added section on the preparation and conduct of on-line meeting

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	4.2. Preparation of Meeting Minutes	

1. Policy Statement

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

2. Purpose

To describe procedures for the preparation and approval of the minutes of the RERB full board meeting to ensure the proper documentation of the procedures and decisions in a full board meeting.

3. Scope

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

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE (DAYS)
1	Prepares and enter preliminary information on the minutes template	Secretariat staff	Within 7 days
2	Preparation of the draft of the minutes of the meeting	Member secretary	
3	Correction and finalization of the draft of the minutes	Chair/ RERB members	
4	Approval of the minutes in the next meeting	Secretariat staff	1 day
6	Filing of the approved minutes	Secretariat staff	1 day

5. Detailed Instructions

5.1. Prepares and enter preliminary information on the minutes template

5.1.1. The Secretariat staff uses Form 4.2 as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.

5.2. Preparation of the draft of the minutes of the meeting

5.2.1. The Member-secretary documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.

5.2.2. The Secretary reviews the proceedings prepared during the meeting and verifies that it contains the following sections:

- Date and venue of meeting
- Member attendance (members present and absent) to determine quorum
- Guests and observer attendance
- Time when the meeting was called to order
- Declaration of Quorum
- Presiding officer
- Conflict of interest declaration by REIRB members
- Discussion of items based on the Meeting Agenda
- Decisions and recommendations arrived at during the meeting
- Name and signature of person who prepared the Minutes
- Name and signature of the Chair with the date of approval

5.2.3. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.

5.2.4. The Secretary submits a complete draft of the minutes within one week after the meeting to the Chair for correction and finalization

5.3. Correction and finalization of the draft of the minutes

5.3.1. The minutes of the RERB full board meeting, once they are finalized, are sent to the members for comments or correction.

5.4. Approval of the minutes in the next meeting

5.4.1. The minutes are formally approved during the next full board meeting.

5.5. Filing of the approved minutes

5.5.1. The Secretariat files the signed minutes in the Minutes of the Meeting folder of the RERB

6. Forms

FORM NO	FORMS
4.2	Minutes of the Meeting template

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Sections preparation and distribution of meeting agenda and preparation meeting minutes transferred from Chapter 5 to this chapter 4
7	July 18, 2022	RERB members	Change the process flow of meeting minutes
7	July 18, 2022	RERB Members	Change secretariat to member secretary in the documentation of minutes during the meeting

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7
	4.3. Conduct of Full Board Meeting (Regular)	Date of Approval: 09 September 2025 Effective Date: 09 September 2025

1. Policy Statement

Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review. Regular monthly meetings shall be conducted every third Thursday of the month and special meetings shall be convened as needed.

2. Purpose

To describe the procedures in the conduct of a regular full board RERB meeting

3. Scope

This SOP starts with the calling of the meeting to order and ends with the collection, compilation and storage of meeting materials.

4. FLOWCHART

NO	ACTIVITIES	PERSON/S RESPONSIBLE
1	Call the meeting to order	RERB Chair
2	Determination of quorum	Member secretary
3	Disclosure of conflict of interest	Members
4	Approval or modify agenda	Members
5	Approval of the minutes of the last meeting	Member secretary
6	Discussion of business arising from the minutes of the previous meeting	Members
7	Review of protocols and protocol-related submissions	Primary reviewers/ members
8	Review of post-approval reports	Primary reviewers/ members
9	Reporting of approved expedited review	Chair
10	Reporting for exempted from review	RERB members
11	Discussion of operations-related matters	Members
12	Adjournment	RERB Chair
13	Collection, compilation and storage of meeting materials	Secretariat staff

5. Detailed Instructions

5.1. Call to order

5.1.1. The Chairperson declares the formal opening of the meeting at the appointed time and place once majority of the members are present.

5.1.2. The full-board meeting may be conducted face-to-face, on-line or hybrid. For online and hybrid meetings, secretariat staff sends zoom link 1 week before the meeting

5.2. Determination of quorum

5.2.1. The Member-Secretary checks and reports if the quorum requirements are met to enable the meeting to start. REC quorum requirements should comply with National and International requirements and as defined in these SOPs.

5.2.2. Quorum should be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision.

5.2.3. Quorum will be declared if there's 50% +1 present. Moreover, at least 1 member whose primary area of interest is 1 non-medical and at least 1 member who is independent of the institution (who can be represented by the non-medical as the case may be) must be present.

5.2.4. If there is a quorum, the Chair shall proceed. If no quorum exists, the Chair shall declare adjournment

5.3. Disclosure of conflict of interest

- 5.3.1. The Chair shall ask if any member of the RERB has a conflict of interest in any of the proposals for review.
- 5.3.2. Conflict of Interest is present when an RERB member has affiliation with a Principal Investigator or institute which will undermine his/her ability to make a free and independent evaluation. If any member of the RERB declares a conflict of interest in any of the protocols for review, the Chair shall request the concerned member not to participate in the decision-making of the specified protocol. Members with conflict of interest (COI) should not participate in the discussion of their protocol and leave the room and come back after decision has been made on the said protocol.
- 5.3.3. If there is no declaration of any conflict of interest, the Chair shall proceed with the next item in the Agenda.
- 5.4. Approval of the agenda
 - 5.4.1. The Chair shall ask the Members to examine and approve the items in the Meeting Agenda.
 - 5.4.2. Members may suggest additional items for discussion and the meeting agenda may be modified to include them.
- 5.5. Approval of the minutes of the last meeting
 - 5.5.1. The Minutes of the previous meeting should have been sent to all members before the meeting for review and comments. The Chair asks the Members to voice out their comments/corrections, if any, and thereafter asks them to approve the minutes of the last meeting.
- 5.6. Discussion of business arising from the minutes of the previous meeting
 - 5.6.1. The Chair shall also ask the members to comment about issues arising from the Minutes and the discussions are recorded in the current Minutes by the staff.
- 5.7. Review of protocols and protocol-related submissions
 - 5.7.1. The Primary Medical Reviewer summarizes the protocol to enable the members to understand it.
 - 5.7.2. He/she uses the assessment form to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.
 - 5.7.3. The Non-Medical / Non-Scientific Reviewer presents his / her assessment of the Patient Information Sheet and Informed Consent Form making use of the Informed Consent Assessment Form. The comments should note the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.
 - 5.7.4. The Independent Consultant as technical resource person if invited shall present his/her review or comments on the protocols.
 - 5.7.5. The Chair opens the protocol for discussion of Members taking note of additional and contradictory comments.

- 5.7.6. The Principal Investigator, if needed, is called to enter the room to answer questions and clarify certain protocol related matters, after which, s/he is asked to leave the room.
 - 5.7.7. The Chair summarizes the points raised and recommendations made by the Members.
 - 5.7.8. The Chair asks the members to vote based on the decision points in the SOPs:
 - Approval (no further revision of the documents is required)
 - Minor Revision
 - Major Revision
 - Disapproval
 - 5.7.9. The Member-Secretary takes note of voting results, records them and includes them in the Minutes of the meeting.
 - 5.7.10. The CGHMC RERB also allows, at the discretion of the Chair, guests (such as surveyors) or observers (such as trainees or students) to observe CGHMC full board meetings. Non-members who are attending any CGHMC RERB meetings are required to sign the Confidentiality Agreement Form for Guest Attendees to RERB Meetings (Form 4.3).
- 5.8. Review of post-approval reports
- 5.8.1. Protocol Amendments
 - 5.8.2. Serious Adverse Events Reports
 - 5.8.3. Protocol Deviations/ non-compliance
 - 5.8.4. Continuing review
 - 5.8.5. Protocol deviations
 - 5.8.6. Early termination
 - 5.8.7. SUSARs/ SAE reports
- 5.9. Reporting of approved expedited review protocols
- 5.9.1. The Chair reports the approved expedited review protocols.
- 5.10. Reporting of exempted from review protocols
- 5.10.1 The chair reports all protocols that were exempted from review.
- 5.11 Discussion of operations-related matters
- 5.11.1 The Chair / Member-Secretary or any Member may suggest items or other matters for the information or discussion by the Full Board.
- 5.12 Adjournment
- 5.12.1 The Chair shall adjourn the meeting after confirmation of the date of the next Regular Meeting.
 - 5.12.2 A group photo shall be done for online meetings
- 5.13 Collection, compilation and storage of meeting materials
- 5.13.1 The secretariat staff shall collect and compile protocols and related documents and evaluation forms

5.13.2 The secretariat shall collect all binders and keep these on file at the RERB Office

6. Forms

FORM NO	FORMS
4.3	Confidentiality Agreement Form for Guest Attendees to RERB Meetings

History

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Added new section Conduct of full board meeting
7	July 18, 2022	RERB Members	Change secretariat to member secretary in the documentation of minutes during the meeting
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 16, 2024	Dr. Bernice Ong-Dela Cruz	Added meetings can be conducted hybrid or on-line
7	July 16, 2024	Dr. Bernice Ong-Dela Cruz	Revise process flow and detailed instructions included pertinent activities

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	4.4. Conduct of Special/ Emergency Meeting	

1. Policy Statement

The CGHMC RERB shall conduct special or emergency meeting to resolve issues that require immediate attention, such as oversight problems involving safety of participants and urgent administrative and operational concerns of the RERB

2. Purpose

To describe the procedures and process in conducting special meetings

3. Scope

The SOP begins with the preparation for the special meeting and ends with the collection, filing and storage of meeting documents

4. FLOWCHART

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Evaluating events/ situations	RERB Chair	1 day

2	Making a decision to have an emergency meeting	RERB Chair	1 day
3	Sending notice of Emergency Meeting	Secretariat staff	1 day
4	Conduct of Meeting	RERB members	1 day
5	Communication of decision and filing of documents	Secretariat staff	1 day

5. Detailed Instructions

5.1. Evaluating events/situations and deciding to call for an emergency meeting of the RERB:

5.2. The following events/situations will require an emergency meeting of the RERB:

5.2.1. Occurrence of an unexpected serious adverse event that will be life-threatening to study participants

5.2.2. Recall of study drug by regulatory authorities

5.2.3. Matter of life and death

5.2.4. Other urgent issues as identified by RERB members or administration officials

5.3. After an evaluation of the event/situation, the RERB Chair shall call for an emergency meeting of the RERB

5.3.1. The Secretariat shall send a Notice of Emergency Meeting to RERB members, including resource persons, if needed.

5.3.2. The Secretariat shall prepare the Agenda and relevant materials for the emergency meeting

5.4. Conduct of Meeting

5.4.1. The RERB Chair shall determine the presence of a quorum.

5.4.2. The RERB Chair shall immediately present the relevant issues for discussion and shall ensure that the issues are resolved in the meeting.

5.4.3. The RERB shall make a decision on the issues by majority vote. The Secretary shall record and take minutes of the meeting.

5.5. Communication of decision and filing of documents

5.5.1. The Secretariat shall prepare the Notice of Action to be signed by the RERB Chair

5.5.2. The Secretariat shall deliver the notification to the person concerned.

5.5.3. The Secretariat shall file the relevant materials and documents appropriately

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Added Conduct of special/emergency meeting
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope

7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
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5. Documentation and Archiving

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	5.1. Communicating RERB Decisions	

1. Policy Statement

The CGHMC RERB shall communicate its decisions to the investigator within seven (7) days after the meeting date for Full Board or seven (7) days after receipt of Expedited review results. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the RERB and signed by the Chair.

2. Purpose

The management of communicating RERB decisions is described to ensure that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REC.

3. Scope

This SOP begins with the finalization of recommendations of the board or the reviewers and ends with the filing of the decision document in the protocol file and updating of the protocol database.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Organize all communications received and issued by the RERB	Secretariat staff	1 day
2	Record the details of the communication	Secretariat staff	1 day
3	File the communication documents	Secretariat staff	1 day

5. Detailed Instructions

5.1. Organize all communications received and issued by the RERB

5.1.1. RERB communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all RERB communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries.

5.1.2. The RERB Secretariat organizes a log of communication which also functions as a log of submissions if the communication comes with a submission. This log should have at least the following elements:

- Date of communication/submission
- Name of RERB party contacted
- Study information, i.e., sponsor, protocol number, principal investigator, etc.
- Content of communication or submission
- Notation of any follow-up necessary
- Type of submission (if communication refers to a submission)
- Contact information (address, telephone number, and e-mail) of sending party
- Name and signature of individual who received the communication and completed the record

5.2. Record the details of the communication

5.2.1. Store the communication records upon completion of the log of submission

- The Secretariat files a copy of the communication in the study file
- The Secretariat then writes in the protocol folder index as each communication is filed.

5.3. File communication documents

5.3.1. A copy of the communication/submission is filed in the:

- Protocol file folder
- RERB Communications folder
- Others, as appropriate

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
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7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	5.2. Management of Active Study Files, Documents, and Records	

1. Policy Statement

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

2. Purpose

RERB procedures related to the management of active study files, documents and records is described 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. Process Flow/ Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Design a standard coding system for all protocols submitted for review	Secretariat staff	1 day
2	File protocol and other related documents in an organized manner	Secretariat staff	1 day
3	Update protocol file regularly and store properly in an appropriately labeled file storage cabinet	Secretariat staff	3 days
4	Create an electronic protocol database and update frequently	Secretariat staff	1 day
5	Keep other RERB files in storage cabinets	Secretariat staff	1 day

5. Detailed Instructions

- 5.1. Protocol files of CGHMC RERB – approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. It is necessary to use a unique identifier or code to refer to this file for efficient file management.

Code active study files as follows:

CGHMC RERB					-		-		
Year					Classification		Series No		

Classification: **R** - resident; **F** – fellows; **CT**- clinical trials/ sponsor-initiated protocol; **N** – nurse; **I** – intern

For example, the code CGHMC RERB 2018-F-03 shall mean “Third (03) protocol received in 2018 is a fellow submitted protocol

- 5.2. File protocol and other protocol related documents in an organized manner

5.2.1. File protocol documents in sturdy file folders, using one folder per study protocol title.

5.2.2. File folders are labeled using the code of the study file. The folders are kept in secured well-identified locked cabinets.

The study file folder contains the following documents and should have an index:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and Co-investigator’s CVs
- Reviewers’ assessment forms
- Amendment reports
- Continuing review applications
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Approval letters

- Notifications of RERB Decision
- Miscellaneous communication
- Final report

5.3. Update protocol file folders regularly and store properly in an appropriately labeled file storage cabinet

5.3.1. The active files, records, and documents should be properly maintained and updated

5.3.2. All active protocol file folders are maintained in the “Active Files” cabinet until the Final Report Form is approved by the CGHMC RERB. All active study files are kept in a secured file cabinet, with access limited only to the Secretariat and the Chair who will be entrusted to keep the lock and key.

5.3.3. Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and RERB Documents. (Form 33)

5.4. Create an electronic protocol database and update it regularly with PI submissions and RERB decisions/actions

5.4.1. Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status. The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:

- Protocol Code
- Protocol title
- Department
- PI and details
- Submission date
- Full board or Expedited Review date
- Reviewers
- Review decision
- Board meeting date
- Approval date
- Date for progress report

5.5. Keep other RERB files in storage cabinets

5.5.1. The secretariat files other RERB documents that include the SOPs, membership files, international and national guidelines and regulations in the office cabinets and regularly update them for reference of the RERB members

6. Forms

FORM NO	FORMS
5.1	Confidentiality Agreement Form for Non-Members requesting access to CGHMC RERB Documents

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Coding system of the protocol identifiers indicated (CT, R, F)
6	Sep 26, 2018	RERB Members	Clarified that the specific personnel who will be entrusted with the lock and key – Chair and secretariat
7	July 18, 2022	SOP Team	Revise the flow steps of archiving
7	July 18, 2022	SOP Team	Added N-nurse for the code system
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	5.3. Archiving of Terminated, Inactive or Completed Studies	

1. Policy Statement

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for 3 years. Studies of Researchers who have not resubmitted their proposals within 6 months after receiving the Notification Letter shall be considered inactive.

2. Purpose

To describe RERB procedures related to archiving of terminated, inactive and completed studies

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. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Identify inactive protocol files	Member secretary/ Secretariat staff	1 day
2	Archiving documents	Secretariat staff	3 day
3	Reviews the contents of protocol file and transfers from active study filing area to the designated archive room	Secretariat staff	7 days
4	Update protocol database	Secretariat staff	1 day

5. Detailed Instructions

5.1. Identify inactive (Completed/ Inactive/ Terminated) protocol files

5.1.1. The following protocols shall be considered inactive:

- The final report of the study has been reviewed and approved by the RERB.
- No further communication has been received by the RERB after two (2) years.
- If protocol related revisions are not received within six (6) months
- Protocols that underwent early termination are subsequently classified as inactive upon receipt of relevant information about termination.

5.1.2. The secretariat staff removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.

5.1.3. The secretariat shall shred extra copies that are not needed

5.2. Archiving Documents

5.2.1. Archived study files refer to protocols that are completed/inactive/terminated (or withdrawn). They are retained for at least three years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors.

5.2.2. Upon approval of the Final Report or Early Study Termination, the protocol is reclassified as inactive and the Secretariat initiates archiving procedure.

5.2.3. An archive number is assigned to the protocol by adding the (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of Protocol CGHMC RERB 2010-002 is approved in 2012, the archiving code is CGHMC RERB 2010-002/2012.

5.3. The Secretariat reviews the contents of the protocol file and transfers it from the active study filing area to the designated archive room

5.3.1. Secretariat staff transfers the protocol files to the designated secure archive room

5.3.2. As in active study files, protocol files in the secure storage cabinet for inactive protocols are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.

5.3.3. Completed study files are archived for a minimum of three (3) years (National Guidance for Health Research, Philippine Health Research Ethics Board and WHO 2000)

5.3.4. Archived protocols can be borrowed upon written request by the PI or the CGHMC RERB personnel and only for office use. (See SOP on Maintenance of Confidentiality of Study Protocol Files and RERB Documents).

5.4. Update protocol database

5.4.1. The archived data should be entered accordingly in the protocol database.

5.4.2. The secretariat reviews entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Revised timeline to 6 months to protocol with revisions will be considered inactive

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	5.4. Maintenance of Confidentiality of Study Files and RERB Document	

1. Policy Statement

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

2. Purpose

To describe RERB procedures related to maintaining the confidentiality of the study files and other RERB documents

3. Scope

This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

4. Process Flow/ Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Manage all active and inactive CGHMC RERB files	Secretariat staff/ member secretary	3 days
2	Receives request to access confidential files	Secretariat staff	1 day
3	Approve and log in requests for access and retrieval of documents	Chair/ Member secretary	3 days
4	Supervise the use of retrieved confidential document and making copies of documents	Secretariat staff	1 day
5	Return document to the protocol file folder	Secretariat staff	1 day

5. Detailed Instructions

5.1. Manage all active and inactive CGHMC RERB files

Properly handle original documents and copies of these documents during the day-to-day operation of the RERB to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the RERB.

Study files submitted to the CGHMC RERB and related documents are considered confidential, such as:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- RERB documents (Meeting minutes, advice, and decisions)
- Correspondence (experts, auditors, study participants, etc.)

5.2. Receives request to access confidential files

5.2.1. Access to CGHMC RERB confidential documents is subject to the following limitations:

- CGHMC RERB members and staff with a signed CGHMC RERB Letter- Confidentiality Agreement and Conflict of Interest Disclosure can access confidential documents outside of regular protocol review, upon request
- Non-members can request access to specific documents by submitting a formal request (Form 33). The Secretariat will provide a copy of the *Confidentiality Agreement Form for Non-members requesting for Copies of CGHMC RERB Documents* (Form 5.1) to be accomplished by the person making the request, and signed by the Chair.
- Regulatory authorities have full access to CGHMC RERB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

5.3. Approve and log-in requests for access and retrieval of documents.

5.3.1. A separate log is kept in the protocol folder to record access as described above. It contains the following information:

- CGHMC RERB Study Protocol Code

- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval
- Signature of RERB secretariat upon return of document to the protocol file folder
- Document copied
- Number of copies made
- Number of copies received

5.4. Supervise the use of retrieved confidential document

5.4.1. Access to RERB documents is generally for room use only, but requests to make copies can be accommodated on a case-to-case basis.

5.4.2. The secretariat makes only the exact number of copies requested

5.4.3. The recipient signs the RERB Log of Request for Copies of Documents upon receipt of the documents.

5.4.4. The secretariat shall ensure the diligent recording of all document copies issued in the Log of Request for Copies of Documents. This Log is filed in a separate folder labeled “Log of Copies Issued”.

5.5. Return document to the protocol file folder

5.5.1. The RERB secretariat shall return the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per protocol file index.

6. Forms

FORM NO	FORMS
5.4	Confidentiality Agreement Form for Non-Members requesting access to CGHMC RERB Documents

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added timeline to flowchart

6. Writing and Revising SOPs

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	6.1. Writing SOPs	

1. Policy Statement

The RERB shall designate a team to write and revise its set of SOPs to determine its continuing relevance and effectiveness to its operations.

2. Purpose

To define the process for writing SOPs used by the CGHMC RERB

3. Scope

This SOP begins with the organization of a SOP Team for writing of a new SOP and ends with the distribution of approved SOPs and keeping of copies in the REC files.

4. Process flow/Steps for New SOP

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Organize an SOP Team	RERB Chair	5 Days

2	Identify reference templates with corresponding layout	SOP Team	5 days
3	Draft new SOP and submit to Chair	SOP Team	60 days
4	Review and finalize new SOP in full board meeting and submit to the medical director	RERB members	1 day
5	Distribute approved SOPs and keep copies in the RERB files	Secretariat staff	2 days

5. Detailed Instructions

5.1. Organize an SOP team

- 5.1.1.** The Chair designates members to be part of the SOP Team and invites resource person as needed.
- 5.1.2.** The SOP Team receives an orientation from the Chair regarding duties and responsibilities.
- 5.1.3.** The Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

5.2. Identify reference templates with corresponding layout

- 5.2.1.** Identify reference templates with corresponding layout from SOPs of other Ethics Committees to guide the SOP team in drafting new SOPs.
- 5.2.2.** An SOP is written according to the following format:
 - Number and version
 - Date of revision
 - Title
 - Objectives of the SOP
 - Scope which includes description and purpose of the SOP
 - A flowchart when necessary
 - Detailed instructions
 - Standard forms and checklists to be used
 - Glossary
 - Reference

Assign an identifier to the SOP

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. For the CGHMC RERB SOPs, the following format is used: CGHMC RERB SOP WW/XX-YY-ZZZZ where WW corresponds to chapter-section in the manual where the SOP is found, XX corresponds to the version, YY pertains to number of revisions made, and ZZZZ is a four-digit number identifying the year SOP was drafted or revised.

Thus, the SOP on writing of SOPs is identified as SOP 05-5.1/01-0-2012 meaning that this SOP can be seen in Chapter 5 section 5.1 (05-5.1), first version (05-5.1/01) and has no changes, (05-5.1/01-0) as of 2012 when it was drafted.

The layout of SOP uses a header with the following elements:

- Institutional seal or logo
- Name of institution
- SOP Title
- SOP Version
- Approval Date

- Effective Date

The SOP is introduced by a cover laid out as a typical SOP page with the following additional items included:

- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version; if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
- Approval information such as approving authorities and offices

5.3. Draft the SOP and submit to Chair

5.3.1. The CGHMC RERB SOPs shall contain details under the following main topics:

- 5.3.1.1. Structure and Composition of the RERB – describes the composition of the RERB membership with specific review functions
- 5.3.1.2. Initial Review Procedures – describe the types of review and initial review procedures
- 5.3.1.3. Monitoring procedures (Post-Approval Procedures) – describe how the RERB monitor implementation of approved protocols
- 5.3.1.4. Conduct of the meeting – describes the preparation of the agenda and minutes of the meeting and conduct of full board and special (emergency meeting)
- 5.3.1.5. Documentation and archiving – describe administrative procedures that support the review functions
- 5.3.1.6. Writing and revising SOPs – describes how to draft and revise SOPs

5.4. The SOP Team submits completed draft to the Chair.

- 5.4.1. Review and finalize the new SOPs during full board meeting and submit to the Medical Director.
- 5.4.2. The Chair submits the draft to full board review where RERB members deliberate and finalize the draft
- 5.4.3. Upon full board approval, the Chair submits the approved draft to the Medical Director for final approval.
- 5.4.4. The CGHMC Medical Director approves the SOP by signing in the appropriate section in the cover page.
- 5.4.5. The approved SOPs will be implemented from the date of approval by the Medical Director

5.5. File and distribute the SOP

- 5.5.1. Once the SOP has been granted approval by the Medical Director, the secretariat submits a copy of the SOP to the Office of Quality Management Team (QMT). The QMT takes charge of assigning quality control number to the document and publishing the SOP through the Hospital website.
- 5.5.2. The Secretariat distributes the printed copy of the approved SOPs to the RERB members and staff; with an electronic copy published through the Hospital website.
- 5.5.3. The Secretariat retains one complete originally signed SOP copy in file.

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	6.2. Revising SOPs	

1. Policy Statement

Existing SOPs shall be reviewed every three (3) years, unless regulations on which these documents are based have significantly changed in the interim, or as the IERB sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial). Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary.

2. Purpose

To describe the procedures for revising SOPs used by the CGHMC RERB.

3. Scope

This SOP begins with the recommendation to revise existing SOP and ends with the retrieval and archiving of copies of superceded SOP.

4. Process Flow/Steps

NO	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Recommend amendment of SOP	Member	3 days
2	Revise and submit new SOP	SOP Team	60 days
3	Review and discuss new SOP version	SOP Team	1 day
4	Approval of new SOP version	Medical Director	5 days
5	File and distribute new SOP version	Secretariat staff	1 day
6	Retrieve and archive copies of superseded SOP	Secretariat staff	1 day

5. Detailed Instructions

5.1. Recommend amendment of SOP

5.1.1. Any RERB member of the LCPIERB can propose a revision of the SOP. The proposed revision or amendment shall be submitted in writing to the secretariat to be placed on the agenda of the next full board meeting.

5.1.2. The proposal is discussed and acted upon during a full board meeting.

5.2. Revise and submit new SOP

5.2.1. When the need for a revision of SOP has been identified and agreed on, the Chair shall appoint the SOP team or a designated member to draft the revision.

5.2.2. The SOP team prepares the draft of revision and the Chair presents the revised SOP to the board for deliberation during a full board meeting.

5.2.3. Minor revisions may be done by one or more RERB members provided they are approved by the Board

5.2.4. The SOP team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.

5.3. Review and discuss new SOP

5.3.1. The Chair submits the draft to full board review where RERB members deliberate and finalize the draft.

5.4. Approval of new SOP version

5.4.1. The Chair submits the approved draft to the Medical Director for final approval.

5.4.2. The CGHMC Medical Director approves the revised SOP by signing on the appropriate section of the cover page.

5.4.3. The approved revised SOP will be implemented from the date of approval by the Medical Director

5.5. File and distribute the revised SOP

5.5.1. Upon approval of CGHMC DMER Chairperson, a copy will be submitted to the Office of Quality Management Team. The QMT assigns a quality control number to the document and takes charge of publishing the SOP through the Hospital website.

5.5.2. The Secretariat distributes revised SOP to CGHMC RERB Members, updates the SOP manual.

5.5.3. The Secretariat maintains an updated SOP manual in the hospital, but retains the original manual in the archives.

5.5.4.The Secretariat distributes the printed copy of the approved SOPs to the RERB members and staff; with an electronic copy published through the Hospital website.

5.5.5.The Secretariat retains one complete originally signed SOP Copy for filing.

5.6. Retrieve and archive copies of superseded SOP

5.6.1.The Secretariat archives the superseded version of the SOP in the historical file maintained by the RERB

5.6.2.Superseded SOPs are clearly marked “superseded” with the year of archiving stamped in the cover page

History of SOP

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Date of revision was added as an item in sec 6.2.5.6
6	Sep 26, 2018	RERB Members	Flow charts were revised to ensure consistency in all chapters
6	Sep 26, 2018	RERB Members	Frequency of revision indicated
6	Sep 26, 2018	RERB Members	History of changes/ revisions included
7	July 18, 2022	SOP Team	Changed 2 years to 3 years
7	October 23, 2023	Dr. Bernice Ong-Dela Cruz	Added that minor revisions may be done by one or more RERB members provided they are approved by the Board
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Added policy statement and revised scope
7	July 8, 2024	Dr. Bernice Ong-Dela Cruz	Removed responsibility section and incorporate in detailed instruction

Appendices

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	Glossary	

Adverse event – any untoward medical occurrence in a clinical investigation participant given an investigational product and which does not necessarily have a causal relationship with treatment received.

Alternate member - a member who have similar expertise as the regular member for who he/she is serving as a replacement. He/she will assume all the responsibilities of the member for whom he/she is serving as a replacement

Approved – affirmative decision of the RERB that the clinical trial and all pertinent documents have been reviewed and maybe conducted in the institution within the constraints set forth by the RERB, the institution, Good Clinical Practice, and applicable regulatory requirement.

Audit – a systematic and independent examination of trial related activities and documents to determine whether all activities were conducted according to ethical standards and applicable regulatory requirements

Case report form – a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.

Conflict of interest – A conflict of interest arises when member/s of the RERB hold/s interests with respect to specific applications for review that may jeopardize his/her ability to provide a free and independent evaluation of the proposal focused on the protection of human participant. Some forms of conflicts may include, but not limited to, financial, material, institutional, or social ties to the research.

Expedited review – a form of protocol review on studies that enroll participants in a low-risk study with minimal risk to study participants and minor revisions in the protocol or informed consent

Full board review – form of protocol review on high risk studies that enroll participants, including but not limited to heart failure, COPD in exacerbation, pediatric patients, special/vulnerable population, and major revisions in the protocol or informed consent

Good Clinical Practice – a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and results are accurate and credible, and that the rights, integrity, and confidentiality of trial subjects are protected.

Independent consultant – a professional/expert who is invited by the RERB to assist in reviewing protocols where RERB lacks expertise.

Investigator's Brochure – a compilation of the clinical and nonclinical data on the investigational product which is relevant to the study of the product in human participant

Lay member – member of the RERB who can either be a non-practicing medical doctor, non-medical, but maybe an allied health professional, or non-scientific, or non-institutionally related

Progress Report - An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the RERB. Generally, these reports are due annually with the RERB sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the RERB.

Protocol – a document that describes the objectives, design, methodology, statistical considerations, and organization of a trial. This usually gives the background and rationale for the trial.

Protocol Amendment - A change to the study protocol during the planning or course of the trial. The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Serious adverse events (SAE) or serious adverse drug reactions (SADR)

Any untoward medical occurrence that at any dose:

- Results in death
- Is organ or life threatening
- Requires in patient hospitalization
- Results in persistent or significant disability
- Results in pregnancy

Vulnerable subjects - A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	References	

1. Standards and Operational Guidelines for Ethics Review of Health-Related Research with Human Participants. World Health Organization (WHO) Geneva 2011
2. World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research involving Human Subjects amended by the 64th WMA General Assembly, Fortaleza Brazil, October 2013
3. (PNHRS) Philippine National Health Research System (2014), Philippine National Ethical Guidelines for Health Research (PNEGHR 2013), National Ethical Guidelines for Health and Health-Related Research (2022)
4. Council of International Organization of Medical Services: Epidemiological Research Involving Human Subject - CIOMS (2011)
5. International Ethical Guidelines for Biomedical Research involving Human Subjects. Geneva Council for International Organizations of Medical Sciences- CIOMS (2002, 2006, 2009)
6. The Belmont Report 1998 Update
7. Guideline for Good Clinical Practice ICH Harmonized Tripartite Guideline E6 (R2) 2015.
8. Ethical and Policy Issues in Research involving Human Participants 2001
9. Universal Declaration on Bioethics and Human Rights: United Nations Educational, Scientific and Cultural Organization 2005

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	Forms	

LETTER OF APPOINTMENT OF RERB CHAIR (FORM 1.2A)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as Chair of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). CGHMC RERB is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees. The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection.

The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As Chair of the RERB, your specific responsibilities include:

- Finalize and approve the agenda and preside in all RERB meetings.
- Conduct a preliminary review of all protocols and decide on the nature of review – expedite, exempt or full board
- Assign primary reviewers to initial protocols submitted
- Ensure that a final decision on all protocols reviewed is made and break a tie whenever a deadlock in RERB voting occurs
- Sign the following communications: Notice of Meetings, Notice of Action to Principal Investigators and Sponsors
- Represent Chinese General Hospital and Medical Center in ethics-related symposia or meetings that require institutional participation
- Ensure that appropriate decisions/actions are made by the RERB on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator, etc.
- Submit annual reports on the accomplishments of the RERB to PHREB
- Communicate decisions of the RERB to research proponents
- Ensures that all RERB members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter
- Prepares budget plan for the RERB

The following are addition to your roles and responsibilities as member:

- Participate in regular RERB/SJREB meetings
- Serve as Primary Reviewer for research protocol within your area of expertise and as a primary medical reviewer, your review shall focus on the technical or scientific issues and ethical issues/as a non-medical reviewer, your review shall focus on the human participants' concerns, review the informed consent process and informed consent forms
- Perform post-approval review procedures as follows:
 - o Assess serious adverse event reports and recommend appropriate action(s)
 - o Review the progress reports and monitor ongoing studies as appropriate
 - o Evaluate final reports;
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

Your term of office is two (2) years effective _____ until _____ with possible renewal for every three (3) years.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

LETTER OF APPOINTMENT OF VICE-CHAIR (FORM 1.2B)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as Vice-Chair of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). CGHMC RERB is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees. The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection.

The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As Vice-chair of the RERB, your specific responsibilities include:

- Be appointed by the Chair and selected based on experience and expertise from among the current RERB members
- Have the authority to perform all the duties of the Chair when the latter is unavailable or unable to perform them
- Perform other tasks as delegated by the Chair
- Serve as SAE subcommittee chair

The following are addition to your roles and responsibilities as member:

- Participate in regular RERB/SJREB meetings
- Serve as Primary Reviewer for research protocol within your area of expertise and as a primary medical reviewer, your review shall focus on the technical or scientific issues and ethical issues/as a non-medical reviewer, your review shall focus on the human participants' concerns, review the informed consent process and informed consent forms
- Perform post-approval review procedures as follows:
 - o Assess serious adverse event reports and recommend appropriate action(s)
 - o Review the progress reports and monitor ongoing studies as appropriate
 - o Evaluate final reports;
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

Your term of office is two (2) years effective _____ until _____ with possible renewal every three (3) years.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

LETTER OF APPOINTMENT OF MEMBER SECRETARY (FORM 1.2C)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as secretary of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). CGHMC RERB is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees. The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection.

The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As secretary of the RERB, your specific responsibilities include:

- Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
- Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting
- Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submission
- Supervises the RERB Secretariat staff in the preparation of the agenda and minutes
- Review minutes of the meeting
- Accurately record (real-time) minutes of the meeting of the RERB

The following are addition to your roles and responsibilities as member:

- Participate in regular RERB/SJREB meetings
- Serve as Primary Reviewer for research protocol within your area of expertise and as a primary medical reviewer, your review shall focus on the technical or scientific issues and ethical issues/as a non-medical reviewer, your review shall focus on the human participants' concerns, review the informed consent process and informed consent forms
- Perform post-approval review procedures as follows:

- Assess serious adverse event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Evaluate final reports;
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

Your term of office is two (2) years effective _____ until _____ with possible renewal every three (3) years.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

LETTER OF APPOINTMENT OF RERB MEMBER (FORM 1.2D)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as member (regular / alternate) of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). CGHMC RERB is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees. The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection.

The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As a member, you will have the following roles and responsibilities:

- Participate in regular RERB/SJREB meetings
- Serve as Primary Reviewer for research protocol within your area of expertise and as a primary medical reviewer, your review shall focus on the technical or scientific issues and ethical issues/as a non-medical reviewer, your review shall focus on the human participants' concerns, review the informed consent process and informed consent forms
- Perform post-approval review procedures as follows:
 - o Assess serious adverse event reports and recommend appropriate action(s)
 - o Review the progress reports and monitor ongoing studies as appropriate
 - o Evaluate final reports;
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

Your term of office is two (2) years effective _____ until _____ with possible renewal every three (3) years.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

LETTER OF APPOINTMENT OF SAE SUBCOMMITTEE MEMBER (FORM 1.2E)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as member of the SAE subcommittee. As a member your responsibility is to attend quarterly meetings to review all types of serious adverse events (SAEs), including unsuspected serious adverse reactions (SUSARs) occurring on or off site and give recommendations to the RERB about an appropriate action to full board to ensure safety of patients.

If you agree with the terms of this appointment, effective on _____ to _____. Please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

APPOINTMENT LETTER OF ALTERNATE MEMBER (FORM 1.2F)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

Part OF THE MISSION VISION OF THE Research Committee under the Department of Medical Education and Research is to encourage and strengthen research output from our staff and trainees. This can only be realized with the active participation of the majority.

As an alternate member, you will have the following roles and responsibilities:

1. Participate in regular RERB meetings
2. Review, discuss, and consider all research proposals submitted to the RERB for evaluation and approval.
3. Assess serious adverse event reports arising from the trials and recommend appropriate action/s.
4. Review the progress reports and monitor ongoing trials as appropriate.
5. Check progress and final reports of trials.
6. Maintain confidentiality of the documents and deliberations of RERB meetings.
7. Declare any conflict of interest.
8. Participate in continuing educational activities in research methodology and research ethics.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

APPOINTMENT LETTER OF INDEPENDENT CONSULTANT (FORM 1.2G)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

The Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) is inviting you to be an Independent Consultant, in your capacity as a (EXPERTISE), to provide expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which board has ascertained to require additional expert review.

CGHMC RERB is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees. The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection.

The responsibilities of an Independent Consultant are as follows:

1. Review, discuss, and evaluate research proposals assigned and accomplished study assessment forms
2. Maintain confidentiality of the documents and deliberations of RERB meetings
3. Declare any conflict of interest

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

Chair, Research Ethics Review Board
CGHMC

Date

Chair,
Department of Medical Education and Research
CGHMC

Date

Conforme:

(Print name & sign)

Date

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT (Form 1.3A)

Know all Men by these Presents:

In view of the appointment of (TITLE, NAME, INSTITUTIONAL AFFILIATION), as a member of the Chinese General Hospital and Medical Center Institutional Review Board (RERB), and hereinafter referred to as the *Undersigned*, and

Whereas:

The *Undersigned* has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with

the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the *Undersigned* as a member of the CGHMC RERB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an RERB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CGHMC RERB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed RERB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the RERB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the *Undersigned* in conjunction with and/or in the course of the performance of his/her duties as a member/independent consultant of the CGHMC RERB.

Any written information provided to the *Undersigned* that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the RERB.

As such, the *Undersigned* agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the *Undersigned* agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The *Undersigned* further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the *Undersigned* confirms that her performance of this agreement is consistent with Chinese General Hospital and Medical Center policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the RERB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the RERB that no member/consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the RERB.

The *Undersigned* will immediately disclose to the Chair of the CGHMC RERB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the RERB, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an RERB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exist with the RERB member(s) in question. The RERB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, the member should notify the Chairperson and may not participate in the RERB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- ☐ A member/independent consultant is involved in a potentially competing research program.
- ☐ Access to funding or intellectual information that may provide an unfair competitive advantage.
- ☐ A member's/independent consultants' personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[To the *Undersigned*: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CGHMC RERB. A copy will be given to you for your records.]

In the course of my activities as a member of the CGHMC RERB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an RERB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accepted the aforementioned terms and conditions as explained in this Agreement.

Title/Name

Date

CGHMC RERB Chair

Date

Chair, Department of Medical Education and Research
CGHMC

CURRICULUM VITAE (FORM 1.3B)

Name			
Residence Address			
Contact No.		Email Address	
Highest Educational Attainment			

Research and Ethics Training/s	
Research Works	
WORK EXPERIENCE (Please include year)	
A. Occupation	
B. Previous work experience	
C. Present work	
D. Research –related experience	

SIGNATURE ABOVE PRINTED NAME

Date

TRAINING RECORD OF RERB MEMBER (FORM 1.4)

Last name		First name		
BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				

3. RERB Standard Operating Procedures (SOP)				
CONTINUING ETHICS EDUCATION: <i>(incl Research Ethics Workshops, Conferences, Meetings, Lectures)</i>	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1.				
2				
3				
4				
5				

TERMS OF REFERENCE (RERB MEMBERS) (FORM 1.5A)

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection. In accordance to provisions set forth in the national and international guidelines, it has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance of its researchers with all relevant procedures after approval of trials.

Membership

While the RERB remains under the authority of the DMER, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines.

The CGHMC RERB shall be composed of a pool of at least 8 members.

The RERB membership shall allow for multidisciplinary and multisectoral representation to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. The RERB also includes a person who will represent the interest and concerns of the community, have at least one member who is in a non-medical/non-scientific area, and one who is non-affiliated to the institution. It shall aim for gender balance in its membership, with representation from both old and young generation. An independent consultant may also be invited to provide expert opinion and expertise to protocols under review, with no voting privilege.

Appointment of Members and Terms of Office

RERB members shall nominate qualified candidates for new members to the Chair. The Chairman of DMER selects from the list of nominees for RERB members and issues an appointment letter.

Members are appointed for a maximum period of two (2) years on the initial appointment. The appointments may be renewed by the Appointing Authority every three (3) years.

Training of Members

It is the responsibility of all the RERB officers, members and staff to have themselves educated and trained regularly. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in RERB standard operating procedures (SOP). In addition, they should be provided with external training opportunities at least once a year from information on courses/conferences gathered from various media channels in coordination with the Secretariat.

Review of Research Proposals

The CGHMC RERB accepts the following protocols for review: 1) CGHMC funded researches, 2) researches done in CGHMC by medical house staff, 3) research proposals submitted by CGHMC personnel for thesis defense, 4) industry sponsored researches to be conducted by CGHMC active/visiting medical staff to be conducted off-site (in the event the institution does not have ethics review board in place). In consideration to multi-center trials or studies, each Center/trial site has to have an independent or its own RERB approval for the said protocol.

Other than obtaining RERB approval, researches to be conducted by trainees that entail retrospective review of charts/medical records (with no actual participant/subject contact in whatever manner) will need to be approved by the Medical Director prior to implementation. All clinical study agreement (CSA) of externally supported/funded studies/trials should undergo approval by the Legal Division of the Hospital. RERB approval letter will not be released until CSA is approved by the office of the legal counsel.

Protocols submitted for RERB review (either for full board or expedited reviews) should follow the detailed steps set forth in the SOP. The RERB conducts regular reviews of approved protocols until end-of-study period. The Secretariat keeps close communication with the principal investigator for any concerns that need further clarification or actions.

Meetings

Monthly RERB meeting is held to discuss all concerns related to new protocols and ongoing studies. Notice of meeting as well as agenda set for the date will be closely coordinated to all by the Secretariat. For each meeting, an invitation to more than half of the general membership shall constitute a quorum, which includes community representative/lay member who is independent of the institution or research site. In any case that an RERB member has conflict of interest to a particular protocol, s/he may give insights/inputs during deliberation but should inhibit her/himself from voting.

Post Approval Responsibilities

The RERB will continue to monitor approved projects in terms of compliance with national and international as well as local ethical approval. The RERB requires researchers to provide regular reports (frequency depends upon manner of review – full board or expedited review) and on completion of the study. It may request for additional information from the researchers on any relevant aspects of the project at any time. It will also require the researchers to report any form of protocol amendments, serious adverse events, protocol violation and deviation, early termination, as well as participant's requests or queries as soon as possible. Appropriate mechanism for site monitoring and random audits are also in place.

Amendments to the Terms of Reference

The Board may amend the Terms of Reference at anytime or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)

CGHMC RERB Member

Date:

Chair, Research Ethics Review Board
CGHMC

Chair, Department of Medical Education and Research
CGHMC

TERMS OF REFERENCE
(INDEPENDENT CONSULTANTS) (FORM 1.5B)

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

An independent consultant is invited to attend the RERB meeting, present his/her assessment, and participate in the discussion but without voting rights. The report becomes a permanent part of the study file.

Appointment of Independent Consultant and Terms of Office

The RERB Board members nominate independent consultants based on their specialties to help review research where the RERB lacks expertise. The DMER Chairman appoints independent Consultants for initial period of two (2) years, and renewable every two (2) years by Authority Body

Once independent consultant signs the terms of appointment (Form 1.2G), the Secretariat will ask him/her to provide the following: an updated curriculum vitae (Form 1.3 B), a signed Terms of Reference (Form 1.5B), a signed Confidentiality/Conflict of Interest (Form 1.3A). The Secretariat then keeps copies of pertinent documents.

Termination of Services

Independent consultant's services may be terminated by either the consultant or by the DMER Chairman upon recommendation of the Board.

Upon termination of the independent consultant's services, the Secretariat shall ensure that all the necessary documents is completely filed up with the other administrative documents.

Amendments to the Terms of Reference

The Board may amend the Terms of Reference at any time or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)

Independent Consultant

CGHMC RERB

Date:

Chair, Research Ethics Review Board
CGHMC

Chair, Department of Medical Education and Research
CGHMC

TERMS OF REFERENCE
(ALTERNATE MEMBERS) (FORM 1.5C)

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection. In accordance to provisions set forth in the national and international guidelines, it has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance of its researchers with all relevant procedures after approval of trials.

Membership

While the RERB remains under the authority of the DMER, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines.

The CGHMC RERB shall be composed of a pool of at least 8 members.

The RERB membership shall allow for multidisciplinary and multisectoral representation to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. The RERB also includes a person who will represent the interest and concerns of the community, have at least one member who is in

a non-medical/non-scientific area, and one who is non-affiliated to the institution. It shall aim for gender balance in its membership, with representation from both old and young generation. An independent consultant may also be invited to provide expert opinion and expertise to protocols under review, with no voting privilege.

Appointment of Alternate Members and Terms of Office

RERB members shall nominate qualified candidates for new members to the Chair. The Chairman of DMER selects from the list of nominees for RERB members and issues an appointment letter.

Members are appointed for a maximum period of two (2) years on the initial appointment. The appointments may be renewed by the Appointing Authority for another term for a maximum period of three (3) years.

Training of Alternate Members

It is the responsibility of all the RERB officers, members and staff to have themselves educated and trained regularly. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in RERB standard operating procedures (SOP). In addition, they should be provided with external training opportunities at least once a year from information on courses/conferences gathered from various media channels in coordination with the Secretariat.

Review of Research Proposals

The CGHMC RERB accepts the following protocols for review: 1) CGHMC funded researches, 2) researches done in CGHMC by medical house staff, 3) research proposals submitted by CGHMC personnel for thesis defense, 4) industry sponsored researches to be conducted by CGHMC active/visiting medical staff to be conducted off-site (in the event the institution does not have ethics review board in place). In consideration to multi-center trials or studies, each Center/trial site has to have an independent or its own RERB approval for the said protocol.

Other than obtaining RERB approval, researches to be conducted by trainees that entail retrospective review of charts/medical records (with no actual participant/subject contact in whatever manner) will need to be approved by the Medical Director prior to implementation. All clinical study agreement (CSA) of externally supported/funded studies/trials should undergo approval

by the Legal Division of the Hospital. RERB approval letter will not be released until CSA is approved by the office of the legal counsel.

Protocols submitted for RERB review (either for full board or expedited reviews) should follow the detailed steps set forth in the SOP. The RERB conducts regular reviews of approved protocols until end-of-study period. The Secretariat keeps close communication with the principal investigator for any concerns that need further clarification or actions.

Meetings

Monthly RERB meeting is held to discuss all concerns related to new protocols and ongoing studies. Notice of meeting as well as agenda set for the date will be closely coordinated to all by the Secretariat. For each meeting, an invitation to more than half of the general membership shall constitute a quorum, which includes community representative/lay member who is independent of the institution or research site. In any case that an RERB member has conflict of interest to a particular protocol, s/he may give insights/inputs during deliberation but should inhibit her/himself from voting.

Post Approval Responsibilities

The RERB will continue to monitor approved projects in terms of compliance with national and international as well as local ethical approval. The RERB requires researchers to provide regular reports (frequency depends upon manner of review – full board or expedited review) and on completion of the study. It may request for additional information from the researchers on any relevant aspects of the project at any time. It will also require the researchers to report any form of protocol amendments, serious adverse events, protocol violation and deviation, early termination, as well as participant's requests or queries as soon as possible. Appropriate mechanism for site monitoring and random audits are also in place.

Amendments to the Terms of Reference

The Board may amend the Terms of Reference at anytime or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)

CGHMC RERB Member

Date:

Chair, Research Ethics Review Board

CGHMC

Chair, Department of Medical Education and Research

CGHMC

APPLICATION FORM FOR PROTOCOL REVIEW (FORM 2.1A)

CGHMC RERB Protocol Number		Sponsor Protocol No:	
Submission Date			
Protocol Title:			
Principal Investigator			
Study Site			
Contact details:	 :		
	Mobile:		
	Fax:		
	Email address:		
Sponsor:			
PI Conflict of Interest/ Declaration (Relationship with Sponsor)	Are you a regular employee of the sponsor? ☐ Yes ☐ No		
	Did you do consultancy or part time work for the sponsor? ☐ Yes ☐ No		
	In the past year, did you receive P250,000 or more from the sponsor? ☐ Yes ☐ No		
	Other ties with the sponsor		

By signing the application form, I undertake to address my competing interests, uphold scientific integrity, respect and protect human subjects during the conduct of my research in this institution.	
PI Signature:	

CHECKLIST OF DOCUMENTS SUBMITTED FOR PROTOCOL REVIEW (FORM 2.1B)

CGHMC RERB PROTOCOL NO:		Sponsor Protocol No.
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
Study Site		

Documents submitted: (Please check all applicable)

Documents
☐ Protocol
☐ Patient information form
☐ Informed consent form (English and Tagalog Version)
☐ Assent Form in English and Tagalog (for studies involving minor and relevant subjects incompetent to sign an ICF)
☐ Advertisement
☐ Investigator's brochure
☐ Protocol summary
☐ Ethical Considerations – description/statement of compliance with ethical principle
☐ Data Protection Plan
☐ Data Collection Forms/ Case report forms (CRFs)
☐ Research team list

☐ Curriculum vitae (CV) (all team members)
☐ valid GCP certificates (team) updated (3 years validity)
☐ Study budget
☐ Revised protocol
☐ Revised consent form
☐ Amendments
☐ Technical Review Approval
☐ Insurance certificate (if applicable)
☐ FDA approval (if applicable)
☐ Others (Please specify)

PROTOCOL SUMMARY SHEET (Form 2.1C)

CGHMC RERB Protocol No.			Sponsor Protocol No.
Date Submitted			
Title:			
Principal Investigator		Sponsor	
Study Site			
Rationale			
Objectives			
Study Design/ Methodology			
Inclusion Criteria			

Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	

REVIEWER'S PROTOCOL EVALUATION FORM (FORM 2.1D)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Date Submitted			
Protocol Title			
Principal Investigators:		Contact details:	
Department:			
Co-investigator(s):		Contact details:	
Study Site: (Name & Address)			
Overall/Total No. of Participants (onsite and off-site):	Total no. of onsite participants:	No. of Study sites (if applicable):	
Sponsor		Contact Person/ contact details:	
Clinical Research Organization		Contact Person/ contact details	

Duration of the Study (mos/years):		Status: ☐ New Protocol ☐ Amended Protocol (Pls state version number/date)
Reviewers:		
Type of the Study	☐ Intervention ☐ Observational study ☐ Document review ☐ Individual based	☐ Epidemiology ☐ Genetic ☐ Social Survey ☐ Others, specify
Review Status	☐ Full Board	☐ Expedited
Description of the study in brief: (Mark whatever applies to the study.)		
☐ Randomized	☐ Drug	☐ Use of Genetic materials
☐ Double blind	☐ Medical device	☐ Multicenter study
☐ Single blind	☐ Vaccine	☐ Global protocol
☐ Open label	☐ Diagnostics	☐ Sponsor initiated
☐ Observational	☐ Questionnaire/Survey	☐ Investigator Initiated

A. PROTOCOL DOCUMENT REVIEW (to be filled up by reviewer)

ASSESSMENT POINTS	YES	NO	N/A	REVIEWER COMMENTS
1. SCIENTIFIC DESIGN				
1.1 Objectives Review of viability of expected output				
1.2 Literature Review Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials				
1.3 Research Design Review of appropriateness of design in view of objectives				
1.4 Sampling Design Review of appropriateness of sampling methods and techniques				
1.5 Sample Size Review of computation of sample size				
1.6 Statistical Plan Review of appropriateness of statistical methods to be used and how participant data will be summarized				
1.7 Data Analysis Plan Review of appropriateness of statistical and non-statistical methods of data analysis				
1.8 Inclusion criteria				

Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection				
1.9 Exclusion criteria Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion				
1.10 Withdrawal criteria Review of criteria precision both for scientific merit and safety concerns				
2. CONDUCT OF THE STUDY				
2.1 Specimen handling Review of specimen storage, access, disposal, and terms of use				
2.2 PI qualifications Review of CV and relevant certifications to ascertain capability to manage study related risks				
2.3 Suitability of Site Review of adequacy of qualified staff and infrastructure				
2.4 Duration Review of length/extent of human participant involvement in the study				
3. ETHICAL CONSIDERATIONS				
3.1 Conflict of Interest Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site				
3.2 Privacy and confidentiality Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans				
3.3 Informed consent process Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances				
3.4 Vulnerability Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group				
3.5 Recruitment				

Review of manner of recruitment including appropriateness of identified recruiting parties				
3.6 Assent Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children: 0-under 7: No assent; 7-under 12; Verbal Assent 12-under15; Simplified Assent Form 15-under18; Co-sign informed consent form with parents				
3.7 Risks Review of level of risk and measures to mitigate these risks (including physical ,psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)				
3.8 Benefits Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant				
3.9 Incentives or compensation Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses				
3.10 Collaborative study terms of Reference Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproved
Comments (Identify items for revision)		

Reviewer's Name		Date	
Signature			

INFORMED CONSENT EVALUATION FORM (FORM 2.1E)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co- investigator/s:	

INFORMED CONSENT DOCUMENT REVIEW	YES	NO	N/A	REVIEWER COMMENTS
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
2. Are procedures for obtaining Informed Consent appropriate?				
3. Does the Informed Consent document contain comprehensive and relevant information?				
4. Is the information provided in the protocol consistent with those in the consent form?				
5. Is the expected duration of the study stated?				
6. Is the approximate number of participants stated?				
7. Are study related risks mentioned in the consent form?				
8. Is the language in the Informed Consent document understandable?				
9. Is the Informed Consent translated into the local language/dialect?				
10. Is there adequate protection of vulnerable participants?				
11. Are the different types of consent forms (assent, legally acceptable representative) appropriate for the types of study participants?				
Should assent be required? ☐ verbal assent (7 – 11 y/o) ☐ simplified assent (12 -14 y/o)				

☐ co-sign (15 – 17 y/o)				
12. Is there a description of any reasonably foreseeable risks or discomfort to the subject?				
13. Is there a description of any benefits to the subject or to others which may reasonably be expected from the research?				
14. Is there a disclosure of appropriate alternative procedures or courses of treatment, if any, might be advantageous to the subject?				
15. Are names and contact numbers from the research team and the RERB in the informed consent?				
16. Does the ICF mention privacy & confidentiality protection?				
17. Is there any inducement for participation?				
18. Is there provision for medical / psychosocial support?				
19. Is there provision for treatment of study-related injury?				
20. Is there provision for compensation?				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproved
Comments (Identify items for revision)		
Reviewer's Name		Date
Signature		

CHILD ASSENT FORM (FORM 2.2)

This sample is intended to assist researchers on introducing the required elements of an assent form in a way that is considered simple and easy for a child to understand.

Study Title:

Investigator:

Sponsor:

We are doing a research study about **(purpose in simple language)**. A research study is a way to learn more about people with a certain condition. We are therefore inviting you to participate in the study. If you decide that you want to be part of this study, you will be asked to **(study description, including estimate time involved in participating)**.

There are some things about this study you should know. These are **(procedures, things that take a long time, other risks, discomforts, etc)**.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to the participant. We think these benefits might be **(brief description on what is known)**.

If you do not want to be in this research study, we will tell you what other kinds of treatments that are currently available for you. **(This statement applies to research projects that offer treatment or intervention.)**

When we are finished with this study, we will write a report about what was learned. The report will not include your name or that you were involved in the study.

You do not have to be in this study if you do not want to. Your doctor will not be mad at you. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

You can ask anything about the study that is not clear to you. If everything is clear to you and you decide you want to be in this study, please write and sign your name below.

I, _____, want to be in this research study.

(Sign your name here)

(Date)

(Parts in Italics should be modified for your specific project. Other parts may need to be modified as well depending on your research methods. It is very important that the language be appropriate to the subject's level of understanding; if the subject population includes a wide range of ages, it may be necessary to use more than one form.)

REQUEST TO WAIVE WRITTEN AND VERBAL INFORMED CONSENT (Form 2.3)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co- investigator/s:	

I am requesting a waiver of written and verbal informed consent. I believe that this protocol is eligible for waiver or alteration of all required elements of informed consent because the protocol meets all of the following criteria:

1. The risk to the subject's privacy is minimal.

The investigator of this study will use the minimum amount of protected health information necessary to conduct the research. This study will only need charts of eligible subjects. There will be no sensitive information (e.g. illegal drug use, sexual practices) to be collected. There is an assurance written below that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.

2. This research cannot practicably be conducted without the use of the protected information.

3. This research cannot practicably be conducted without the waiver.

- a. The number of research subjects proposed.
- b. Difficulty of obtaining individual authorization and time since last contact with the research subjects.

RESEARCH ASSURANCES:

As a principal investigator of the research described above, I make the following assurance to the Institutional Ethics Review Board regarding the use and disclosure of protected health information.

"The investigators and research staff who used the disclosed protected health information in connection with this research will not reuse the protected health information or disclose to any other person or entity other than those authorized to receive it, except:

1. As required by law,
2. For authorized oversight of the research study, or
3. For other research which the use or disclosure of protected health information would be permitted by the Privacy Rule"

Principal Investigator

Date

NOTIFICATION OF RERB DECISION (FORM 2.4)

Date _____

To: (Name of PI) _____
Affiliation _____

This is to inform you of the RERB decision related to your application for review of the following documents:

CGHMC RERB Protocol No.		Sponsor Protocol No.	
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Type of Submission ☐ Initial review of Documents submitted
 ☐ Resubmission
 ☐ Amendment
 ☐ Others

Principal Investigator/s		Sponsor	
Study Site (Name and Address)			
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

Type of review ☐ Expedited	☐ Full Board Meeting
RERB Decision ☐ Approved	☐ Minor revisions required
☐ Major revisions required	☐ More information needed
☐ Others	

Actions required from PI:

- 1.
- 2.

RERB Chair Person	Name	Signature	Date
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APPROVAL LETTER (FORM 2.5)

Date _____

This is to certify that the following protocol and related documents have been granted approval by the CGHMC RERB for implementation

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Principal Investigator		Sponsor	
Study Site			
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			
Type of review	☐ Expedited ☐ Full board Meeting date: _____	Duration of Approval From _____ to _____	Frequency of continuing review
RERB Chair	Name	Signature	Date

Investigator Responsibilities after Approval:

9. Submit protocol amendment documents using CGHMC Form 3.1: Protocol Amendment Application Form for RERB approval before implementing them.
10. Submit revisions in the Informed Consent Form using CGHMC Form 3.1: Protocol Amendment Application Form.
11. Submit on-site SAE reports to the RERB using CGHMC Form 3.4: SAE report within 72 hours from the knowledge of the event and a complete report within 14 days. For off-site SUSARs, submit a cumulative notification to RERB quarterly (every 3 months)
12. Submit progress report/continuing review application every 12/6 months or as deemed necessary. Submit 60 days before the expiration of RERB approval. Use CGHMC Form 3.3 A and 3.3B: Continuing Review Application/Progress Report Form.

13. Submit final report using CGHMC Form 3.9: Final Report Form after completion of protocol procedures at the study site
14. Report protocol non-compliance/deviation/ violation using CGHMC Form 3.5: Non-compliance/violation/deviation Report Form.
15. Submit Notice of early termination of the study and reasons for such using CGHMC Form 3.8: Early Study Termination Form.
16. Comply with all relevant international and national guidelines and regulations.
17. Abide by the principles of good clinical practice and ethical research.

Received by:

Name and Signature: _____

Date Received: _____

REVIEW EXEMPTION APPLICATION FORM (FORM 2.6)

Date Submitted:		
CGHMC RERB Protocol No:		Sponsor Protocol No
Title:		
Principal Investigator		Sponsor
Brief Description of the Project (Please give a brief summary of the nature of the proposal. Including objectives, rationale, participants' description, and procedures/ methods to be used in the project. Please also fill up Research Protocol Application Form		
State reasons why exemption from review is requested? ☐ audits of educational practices ☐ research on microbes cultured in the laboratory ☐ research on immortalized cell lines ☐ research on cadavers or death certificates provided such research reveals no identifying personal data ☐ Analysis of data freely available in public domain ☐ Any other		
NAME OF PRINCIPAL INVESTIGATOR SIGN / DATE		

CHECKLIST FOR EXEMPTION FROM REVIEW (Form 2.7)

STUDY PROTOCOL INFORMATION

Protocol Code:	
Study Protocol Title:	
Principal Investigator:	
Contact details and email address:	
Study Site:	
Study Protocol Submission Date:	

INSTRUCTIONS

Please evaluate how the exemption criteria outlined below apply to the study protocol by confirming the submitted information and putting your comments in the space provided under “EVALUATOR’S COMMENTS.” Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and signing in space provided.

	To be filled out by Evaluator		
CRITERIA FOR EXEMPTION			REVIEWER COMMENTS
1. PROTOCOL ASSESSMENT	YES	NO	
1.1. Does this research involve human participants?			
1.2. Does this research involve use of non-identifiable human tissue/ biological samples?			
1.3. Does this research involve use of non-identifiable publicly available data? <i>*Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGRIHP 2022)</i>			
1.4. Does this research involve interaction with human participants?			
1.5. Type of research 1.5.1. Institutional quality assurance 1.5.2. Evaluation of public service program 1.5.3. Public health surveillance 1.5.4. Educational evaluation activities 1.5.5. Consumer acceptability test <i>*These 5 have been identified in the NEGRIHP 2022 as exemptible, as long as it does not involve more than minimal risk.</i>			
1.6. What is/are the method/s of data collection			

• Surveys and/or questionnaire, Interviews, or observations of public behavior • Audio/video recordings of public behavior • Research which only uses existing data			
1.7. Will the collected data be anonymized or de-identified?			
1.8. Is there a data protection plan? <i>Measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators)); Plan on processing personal data, storage of data, access, disposal, and terms of use (; Data Privacy Act of 2012)</i>			
1.9. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? <i>*Please refer to section 2. Risk Assessment, prior to answering this item</i> <i>*If YES, then this protocol does not qualify for exemption</i>			
2. RISK ASSESSMENT	YES	N/A	
Does this research involve the following (<i>please select all that apply</i>):			
Any vulnerable groups?			
Sensitive topics that may make participants feel uncomfortable (<i>i.e. sexual behavior, illegal activities, racial biases, etc.</i>)			
Use of drugs			
Invasive procedure (e.g. blood sampling) and specify			
Physical stress/distress, discomfort			
Psychological/mental stress/distress			
Deception of/or withholding information from subjects			
Access to data by individuals or organizations other than the investigators			
Conflict of interest issues			
Or any other ethical dilemmas			
Is there any blood sampling involved in the study?			
RECOMMENDED ACTION: ☐ QUALIFIED FOR EXEMPTION ☐ NOT QUALIFIED FOR EXEMPTION			
TYPE OF REVIEW			

☐ Expedited ☐ Full Board		
SUMMARY OF RECOMMENDATIONS: 1. 2. 3. 4. 5.		
JUSTIFICATION FOR RECOMMENDED ACTION		
EVALUATOR	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

CERTIFICATE OF EXEMPTION FROM REVIEW (FORM 2.8)

Date:

This is to certify that the following protocol and related documents have been reviewed and is hereby granted EXEMPTION FROM REVIEW by the Chinese General Hospital and Medical Center CGHMC RERB for implementation.

CGHMC RERB Protocol No:		Sponsor Protocol No.	
Title:			
Principal Investigator		Sponsor	
Study Site			
Protocol Version No		Version Date	
Other Documents			
RERB Chair	Signature	Date	

NOTE:

- Final/Closure Reports should be submitted at the end of the study.
- **Any amendment to the protocol that may affect safety of participants should be submitted to RERB for re-evaluation of exemption**

Received by:

Signature over printed name/ Date

RESUBMITTED STUDY PROTOCOL (Form 2.9)

RERB Protocol No.		Date of Submission
Protocol Title:		
Principal Investigator:		Contact No.
Study Site: (Name & Address)		
Date of Initial Submission: _____		
Initial Review Date:		Last Review Date:
Name and Signature of PI:		Date Submitted: (dd/mm/yyyy)

Recommendations from last review:	Revisions made by the PI	Reviewer's comments (To be filled up by primary reviewer)

To be filled by RERB

Recommendation ☐ Approved ☐ Minor revision ☐ Major revision ☐ Disapproved	Primary Reviewers: Signature _____ Date _____
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WITHDRAWAL OF PROTOCOL SUBMISSION APPLICATION (FORM 2.10)

Date Submitted:		
CGHMC RERB Protocol No:		Sponsor protocol No.
Title:		
Principal Investigator		Sponsor
Study Site: (Name & Address)		
Reason For Withdrawal of Protocol Submission		
Name and Signature of PI:	Date Submitted: (dd/mm/yyyy)	

To be filled by RERB

RECOMMENDED ACTION: ☐ No Further Action ☐ Request Information: (Specify) ☐ Recommend Further Action: (Specify)	Type of Review ☐ Full Board ☐ Expedited Meeting Date: _____
PRIMARY REVIEWER: _____ Signature over name Date	

RERB CHAIR:	_____	_____
	Signature over name	Date

PROTOCOL AMENDMENT REVIEW (FORM 3.1)

CGHMC RERB Protocol No.	Sponsor Protocol No	Date of Submission
PROTOCOL TITLE		
Principal Investigator		
Contact Number		
Study Site		
Name and Signature of PI	Date Submitted: (dd/mm/yyyy)	

List of Amendments	Reason for amendment	Reviewer's Comments <i>(To be filled up by primary reviewer)</i>

To be filled up by RERB

Type of Review
☐ Full Board ☐ Expedite

Date of Meeting: _____		
RERB Decision ☐ Uphold approval ☐ Need further Information ☐ Require specific action ☐ Disapproved	Name/Signature of Chair	Date

REMINDER LETTER FOR CONTINUING REVIEW (FORM 3.2)

Date

Principal Investigator

Affiliation

RE: PROTOCOL CODE/ PROTOCOL TITLE

Dear Dr. ,

We wish to remind you that the RERB approval for the study protocol <Study Protocol Title> with <RERB Code> will expire on <expiration date of approval >. Based on the records of the CGHMC RERB, there had been no communication regarding the progress of this study, which is still in our active file. If the study had been concluded or terminated, kindly fill out a final report form; or if still ongoing, a continuing review form.

Kindly submit the relevant report/form within thirty (30) days of receiving this letter. If no submission is received within the indicated grace period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the CGHMC RERB Secretariat at (02) 711-4141 local 418.

The CGHMC RERB looks forward to your immediate response and action.

Thank you.

Very truly yours,

<NAME OF CHAIR>

Chair, CGHMC RERB

PROGRESS REPORT (FORM 3.3A)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title	
Investigator:	Contact Details:
Study Site	Approval Date: (dd/mm/yyyy)
Annual Progress Report: (Please indicate inclusive period): Total number of screened subjects: Total number of randomized subjects: Total number of withdrawn patients: Total number of SAEs: Total number of lost to follow up: Total number of completed subjects:	
Summary of Amendments	
Summary of protocol deviations/ non-compliance	
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.	
Name and Signature of PI:	Date Submitted: (dd/mm/yyyy)

To be filled up by RERB

Date Received:	Received by: (Printed Name/Signature)	
Primary Reviewers/Signature:		Date
Recommendations		Type of review:

☐ Approved ☐ Request further information ☐ Suspend or terminate the study ☐ Others: _____		☐ Expedited review ☐ Full board review Date of meeting: _____
RERB Final Decision:		
Certified by: Name of CGHMC RERB Chair	Signature	Date

CONTINUING REVIEW APPLICATION FORM (FORM 3.3B)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title	
Investigator	Contact details
Study Site	Approval Date: (dd/mm/yyyy)
ACTION REQUESTED: ☐ Renew – New participant accrual to continue ☐ Renew – Enrolled participant follow up only ☐ Terminate – Protocol discontinued	
Any amendment since last review? ☐ Yes ☐ No (Discuss briefly)	
Any change in participant population recruitment or selection criteria since the last review? (Explain the changes if any) ☐ Yes ☐ No	
Any change in the Informed Consent process or documentation since the last review? (Please explain, if yes.) ☐ Yes ☐ No	

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.) ☐ Yes ☐ No
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.) ☐ Yes ☐ No
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal) ☐ Yes ☐ No
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.) ☐ Yes ☐ No
Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.
Summary of protocol participants: ☐ Reached the target number of participants approved by CGHMC RERB ☐ New participants recruited/enrolled since last review ☐ Total participants screened since protocol began ☐ Total participants enrolled and ongoing since the last review ☐ Total number of SAEs since the last review ☐ Total number of participants withdrawn or terminated
ACCRUAL EXCLUSIONS ☐ None ☐ Male ☐ Female ☐ Others (Specify) _____
Impaired participants ☐ None ☐ Physically ☐ Cognitively ☐ Both

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Name and Signature of PI	Date
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To be filled up by RERB

Date Received:	Received by: (Printed Name/Signature)	
Primary Reviewers/Signature:		Date:
Recommendations ☐ Approved ☐ Request amendment to the protocol or the consent form ☐ Request further information ☐ Suspend or terminate the study ☐ Others: _____		Type of review: ☐ Expedited review ☐ Full board review Date of meeting: _____
RERB Final Decision:		
Certified by: Name of CGHMC RERB Chair	Signature	Date

SERIOUS ADVERSE EVENT REPORT FORM (FORM 3.4)

Whenever there is any SAE event in any research approved by the CGHMC RERB, it has to be reported by the principal investigator (PI) to the RERB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator: (Name)			
CGHMC RERB Protocol No.		Sponsor Protocol No.	
Date Submitted		Signature	
Study Title:			
Study Site: (Name & Address)			
Name of the study medicine/device:		Report Date:	
		☐ Initial ☐ Follow-up	
		Onset Date:	
Sponsor:		Date of first use of drug/device:	
Title of the Report			
Subject's Number:		Age:	☐ Male ☐ Female
Subject's history:		Laboratory findings:	

SAE:	Treatment Outcome: ☐ Resolved ☐ On-going
Seriousness: ☐ Death ☐ Life Threatening Hospitalization: ☐ Short-stay ☐ Prolonged ☐ Disability/Incapacitated ☐ Congenital Anomaly ☐ Others	Relation to ☐ Drug ☐ Device Study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown
Name and Signature of PI	Date

Note: PI should attach standard SAE report form to this RERB form.

SECTION 2 (to be filled up by the designated SAE Subcommittee reviewer)

Document received by the RERB Secretariat	Signature	Date
Reviewer's Name/Signature:		Date: (dd/mm/yyyy)

Changes to the protocol recommended?	☐ Yes	☐ No
Comments:		
Changes to the informed consent form recommended?	☐ Yes	☐ No
Comments:		

RERB Final Action: ☐ Request an amendment to the protocol or the consent form. ☐ Request further information. ☐ Suspend or terminate the study ☐ Take note and no further action ☐ Others: _____	Type of review: ☐ Expedited review ☐ Full board review Date of meeting _____
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Name of RERB Reviewer:	Signature	Date (dd/mm/yyyy)
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DEVIATION / NON-COMPLIANCE / VIOLATION REPORT (FORM 3.5)

CGHMC RERB Protocol No.	Sponsor Protocol No.	Date of Submission: (dd/mm/yyyy)
Study Title:		
Investigator	Contact Detail/s:	
Study Site		
Sponsor		
Reported by:	Role in study:	
DESCRIPTION OF REPORTED DEVIATION/ VIOLATION (<i>Identify who committed the deviation and describe the reported deviation</i>): ☐ PATIENT ☐ INVESTIGATOR ☐ SPONSOR DETAILS:		
Nature of Protocol Deviation Report ☐ Major ☐ Minor		
Corrective Actions taken by PI/study team		
Preventive Actions taken by PI/ study team		
Does the protocol deviation have impact on the safety of participants? Yes or No? If yes, please specify.		

Does the protocol deviation have an impact on the integrity of data? Yes or No? If yes, please specify.	
Name and Signature of PI	Date

To be filled up by RERB

COMMENTS BY PRIMARY REVIEWER	
RECOMMENDED ACTION:	
☐ Acknowledged (No Further Action) ☐ Request Information: (Specify) ☐ Corrective Action required: (Specify) ☐ Site visit required Others: _____	Meeting Date:
PRIMARY REVIEWER: _____ Signature over name Date	
RERB CHAIR: _____ Signature over name Date	

REQUEST/QUERY RECORD (Form 3.6)

Date Received by CGHMC RERB: (dd/mm/yyyy)	Received by:
Request from: ☐ Telephone call number ☐ Fax number ☐ Mailed letter/ Date ☐ E-mail / Date ☐ Walk-in / Date / Time ☐ Others: specify:	
Requesting Party:	Relationship to Participant:
Participant's Name	
Contact Address:	
Title of the Study Participated	
Starting date of Participation	
What are requested?	
Action Taken:	
Outcome:	

SITE VISIT REPORT (FORM 3.7)

CGHMC RERB Protocol No.		Date of the Visit: (dd/mm/yyyy)	
Study Title:			
Principal Investigator:		Phone:	
Department:		Address:	
Study Site			
Sponsor:		Address:	
Total number of targeted subjects:		Total subjects enrolled:	
Are site facilities appropriate? ☐ Yes ☐ No		Comment:	
Are Informed Consent Forms Recent? ☐ Yes ☐ No		Comment:	
Any adverse events found? ☐ Yes ☐ No		Comment:	
Any protocol non-compliance/ violation? ☐ Yes ☐ No		Comment:	
Are all case record forms up to date? ☐ Yes ☐ No		Comment:	
Are storage of data and investigating products locked? ☐ Yes ☐ No		Comment:	

How well are participants protected? ☐ Good ☐ Fair ☐ Not good		Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No		Give details:
Other comments:		
Duration of visit: (hours)	Starting from:	Finished at:
Names of CGHMC RERB Site Visit Team		
Completed by:		Date:
RECOMMENDED ACTION: ☐ No Further Action ☐ Request Information: (Specify) ☐ Recommend Further Action: (Specify)		

STUDY TERMINATION (FORM 3.8)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title:	
Principal Investigator:	
Date of Submission	Contact No/ E-mail
Department:	Sponsor
Study Site	
RERB Approval Date:	Date of Last Progress Report:
No. of Participants Screened:	No. of Participants Enrolled:
Reason for Termination	
Summary of results	
Accrual Data:	
Plan for Follow-up for Enrolled participants	
P.I. Signature	Date

To be filled up by RERB

COMMENTS OF PRIMARY REVIEWER

RECOMMENDED ACTION:		Type of Review
☐ No Further Action		☐ Full Board
☐ Request Information: (Specify)		☐ Expedited
☐ Recommend Further Action: (Specify)		Meeting Date:
PRIMARY REVIEWER: _____		
	Signature over name	Date
RERB CHAIR: _____		
	Signature over name	Date

FINAL REPORT (FORM 3.9)

CGHMC RERB Protocol No.	Approval Date: (dd/mm/yyyy)
Protocol Title	
Principal Investigator	Contact Number
Study Site	
Total number of participants	Study Arms
Study materials ☐ Drug ☐ Device ☐ Biologic specimen ☐ Others	
Summary of Recruitment Accrual ceiling set by RERB New participants accrued since last review Total number of participants accrued since protocol began No. of participants who are lost to follow up No. of participants withdrawn from the study No. of participants who experienced SAEs/ SUSARs Number of participants who completed the study	
Duration of the Study	
Study objectives	
Summary of Findings in the Site	

Signature of Principal Investigator	Date Submitted
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To be filled up by RERB

Date Received:	Received by: (Printed Name/Signature)
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COMMENTS OF PRIMARY REVIEWER

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RECOMMENDED ACTION: ☐ Accepted ☐ Request additional Information: (Specify) ☐ Recommend Further Action: (Specify) ☐ Not accepted	Type of Review ☐ Full Board ☐ Expedited Meeting Date:
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PRIMARY REVIEWER: _____ Signature over name	_____ Date
RERB CHAIR: _____ Signature over name	_____ Date

**ACTION LETTER TO CONTINUING REVIEW APPLICATION / FINAL REPORT / STUDY PROTOCOL NON-COMPLIANCE REPORT / SAE REPORT / EARLY STUDY TERMINATION REPORT / SITE VISIT
(FORM 3.10)**

Date:

Principal Investigator
Affiliation

CGHMC RERB Protocol No: Sponsor Protocol No.
Protocol Title

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) acknowledged receipt of <Continuing Review Application/Final Report / Study Protocol Non-Compliance Report / SAE Report / Site Visit Report> dated <date of document>.

Upon review of < Continuing Review Application Form / Final Report Form / Study Protocol Non-Compliance Report Form / Serious Adverse Event Report Form / Site Visit Report Form > and <submitted document/s>, RERB action is

<REQUEST INFORMATION/RECOMMENDATION FOR FURTHER ACTION>.

Recommended revisions and/or clarifications are summarized below:

Should you have any questions or clarifications regarding the above-mentioned recommendations, please contact the undersigned through the CGHMC RERB Secretariat at (02) 711-4141 local 418.

The CGHMC RERB looks forward to your immediate response and action.

Very truly yours,

<NAME OF CHAIR>

Chair, Research Ethics Review Board
CGHMC

AGENDA OF THE MEETING (FORM 4.1)

NOTICE OF MEETING

To : CGHMC Research Ethics Review Board Members:

Date of Meeting:

Time of Meeting:

Venue of Meeting:

AGENDA:

1. CALL TO ORDER
2. DETERMINATION OF QUORUM
3. APPROVAL OF THE AGENDA
4. DISCLOSURE OF CONFLICT OF INTEREST
5. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING
6. BUSINESS ARISING FROM THE MINUTES OF THE PREVIOUS MEETING
7. PROTOCOL REVIEW
 - 7.1. New Protocols for review
 - 7.2. Resubmitted Protocols for Modifications
 - 7.3. Protocol for Clarificatory Interview
 - 7.4. Protocol Amendments
 - 7.5. Continuing Review/Progress Report
 - 7.6. Final Reports
 - 7.7. Protocol Deviations
 - 7.8. Early Study Termination
 - 7.9. Site Visit Reports
 - 7.10. SAE Reports
 - 1.11. Queries or Complaints
8. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR

9. REPORT ON EXEMPTED PROTOCOLS

10. OTHER MATTERS

11. ADJOURNMENT

Prepared by:

(Name of CGHMC RERB Member-Secretary)

Approved by:

(Chair, CGHMC Research Ethics Review Board)

MINUTES OF THE MEETING (FORM 4.2)

(Date)

(Venue)

(Time)

1. ATTENDANCE

Present:

Absent:

2. CALL TO ORDER

3. DETERMINATION OF QUORUM

4. DISCLOSURE OF CONFLICT OF INTEREST (COI)

5. READING AND APPROVAL OF THE AGENDA

6. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING

7. BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING

8. STUDY PROTOCOL REVIEW

8.1. New Protocols for Initial Review

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary reviewers	
Technical Review	
Sponsor/ CRO	
Quorum Status	
Conflict of interest	

Assessment of Ethical Issues

Privacy and Confidentiality of data	
Protection Plan	

Vulnerability	
Risks	
Benefits	
ICF process and recruitment	
ICF including translation	

Recommendations

Decision

Approval/ expiration date

Frequency of continuing review (in case of approval)

8.2 RESUBMITTED **PROTOCOLS FOR MODIFICATIONS**

8.2.1.

Protocol code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Quorum status	
Conflict of interest	
Assessment of PI response to initial review	
Recommendations	
Decision	
Approval expiration date	
Frequency of continuing review (in case of approval)	
Protocol Code	

7.3 **PROTOCOL AMENDMENTS**

7.3.1.

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	

Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	
Recommendations	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.4 PROGRESS REPORT/CONTINUING REVIEW

7.4.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of progress reported	
Recommendations	
Decision	(Approved, Major Modification, Minor Modification, Disapproved)

8.5 FINAL REPORT

7.5.1.

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	

Assessment of final report	
Recommendations	
Decision	

8.6 PROTOCOL DEVIATIONS

7.6.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of deviation report	
Recommendations	
Decision	

8.7. EARLY STUDY TERMINATION

7.7.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of risks from early termination	
Recommendations	
Decision	

7.8. SITE VISIT REPORTS

7.8.1.

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of Site Visit report	
Recommendations	
Decision	(Uphold original approval with no further action, Request information, Recommend further action)

8.9. SAE/AE Reports

7.9.1.

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of SAEs reported	
SAE	
Submission Date	
Date of SAE	
Date of randomization	
Age	
Sex	
Country	
Nature of AE	
Co-morbidities	

Status	
Recommendations	
Decision	

8.10. QUERIES OR COMPLAINTS

7.10.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of query or complaint	
Recommendations	
Decision	

APPENDICES

9. REPORT OF RESULTS OF EXPEDITED REVIEW

8.1. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.2. PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	

Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.3. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Date of Amendment Submission	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

10. REPORT ON EXEMPTED PROTOCOLS

9. OTHER MATTERS

10. ADJOURNMENT

Prepared by:

Approved by:

Signature over Name
CGHMC RERB SECRETARIAT
Date:

Signature over Name
CGHMC RERB Chair
Date:

CONFIDENTIALITY AGREEMENT FORM FOR GUEST ATTENDEES TO RERB MEETINGS (FORM 4.3)

I, _____, understand that I am allowed to attend the RERB meeting as a guest or an observer. In the course of this meeting, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take the necessary measures to keep the information as confidential, and to be held responsible if any leak occurred within the sphere of my discretion.

Indicate the details (date and number) of the RERB Meeting(s) attended:

.....
.....
.....

Signature of the Guest or Observer

Date:

**CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING TO ACCESS CGHMC RERB
DOCUMENTS (FORM 4.4)**

I, (Name, Surname) as a non-member of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) , understand that the documents I am given access to by the CGHMC RERB are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the CGHMC Research Ethics Review Board. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT	Signature _____
Date: <dd/mm/yyyy>	Name <Title, Name, Surname>
RERB MEMBER - SECRETARY	Signature _____
Date: <dd/mm/yyyy>	Name <Title, Name, Surname>

**PROTOCOL TRACKING FORM
(FORM 4.5)**

Protocol No.	Department
Protocol Title:	
Principal Investigator	Contact No.

Date	Particulars	IN		OUT	REMARKS	Received by INITIAL
		FA	FYI			

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Legend: FA – For approval
FYI – For information

CASE REPORT REVIEW APPLICATION FORM (FORM 5.1A)

REPORT TITLE	
AUTHOR/S	
DEPARTMENT	
TELEPHONE	
EMAIL	

BRIEF DESCRIPTION OF THE PROPOSED REPORT:
WHERE DO YOU INTEND TO PUBLISH/PRESENT (if applicable) ?

Proposed Commencement Date:			
How many cases are to be included in this report?			
Will consent be obtained from the patients and/or their families?	☐ Yes	☐ No	
<i>Consent is for the review of patients record(s), use of images and permission to publish</i>			
If YES, ensure that the attached consent form is completed for each patient. If NO, please provide a rationale for not obtaining consent.			

Please select all options applicable to your Case Report
☐ Medical Records Review

☐ Imaging File Review ☐ Local Departmental Records

Name of Investigator	-----
Signature:	----- Date: -----

CONSENT FORM FOR CASE REPORTS (5.1B)

Case Report Title:

Principal Investigator:

You are being asked to consider allowing Dr. _____ to use information about your _____ to write what is called a case report. Your information being used for this case report includes relevant to this case - history, laboratory findings, photographs and prescribed treatment protocols. A case report may be published in a medical journal (in print and/or via on line) for others to read, and/or presented at a conference. This form explains the purpose of this case report. Please take time to read the following information carefully and ask any questions that you might have.

The purpose of this case report is to inform other physicians that _____.

Your privacy will be protected and your personal information (information about you and your health that identifies you as an individual e.g. name, date of birth, medical record number) will not be disclosed. The information collected will be stored securely and will only be accessible to the named investigators. When the case report is published or presented, your identity will not be disclosed.

Although your personal information collected or obtained will be kept confidential and protected to the fullest extent of the law, there is a limited risk associated with this case report that could result in a loss of confidentiality by virtue of your unique experience.

You will not directly benefit from participating in this case report. The information that can be shared with other health care professionals, however, may improve the care that is received by others in the future.

Allowing your information to be used in this case report will not involve any additional costs to you. You will not receive any compensation.

Your participation is entirely voluntary, and you may withdraw permission to participate in this case report at any time. However, once the case report is written and published, it will not be possible for

you to withdraw it. Your decision will not result in any penalty or loss of benefits to which you are entitled including the quality of care you receive.

Your signature below means that you have read the above information about this form and have had a chance to ask questions to help you understand how your information will be used and that you give permission to allow your information to be used in this case report.

If you have any questions please contact _____ at _____.

SUBJECT CONSENT TO PARTICIPATE (FORM 5.1C)

Case Report Title:

Name of Participant: _____

Participant/Legally Authorized Representative

By signing this form, I confirm that:

- The case report has been fully explained to me and all of my questions have been answered to my satisfaction
- I have been informed of the risks and benefits, if any, of allowing my information to be used in this case report
- I have been informed that I do not have to participate in this case report
- I have read each page of this form
- I authorize access to my personal health information (medical record) as explained in this form
- I have agreed to participate in this case report

_____ Name of Participant/Legally Authorized Representative (print)	_____ Signature	_____ Date
---	--------------------	---------------

_____ Name of Person Obtaining Consent (print)	_____ Signature	_____ Date
--	--------------------	---------------

PATIENT INFORMATION SHEET AND ICF (ENGLISH TEMPLATE) (FORM 5.2A)

PATIENT INFORMATION AND INFORMED CONSENT FORM

TITLE OF STUDY : _____
SPONSOR : _____(if applicable)_____
NAME OF PRINCIPAL INVESTIGATOR: _____

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE RERB FOR REVIEW.

This template serves as a guide and may be modified according to your research requirements. This document is for a prospective participant who may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. Use a language that is simple and understandable. Use at least a 12pt font for the entire document.

1. Introduction

Briefly state that you are inviting them to participate in the research you are doing.

I am doing a study about (Describe what the study is about). I would like to invite you to join this study because you (Explain why they are being considered/chosen to participate in the study).

Before you can take part in this study, it is important that you understand what the study involves. Please take time to read the following information carefully and ask any questions that you might have.

2. Purpose of the Study

Explain why you are doing the research in lay terms. The language used must clarify rather than confuse. Do not use technical terms. If you must, then provide an explanation of the technical term in a simple language can be easily comprehended. Use local and simplified terms.

The purpose of this study is to _____.

3. Approximate Number of Participants and the Expected Duration of Your Participation in the Study

The study will take place at Chinese General Hospital and Medical Center (if outside state the place). About (write in numbers not in words) or more participants will be enrolled to participate in the study. Participants must meet all the qualifications to be included. If you are enrolled, the duration of your participation is (Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.).

4. Procedures (Type of Research Intervention)

Briefly state the type of intervention/ procedure that will be undertaken. (e.g. research involves interview, a questionnaire or collection of data/ medical records) Describe research procedures step by step in the simplest way understandable to a lay person. Avoid using scientific/medical terms. If not possible, define or describe such terms so that the participant may understand. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. Do not copy paste study maneuver of the protocol.

During your stay some information collected about you in the course of standard care provided to you by the medical staff may be used for this study. This information includes your medical history, laboratory tests, medications and other chart information. You will be asked to answer a set of questions that would inquire on your medical condition which would last approximately __ mins. Data /information collected is primarily for research purposes. (for observational studies).

Also include follow-up intervals (if relevant)

You will be asked to fill out a survey/ questionnaire which will be provided by your study doctor. This will approximately last for ____ mins. You may answer it by yourself or it can be read to you (if applicable)

(for questionnaire/surveys)

5. Benefits

Describe the benefits the PARTICIPANT may gain by joining the study and not those to which they are entitled regardless of participation. You may include benefits to the individual, benefits to the community in which the individual lives, and benefits to society as a whole as a result of finding an answer to the research question. If there is no direct benefit, you may say so, but there should at least be a benefit to the society.

There will be no additional direct medical benefit to you from taking part in this study. However, with your participation, you will be able to contribute to a better knowledge in the management of _____ in the Philippines. (or the information learned from this study can be used in the future to benefit other people with _____.)

6. Risk

Describe the risk/s or discomfort the study may bring to the participant, what will be done to minimize it. Provide enough information about the risks so that the participant can make an informed decision.

This study is only observational and does not involve drugs, laboratory, medical or surgical procedures outside of the treatment that you are receiving from your attending physician. As such, there will be no additional direct risk to you from your participation much as the same way if you do not participate. for observational studies

7. Compensation If there is no compensation, the standard line is

You will not be paid for joining this study.

8. Voluntary Participation / Withdrawal from the Study

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you choose not to participate in this study, you are free to refuse and it will not interfere with your future care. If you join the study and change your mind later, you may withdraw from the study at anytime in the future by informing the study doctor, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

9. Permission for Review of Records, Confidentiality and Access to Records

Your study doctor will collect information. This information, called data, will be entered without your name, on a data collection form. In all of these data collection forms, a code will replace your name. All the data collected will be kept confidential and will be used only as permitted by this consent form or as required by law.

10. Questions/Information

- If you or your representative(s) have any questions regarding the study (or in case of study related injuries, if study involves any form of intervention or procedures), you should contact your study doctor: Study Doctor's name in BOLD letters , Phone number: _____

- If you or your representative(s) have any questions/ concerns regarding your rights as a research subject, you should contact **Dr. Bernice T. Ong-Dela Cruz**, Chair of the Research Ethics Review Board (RERB) of Chinese General Hospital and Medical Center, Manila, Philippines, Tel: 711-4141 loc. 418.

11. Consent Signatures

Please remove "side effects" and "research medication" if there is no research medication to be given as part of the study.

Please read this section carefully and if in agreement please sign and date at the bottom of the page.

- I have had sufficient time to consider the information provided and to ask for advice if necessary
- I have had the opportunity to ask questions and have received satisfactory responses to my questions.
- I have been provided the details of the known or foreseeable side effects and risks of the research medication and study procedures that I may receive.
- I understand that I am free to accept or refuse my participation at any time without giving a reason. My decision to accept or refuse my participation will have no effect on my continuing treatment. I understand that I am free to discontinue my participation at any time without giving a reason. My decision to discontinue my participation will have no effect on my continuing treatment. I will keep all my rights to treatment and alternative therapy.
- I agree that the data collected for the study will be used for the purpose described above.
- I understand that I'm not waiving any of my legal rights as a result of signing this consent form.
- I have read and understood this patient information and Informed Consent Form and that I freely give my consent to participate in this study.
- I will receive a signed and dated copy of this Informed Consent Form.

12) I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY

Sign and date at the same time, all party:

Printed Name of Participant _____

Date (to be entered by participant) _____

Signature _____

Printed Name of Study Personnel _____

Obtaining Consent _____

Date _____

Signature _____

Distribution: original for study doctor, copy to _____ (name of participant)

For emergency situations where consent of the participant cannot be obtained the following signature line must be signed:

Printed Name of Participant's Legally Authorized Representative

Date (to be entered by participant's Legally Authorized Representative)

Signature

Relationship to Participant

If the participant's legally authorized representative cannot read, the following signature line should be signed:

Printed Name of Witness

Date (to be entered by the witness)

Signature

At any given time an incapacitated adult (e.g. intubated patients, unconscious patients, or patients in emergency situations, or patients with impairment in decision making) may explicitly refuse to participate in or request to be withdrawn from the study. The Investigator must respect the request. Wherever possible, the patient will be informed as soon as possible and his/her consent will be requested for the continuation of participation to the study.

PATIENT INFORMATION SHEET AND ICF (TAGALOG TEMPLATE) (FORM 5.2B)

PAMAGAT NG PAG-AARAL : _____
SPONSOR : _____(if applicable)_____
PANGALAN NG DOKTOR NG PANANALIKSIK : _____

TALAAN AT PAHINTULOT PARA SA MGA KALAHOK (PASYENTE)

1. Pakikilahok

Ako ay gumagawa ng pag-aaral tungkol sa _____ Iniimbitahan/ inaanyayahan kayo na sumali sa pag-aaral na ito dahil ikaw ay _____.

Bago ka makilahok sa pag-aaral na ito, mahalagang mabasa at maintindhan mo kung ano ang nakapaloob sa pag-aaral na ito. Isinasaad sa kasulatang ito ang lahat ng impormasyong malalaman ninyo tungkol sa pag-aaral. Mangyaring basahin nang mabuti ang impormasyon at magtanong ka ng anumang nais mong itanong.

2. Layunin ng Pag-aaral

Ang layunin ng pag-aaral na ito ay _____

3. Humigit-Kumulang na Bilang ng mga Kalahok at Inaasahang Tagal ng Iyong Pakikilahok sa Pag-aaral

Ang pag-aaral ay isasagawa sa Chinese General Hospital and Medical Center. Humigit kumulang _____ ang isasali sa pag-aaral. Para makasali, dapat matugunan ng kalahok ang lahat ng kwalipikasyon. Kapag ikaw ay napabilang sa mga kalahok, ang iyong pagsali ay inaasahang tatagal ng _____.

4. Mga Pamamaraan ng Pag-aaral

Ang inyong doctor ng pananaliksik ay mangongolekta ng impormasyon sa pamamagitan ng pakikipanayam at/o pagsusuri ng medical tsart ng inyong personal datos, medical na kasaysayan, ang mga gamot na binibigay sa inyo at ang pamamaraan ng pag-aalalaga sa inyo. (if applicable)

Ang pagsusuri ng inyong kalusugan ay susubaybayan pagkatapos ng 1 buwan, 3 buwan, 6 na buwan, at 1 taon ng "research doctor:" o "research assistant" sa pamamagitan ng anumang sumusunod na pamamaraan: pakikipanayam sa telepono, sulat o koreo, o personal na pagbisita sa inyong paninirahan o sa ospital sakaling kayo ay madala sa hospital. (as applicable)

5. Mga Benepisyo

Walang direktang benepisyo kayong makukuha sa paglahok sa pag-aaral na ito, ngunit ang inyong paglahok ay maaaring magbigay ng mas sapat na kaalaman sa pag-gagamot ng _____ sa ating bansa.

6. Mga Panganib

Ang pag-aaral na ito ay isang obserbasyon lamang na pag-aaral. Ang pananaliksik na ito ay walang kasangkot na karagdagang gamot, laboratoryo, o operasyon na bukod sa tamang pangangalaga na ibinigay ng inyong “attending physician” sa kondisyon ninyo. Walang karagdagang direktong panganib na maidudulot sa inyo ng paglahok sa pag-aaral na ito na higit sa maaaring maransan ng mga hindi lumahok.

7. Kabayaran

Kayo ay hindi babayaran sa pagsali sa pag-aaral na ito.

8. Kusang-loob na Pakikilahok / Pag-alis mula sa Pag-aaral

Kusang-loob ang pakikilahok mo sa pag-aaral na ito. Nasa iyo ang desisyon kung makikilahok ka o hindi. Kung ayaw mong lumahok sa pag-aaral, ikaw ay maaring tumanggi at hindi nito maapektuhan ang pangangalaga sa iyo. Kung sumali ka sa pag-aaral at nagbago ang isip mo, maari kang umalis sa pag-aaral sa pamamagitan ng pagsasabi sa doktor ng pag-aaral at hindi nito maapektuhan ang pangangalaga sa kalusugan mo.

9. Permisong Pagrepaso ng mga Talaan, Paglilihim at Pagkuha sa mga Talaan

Kukuha ang inyong doktor ng pag-aaral ng mga impormasyon. Ang impormasyong ito na tinatawag na datos ay ipapasok sa isang data collection form nang wala ang iyong pangalan. Papalitan ng code ang inyong pangalan sa lahat ng mga data collection forms. Lahat ng mga datos na nakolekta ay papanatiliing lihim at gagamitin lamang hanggang sa ipinahihintulot ng kasulatang ito.

10. Mga Katanungan/Impormasyon

- Kung ikaw o ang iyong kinatawan/mga kinatawan ay mayroong anumang katanungan tungkol sa pag-aaral, ang iyong kakausapin ay si Study Doctor’s name in BOLD letters, phone number:

-
- Kung ikaw o ang iyong kinatawan/mga kinatawan ay may katanungan tungkol sa iyong mga karapatan bilang pasyente kaugnay sa pag-aaral, ang iyong kakausapin ay si **Dr. Bernice Ong-Dela Cruz**, Chair ng Research Ethics Review Board ng Chinese General Hospital and Medical Center, Manila Tel: 711-4141 loc. 418.

11. Mga Pirma ng Pagsang-ayon

Basahin nang mabuti ang bahaging ito at kung sumasang-ayon ka ay mangyaring pirmahan at isulat ang petsa sa huling bahagi ng kasulatang ito.

- Ibinigay sa akin ang mga detalye ng mga maaaring di mabuting epekto at mga panganib ng gamot ng pananaliksik at mga pamamaraan ng pag-aaral na maaari kong matanggap.
- Nauunawaan ko na kusang-loob ang aking pagsang-ayon o pagtanggì sa pakikilahok sa anumang oras nang walang ibinigay na kadahilanan. Ang desisyon ko sa pagsang-ayon o pagtanggì sa pakikilahok ay walang epekto sa patuloy na paggagamot sa akin. Nauunawaan ko na may karapatan akong ihinto ang aking pakikilahok anumang oras nang walang ibinigay na kadahilanan. Ang desisyon kong huminto sa aking pakikilahok ay walang magiging epekto sa patuloy kong paggagamot. Mananatili ang aking mga karapatan sa ibang paggagamot at mapagpipiliang paggagamot.

- Sumasang-ayon ako na ang mga impormasyon na makukuha para sa pag-aaral na ito ay gagamitin para sa layunin na inilarawan sa itaas.
- Hindi mawawala ang anumang karapatan na mayroon ako sa ilalim ng batas sa pagpirma ko sa form na ito.
- Nabasa ko at nauunawaan ang impormasyong iniharap sa Ipinaalam na Kasulatan ng Pahintulot na ito. Binigyan ako ng pagkakataon na makapagtanong tungkol dito at pawang nasagot lahat ang aking mga katanungan.
- Ako ay makakatanggap ng kopya ng pirmado at may petsa na Informed Consent Form/Pahintulot.

12. KUSANG-LOOB NA TINATANGGAP KO ANG PAKIKILAHOK SA PAG-AARAL NA ITO

Pirmahan ng sabay-sabay, (halimbawa parehong petsa), nang lahat ng kalahok.

Isinatitik na Pangalan ng Kalahok/ Pasyente	_____
Petsa (Isusulat ng Kalahok)	_____
Lagda	_____
 Isinatitik na Pangalan ng Kawani ng Pag-aaral na humihingi ng Pahintulot	_____
Petsa	_____
Lagda	_____

Pamamahagi: ang orihinal para sa doktor ng pag-aaral, kopya para sa (Kalahok/ Pasyente)

Para sa mga pangyayaring pangmadalian ('emergency'), kapag di makuha ang pahintulot ng kalahok na pasyente ay nararapat idagdag ang sumusunod na linya ng pirma

Isinatitik na Pangalan ng Legal na Kinatawan ng Kalahok/ Pasyente	_____
Kaugnayan sa Pasyente	_____
 Petsa (Isusulat ng Legal na Kinatawan)	_____
Lagda	_____

Kapag ang legal na kinatawan ng kalahok/pasyente ay hindi nakakabasa, nararapat idagdag ang sumusunod na linya ng pirma:

Isinatitik na Pangalan ng Saksi	_____
 Petsa (Isusulat ng Saksi)	_____
Lagda	_____

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	2025 UPDATED BUSINESS SYSTEMS AND PROCEDURES CGHMC RESEARCH ETHICS REVIEW BOARD (RERB)	



Chinese General Hospital and Medical Center
Department of Medical Education and Research



2025 UPDATED BUSINESS SYSTEMS AND PROCEDURES
CGHMC RESEARCH ETHICS REVIEW BOARD (RERB)

1. OBJECTIVE

1.1. to standardize the procedure by which funds are collected and disbursed by the Research Ethics Review Board (RERB), formerly named Institutional Review Board (IRB) - a Committee under the Department of Medical Education and Research

1.2. to monitor the funds and expenses of the RERB

2. SCOPE

This policy covers the collection, recording, safekeeping, and disbursement of funds to and from the RERB

3. POLICY

3.1 Fees/Payments

All checks and cash payments received by the RERB paid to the account of Chinese General Hospital and Medical Center must be handed over to Accounting Department and deposited to the hospital's bank account within five (5) working days from receipt of the payments. The payments include, but not limited to, the following:

3.1.1. **Institutional Fees** – comprises 10% of the total study budget of the clinical trial to be conducted in the Hospital, considering the **number of committed subjects** by the principal investigator. The institutional fee is **non-refundable** and needs to be settled within 2 weeks from site initiation visit (SIV), before 1st patient enrolment. Should the site be able to screen and randomize more than the committed number of subjects, then additional institutional fees based on the remaining patients screened and randomized will be computed and the sponsor/clinical research organization (CRO) needs to settle this fee within 30 days after the last patient enrolled and randomized. A corresponding collection receipt will be issued to either the sponsor, clinical research organization, or principal investigator whichever is applicable pursuant to the clinical trial agreement.

10% of the Institutional fees paid by independent sponsors will be retained by the hospital and 90% of the same will be used and set apart to be deposited separately in the RERB Account/fund

3.1.2. **Legal fees** – should be settled by the sponsor or clinical research organization separately to the legal counsel of the Hospital at least two (2) weeks **before** the review of the clinical study agreement (CSA).

3.1.3. **Amendment fees** – corresponds to appropriate fees to be settled with the Ethics Review Board and/or legal counsel (as necessary) for any substantial amendments to any clinical trial agreement and/or clinical trial protocol that will affect the conduct of the trial in the institution. Fees have to be settled **before** the review of the amendment.

DR. NESTOR GARCIA
ASST TO THE MEDICAL DIRECTOR
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Chinese General Hospital and Medical Center
Department of Medical Education and Research



3.1.4. **Continuing review fees** – yearly renewal fees of an ongoing clinical trial should be settled with the Ethics Review Board at least 30 days before the expiry of the ERB's approval. All study related activities should be kept on hold once the ERB approval has expired, without an updated new approval issued to the study.

3.1.5. **Protocol Review fee** – a one-time fee to be settled with the Ethics Review Board once the protocol is submitted and accepted by the Secretariat for ethics board review. This fee should be settled 2 weeks before the scheduled review of the protocol.

3.1.6. **Room rental fees** – rental period starts once site initiation visit (SIV) has commenced, on or before 1st patient enrolment. All clinical trialists shall utilize a room space for purpose of conducting clinical trial. To defray the costs of using the facility, electricity, drug storage, and wireless internet connection, a monthly room rental fee and costs of utilities will need to be settled for each trial. Fees are dependent on the size of room to be confirmed with ERB admin officer on the available slot. In cases where one industry is conducting simultaneous trials with same principal investigator, a separate study room should be utilized, with separate study budget including all institutions and ethics board fees submitted and settled. Statements of accounts for different fees will be issued quarterly by the Accounting and submitted to the Research Coordinator of the Principal Investigator for proper action.

3.1.7. **Specimen storage fees** – fees to be billed by the Hospital thru Institute of Pathology for any specimen that will need storage based on the requirement of the protocol and availability of the specified storage space or regulated temperature of the freezer or laboratory refrigerator

3.1.8. **Laboratory/Imaging fees** – fees on all local diagnostic tests/procedures required in the protocol that are available in the study site/institution will be billed accordingly by the Department/Unit/Center involved and sponsor has to settle with the Hospital.

3.1.9. **Advanced Payment to the Hospital** – amount equivalent to procedural and non-procedural costs incurred on one patient randomized and completed the study **will be imposed**. A further statement will be issued to the sponsor requesting for additional payment if $\leq 20\%$ remaining funds is left in the Accounting.

*All clinical trial related fees will be handled and followed up by the Finance Department including computation of withholding taxes (as applicable to CTA). The sponsor and/or CRA will need to closely coordinate all payments and details with personnel-in-charge in the Finance Department. Ethics Review Board admin officer and research coordinators of each trial shall be given soft and/or hard copies of all fees settled for proper tracking. No approval or re-approval to conduct clinical trial will be given unless all necessary and applicable fees have been settled by the sponsor or CRO as stipulated on Section 3.1. Continuing monthly rental fees will be imposed if trial documents remain in the site after final close out activities are completed.

3.2. Use of Research Unit

50% of fees paid by independent sponsors for the monthly use of research unit will be retained by the hospital while the remaining 50% will be set apart to be deposited in the RERB account/fund.

DR. NESTOR GARCIA
ASST TO THE MEDICAL DIRECTOR
OFFICE OF THE MEDICAL DIRECTOR

112



Chinese General Hospital and Medical Center
Department of Medical Education and Research



3.3. All RERB funds collected will solely be intended for research and its related programs and activities, subject to approval by the Chairman of the Department of Medical Education and Research (DMER).

3.4. Expenses incurred by the DMER for functions and purposes of all its other Committees will be supported fully by the hospital.

3.5. RERB shall maintain books of accounts to which receipts and disbursements will be recorded.

3.6. RERB shall hire an independent bookkeeper for the above purpose. Retainer's fees of the bookkeeper will be paid through the RERB funds.

3.7. Bookkeeper shall submit reports on the 5th of every month to the Chairman of DMER. The monthly reports shall itemize the receipts and disbursements of the preceding month. Any inconsistencies and related concerns on the report should be raised within ten (10) working days upon receipt of report. Should there be no queries within the time period, the report shall be considered correct and valid.

3.8. The Admin Officer of the RERB is responsible for ensuring that all expenses are properly recorded and approved by authorized parties.

3.10. The RERB, through the authorized parties, shall submit a yearly financial statement to the Medical Director or Hospital Committee or its authorized designate, on or before the end of January the following year.

3.11. Internal Audit Department of the Hospital may conduct a review/audit of the RERB books and/or journals at any time.

4. RESPONSIBLE PARTIES

4.1. RERB Administrative Officer

- Accepts and keeps records of all forms of payments to RERB fund
- Follows up all official/collection receipts from accounting to be given to the sponsors
- Ensures that the Hospital will be given BIR Form 2307 by the sponsor upon turnover of official/collection receipts

4.2. DMER Chair, Medical Director, and/or the Hospital's official designate

- Jointly check all requests for check payments and cash advance and all related expenses
- DMER Chair and/or Assistant Chair review monthly financial reports to ensure that all receipts and disbursements are recorded properly
- Any two (2) of the three (3) will be the assigned signatories for the RERB checkbook

4.3. Disbursement Section Staff or Disbursement Supervisor

DR. NESTOR GARCIA
ASST TO THE MEDICAL DIRECTOR
OFFICE OF THE MEDICAL DIRECTOR

3



Chinese General Hospital and Medical Center
Department of Medical Education and Research



- Prepares all check payments to RERB within three (3) banking days after checks are cleared

4.4. RERB Bookkeeper

- Records receipts and expenses in the RERB books of accounts
- Prepares financial reports/statements of the RERB

4.5. Check Release Staff

- Releases the checks to RERB Secretariat

4.6. Credit and collection staff/supervisor

- Monitors fees, charges, payment and cwt
- Receives new MOA.

5. DETAILED PROCEDURES

5.1 Clinical Trial/Study Agreement (CTA/CSA)

5.1.1 CTA/CSA shall include all fees for payment in advance.

5.1.2 Copy of CTA/CSA will be forwarded to credit and collection for monitoring.

5.1.3 Study shall commence upon receipt of advance payment

5.2. Receipt of Checks from Sponsors

5.2.1. The RERB, through the Chairman of DMER or official designate, shall turnover to Vice-President for Finance all check payments received from the sponsor within five (5) banking days upon receipt of payment.

5.2.2. Vice-President for Finance endorses the check to the Head Cashier for issuance of collection/official receipt to be deposited to the hospital's bank account.

5.2.3. Vice-President for Finance instructs Disbursement Staff or Supervisor to prepare a check for the corresponding collection (based on Sec 4.3) payable to CGHMC-RERB bank account three (3) banking days after clearing.

5.2.4. The Admin Officer of RERB shall photocopy the collection/official receipt for filing before forwarding the original collection/official receipt to the sponsor.

5.2.5. RERB bookkeeper shall record the collected amount to the RERB book of accounts.

5.3. Disbursement from the RERB Fund

5.3.1. The Chairman of DMER shall oversee preparation of all checks and supporting documents for disbursement of expenses.

5.3.2. The RERB Admin Officer shall forward all documents to the Chairman of DMER or his official designate for checking.

DR. NESTOR GARCIA
ASST TO THE MEDICAL DIRECTOR
OFFICE OF THE MEDICAL DIRECTOR

4



Chinese General Hospital and Medical Center
Department of Medical Education and Research



- Prepares all check payments to RERB within three (3) banking days after checks are cleared

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5.3.1. The Chairman of DMER shall oversee preparation of all checks and supporting documents for disbursement of expenses.

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 4

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval:
	Feedback Form	Effective Date:

Please rate your feedback on CGHMC Research Ethics Review Board (RERB) on the following parameters
(1 - Very Dissatisfied 2 - Dissatisfied 3 - satisfied 4 - Very Satisfied)

- **Clarity of Feedback/ recommendation of RERB**

- Was the REC's feedback clear, specific, and easy to understand?

1 2 3 4

- **Responsiveness of REC:**

- Was the REC responsive to your questions and concerns?

1 2 3 4

- **Effectiveness of the Review Process:**

- Was the REC review process efficient and helpful?

1 2 3 4

- **Suggestions for Improvement:**

- Do you have any suggestions for improving the REC's review process?

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: Effective Date:
	CGHMC RERB Members Self-evaluation Form	

Rating Scale (1-5, with 5 being excellent)

1. To what extent do you understand the ethical principles that guide research involving human participants?

1 2 3 4 5

3. How effectively do you review protocols and provide constructive feedback to researchers?

1 2 3 4 5

3. How well do you adhere to deadlines for protocol review and other tasks?

1 2 3 4 5

4. How effectively do you communicate with other board members and researchers?

1 2 3 4 5

5. How would you rate your overall contribution to research ethics review board's work?

1 2 3 4 5

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	Statement of Functional Independence of CGHMC RERB	

NOTICE

Re: **Functional Independence** of the CGHMC Research Ethics Review Board (RERB)

The Research Ethics Review Board (RERB) is established as an independent body established in 2011 mandated to review, evaluate, and provide ethical oversight of all research involving human participants within the institution. Its primary responsibility is to ensure that research activities are conducted in accordance with national and international ethical standards, with the protection of the rights, safety, and well-being of research participants as the highest priority. The independence of the RERB is central to its function. It exercises full autonomy in the review and decision-making processes related to the ethical acceptability of research protocols. This means that the RERB operates free from external pressures or influence from any department, office, or individual within or outside the institution. Its decisions regarding research ethics are final and may not be overruled by any other body.

Despite its independent function, the RERB is administratively under the Department of Medical Education and Research (DMER). This administrative arrangement allows the RERB to receive necessary operational support without compromising its ethical independence. The DMER provides logistical and clerical assistance, including the provision of office space, personnel support, meeting coordination, and record management, among other operational needs. The administrative linkage of CGHMC RERB to DMER is purely for support and does not grant the DMER or any of its units the authority to review, revise, or interfere with the RERB's ethical evaluations and decisions. The RERB remains fully responsible for its ethical mandate, and all institutional departments and researchers are expected to respect and comply with its procedures and decisions.

This structure is in place to uphold transparency, integrity, and accountability in the conduct of research, ensuring that the ethical review process is both robust and independent, in alignment with national and international regulatory requirements and best practices.

Signed by:

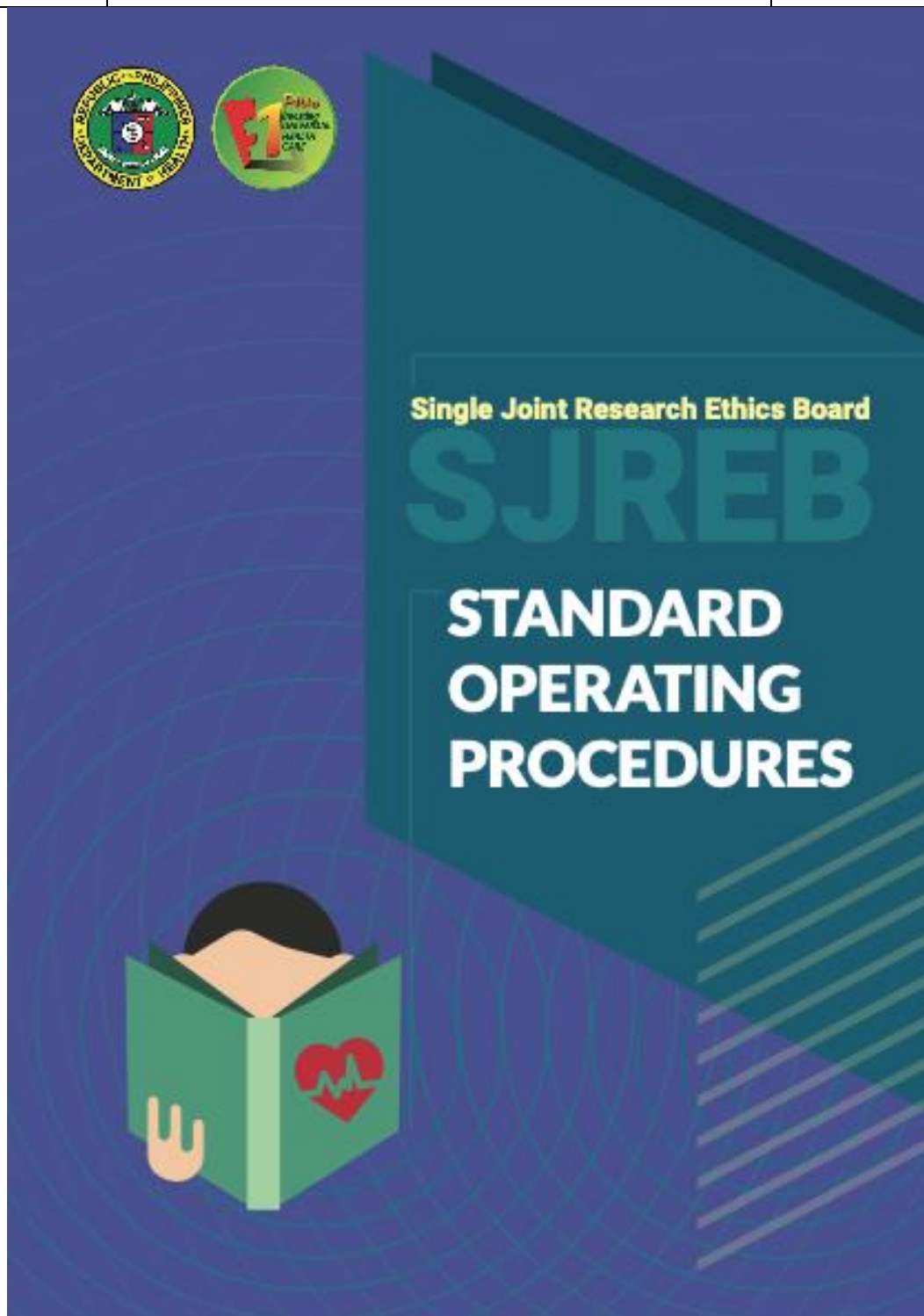

 JULIE LI-YU, MD
 Chairman - Department of Medical Education and Research CGHMC

Approved by:

SAMUEL D. ANG, MD
 Medical Director - CGHMC


 DR. NESTOR GARCIA
 ASST TO THE MEDICAL DIRECTOR
 OFFICE OF THE MEDICAL DIRECTOR

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 7 Date of Approval: 09 September 2025 Effective Date: 09 September 2025
	SJREB SOP	





Single Joint Research Ethics Board

SJREB

STANDARD OPERATING PROCEDURES

Department of Health
Health Policy Development and Planning Bureau
Health Research Division

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TABLE OF CONTENTS

	PAGES
<i>Introduction</i>	2
<i>Ethical Framework of the Single Joint Research Ethics Board</i>	4
<i>SOP 1: SJREB Structure and Composition</i>	6
<i>SOP 2: Joint Review of Protocols</i>	25
<i>SOP 3. Documentation and Archiving</i>	48
<i>SOP 4: Writing and Revising Standard Operating Procedures</i>	54
<i>Appendices and Forms</i>	58

INTRODUCTION

The Single Joint Research Ethics Board (SJREB) was institutionalized in the Department of Health through the issuance of *Administrative Order (AO) No. 2017-0021* in October 2017. This initiative has been put in place to streamline the ethics review process within the Department and contribute in the improvement of the research ethics governance system in the country.

SJREB has started its operations in March 2018. Its primary role is to host and serve as a platform for joint review of multi-site research studies sponsored by DOH and/or to be implemented across various DOH hospitals. In 2019, with the Board's commitment to further improve its processes and promote transparency, SJREB underwent joint accreditation from PHREB and the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP). This accreditation then led to the issuance of the revised *AO No. 2019-0049: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health* in November 2019 which addresses the issues and gaps identified in its pre-existing procedures and reiterates the processes and procedures in the adoption of the single joint review system in the DOH. Further, recognizing the capacity and core functions of the SJREB, the *Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals* was also institutionalized in which the Board's primary responsibility is to assist DOH hospitals research ethics committees in identifying and managing conflict of interest and other study-related complaints.

The SJREB's oversight applies to all DOH units including Centers for Health Development (CHDs), Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), hospitals, and attached agencies with research ethics committees. It also covers private research ethics committees who have agreed to participate in the single joint ethics review process. And with its recent designation by the Sub Technical Working Group (TWG) on Vaccine Development and in accordance with PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal, SJREB shall facilitate the ethics review of all COVID-19 vaccine trials to be implemented in the country following the prescribed process flow set forth by the vaccine experts panel.

This SOPs have been developed based on the DOH harmonized research ethics committee SOPs, PHREB and FERCAP standards, and other relevant local and international guidelines on health research ethics such as:

- a. *National Ethical Guidelines for Health and Health Related Research (NEGHRR)*
 - This PHREB document acknowledges the conduct of a joint review of a group of PHREB accredited ethics committees provided that the review abides by a standard operating procedures (SOPs) approved by PHREB
- b. *Council for International Organizations of Medical Sciences (CIOMS)*
 - This international guideline highlights the conduct of single review of multi-site research in one jurisdiction (country) by one ethics committee to avoid lengthy procedures and ensure quality of the review.

The document contains five (5) important chapters such as: (1) Authority, composition, and structure of SJREB; (2) Joint review process for initial submission; (3) Consolidated post-approval procedures; (4) Documentation and archiving; and, (5) Writing and revising SOPs. This SOP will be periodically reviewed and revised to address new issues and gaps that may arise over time. Also, this document will be updated as new local and international regulations, policies and guidelines are published. Meanwhile, the SJREB encourages stakeholders to send feedback and questions through official SJREB email at sjreb.doh@gmail.com.

ETHICAL FRAMEWORK OF THE SINGLE JOINT RESEARCH ETHICS BOARD

The Single Joint Research Ethics Board is guided by in its review, recommendations, and decisions by the following ethical principles:

1. **Respect for Persons** – principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **Beneficence** – principle that requires investigators to protect participants from harm and secure their well-being.
3. **Justice** – principle that refer to the sense of “fairness in distribution” and “what is deserved”.

Source: Belmont Report, 1979

- A. SJREB is guided and informed by the ethical principles, processes and procedures embedded in the following international guidelines:
 - Declaration of Helsinki (2013 and its subsequent revisions)
 - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2
 - Council for International Organizations of Medical Sciences (CIOMS) Guidelines 2016

- Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)
- B. SJREB shall function in accordance with the existing national laws, policies, regulations, and guidelines such as:
- National Ethical Guidelines for Health Research set forth by the Philippine Health Research Ethics Board (PHREB)
 - Policy issuances (i.e., Administrative Orders, Department Orders, etc.) from the Department of Health, Philippine Food and Drug Administration (FDA) and other relevant agencies such as:
 - Administrative Order No. 2019-0049
 - Department Order No. 2019-0063
- C. SJREB adopts its own standard operating procedures (SOP) based on:
- Operational Guidelines for Ethics Committees that review Biomedical Research (2000) by the WHO
 - DOH-REC SOP Templates
 - FERCAP-SOP Templates
 - PHREB SOP Workbook 2020
- D. In evaluating protocols and ethical issues, SJREB is cognizant of the diversity of the laws, cultures, and practices governing health research in various local sites and countries around the world.
- E. SJREB is strictly aware and abide by the relevant Philippine laws in terms of the conduct of various types of research.
- F. SJREB attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed research is being considered.
- G. SJREB will take the initiative to be informed, as appropriate, by current state-of-the art researches and publications of the impact of the research that it has approved.

6 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

A. SOP 1 SJREB STRUCTURE AND COMPOSITION

1.1 Purpose

- 1.1.1. To describe the authority, composition and structure of the Single Joint Research Ethics Board (SJREB) related to the ethics review of multi-site researches.
- 1.1.2. SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB) with the following objectives:
 - 1.1.2.1. To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines.
 - 1.1.2.2. To shorten the turn-around time of ethics review of multi-site protocols.
 - 1.1.2.3. To harmonize the results of ethics review among various site RECs through joint review.
 - 1.1.2.4. To strengthen the ethics review capacity of PHREB accredited RECs to review different types of protocols that are conducted at their sites.
 - 1.1.2.5. To serve as DOH central ethics committee who shall review DOH funded research.

1.2 Scope of Authority

- 1.2.1. SJREB is a joint review mechanism for multi-site protocols to be implemented at various sites and as adopted by duly accredited PHREB Research Ethics Committees (RECs).
 - 1.2.1.1. It serves as a common review platform for all DOH RECs that will sign a letter of intent to participate and accept its review.
 - 1.2.1.2. It also covers the non-DOH hospital RECs from both the public and the private sectors that will sign a letter of intent to participate and accept its review.
- 1.2.2. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines.
 - 1.2.2.1. All DOH funded research studies shall be reviewed by SJREB.
 - 1.2.2.2. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.
 - 1.2.2.2.1. At least one site is a Level 3 PHREB-accredited hospital with letter of intent.
 - 1.2.2.3. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities.
 - 1.2.2.4. SJREB also accepts and reviews multicenter researches that are community-based.
- 1.2.3. SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.
- 1.2.4. SJREB facilitates the ethics review of all COVID-19 vaccine trials to be conducted in the country in compliance with its designation by the Sub-Technical Working Group for Vaccine Development and PHREB's Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal.

8 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

- 1.2.5. It serves as a Central REC to review DOH Central Office funded researches. It invites all site RECs to participate in the review of DOH protocols. However, SJREB may also review the following; (a) for DOH hospital RECs that lack the required level of PHREB accreditation; and, (b) have lost or have pending reaccreditation according to the following procedures:
 - 1.2.5.1. The site REC shall receive submissions and reports from the site PIs, review the issues through expedited or full board as prescribed in their SOPs, and arrive at a recommended decision. There should be an interim agreement between SJREB and the site;
 - 1.2.5.2. The site REC should forward their recommended decision and attach relevant documents (PI submission, site REC assessment forms, minutes, etc.) to SJREB together with a request for SJREB review and oversight.
 - 1.2.5.3. The SJREB secretariat shall receive the request, determine the appropriate review channels and procedures.
 - 1.2.5.4. SJREB shall review the issues and arrive at an appropriate decision to be forwarded to the site REC which in turn will forward the decision to the site investigator.
- 1.2.6. SJREB may also be involved in resolving conflict of interest issues and other study-related complaints implicating a DOH REC that may be constrained to fulfill its ethical mandate. SJREB may intervene and recommend the course of action to be implemented by the DOH research unit and/or REC in accordance with Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals.

1.3 Structure of the Single Joint Research Ethics Board

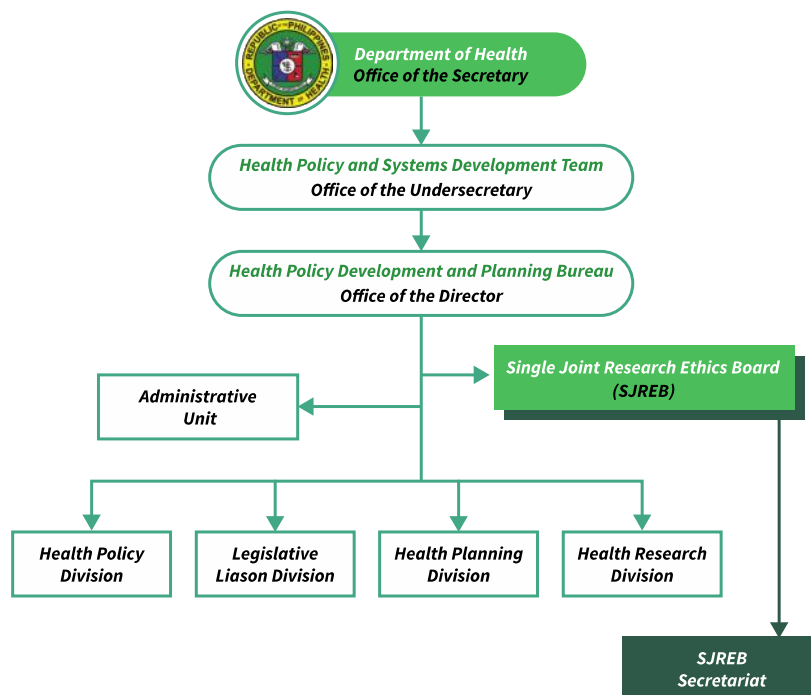
1.3.1. Organizational Structure. The Single Joint Research Ethics Board shall be placed directly under the Health Policy Development and Planning Bureau (HPDPB), Office of the Director to ensure independence of the board. This Bureau has the responsibility to set-up and support the SJREB office and secretariat to assist the Boards in its day-to-day operations. See Figure 1 for the Organogram of the SJREB.

1.3.2. HPDPB Roles and Responsibilities

1.3.2.1. Administrative support to the Board.

- 1.3.2.1.1. It ensures the independence of the decision making of SJREB.
- 1.3.2.1.2. It approves the SJREB Standard operating procedures to ensure that it is in agreement with policies of DOH.
- 1.3.2.1.3. It ensures that SJREB provides a mechanism to educate its reviewers and staff, including site RECs to develop the necessary knowledge, skills and practice to improve the review of various types of protocols submitted.
- 1.3.2.1.4. It requires progress report from SJREB to assess performance as basis for continuous quality improvement.
- 1.3.2.1.5. It provides sufficient staff to support the SJREB operations.
- 1.3.2.1.6. It allocates space, office equipment, IT infrastructure and all the necessary logistical support to enable SJREB to conduct its joint review functions efficiently and effectively.
- 1.3.2.1.7. It provides a budget for annual update training to SJREB Members and all DOH RECs and non-DOH RECs that submitted an LOI to the Board.
- 1.3.2.1.8. It screens nominees and recommends SJREB members to the Secretary of Health.

Figure 1. Organogram of SJREB



1.3.3. Process flow and Steps for Appointment of SJREB members

Table 1. Process flow and Steps for Appointment of SJREB members

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Nomination and Selection of SJREB Members	SJREB Chair and permanent members
2	Screening of Nominees and Recommendations	HPDPB Director
3	Appointment of the SJREB members	Secretary of Health

1.3.4. Nomination Process

- 1.3.4.1. The permanent REC members, secretariat, and all participating REC members with an active LOI may nominate potential SJREB members.
- 1.3.4.2. The identified list of nominees shall be presented to the SJREB members during a regular full board meeting for the Board to finalize such a list.
- 1.3.4.3. The list of nominees will then be endorsed by the SJREB Chair to the HPDPB Director for final screening.

1.3.5. Screening of Nominees and Recommendations

- 1.3.5.1. The HPDPB Director, upon receipt of the list of nominees for SJREB membership from the SJREB Chair, shall assess the submitted documents and recommends the final list of proposed new set of SJREB members to the Secretary of Health (SOH).
- 1.3.5.2. The HPDPB Director has the prerogative to recommend the Chair based on his/her knowledge of the competence and capacity of such nominee. This privilege is guided by the common understanding that despite the nature of such recommendation, the independence of the decision making of the Board should still be strictly observed and exercised at all times.
- 1.3.5.3. A formal endorsement of the HPDPB's recommendation for the SJREB membership shall be forwarded to the Office of the Secretary for approval.
- 1.3.5.4. After the approval of the of the SOH, the SJREB Secretariat shall prepare the necessary documentary requirements to formalize appointment of the new SJREB members.

1.3.6. Appointment Process

- 1.3.6.1. The SJREB Secretariat shall ensure that the appointment documents are completed prior to engaging the SJREB members as described below.

1.3.6.2. SJREB Members

- 1.3.6.2.1. The Secretary of Health appoints an appropriate number of persons to form the SJREB membership to manage the SJREB operations. It may appoint consultants with relevant skills to help SJREB perform its review functions.
- 1.3.6.2.2. It appoints the SJREB Chair with a three-year term of office from participating RECs. It ensures that the Chair has sufficient background, training and experience in ethics review of various types of protocols.
- 1.3.6.2.3. It appoints a non-medical/non-scientific member, depending on the type of review, shall review the informed consent forms (ICF) and provide inputs from the community/people's perspective.
- 1.3.6.2.4. It ensures that there is a non-affiliated member (i.e representative not coming from any of the hospital sites specified in the research being reviewed) during the SJREB meetings.
- 1.3.6.2.5. It invites the Philippine Health Research Ethics Network (PHREN) to nominate its representative with a fixed term, preferably from the private sector.
- 1.3.6.2.6. It appoints an appropriate number of designated subject experts/independent consultants who can assist SJREB review of multi-site protocols.
- 1.3.6.2.7. It ensures that a representative from a DOH-specialty hospital (e.g. Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.) is invited to attend review meetings related to their expertise.
- 1.3.6.2.8. It shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
- 1.3.6.2.9. It shall have representatives from ages below 50 years old and above 50 years old.

- 1.3.6.2.10. In order to ensure continuity of functions, at least half of the SJREB shall be retained/re-appointed for at least one (1) year before a new set shall be appointed.

1.3.7. SJREB Membership and Secretariat

1.3.7.1. SJREB Membership. The SJREB membership is composed of seven (7) permanent and non-permanent members as indicated below. Independent consultants are also engaged for the review of specialized protocols.

1.3.7.1.1. Permanent Members

- 1.3.7.1.1.1. The **Chair** is a dedicated individual from an REC with experience to review different types of researches with fixed term of three (3) years as stipulated in the joint review SOPs.
- 1.3.7.1.1.2. A **Vice Chair** may be assigned from the existing permanent members
- 1.3.7.1.1.3. The **Member Secretary** shall oversee the protocols being reviewed by the Board and ensure the accuracy of the minutes of the meeting. He/she is a plantilla staff affiliated with the DOH.
- 1.3.7.1.1.4. Designated **Philippine Health Research Ethics Network (PHREN) Representative** from a private institution with a fixed term of three (3) years as stipulated in the joint review SOPs.
- 1.3.7.1.1.5. The **non-medical or non-scientific member**, depending on the type of protocol submission, shall review the informed consent forms (ICF) and provide inputs from the community/people's perspective.
- 1.3.7.1.1.6. **Subject matter experts (SME)** on Health Systems, Ethics, Social science, and Public Health.

1.3.7.1.2. Non-Permanent Members

1.3.7.1.2.1. The **participating site REC representatives** are identified point persons or subject matter expert from the sites who are knowledgeable on the study protocols being reviewed

1.3.7.1.2.2. **Subject Matter Expert (SME)/Non-medical member from the specialty hospitals** who is a designated representative from the DOH specialty hospitals to review a multi-site research i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.

1.3.7.1.3. **Independent consultant** is an individual who has the specialization that is not present on the permanent members assigned to review a multi-site protocol.

1.3.7.2. Secretariat

1.3.7.2.1. **Member Secretary** is an affiliated plantilla technical staff who sits as a permanent member of the Board and ensures compliance with the SOP during the entire review process.

1.3.7.2.2. **Head of Secretariat (HoS)** is a plantilla technical staff who shall supervise the day-to-day operations of the Board

1.3.7.2.3. **Administrative Staff** is a dedicated staff who provides support to the HoS and Member Secretary in the administrative and clerical management of the SJREB.

1.3.8. Roles and Functions

1.3.8.1. SJREB Members

1.3.8.1.1. The SJREB Chair presides over full board meetings and ensures appropriate review of protocol related documents in accordance with international and national guidelines and regulations. He/she may designate the Vice Chair or a representative from an accredited

REC to preside over a meeting that he/ she cannot attend.

- 1.3.8.1.2. The SJREB members shall evaluate and manage conflict of interest that cannot be resolved at the institutional level especially for hospitals within the purview of the Department following the processes and procedures in the Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH hospitals

1.3.8.2. SJREB Secretariat

1.3.8.2.1. Member Secretary

- 1.3.8.2.1.1. Oversees the conduct of the full board meeting and ensures that the review process is in accordance with the SOP
- 1.3.8.2.1.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting

1.3.8.2.2. Head of Secretariat

- 1.3.8.2.2.1. Manages the day-to-day activities of SJREB to include office procedures
- 1.3.8.2.2.2. Conducts ethical review of assigned protocols as primary reviewer and presents review during expedited or full board meeting
- 1.3.8.2.2.3. Conducts screening and identifies type of review of initial protocol submissions and post approval submissions
- 1.3.8.2.2.4. Recommends exemption for review to the Chair
- 1.3.8.2.2.5. Reviews all technical and administrative documents relative to SJREB operations to include but not limited to agenda of the meeting, minutes of the meeting, notification of approval/modifications and other post approval communication letters and documents

1.3.8.2.3. Administrative Staff

- 1.3.8.2.3.1. Communicates with various clients and stakeholders, and ensuring appropriate REC and site representation during the conduct of review.
- 1.3.8.2.3.2. Invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study.
- 1.3.8.2.3.3. Ensures completeness of protocols package submitted by the Coordinating PI for SJREB review.
- 1.3.8.2.3.4. Checks the site REC's level of PHREB accreditation. Only level 3 REC representatives can vote during full board review of clinical trial protocols intended for FDA registration, while both levels 2 and 3 REC representatives can vote during the review of public health protocols and clinical research not intended for FDA registration. Further, it ensures fair representation in terms of the counts of votes; only one (1) vote per site.
- 1.3.8.2.3.5. Invites observers from study sites, without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.
- 1.3.8.2.3.6. Prepares the meeting agenda and minutes of all SJREB meetings for approval of the Chair.
- 1.3.8.2.3.7. Checks completeness of all assessment forms accomplished by the designated primary reviewers.
- 1.3.8.2.3.8. Issues an appropriate decision document (i.e. Notice of Approval, Notice of Protocol Modification, Certificate of Exemption, Notification Letter) to

all participating site RECs as reviewed and approved by the HoS and Member Secretary and duly signed by the SJREB Chair.

- 1.3.8.2.3.9. Ensures that Letter of Intent to participate in SJREB are secured prior to attendance to any SJREB meetings.

1.3.8.3. SJREB Participating Sites

- 1.3.8.3.1. DOH Hospital RECs and non-DOH RECs need to submit a Letter of Intent (LOI) to SJREB to participate in joint review when their sites are selected by the sponsor for the conduct of multi-site researches. The LOI shall apply for the entire duration of participation of the RECs in the single joint ethics review. In any given circumstances, the REC may opt to withdraw any time from participation in the review process by submitting a letter of withdrawal to the SJREB Secretariat. Should an REC wish to participate in the joint review after withdrawal, they should submit a new LOI to SJREB.
- 1.3.8.3.2. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. For non-DOH hospitals, their RECs retain the option to accept or reject SJREB decision.
- 1.3.8.3.3. All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:
 - 1.3.8.3.3.1. Authority is shared by a duly accredited site REC with SJREB to conduct joint review with representatives from site RECs of multi-site researches. Joint review by SJREB is done only for initial review and renewal of approval. SJREB

conducts full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low risk protocols may be exempted from review or may go through expedited review procedures.

- 1.3.8.3.3.2. All RECs who will participate in joint review should submit their membership list with their CVs and they should identify representatives qualified to do scientific and ethical review for various types of protocols commonly submitted for review.
- 1.3.8.3.3.3. All DOH Hospital RECs and non-DOH RECs are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. All site RECs will issue a Certificate of Approval together with the Notice of Decision from SJREB.
- 1.3.8.3.3.4. The site REC retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports and final reports, all of which involve events at specific sites. The site REC, meanwhile, has the prerogative to elevate protocol deviation to SJREB and provide corrective actions.
- 1.3.8.3.3.5. The site REC maintains active collaboration and communication with SJREB for joint review to achieve its stated objectives and for mutual benefit of improving the research environment in the Philippines.

- 1.3.8.3.3.6. For site RECs that have lost or pending accreditation, the REC should still conduct review of the protocol. The REC then has the responsibility to submit the result of the review to SJREB for any further discussion or approval.

1.4 SJREB Letter of Intent and Oversight Function

1.4.1. Purpose

To describe the process of engaging participating sites in the joint ethics review process and define the oversight function of the SJREB

1.4.2. Scope

The Letter of Intent (LOI) is an agreement between the participating site(s) and SJREB whereby the site acknowledges and agrees to participate in the joint review process being conducted by the SJREB and abide by all its policies and guidelines set forth in this SOP and other relevant issuances.

1.4.3. Responsibility

- 1.4.3.1. It is the responsibility of the participating sites to submit a letter of intent (See SJREB Form 12) to SJREB through its Secretariat expressing the interest to participate in the joint review process
- 1.4.3.2. The SJREB Secretariat shall receive and facilitate the necessary documents to formalize such engagement. The LOI shall then be endorsed to the Director of the HPDPB for conforme.
- 1.4.3.3. For sites who have been identified to participate in a clinical trial but do not have the required PHREB accreditation level, the SJREB may assume oversight functions following the conditions below:
 - 1.4.3.3.1. Adopt the SJREB standard operating procedures as part of the REC's SOPs in compliance with AO no. 2019-0049;

20 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

- 1.4.3.3.2. Attend SJREB meetings when the indicated protocol is being discussed.
- 1.4.3.3.3. Accept the decision of the SJREB for implementation at the site.
- 1.4.3.3.4. Submit results of the REC review of the protocol to SJREB.
- 1.4.3.3.5. Monitor the study implementation and submit the REC's recommendations to SJREB about action on reports submitted by the PI.
- 1.4.3.3.6. Inform SJREB at any time that the REC has been given its PHREB accreditation.

1.4.4. Process Flow/Steps

Table 2. Process flow and Steps for LOI and Oversight Function		
NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Submit LOI to SJREB Secretariat	Participating site(s)
2	Receive and process documents formalizing engagement	Secretariat
3	Issue conforme letter to the participating site	HPDPB Director, Secretariat

1.4.5. Detailed instructions

- 1.4.5.1. Submit LOI to SJREB Secretariat
 - 1.4.5.1.1. The participating site shall prepare the LOI duly signed by their respective REC Chairperson using SJREB Form 12.
 - 1.4.5.1.2. The signed LOI shall be submitted to the SJREB Secretariat for approval of the HPDPB Director.
- 1.4.5.2. Receive and process documents
 - 1.4.5.2.1. The SJREB Secretariat shall acknowledge and process the necessary documents

- to formalize the engagement with the participating site.
- 1.4.5.2.2. Issue conforme letter to the participating sites
- 1.4.5.2.3. The signed conforme letter from the HPDPB Director shall be provided and issued to the participating site by the SJREB Secretariat

1.5 Training of SJREB Members and Staff

1.5.1. Purpose

To describe **SJREB** procedures to ensure initial and continuing training of members and staff

1.5.2. Scope

The SJREB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of SJREB members and staff from initial training to continuing education to maintain and update competence in the review of different types of protocols.

1.5.3. Responsibility

- 1.5.3.1. It is the responsibility of the SJREB members and staff to have themselves educated and trained regularly.
- 1.5.3.2. It is the responsibility of the SJREB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff. The chair may assign a permanent member to lead capacity building related activities.
- 1.5.3.3. The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

1.5.4. Process Flow/Steps

Table 3. Process flow and Steps for LOI and Oversight Function			
NO.	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Require basic research ethics training for all members and staff	Chair	Needs assessment to be done at the beginning of the year
2	Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses	Chair, Secretariat	
3	Track member and staff participation initial and continuing ethics training and file the documents in the Membership File	Members, Secretariat	

1.5.5. Detailed instructions

1.5.5.1. REC members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

- 1.5.5.2. Require Research Ethics Training for all members and staff
 - 1.5.5.2.1. All members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:
 - 1.5.5.2.2. Member's/Staff's responsibilities;
 - 1.5.5.2.3. Confidentiality and Conflict of Interest Agreement;
 - 1.5.5.2.3.1. Review process and use of Protocol and ICF Assessment forms; and,
 - 1.5.5.2.3.2. SOPs.
 - 1.5.5.2.4. The Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.
- 1.5.5.3. Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses
 - 1.5.5.3.1. The Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
 - 1.5.5.3.2. The Chair and Secretariat plan the training activities for individual members based on their training needs.
 - 1.5.5.3.3. The Chair and Secretariat track and facilitate attendance of members and staff of specific training activities needed to ensure that each one gets training at least once a year.
 - 1.5.5.3.4. The members who participate in research ethics training course or seminar-workshops either through personal or through REC efforts/funding are encouraged to:
 - 1.5.5.3.4.1. Share information with other members during meetings; and,

24 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

- 1.5.5.3.4.2. Distribute photocopies/e-copies of relevant materials to the other members.
- 1.5.5.4. Track member and staff participation in initial and continuing ethics training and file the documents in the Membership File
 - 1.5.5.4.1. For in-house training, the SJREB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.
 - 1.5.5.4.2. All members and staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the REC Staff for filing.
 - 1.5.5.4.3. Administrative Staff should update the Training Record of individual Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.
- 1.5.5.5. The joint review process shall serve as an avenue for building capacity of the RECs by exposing them to wide variety of protocols and best review practices from expert primary reviewers. SJREB may also invite observers from study sites without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

B. SOP 2 JOINT REVIEW OF PROTOCOLS

2.1 Purpose

To describe the Single Joint Research Ethics Board (SJREB) requirements and procedures in conducting initial and continuing review of multi-site protocol related documents, vis-a-vis the site RECs.

2.2 Scope

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review.

2.2.1. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:

2.2.1.1. Sponsored or funded by the Department of Health

2.2.1.2. Multi-site protocol to be conducted in at least 3 sites with at least one (1) site identified as site with the ff qualifications:

2.2.1.2.1. Level 3 hospital

2.2.1.2.2. At least one (1) site with a Letter of Intent (LOI) which specifies that:

26 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

- 2.2.1.2.2.1. SJREB reviews the country protocol
 - 2.2.1.2.2.2. PIs shall submit to both SJREB and the sites
 - 2.2.1.2.2.3. Sites accept the SOPs of SJREB for the joint review of protocols
 - 2.2.1.2.2.4. Only site specific modifications shall be allowed. No modifications to the approved country protocol shall be required by the participating sites.
 - 2.2.1.2.2.5. Site accepts the decision of SJREB unless there is compelling ethical, legal or scientific concerns. Reasons for site disapproval shall be submitted to SJREB and must be justified.
 - 2.2.1.2.2.6. Disapproval of protocol shall mean that the site is opting out as a site for the study.
- 2.2.2. SJREB requires an LOI to regularly participate in joint review from all Research Ethics Committees when their sites are selected by the sponsors as a study. The LOI shall be effective unless a withdrawal of the intent to participate is submitted in writing.
 - 2.2.3. SJREB requires the site RECs to agree and abide with the procedures of SJREB
 - 2.2.4. All research sites agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.
 - 2.2.5. In sites with no REC or has a functional REC with PHREB accreditation that is not appropriate for the type of protocol being reviewed, SJREB may either assume the oversight function of the site or choose to assign a PHREB-accredited REC to do the review and oversight. The determination will depend on the type and nature of the protocol to be implemented. The designated oversight REC shall issue the certificate of approval and assume stewardship and monitoring functions.

2.3 Responsibility

- 2.3.1. The permanent members, independent consultant, and participating sites representatives act as primary reviewers and attend board meeting
- 2.3.2. The members review and decide make decisions on the protocol
- 2.3.3. The SJREB Secretariat manages all protocol submissions to the SJREB.

2.4 Types of Review Classification of Protocols Submitted for Initial Review

SJREB classifies protocols into 3 types to determine the appropriate type of review of multi-site protocols. The Head of Secretariat makes a preliminary assessment of protocols and recommends the type of review to the Chair who approves the classification.

2.4.1. Detailed procedures for the three review types

2.4.1.1. Exemption from Ethics Review:

- 2.4.1.1.1. The Head of Secretariat makes a preliminary assessment of the protocol using the SJREB Form 6: Checklist for Exemption from Full Ethical Review Form to determine if it meets the exemption criteria as follows:
- 2.4.1.1.2. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g. meta-analysis protocols)
- 2.4.1.1.3. Protocols that involve human participants or identifiable human tissue, biological samples, and data provided that the following do not involve more than minimal risks or harm:
 - 2.4.1.1.3.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation

- activities, and consumer acceptability tests;
- 2.4.1.1.3.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
 - 2.4.1.1.3.3. No disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their final standing, employability, or reputation; and
 - 2.4.1.1.3.4. Information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant
 - 2.4.1.1.3.5. Protocols that involve the use of publicly available data or information
- 2.4.1.1.4. The Head of Secretariat and a senior member of the board reviews the protocol and makes a determination for exemption. In certain circumstances, exemption may be discussed in an expedited meeting. The protocol for exemption shall be reported in the full board review for the information of the Board. The reviewer(s) submits the SJREB Form 4: Checklist for Exemption to the Secretariat seven (7) calendar days before the full board meeting.
 - 2.4.1.1.5. SJREB issues a Certificate of Exemption (SJREB Form 4.1) signed by the Chair within seven (7) calendar days after the decision.
 - 2.4.1.1.6. Should there be any major protocol change after the issuance of the Certificate of Exemption, the Coordinating PI shall submit an amendment to SJREB to make a decision about change of classification.

2.4.1.2. Expedited Review:

- 2.4.1.2.1. The Head of Secretariat makes a preliminary assessment of the protocol and determines qualification for expedited review based on the following criteria:
 - 2.4.1.2.1.1. Does not involve more than minimal risks or harm but does not qualify for exemption
 - 2.4.1.2.1.2. About a topic that should not result in causing social stigma
 - 2.4.1.2.1.3. Does not involve vulnerable populations
 - 2.4.1.2.1.4. Retrospective studies using anonymized data from medical records
 - 2.4.1.2.1.5. Studies using simple questionnaires without identifiers
 - 2.4.1.2.1.6. Proposals such as:
 - 2.4.1.2.1.6.1. Chart review
 - 2.4.1.2.1.6.2. Survey of non-sensitive nature
 - 2.4.1.2.1.6.3. Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data
- 2.4.1.2.2. The Head of Secretariat recommends the type of review to the Chair who approves the classification.
- 2.4.1.2.3. The Head of Secretariat identifies two or more primary reviewers from the permanent members and/or participating sites to conduct initial review through expedited procedures. SJREB may also call for a meeting of the sites to expedite the review.
- 2.4.1.2.4. The primary reviewer(s) should review within seven (7) calendar days using appropriate SJREB assessment forms. The primary reviewers may recommend modifications and decide on the approval of the protocol documents.
- 2.4.1.2.5. If any of the PR recommends disapproval, it is automatically elevated to full board.
- 2.4.1.2.6. The Head of Secretariat may recommend to

hold an expedited meeting when necessary, with the attendance of the secretariat and the primary reviewers. The expedited review report shall be finalized by the Member Secretary for reporting in the full board meeting.

- 2.4.1.2.7. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating Principal Investigator (PI) within fourteen (14) calendar days after protocol submission.
- 2.4.1.2.8. The SJREB secretariat endorses the decision of SJREB to participating sites. SJREB expects the participating sites to accept its decision. Each site may add site specific recommendation to SJREB Decision.
- 2.4.1.2.9. The site REC issues a Certificate of Approval.

2.4.1.3. Full-Board Review:

- 2.4.1.3.1. The Head of Secretariat makes a preliminary assessment of the protocol and identifies more than minimal risk protocols for full board review.
- 2.4.1.3.2. The Head of Secretariat assigns primary reviewers from site RECs or invites independent consultants to review the protocol and the ICF.
- 2.4.1.3.3. The SJREB secretariat informs the site RECs of its receipt of protocols for full board joint review. Participating RECs conduct a preliminary assessment of the protocol and prepare comments/ recommendations on the protocol to be presented during the full board review.
- 2.4.1.3.4. The assigned primary reviewers shall prepare their comments using appropriate SJREB assessment forms and lead the discussion about the protocol during the board meeting. Other SJREB and participating sites representatives contribute to the discussion.

- 2.4.1.3.5. The SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda and informs the members of the board, the site REC representatives, the assigned primary reviewers, as well as SME from necessary fields of experience to attend the meeting.
- 2.4.1.3.6. The Coordinating PI shall be invited for a clarificatory interview to answer queries about the protocol.
- 2.4.1.3.7. The board adopts one of the following decisions during joint review:
 - 2.4.1.3.7.6.1. Approval
 - 2.4.1.3.7.6.2. Minor modification required
 - 2.4.1.3.7.6.3. Major modification required
 - 2.4.1.3.7.6.4. Disapproved
- 2.4.1.3.8. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating PI and to all the participating sites within fourteen (14) calendar days after the Full Board meeting.
- 2.4.1.3.9. For protocols with recommendations for modification, the Coordinating PI is given fifteen (15) calendar days to submit a revised protocol.
- 2.4.1.3.10. Site RECs acknowledges SJREB decision and make site-specific decisions in an expedited meeting.
- 2.4.1.3.11. All DOH Hospital RECs and non-DOH RECs with LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. Each site REC shall issue a Certificate of Approval, or a notice of its decision clearly stating the ethical issues,

32 | STANDARD OPERATING PROCEDURES

SINGLE-JOINT RESEARCH ETHICS BOARD

if it chooses to disapprove the protocol.

- 2.4.1.3.12. The site in general can no longer introduce major modification on the country protocol. However, the site RECs can disapprove the protocol only when they think that there are strong ethical issues or site specific concerns that were not addressed. Reasons for disapproval should always be stated in the decision letter. Meanwhile, the ICF may be revised in any manner the site REC requires.

2.5 **Management of Initial Protocol Submissions**

- 2.5.1. Receive the initial protocol package for review and check the completeness of the documents submitted
- 2.5.2. SJREB Secretariat ensures that SJREB Form 1: Application for SJREB Initial Review and SJREB Form 1.2: Protocol Summary Sheet are completely filled out, signed and dated by the Coordinating PI submitting the protocol documents.
- 2.5.3. The following documents should be submitted in the initial protocol package:
 - 2.5.3.1. Basic Documents:
 - 2.5.3.1.1. Application Form [SJREB Form 1 - Application Form]
 - 2.5.3.1.2. Protocol Summary Sheet [SJREB Form 1.2 - Protocol Summary Sheet]
 - 2.5.3.1.3. Study Protocol
 - 2.5.3.1.4. Informed Consent Forms
 - 2.5.3.1.5. Recruitment and Advertisement Materials
 - 2.5.3.1.6. Data Collection Forms
 - 2.5.3.1.7. Curriculum vitae of principal investigators
 - 2.5.3.1.8. Study Budget
 - 2.5.3.1.9. Technical Clearance
 - 2.5.3.1.10. Proof of submission to at least three (3) study sites
 - 2.5.3.2. Study-specific Documents (submit as needed)
 - 2.5.3.2.1. FDA Approval/ Proof of submission (for clinical trials)
 - 2.5.3.2.2. Patient Information Sheet (for clinical trials)
 - 2.5.3.2.3. Investigator Brochure (for clinical trials)
 - 2.5.3.2.4. Basic Research Ethics Training Certificates of PIs (for non-clinical trials)
 - 2.5.3.2.5. GCP certificates of PIs (for clinical trials)
 - 2.5.3.2.6. Other protocol-related documents
- 2.5.4. SJREB may require Coordinating PI to submit to SJREB specific protocol-related documents submitted to the local

- RECs.
- 2.5.5. SJREB requires proof of submission of protocol to at least three (3) sites, with at least one (1) DOH hospital or a level 3 REC with LOI identified as site, prior to acceptance for ethics review.
- 2.5.6. One (1) hard copy and soft copy (sent either via email, flash drive, or CD) of the above documents shall be submitted to the SJREB.
- 2.5.7. The SJREB full board meeting is scheduled every second Wednesday of the month. The deadline for protocol submission for full board meeting is fourteen (14) calendar days prior (last Wednesday of the preceding month) to the next meeting.
- 2.5.8. Assign a permanent code to the protocol package
 - 2.5.8.1. For efficient file management, it is necessary for SJREB staff to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: SJREB-yyyy (year) –number (chronological number based on order of receipt).
 - 2.5.8.2. For example, if the protocol entitled “Clinical Drug Trial of XYZ on Pediatric Patients” is the first protocol received in 2017, the code SJREB-2017-01 should be used to identify this protocol. The code shall be used on all communications regarding the protocol.
- 2.5.9. Determine the Type of Review and assign primary reviewers
 - 2.5.9.1. The Head of Secretariat makes a determination about the appropriate type of review and seeks approval of the Chair on the review classification.
 - 2.5.9.2. The Head of Secretariat identifies one (1) protocol reviewer and one (1) as ICF reviewer from the permanent members or from members of participating site RECs for full board and expedited protocols.
- 2.5.10. Distribute the Initial Protocol Documents to the Primary Reviewers
 - 2.5.10.1. The SJREB Staff sends copies of protocol documents together with the SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form, with the transmittal letter

to the primary reviewers.

- 2.5.10.2. The initial protocol documents should be distributed to the Primary Reviewers seven (7) calendar days

2.6 Full-Board Review Procedures

2.6. Full-Board Review Procedures

2.6.1. Before Full-Board Meeting

- 2.6.1.1. The Coordinating PI submits the multi-site protocol documents to the identified sites at least two (2) weeks prior to submission to SJREB.
- 2.6.1.2. The site RECs conduct their preliminary review of the protocol documents and identify a representative who will participate in the discussion during the Full-Board SJREB meeting to reflect the views of their own REC.
- 2.6.1.3. The SJREB staff schedules the Joint Review meeting and checks the availability of the regular SJREB members, independent consultants, and representatives of the participating RECs to determine if quorum will be met. Quorum requires attendance of at least five (5) SJREB voting members inclusive of the presence of at least 4 out of 7 permanent members and at least one (1) participating site representative. Further, there should be at least one (1) member who is non-medical/non-scientific and at least one (1) member who is non-affiliated (from a non-DOH site).
- 2.6.1.4. Attendance of members through video conference is allowed.
- 2.6.1.5. The SJREB secretariat prepares and sends the agenda to all participating sites. Prior to dissemination, the HoS should review the prepared agenda of the meeting to check if items are properly classified and presented. The agenda should include information about the following: a. date, time, and venue of the joint SJREB full-board meeting, b. full details about the protocol (number, title, sponsor, coordinating PI,

sites) for initial review and renewal of approval.

- 2.6.1.6. The SJREB full board meeting is regularly scheduled on the second Wednesday of the month or more frequently depending on the volume of protocol submissions. An emergency meeting may also be conducted to facilitate review of urgent protocols (See Appendix B. Guidelines for review procedures during a public health emergency or during an epidemic) and critical issues needing the Board's immediate decision.

2.6.2. During Full-Board Meeting

- 2.6.2.1. A full-board SJREB meeting is convened to discuss and recommend a decision about the protocol and related documents. The SJREB members attending the full board meeting have to review and comment on the following:
 - 2.6.2.1.1. Protocol;
 - 2.6.2.1.2. Informed Consent;
 - 2.6.2.1.3. PI and research team;
 - 2.6.2.1.4. Study sites covered by the application;
 - 2.6.2.1.5. Advertisements, etc.
- 2.6.2.2. Designated primary reviewers shall submit the accomplished and signed SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form during the full-board meeting.
- 2.6.2.3. The SJREB secretariat invites the Coordinating PI to attend the meeting for clarificatory interview to answer questions about the protocol.
- 2.6.2.4. The SJREB members discuss protocol documents and vote on specific items to arrive at a decision as follows (voting requirements are discussed in Chapter 1):
 - 2.6.2.4.1. Approval (when no further modification is required)
 - 2.6.2.4.2. Minor modification (requires minor changes in the documents such as typographical errors, administrative

issues, additional explanations, etc.)

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

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

2.6.2.5. If the study is approved, SJREB determines the frequency of continuing review. All meeting deliberations and decisions regarding a protocol shall be noted in the meeting minutes.

2.6.2.6. Copies of meeting minutes and SJREB decision pertaining to the specific protocol are sent to the site RECs for their information.

2.6.2.7. Site RECs shall submit to SJREB copies of their Certificate of Approval/Notice of Decision.

2.6.3. After the Full-Board Meeting

2.6.3.1. The SJREB secretariat communicates the notice of modification decision to the Coordinating PI.

2.6.3.2. Once the SJREB board approves the protocol related documents, the decision of SJREB is communicated to the Coordinating PI and all the participating site RECs.

2.6.3.3. Investigators may appeal the decision of SJREB by writing a letter requesting for reconsideration with reasons clearly stated and submission of a new protocol. Any appeal shall be taken up at full board meeting.

2.6.3.4. All DOH Hospital RECs and non-DOH RECs with an LOI are expected to accept the results of SJREB review where qualified site RECs participated in the deliberations and decision making except when there are strong ethical issues and/or site specific concerns that cannot be addressed. The site REC conducts an expedited review of the approved protocol to address site specific concerns and inform the PI of the local site of the outcome of the SJREB review as well as the outcome of the local REC

review. All site REC decisions should be reported to SJREB and copy of decisions should be provided to the SJREB Secretariat.

2.6.3.5. The SJREB secretariat prepares the Minutes of the SJREB Full-Board Meeting as follows:

2.6.3.5.1. The SJREB secretariat fills out the basic information about each protocol submission for review in the SJREB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.

2.6.3.5.2. As the SJREB meeting proceeds, the SJREB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the SJREB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the SJREB Chair/ Presiding Officer. The SJREB decisions and recommendations are collective in nature. No attribution to specific SJREB member is stated in the minutes. The meeting minutes should include the following items:

2.6.3.5.2.1. Date and venue of the meeting

2.6.3.5.2.2. Presiding Officer

2.6.3.5.2.3. Attendance of REC representatives (medical/scientific; non-medical/non-scientific; non-affiliated with the study site)

2.6.3.5.2.4. Attendance of independent consultants

2.6.3.5.2.5. Attendance of coordinating PI and guests or observers, if any

2.6.3.5.2.6. Time when the meeting was called to order

2.6.3.5.2.7. Status of quorum at the start of the meeting and before every decision making

2.6.3.5.2.8. Discussion of items based on the order

- in the meeting agenda
- 2.6.3.5.2.9. Summary of technical and ethical discussion points and recommendations
- 2.6.3.5.2.10. SJREB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.
 - 2.6.3.5.2.10.1. If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress reports are determined.
 - 2.6.3.5.2.10.2. If the review decision is disapproved, the reasons for the disapproval are stated.
 - 2.6.3.5.2.10.3. If the review decision (for initial and continuing reviews) is “for modification”, the items to be revised are identified and the type of review for the resubmission is defined.
- 2.6.3.5.2.11. Attach the list of protocols for exemption and protocols approved through expedited review report for the information of the board.
- 2.6.3.5.2.12. Name and signature of the person who prepared the minutes
- 2.6.3.5.2.13. Name and signature of the Chair who approved the minutes with the date of approval
- 2.6.3.6. The SJREB secretariat sends the draft meeting minutes to the SJREB Members for their review and comments within 7 calendar days before the succeeding meeting. Prior to dissemination of the minutes of the meeting, the secretariat shall seek approval from the HoS for the release of the document.
- 2.6.3.7. During the next full board meeting, the Chair asks the members to approve the Minutes.
- 2.6.3.8. The SJREB Staff files approved meeting minutes in the

2.7 Continuing Review Procedures

2.7. Continuing Review Procedures

2.7.1. The following documents shall be submitted to SJREB for continuing review:

- 2.7.1.1. Amendment of the country protocol
- 2.7.1.2. Progress report
- 2.7.1.3. Final report
- 2.7.1.4. Protocol violation/ deviation
- 2.7.1.5. Early termination report

2.7.2. The SJREB secretariat keeps the continuing review application package together with the review comments of the primary reviewer/s and the SJREB decision in the protocol file folder and updates the Online Database of Active Study Files.

2.7.3. Detailed Procedures

- 2.7.3.1. Amendment of the country protocol
- 2.7.3.2. The Coordinating PI submits to SJREB any amendments to the previously approved protocol documents.
- 2.7.3.3. The Head of Secretariat makes a preliminary assessment of the amendment and determines the type of review necessary.
- 2.7.3.4. Amendments that may potentially alter the risk/benefit ratio is referred to full board review for discussion, including but not limited to the following:
 - 2.7.3.4.1. Change in study design
 - 2.7.3.4.2. Change in the number of subjects
 - 2.7.3.4.3. Change in the inclusion or exclusion criteria
 - 2.7.3.4.4. Addition or removal of treatments
 - 2.7.3.4.5. Change in the method or route of drug administration
 - 2.7.3.4.6. Change in drug dosage
- 2.7.3.5. Minor changes that does not potentially alter the risk/benefit ratio is referred to the original Primary

Reviewers.

- 2.7.3.6. The SJREB secretariat sends the amendment report to the primary reviewers at least seven (7) calendar days before full-board meeting.
- 2.7.3.7. The SJREB secretariat notifies all site RECs about the amendment application.
- 2.7.3.8. Approval of amendment application reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.
- 2.7.3.9. The SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.
- 2.7.3.10. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.4. Progress report

- 2.7.4.1. Progress reports shall be submitted annually unless an earlier or more frequent schedule is decided by the board.
- 2.7.4.2. The SJREB secretariat communicates to the Sponsor/ Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.
- 2.7.4.3. The Coordinating PI submits to SJREB the latest versions of the Investigator
- 2.7.4.4. Brochure (IB), current versions of the protocol, informed consent forms (ICF) and other relevant documents, along with a summary of all protocol amendments, protocol deviations/ violations and on-site SAEs/SUSARs etc., as well as participant recruitment since the last SJREB approval.
- 2.7.4.5. The SJREB secretariat notifies all site RECs about the continuing review submissions. The Site RECs collect specific information from their site about protocol amendments, protocol deviations/ violations and local SAEs/ SUSARS, including participant

- recruitment data to provide inputs during joint review.
- 2.7.4.6. The SJREB secretariat sends the progress report package to the primary reviewers at least seven (7) calendar days before full-board meeting.
 - 2.7.4.7. Primary reviewers refer to the progress report document to determine whether they contain updated information related to patient safety. Review comments should consider the following:
 - 2.7.4.7.1. Risk Assessment: the risks to the subjects are minimized; the risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.
 - 2.7.4.7.2. Adequacy of Informed Consent: Informed consent/Assent forms current (most recent); appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)
 - 2.7.4.7.3. Local Issues: Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials); Evaluation, investigation and resolution of complaints related to the research, if any; Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.); Report from third party observation of the research (including the informed consent process) carried out; Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by

institutional policies), if any.

2.7.4.7.4. Trial Progress: Start date of the study and expected duration; Total subject enrollment (expected enrollment, actual enrollment, enrollment issues), subject withdrawal (number of subjects who withdrew, lost to follow-up, summary of reasons for withdrawal at local site)

2.7.4.8. Progress report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.4.8.1. Renew approval

2.7.4.8.2. Request additional information

2.7.4.8.3. Recommend modification

2.7.4.8.4. Suspend:

2.7.4.8.5. Enrollment of new subjects

2.7.4.8.6. Research procedures in currently enrolled subjects

2.7.4.8.7. Entire study

2.7.4.8.8. Disapprove renewal

2.7.4.9. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting.

2.7.4.10. SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.4.11. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required and prepares Notification of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.5. Final report

2.7.5.1. Final reports shall be submitted by the Coordinating PI upon completion of the study using SJREB Form 9. Closure/Final Report Form. The final report shall contain consolidated information from all the sites

- included in the study.
- 2.7.5.2. The SJREB secretariat communicates to the Coordinating PI about the need to submit progress report 30 calendar days before the expiry of the Notice of Approval.
- 2.7.5.3. The SJREB head of secretariat classifies the submission as either for full board or for expedited review based on the original protocol review classification.
- 2.7.5.4. The SJREB secretariat sends the final report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.
- 2.7.5.5. Primary reviewers refer to the final report document to determine whether they are in accordance with the protocol and related documents approved by the SJREB during initial review and review of amendments, as applicable.
- 2.7.5.6. Final report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:
 - 2.7.5.6.1. Approve final report and classify the protocol as inactive
 - 2.7.5.6.2. Request additional information from the coordinating PI
- 2.7.5.7. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported during the board meeting.
- 2.7.5.8. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required
- 2.7.5.9. The SJREB Secretariat prepares the Notice of Approval for signature of SJREB Chair.
- 2.7.5.10. The SJREB staff communicates the decision of the

SJREB to the Coordinating PI and site RECs.

2.7.6. Protocol Violation/ Deviation

- 2.7.6.1. Protocol violation or deviation, whether minor or major, from any of the sites included in the study shall be reported to the SJREB by the coordinating PI through the Progress Report Form including relevant documents needed to explain or provide details for the information indicated in the report.
- 2.7.6.2. The Head of Secretariat classifies the submission as either for full board or for expedited review:
- 2.7.6.3. Minor Protocol Deviation- are non-systematic protocol noncompliance with minor consequences to the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature
- 2.7.6.4. Major Protocol Deviation or Protocol Violation - are persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk
- 2.7.6.5. The SJREB secretariat sends the protocol non-compliance report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.
- 2.7.6.6. Primary reviewers refer to the protocol non-compliance report package to determine the appropriate course of action depending on the seriousness of the non-compliance.
- 2.7.6.7. Non-compliance identified for full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:
 - 2.7.6.7.1. Uphold Original Approval
 - 2.7.6.7.2. Request Further Information
 - 2.7.6.7.3. Suspension of Ethical Clearance
 - 2.7.6.7.4. Cancellation of Ethical Clearance
 - 2.7.6.7.5. Deferred Action pending major clarification
- 2.7.6.8. Non-compliance report reviewed by the Primary

Reviewers by expedited procedure is reported during the board meeting.

- 2.7.6.9. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required
- 2.7.6.10. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.
- 2.7.6.11. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

2.7.7. Early Termination

- 2.7.7.1. Early termination of protocol implementation shall be reported to the SJREB by the coordinating PI through the Early Termination Application Form (SJREB Form 11).
- 2.7.7.2. The SJREB secretariat sends the early termination report to the primary reviewers at least seven (7) calendar days before the full-board meeting.
- 2.7.7.3. Primary reviewers refer to the early termination application to determine the appropriate recommendations
- 2.7.7.4. Early termination application shall be included in the agenda for discussion in the full board meeting to determine the early termination's implication to the participants and arrive at recommendations for continued protection of study participants including follow-up plan to those who are still actively enrolled.
- 2.7.7.5. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required
- 2.7.7.6. The SJREB Secretariat prepares the Notification of Decision for signature of SJREB Chair.
- 2.7.7.7. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

C. SOP 3 DOCUMENTATION AND ARCHIVING

3.1 Purpose

- 3.1.1. To describe the Single Joint Research Ethics Board (SJREB) procedures in documenting all protocol submissions and archiving completed and inactive studies.

3.2 Scope

- 3.2.1. This procedure applies to documentation and archiving of all protocols submitted to SJREB for ethics review.

3.3 Process Flow and Procedures for Documentation

Table 4. Process Flow and Procedures for Documentation

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Input of protocol submission in the online database	Secretariat staff
2	Input digital and hard copy of protocol related files in their respective storage areas	Secretariat staff

3.4 Documentation

The secretariat staff maintains a protocol file to contain all submissions and action taken on protocols submitted for SJREB review.

3.4.1. Online database

3.4.1.1. The secretariat staff It maintains an online database that contains complete and updated information about all protocol submissions.

3.4.1.2. The database should contain the following information:

- 3.4.1.2.1. Protocol code
- 3.4.1.2.2. Protocol title
- 3.4.1.2.3. Type of protocol
- 3.4.1.2.4. Sponsor
- 3.4.1.2.5. Study sites
- 3.4.1.2.6. Coordinating investigator
- 3.4.1.2.7. Submission date
- 3.4.1.2.8. Type of review
- 3.4.1.2.9. Primary reviewers
- 3.4.1.2.10. Date of meeting
- 3.4.1.2.11. Review decision
- 3.4.1.2.12. Date of issuance of decision
- 3.4.1.2.13. Resubmission date
- 3.4.1.2.14. Date of decision of resubmission
- 3.4.1.2.15. Approval date
- 3.4.1.2.16. Expiration date
- 3.4.1.2.17. Due date for progress report
- 3.4.1.2.18. Date of submission of progress report
- 3.4.1.2.19. Submission of amendment report
- 3.4.1.2.20. Date of approval of amendment report
- 3.4.1.2.21. Submission of final report Date of approval of final report
- 3.4.1.2.22. Other reports (SAEs, protocol violations, etc.)

3.4.1.3. All protocol submissions should be logged in the database.

- 3.4.2. Digital and hard copies of protocol related files should be submitted to the secretariat staff.
- 3.4.2.1. All protocol submissions should be properly labeled with protocol code (Refer to chapter 2 on proper labelling, see 2.5.8).
- 3.4.2.2. Digital copies are stored in their separate google drive folders that are password protected.
- 3.4.2.3. Hard copies are kept in separate folders in the cabinet with locks and keys
- 3.4.2.3.1. All protocol submission should be stored in separate folders.
- 3.4.2.3.2. Folders should be properly labeled with their protocol code. For protocols with multiple folders, the label format should be: Protocol Code + letter (in chronological order based on the oldest files).
- 3.4.2.3.3. Folders should be stored in cabinets properly labeled with active or inactive status. All cabinets should be secured by a lock and key. Only the secretariat staff should have the key and its duplicate.
- 3.4.2.3.4. Each folder should contain an index at the beginning of the file to identify the protocol documents found in the folder
- 3.4.2.4. Any document submitted by the investigator is added to the protocol files

3.5 | **Process Flow and Procedures for Archiving**

Table 5. Process Flow and Procedures for Archiving

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Identify inactive protocols files	Secretariat staff
2	Update protocol database	Secretariat staff
3	Affix appropriate label to files for archiving	Secretariat staff
4	Transfer files to the proper cabinet	Secretariat staff

3.6 Archiving

The secretariat staff will follow the following procedures:

- 3.6.1. Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by SJREB.
- 3.6.2. Incomplete studies are classified as inactive when no further communication or submission has been received by SJREB after two years. Studies that are terminated earlier before completion will also be classified as inactive files.
- 3.6.3. Once the final report has been approved, the Secretariat staff marks the database as completed.
- 3.6.4. Digital file folders are marked with an I or C to indicate that they are incomplete and complete respectively. Hard copy folders are marked with a red sticker to indicate that they are inactive.
- 3.6.5. At the end of the year, the secretariat staff transfers all completed/inactive protocol folders to the archive.
- 3.6.6. Protocols are archived for 3 years. After 3 years in the archive, the protocol files may be transferred to a password protected offline hard disk

3.7 Process Flow and Procedures for Retrieval of Documents

Table 6. Process Flow and Procedures for Retrieval of Documents

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Receive requests to access SJREB protocol documents	Secretariat staff
2	Approve and input all requests and transaction in the database	Secretariat staff
3	Supervise the use of retrieved documents	Secretariat staff
4	Return of document to the protocol file folder	Secretariat staff

3.8 **Retrieval**

The secretariat staff will follow the following procedures:

- 3.8.1. Receive requests to access SJREB protocol documents.
 - 3.8.1.1. Access to SJREB files is subject to the following limitations:
 - 3.8.1.1.1. Participating site members with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access documents outside of regular protocol review access, upon request.
 - 3.8.1.1.2. Non-members can access specific documents by submitting a formal request. The secretariat staff will require a signed Confidentiality Agreement and Conflict of Interest Disclosure. This request needs to be approved by the Member Secretary.
 - 3.8.1.1.3. Regulatory authorities (e.g. Philippine FDA) can have full access to SJREB documents provided it is within their mandate and within a reasonable notice to make the files available.
- 3.8.2. Approve and input all requests and transaction in the database.
 - 3.8.2.1. All requests are put into the online database. The following information should be included:
 - 3.8.2.1.1. Protocol code
 - 3.8.2.1.2. Date borrowed
 - 3.8.2.1.3. Name of borrower
 - 3.8.2.1.4. Document requested or copied
 - 3.8.2.1.5. Number of copies made
 - 3.8.2.1.6. Date returned of borrowed documents
- 3.8.3. Supervise the use of retrieved documents.
 - 3.8.3.1. Access to SJREB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.
 - 3.8.3.2. The secretariat staff makes only the exact number of copies requested.

- 3.8.4. Return document to the protocol file folder.
 - 3.8.4.1. The secretariat staff is responsible for returning the documents in the protocol file folder in the cabinet after making sure that all documents are complete as per protocol file index

D. SOP 4 WRITING AND REVISING STANDARD OPERATING PROCEDURES

4.1 Writing SOPs

4.1.1. Purpose

To describe the procedure for writing and revising SOPs used by the Single Joint Research Ethics Board

4.1.2. Scope

This SOP provides instructions on how the new SJREB SOPs are prepared.

4.1.3. Responsibility

4.1.3.1. It is the responsibility of the Chair of SJREB to organize an SOP Team to formulate the SOPs of the REC.

4.1.3.2. The SOP Team is an ad hoc committee composed of designated SJREB members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.

4.1.3.3. The Chair convenes an SJREB meeting to review and finalize the draft SOPs and ensures that all SJREB members have an access to current versions of SOPs to guide them in the performance of their functions.

4.1.4. Process Flow

Table 7. Process Flow for Writing SOPs		
NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Organize an SOP Team	SJREB Chair
2	Identify reference templates with corresponding layout	SOP Team
3	Draft revised SOPs and submit to Chair	SOP Team
4	Review and finalize revised SOP in an SJREB meeting and submit to the HPDPB Director	Chair, SJREB Members
5	Approve and sign revised SOPs	HPDPB Director
6	Distribute approved SOPs and keep copies in the SJREB files	Secretariat

4.1.5. Detailed Instructions

4.1.5.1. Organized an SOP Team

- 4.1.5.1.1. HPDPB Director assigns members of the SOP Team, and invites resource persons as needed.
- 4.1.5.1.2. The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.
- 4.1.5.1.3. The Chair may organize a SOP Team workshops to facilitate the drafting of SOPs.

4.1.5.2. Identify reference templates with corresponding layout

- 4.1.5.2.1. Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP Team in drafting new SOPs.
- 4.1.5.2.2. An SJREB SOP have the following format:
 - 4.1.5.2.2.1. SOP Number
 - 4.1.5.2.2.2. Title

- 4.1.5.2.2.3. Purpose of the SOP
- 4.1.5.2.2.4. Scope which defines the extent of coverage of the SOP and its limitations
- 4.1.5.2.2.5. Responsibility identifies the persons assigned to perform specific tasks during SOP implementation
- 4.1.5.2.2.6. Process Flow/ Steps
- 4.1.5.2.2.7. Detailed instructions which elaborates the steps outlined in the process flow
- 4.1.5.2.2.8. Standard forms and checklist to be used
- 4.1.5.2.2.9. Glossary
- 4.1.5.2.2.10. References
- 4.1.5.2.2.11. List of Acronyms
- 4.1.5.2.3. Each SOP should be given a number and a title that is self-explanatory and is easily understood.
- 4.1.5.2.4. The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP Masterfile.
- 4.1.5.2.5. The typical SOP uses a header with the following elements
 - 4.1.5.2.5.1. Institutional seal or logo
 - 4.1.5.2.5.2. Name of institution
 - 4.1.5.2.5.3. SOP Identifier
 - 4.1.5.2.5.4. SOP Title
 - 4.1.5.2.5.5. Effectivity date
 - 4.1.5.2.5.6. Page number

4.1.5.3. Draft new SOPs and submit to the Chair

- 4.1.5.3.1. The SJREB SOPs should contain details under the following main topics:
 - 4.1.5.3.1.1. Introduction - contains a statement of ethical principles that will guide SJREB
 - 4.1.5.3.1.2. Authority, Composition, and Structure of SJREB - describes the composition of SJREB Membership with specific review functions

- 4.1.5.3.1.3. Joint Review of Initial Submission - describes types of review and initial review procedures
- 4.1.5.3.1.4. Continuing Review Procedures - describes how SJREB conducts post-approval review procedure
- 4.1.5.3.1.5. Documentation, and Archiving - describes administrative procedures that support the review functions
- 4.1.5.3.1.6. Writing and Revising SOPs - describes how to draft and revise SOPs
- 4.1.5.3.2. The SOP Team submits completed SOP draft to the Chair.

4.1.5.4. Review and finalize new SOPs in an SJREB meeting and submit to the HPDPB Director

- 4.1.5.4.1. The SJREB Chair or any permanent member presents the draft SOPs during an SJREB meeting for the member to discuss and finalize the draft
- 4.1.5.4.2. The SJREB Chair submits the approved draft to the Director of HPDPB for approval.

4.1.5.5. Approve and sign new SOPs

- 4.1.5.5.1. The HPDPB Director reviews and approves the SOPs by signing in the designation section.
- 4.1.5.5.2. The approved SOPs will be implemented after approval by the HPDPB Director.

4.1.5.6. Distribute approved SOPs and keep copies in the SJREB files

- 4.1.5.6.1. The SJREB Secretariat distributes the new SJREB SOPs to all SJREB Members, participating site RECs with active LOI, and Staff and files the original copy in the SJREB storage cabinet.
- 4.1.5.6.2. The SOP Manual with downloadable forms are uploaded on the SJREB website for the use of and guidance of researchers.

APPENDICES AND FORMS

Appendix A.	
SJREB FORM 1	Application for SJREB Initial Review
SJREB FORM 1.2	Protocol Summary Sheet
SJREB FORM 2	Protocol Assessment Form
SJREB FORM 3	Informed Consent Assessment Form
SJREB FORM 4	Checklist of Exemption
SJREB FORM 4.1	Certificate of Exemption from Ethics Review
SJREB FORM 5	Notice for Protocol Modification
SJREB FORM 5.1	Protocol Resubmission Form
SJREB FORM 6	Notice of Approval
SJREB FORM 7	Progress or Annual Report for Philippine Sites
SJREB FORM 7.1	Progress Report for Government Funded Protocols
SJREB FORM 8	Protocol Amendment Application Form
SJREB FORM 9	Closure or Final Report Form
SJREB FORM 9.1	Early Study Termination Application
SJREB FORM 10	Notice for Post-Approval Modification
SJREB FORM 11	Onsite Serious Adverse Event Report
SJREB FORM 12	Protocol Violation_Deviation Report
SJREB FORM A	Declaration of Conflict of Interest

APPENDIX A



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 1
APPLICATION FOR SJREB INITIAL REVIEW
To be filled up by the Coordinating Investigator

SJREB Protocol Number <i>(to be filled-up by secretariat staff)</i> :																			
Sponsor Protocol Number:	Submission Date:																		
Protocol Title:																			
Type of Research:	<table style="width: 100%; border: none;"> <tr> <td style="border: none; padding: 2px 10px;">Clinical Research</td> <td style="border: none; padding: 2px 10px;">☐</td> <td style="border: none; padding: 2px 10px;">Clinical Trial</td> <td style="border: none; padding: 2px 10px;">☐</td> <td style="border: none; padding: 2px 10px;">Laboratory Research</td> <td style="border: none; padding: 2px 10px;">☐</td> </tr> <tr> <td style="border: none; padding: 2px 10px;">Genetic Research</td> <td style="border: none; padding: 2px 10px;">☐</td> <td style="border: none; padding: 2px 10px;">Socio-behavioral</td> <td style="border: none; padding: 2px 10px;">☐</td> <td style="border: none; padding: 2px 10px;">Public health</td> <td style="border: none; padding: 2px 10px;">☐</td> </tr> <tr> <td colspan="6" style="border: none; padding: 2px 10px;">Others <i>(specify)</i>: _____</td> </tr> </table>	Clinical Research	☐	Clinical Trial	☐	Laboratory Research	☐	Genetic Research	☐	Socio-behavioral	☐	Public health	☐	Others <i>(specify)</i> : _____					
Clinical Research	☐	Clinical Trial	☐	Laboratory Research	☐														
Genetic Research	☐	Socio-behavioral	☐	Public health	☐														
Others <i>(specify)</i> : _____																			
Study Duration:																			
Sponsor:																			
Coordinating Investigator: <i>(Please assign one person only)</i>																			
Sites and Site Principal Investigators: <i>(List all sites and site investigators)</i>																			
Telephone number:	Email																		
Institution:																			
Declaration of Conflict of Interest (COI)																			
Are you an employee of the sponsor/s?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">x</td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%; text-align: center;">x</td> <td style="width: 10%; text-align: center;">No</td> </tr> </table>	x	Yes	x	No														
x	Yes	x	No																
Did you do consultancy or part time work for the sponsor/s?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">x</td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%; text-align: center;">x</td> <td style="width: 10%; text-align: center;">No</td> </tr> </table>	x	Yes	x	No														
x	Yes	x	No																

In the past year, did you receive P500,000 or more from the sponsor/s?	x	Yes	x	No
Other ties with the sponsor:				
<u>Ethical Responsibility and COI Statement</u> I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI).				
CI Signature:				

Documents submitted: *(Please check the documents submitted)*

Basic documents:	
	Application Form [SJREB FORM 1 – APPLICATION FORM]
	Protocol Summary Sheet [SJREB Form 1.2 – Protocol Summary Sheet]
	Informed Consent Forms (in English and in local language)
	Recruitment and Advertisement Materials
	Data Collection Forms
	CVs of PIs
	Study Budget
	Study Protocol
	Technical Clearance
	Proof of parallel submission to at least three (3) study sites
Study-specific Documents (submit as needed):	
	FDA Approval/Clearance (for clinical trials)
	Patient Information Sheet (for clinical trials)
	Investigator Brochure (for clinical trials)
	GCP Certificates of PIs (for clinical trials)
	Other protocol-related documents (please specify):

Received by:
(SJREB Secretariat)

Date:



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

FORM 1.2
PROTOCOL SUMMARY SHEET

SJREB Protocol No.	Protocol Title

Coordinating Investigator	Sponsor

Rationale	
Objectives	
Study Design/Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	
Ethical Consideration	



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SJREB FORM 2
PROTOCOL ASSESSMENT FORM

To be filled up by primary reviewer
Instructions: Please do literature search to update your knowledge about this protocol

SJREB Protocol No.:		Date (D/M/Y.):	
Protocol Title:			
Coordinating Investigator:			
Institution:			
Total No. of Participants:		No. of Study Sites:	
Expected no. from Philippine sites:			
Sponsor:			
Duration of the Study:		Status:	☐ New ☐ For Renewal of Approval
Reviewers:			
☐ Intervention ☐ Document review ☐ Social Survey	☐ Epidemiology ☐ Case study ☐ Others (<i>specify</i>):	☐ Observational study ☐ Genetic	
Review Type:	☐ Full Board	☐ Expedited	☐ Exempted
Description of the Study in brief: Mark whatever applies to the study.			
☐ Randomized	☐ Drug	☐ Use of Genetic Materials	
☐ Double-blind	☐ Medical Device	☐ Multicenter Study	
☐ Single-blind	☐ Vaccine	☐ Global Protocol	
☐ Open-label	☐ Diagnostics	☐ Sponsor-initiated	
☐ Observational	☐ Questionnaire	☐ Investigator-initiated	

A. PROTOCOL DOCUMENT REVIEW (please put an X before your choice and N/A on the comments if there are no further comments)

Questions	Comment/s:
1. Objectives of the study	
☐ Clear ☐ Not clear	
2. Need for human participants	
☐ Clear ☐ Not clear	
3. Background information	
☐ Sufficient ☐ Not sufficient	
4. Methodology	
☐ Clear ☐ Not clear	
5. Sufficient number of participants	
☐ Yes ☐ No	
6. Control arms (placebo, if any)	
☐ Yes ☐ No	
7. Data analysis plan	
☐ Appropriate ☐ Not Appropriate	
8. Study outcomes	
☐ Defined ☐ Incomplete ☐ Not defined	
9. Level of risk	
☐ Low ☐ Medium ☐ High	
10. Risk mitigation in the protocol	
☐ Appropriate ☐ Not Appropriate	
11. Benefits of the participants in the protocol	
☐ Appropriate ☐ Not Appropriate	
12. Inclusion criteria	
☐ Appropriate ☐ Not Appropriate	
13. Exclusion criteria	
☐ Appropriate ☐ Not Appropriate	
14. Withdrawal criteria	

	Appropriate		Not Appropriate	
15. Involvement of vulnerable participants				
	Yes		No	
16. Protection of vulnerable participants				
	Appropriate		Not Appropriate	
17. Voluntary, non-coercive recruitment of participants				
	Yes		No	
18. Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate?				
	Yes		No	
19. Disclosure of potential conflicts of interest				
	Yes		No	
20. Facilities and infrastructure of participating sites				
	Yes		No	
21. Community consultation				
	Yes		No	N/A
22. Involvement of local researchers and communities in the protocol preparation and implementation				
	Yes		No	N/A
23. Contribution to local capacity building				
	Yes		No	N/A
24. Benefit to local community				
	Yes		No	N/A
25. Sharing of study results				
	Yes		No	N/A
26. Are blood or tissue samples sent abroad				
	Yes		No	N/A

B. RECOMMENDATION

Decision:	Approval	Minor Revision
	Major Revision	Disapproval

Summary of comments:	
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Reviewer's Name:		Date:	
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Signature:	
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Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 3
INFORMED CONSENT ASSESSMENT FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Coordinating Investigator:			

A. INFORMED CONSENT DOCUMENT REVIEW *(please put an X before your choice and N/A on the comments if there are no further comments)*

Questions	Comment/s:	
1. Does the Informed Consent document state that the procedures are primarily intended for research?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
2. Are procedures for obtaining Informed Consent appropriate?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
3. Does the Informed Consent document contain comprehensive and relevant information?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
4. Is the information provided in the protocol consistent with those in the consent form?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
5. Are study related risks mentioned in the consent form?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
6. Is the language in the Informed Consent document understandable?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
7. Is the Informed Consent translated into the local language/dialect?		

	Yes		No	
8. Are there vulnerable participants?				
	Yes		No	
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?				
	Appropriate		Not appropriate	
10. Are names and contact numbers from the research team and the REC in the informed consent?				
	Yes		No	
11. Does the ICF provide privacy & confidentiality protection?				
	Yes		No	
12. Is there any undue inducement for participation?				
	Yes		No	
13. Is there provision for medical/psychosocial support?				
	Yes	No	N/A	
14. Is there provision for treatment of study-related injuries				
	Yes	No	N/A	
15. Is the amount paid to participants stated?				
	Yes	No	N/A	

B. RECOMMENDATION

Decision:	Approval	Minor Revision
	Major Revision/ Resubmission	Disapproval

Summary of comments:	
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Reviewer's Name:		Date:	
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Signature:	
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Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 4
CHECKLIST FOR EXEMPTION FROM FULL ETHICAL REVIEW
FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Coordinating Investigator:			

A. Protocol Assessment

Questions	Comment/s:	
1. Does this research involve human participants?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
2. Does this research involve use of non-identifiable human tissue/ biological samples?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
3. Does this research involve use of non-identifiable publicly available data?		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
<i>*Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHR 2017)</i>		
4. Does this research involve interaction with human participants		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
5. Type of research (<i>please tick appropriate box</i>)		
a. Institutional quality assurance		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
b. Evaluation of public service program		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
c. Public health surveillance		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	
d. Educational evaluation activities		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Yes</td> <td style="width: 50%; text-align: center;">No</td> </tr> </table>		Yes
Yes	No	

e. Consumer acceptability test			
☐	Yes	☐	No
*These 5 have been identified in the NEGHR as exemptible, as long as it does not involve more than minimal risk.			
6. What is/are the method/s of data collection (please tick appropriate box)			
a. Surveys and/or questionnaire			
☐	Yes	☐	No
b. Interviews or focus group discussion			
☐	Yes	☐	No
c. Public observations			
☐	Yes	☐	No
d. Research which only uses existing data			
☐	Yes	☐	No
e. Audio/video recordings			
☐	Yes	☐	No
*These 5 have been identified in the NEGHR as exemptible, as long as anonymity and/or confidentiality is maintained.			
7. Will the collected data be anonymized or identifiable?			
☐	Anonymized	☐	Identifiable
☐	De-identified		
8. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHR 2017) *Please refer to section B. Risk Assessment, prior to answering this item			
☐	Yes	☐	No
*If YES, then this protocol does not qualify for exemption			

B. Risk Assessment

Questions	Comment/s		
1. Does this research involve the following: (please check all that applies)			
a. Any vulnerable groups?			
☐	Yes	☐	No
b. Sensitive topics that may make participants feel uncomfortable (i.e. sexual behaviour, illegal activities, racial biases, etc.			

	Yes		No	
c. Use of drugs				
	Yes		No	
d. Invasive procedure (e.g. blood sampling)				
	Yes		No	
e. Physical stress/distress, discomfort				
	Yes		No	
f. Psychological/mental stress/distress				
	Yes		No	
g. Deception of/or withholding information from subjects				
	Yes		No	
h. Access to data by individuals or organizations other than the investigators				
	Yes		No	
i. Conflict of interest issues				
	Yes		No	
j. Or any other ethical dilemmas				
	Yes		No	
k. Is there any blood sampling involved in the study				
	Yes		No	

C. RECOMMENDATION

Decision:	Qualified for Exemption
	Unqualified for Exemption

Summary of comments:	
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Reviewer's Name:		Date:	
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Signature:	
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Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 4.1
CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

Date:

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the SJREB for implementation

SJREB Protocol No.:		Sponsor Protocol No.:	
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Coordinating Investigator:		Sponsor:	
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Title:	
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Protocol Version No.:		Version Date:	
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ICF Version No.:		Version Date:	
Other Documents:			

This protocol is exempted from review for the following reasons: *(check the NEGHHR)*
1.

SJREB Chair	Signature	Date

NOTE:

- Final/Closure Reports should be submitted at the end of the study.
- Any amendment to the protocol should be submitted to SJREB for re-evaluation of exemption.

Received by:

Name: _____

Signature: _____ Date: _____



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5
NOTICE OF PROTOCOL MODIFICATION

Date: 2020

To (name of PI):

Contact Details:

Protocol Title:

SJREB Protocol Code

Sponsor Protocol No.

Protocol Version No. and
Version Date:

ICF Version No. and Version
Date

Type of Submission

☐	Initial Submission
☐	Resubmission
☐	Others

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review		SJREB Decision	
☐	Exempted	☐	Minor revisions required
☐	Expedited	☐	Major revisions required
☐	Full Board	☐	More information required
		☐	Approved
		☐	Others:

Meeting Date:	
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SJREB Chair	Signature	Date
Dr. Jacinto Blas Mantaring III		



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5.1
PROTOCOL RESUBMISSION FORM

To be filled by investigator

SJREB Protocol Number					
Sponsor Protocol Number		Submission Date			
Protocol Title:					
Documents revised		Protocol (<i>latest version number and date</i>)		ICF (<i>latest version number and date</i>)	
		Others (specify):			
Type of Initial Review		Exempted		Expedited	Full Board
Channel of review for resubmission		Expedited		Full Board	
Coordinating PI		Sponsor			
Contact Numbers		Email			
Institution					
REC Recommendations	Revisions made by the PI		Reviewer Comments (<i>to be filled up by primary reviewers</i>)		



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 6
NOTICE OF APPROVAL

Date:

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation in accordance with the International Conference on the Harmonization of Good Clinical Practice and the National Ethical Guidelines on Health and Health-related Research

SJREB Protocol No.:		Sponsor Protocol No.:	
Coordinating Investigator:		Sponsor:	
Title:			
Protocol Version No.:		Version Date:	
ICF Version No.:		Version Date:	
Other Documents:			
Members of research team:			
Study sites:			
Type of Review:	☐ Expedited ☐ Full Board Meeting date:	Duration of Approval From – To (<i>date</i>) December 28, 2018 to December 28, 2019	Frequency of continuing review Annual

SJREB Chair	Signature	Date



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7
PROGRESS/ANNUAL REPORT FOR PHILIPPINE SITES

SJREB Protocol No.:		Initial Approval Date:	
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Protocol Title:	
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Coordinating Investigator:		Sponsor:	
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		Yes		No
Any amendment since the last review? Describe briefly.				
Any change in participant population, recruitment or selection criteria since the last review? Explain the changes.				
Any change in the Informed Consent process or documentation since the last review? Please explain.				
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.				
Any unexpected complication or side effect noted since the last review? Summarize.				

Were there protocol deviation/ violation reports? Summarize. What corrective actions were taken?		Yes		No
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.		Yes		No

Summary of recruitment:	
	Accrual ceiling set by REC
	New participants accrued since last review
	Total participants accrued since protocol began
	No. of participants who are lost to follow up
	No. of participants withdrawn from the study
	No. of participants who experienced SAEs/ SUSARs

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.		Yes		No

FOR SJREB USE

Name of Primary Reviewer	
--------------------------	--

Assessment by the Primary Reviewer:

Questions:	Yes	No	Comments:
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			

Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI

Recommended Action:	
	Approve
	Request further information, <i>specify</i>
	Recommend further action, <i>specify</i>
Other comments:	

Primary Reviewer:

Signature:

Date:



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7.1
PROGRESS REPORT FOR GOVERNMENT FUNDED PROTOCOLS

SJREB Protocol No.:		Initial Approval Date:	
---------------------	--	------------------------	--

Protocol Title:	
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Coordinating Investigator:		Sponsor:	
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Summary of Accomplishments			
Objectives	Activities (for each objective)	Targets	Accomplishments

Results and Discussion (Detailed discussion of outputs / findings for the period based on target activities)

Problems / Difficulties Encountered (Obstacles/hurdles met and experienced during implementation, explanatory notes for deviation(s) in targets and accomplishments, changes in dates of implementation, etc.)

Proposed or Suggested Solutions (Proposed action(s) to solve problems encountered)

Please submit an endorsement letter from the end-user/sponsor that they have fully received and accept the progress of the study

FOR SJREB USE

Name of Primary Reviewer	
--------------------------	--

Assessment by the Primary Reviewer:

Recommended Action:	
	Approve
	Request further information, <i>specify</i>
	Recommend further action, <i>specify</i>
Other comments:	

Primary Reviewer:

Signature:

Date:



Republic of the Philippines
Department of Health
SJREB FORM 8

SJREB FORM 8
PROTOCOL AMENDMENT APPLICATION FORM

Date of submission	SJREB Protocol No.	Sponsor Protocol No.
Principal Investigator	Email/ Mobile No.	Sponsor

Title of Study	
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Study Site/s:		Date of Initial Approval	
		Type of Initial Review: <i>(Full Board, Expedited, Exempted)</i>	

Items to be Amended	List of Amendments	Reasons

Signature of PI:	
Date:	

FOR REC USE:			
Assessment of Primary Reviewers	1. Type of amendments:		
		Minor	Major
	Comment/s:		
	2. Does the amendment decrease the risks to participants		
		Yes	No
	Comment/s:		
	3. Does the amendment decrease the benefits to participants?		

	☐	Yes	☐	No
	Comment/s:			
	4. Is there favorable benefit/ risk ratio?			
	☐	Yes	☐	No
	Comment/s:			

Recommendations:	
☐	Approve
☐	Request for further information/modification
☐	Others

Type of review	
☐	Expedited
☐	Exempted
☐	Full Board

Name of reviewer:		Signature:		Date:	
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Final Decision:	
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SJREB Chair	Signature	Date



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

FORM 9
CLOSURE/FINAL REPORT FORM
(Consolidated report from all sites included in the study)

PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		Mobile:	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		Email:	
1. Study Arms:			
2. Summary of Recruitment:			
Accrual ceiling set by REC			
New participants accrued since last review			
Total number of participants accrued since protocol began			
No. of participants who are lost to follow up			
No. of participants withdrawn from the study			
No. of participants who experienced SAEs/SUSARs			
3. Number of participants who completed the study:			
4. Amendments to the original protocol (including dates of approval):			
5. Summary of onsite SAEs reported:			
6. Summary of participants' complaints or grievances documented regarding conduct of study:			

7. Summary of benefits to participants:	
8. Summary of indemnifications of study related injury (If Applicable):	
9. If terminated early, specify reason for termination:	
10. Progress reports submitted (with dates of approval):	
11. Duration of the study (months):	
12. Informed consent form used (with version no./date) and attach most recent version:	
13. Study objectives and summary of results:	

SIGNATURE OF PI:	
DATE:	
RECEIVED BY:	
REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	
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Final Decision:	
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SJREB Chair	Signature	Date



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 9.1
EARLY STUDY TERMINATION APPLICATION
(Consolidated report from all sites included in the study)

SJREB PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		Mobile:	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		Email:	
TERMINATION DATE:			
1. No. of participants			
2. No. of enrolled			
3. Reason/s for early termination			
4. Summary of results			
Accrual data			
• How many have completed the study?			
• How many are still active?			
• What are the plans for those who are still active in the study?			

SIGNATURE OF PI:	
DATE:	
RECEIVED BY:	
REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	
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Final Decision:	
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SJREB Chair	Signature	Date



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 10
NOTICE OF POST-APPROVAL MODIFICATION

Date:

To (*name of PI*):

Contact Details:

Protocol Title:

SJREB Protocol Code

Sponsor Protocol No.

Protocol Version No. and
Version Date:

ICF Version No. and Version
Date

Initial Approval Date

Type of Submission

☐	Annual Progress Report
☐	Amendment
☐	Final Report

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review		SJREB Decision	
☐	Exempted	☐	Minor revisions required
☐	Expedited	☐	Major revisions required
☐	Full Board	☐	More information required
☐		☐	Approved
		☐	Others

Meeting Date:	
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SJREB Chair	Signature	Date



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 11
ONSITE SERIOUS ADVERSE EVENT REPORT

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Name of Study Medicine:	
Report Date:	
Onset Date:	
Date of First Use:	

Patient Number	Age	Sex

Patient's History:	
Laboratory Findings:	
SAE:	
Treatment Outcome:	
Management of Adverse Reaction:	

Please check the ones applicable:

Seriousness:		Relation to:					
	Life Threatening		Drug		Device		Study
	Death		Not related				
	Hospitalization		Possibly				
	Disability/Incapacity		Probably				
	Congenital Anomaly		Definitely related				

	Others (please specify)		Unknown
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*Please attach standard CIOMS report form

FOR REC USE

Reviewer's Name	Signature	Date

Changes in the protocol recommended?		Yes	Comments:
		No	
Changes to the informed consent form recommended?		Yes	Comments:
		No	

REC Final Action	
	Request an amendment to the protocol or the consent form
	Request further information
	Suspend enrollment of new research participants
	Suspend all trial-related procedures
	Termination of study
	Take note and continue monitoring
	Conduct study site visits
	Others (please specify)



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 12
PROTOCOL VIOLATION/DEVIATION REPORT

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Date of Submission:	
Reported by:	

Protocol deviation:	
Corrective measures done:	

FOR REC USE

Reviewer's Name	Signature	Date

Please check the ones applicable:

Deviation from the protocol:		Participant non-compliance:	
	Minor		Yes
	Major		No
			N/A

REC Recommendation:	
	Noted (no further action needed)
	Correction action needed
	Site visit needed
	Others (please specify)



Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM A DECLARATION OF CONFLICT OF INTEREST

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	

Declaration of Conflict of Interest			
Are you an employee of the sponsor/s?		Yes	No
Have you done consultancy or part time work for the sponsor/s in the past?		Yes	No
In the past year, did you receive P500,000 or more from the sponsor/s?		Yes	No

Other information	
Do you have other financial or non-financial ties with the sponsor (e.g. employment of relative to the 4th level of consanguinity)	
Are you a member of a policy-determining/recommendatory body that is convened by the DOH, DOST, and other national agencies who lead on COVID-19 response?	

List of all studies you are currently managing			
Title of study	Sponsor	Status of implementation	% of time allotted for the study

Ethical Responsibility and COI Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI)

SIGNATURE	DATE

APPENDICES AND FORMS

APPENDIX B

Appendix B.	
	Guidelines for Review of Protocols during Emergency Outbreak

APPENDIX B. Guidelines for Review of Protocols during Emergency Outbreak

Adapted from the WHO Guidelines for Rapid Review of COVID-19 Research

Background

To date, there are no approved treatments or prophylactic products known to be safe and effective for COVID 19, which is similar to previous outbreaks such as Ebola, Zika, or Lassa fever. Consequently, conducting research on new medications or vaccines during this pandemic is essential. Research conducted during pandemics or outbreaks, while in the best interests of communities that are presently affected or could be affected in the future, raises many unique ethical issues.

Different countries will be in different stages of readiness to review epidemic-relevant research. Regardless of preparatory work that has been done so far, there are things that ethics committees can and should do now to prepare for rapid review of COVID-19 protocols. It is necessary that research ethics committees be prepared to rapidly review COVID-19 research.

There have been many articles and reports published after the 2014 Ebola outbreak that address ethical issues in research during outbreaks and research ethics governance^{1,2,3,4,5}. Of note, issues were raised about time sensitivity and the balance between the quality and time to review and ensuring the protection of participants in clinical trials, many of whom are in desperate need for any management protocols, lest they lose their lives.

Recently, two workshops were held to address important issues in this context: 1) "Ethics preparedness": Facilitating *Ethics Review During Outbreaks*, organized by ALERRT⁶ (African coaLition for Epidemic Research, Response and Training)& WHO (World Health Organization) in Dakar, Senegal in March 2018, and 2) "Ethics review of research on Lassa & other infectious disease outbreaks", organized by WHO in Abuja, Nigeria in October 2018. These workshops provided

recommendations for addressing how National/Institutional (Research) Ethics Committees (N(R)ECs) and other research review committees should prepare for changes that may be necessary to their Standard Operating Procedures (SOPs) in order to respond efficiently during this pandemic.

Specific Guidelines

To facilitate the rapid or time-sensitive reviews, the following additions or changes to the ethics committees' existing standard operating procedures are being recommended.

It is important to note that this guidance should come into action once an outbreak is declared as a public health emergency. This declaration will come from the public health authority of the country. To speed up time to start the research, many processes (e.g., drafting documents, translations, approvals, etc.) will be happening in parallel rather than sequentially as is the case in non-emergencies.

When a protocol is being considered for submission in a language different from that in which the review is conducted, the synopsis, plan, documents of consent/assent, and data collection tools/forms at a minimum should be submitted in the official language of the country where the review will take place. Other documents in the reviewing country's language should be submitted as soon as possible.

- 1 World Health Organization (WHO). Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. WHO 2016. ISBN 978 92 4 154983 7
- 2 Schopper D, Ravinetto R, Schwartz L, et al. Research Ethics Governance in Times of Ebola. Public Health Ethics 2016; doi: 10.1093/phe/phw039 First published online: November 1, 2016.
- 3 Nuffield Council of Bioethics. Conducting research and innovation in the context of global health emergencies: what are the ethical challenges? Notes of workshop held on 9 December 2016: 10:00–13:30 28 Bedford Square, London WC1B 3JS.
- 4 Upshur R, Fuller J. Randomized controlled trials in the West African Ebola virus outbreak. Clinical Trials 2016: 1-3. DOI: 10.1177/1740774515617754.
- 5 The Challenge of Timely, Responsive and Rigorous Ethics Review of Disaster Research: Views of Research Ethics Committee Members. Matthew Hunt, Catherine M. Tansey, James Anderson, Renaud F. Boulanger, Lisa Eckenwiler, John Pringle, Lisa Schwartz. PLOS ONE | DOI:10.1371/journal.pone.0157142 June 21, 2016.
- 6 Abha Saxena, Peter Horby, John Amuasi, Nic Aagaard, Johannes Köhler, Ehsan Shamsi Gooshki, Emmanuelle Denis, Andreas A. Reis. The ALERRT-WHO Workshop and Raffaella Ravinetto, Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Medical Ethics 2019; 20:29

Documentary Requirements

A checklist including the following items should be included in addition to the ethics review form (if used by the research ethics committee):

An option to identify the research as epidemic/outbreak-related in order to facilitate fast-tracking;

An opportunity to describe whether prior research data about the disease exists;

Inclusion of at least one PI or co-PI of the country where research and review is taking place;

Qualification of key investigators, including a description of previous track record with outbreak-relevant research among the research group; and,

An indication whether the protocol is part of a multicenter trial. If yes, an opportunity should be provided to describe the status of ethics approval of the master protocol or the ethics approval of the sponsoring country.

Apart from the basic documents submitted for review (Protocol, CVs, etc.), the following should also be submitted:

Letter of collaboration in the form of a Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) with sponsor institution(s) and the funder(s) of the research along with declarations of Conflict of Interest when possible;

Monitoring and safety management plan for the project, as provided by the study sponsor;

Both data sharing and material transfer agreements (MTA) for data and human biological material, especially if samples are being exported out of the country, while honoring the laws of the land (a draft may be submitted initially);

Clear processes and procedures/expectations for follow-up dissemination and publication, co-authorship, co-presentation, and Intellectual Property Rights;

Procedures for dissemination of findings to the affected community (important to ensure maintaining contact and upholding trust of the

affected populations, especially research participants); and,
May include local requirements on insurance policies, particularly on trials/interventions.

Meeting Requirements and Procedures

Considerations

To prepare for the review of COVID-19 research, RECs should agree on a process for rapid review and communicate this to researchers (and communicate any anticipated delays for non-COVID-19 research).

Also, practical aspects like: identify surge capacity for review, set up systems for remote discussions (which software platform, does everybody who needs it have access and know how to use it, what will you do if internet isn't functioning etc.)

Membership and Quorum

It is essential that a certain number of members be pre-identified who will share the major burden of review. These members would require specialized training (or equivalent experience) in reviewing research in outbreaks so that they are able to rapidly review research proposals without compromising the ethics. Additional members should be identified and called for review at times when demand increases.

Once an outbreak is imminent or ongoing, the chair or the secretary of the review committee should alert members and ascertain which members would be available for the rapid review.

Identification as well as contacting in advance subject experts (technical) and people with strong knowledge of ethics (both in-country and abroad) willing to serve as ad hoc or co-opted members during outbreaks, as there is a likelihood of receiving multiple projects that need to be reviewed in a short time.

The quorum shall abide by the ICH-GCP requirements.

If pre-identified REC member submits their review but is unable to join the meeting, they should be considered as part of the quorum requirement.

Procedures

The new SOPs should be circulated to all members of the review committee.

The review meetings could be virtual or electronic especially if the risk of face-to-face meeting in highly infectious outbreak like COVID-19 may be risky to the members.

Protocol submission **should** be done electronically to save time with submission of the hard copy, which if mandatory can follow. PIs should contact RECs as soon as possible to communicate their intention to submit as well as a high-level overview of research (is it a trial of new medicine, vaccine, observational study, survey, etc.) so that RECs are aware of protocols that may be forthcoming.

Face to face meetings with the PIs should not be mandatory and if necessary electronic and or virtual venues may be adopted.

Timelines

Protocols should be sent to reviewers within **24-hours of submission**.

Each reviewer should complete their reviews within a specified period of time (usually **3 calendar days** is sufficient and appropriate during an outbreak).

Consolidated review and suggestions (or approval) should be communicated to the PI within a specified period of time (usually **within 5 calendar days**).

The complete review process until issuance of approval should not exceed **14 calendar days**.

Communication

Electronic or telephonic communication with PIs **should** be initiated to seek clarifications, thus saving time.

The PI **should** respond to the review within 48-hour

Focal points/persons for communication in respective institutions and RECs/NECs should be identified as early in the process as possible.

Documentation and Archiving

All communications **should** be documented and archived following the research ethics committee's standard operating procedures.