2022 Edition

UERM RIHS ERC

STANDARD OPERATING PROCEDURES

UERM MEMORIAL MEDICAL CENTER, INC.

RESEARCH INSTITUTE FOR HEALTH SCIENCES

ETHICS REVIEW COMMITTEE

STANDARD OPERATING PROCEDURES

VERSION 5

Endorsed by:

Maria Milagros U. Magat, MD
Ethics Review Committee Chair

Approval Date:
MAY 15, 2022

Approved by:

JENNIFER M. NAILES, MD, MSPH
Vice President for Research

Effective Date:
MAY 15, 2022

FOREWORD

This Manual is primarily designed to provide the institutional Ethics Review Committee of the University of the East Ramon Magsaysay Memorial Medical Center – Research Institute for Health Sciences with the proper armamentarium on how to properly evaluate and review the research protocols being presented and implemented within the Institution. It will also serve as a guide to Principal Investigators of our medical center who plan to submit research proposals requiring ethics review and approval. In addition, it will serve as a source of information for research agencies and pharmaceutical companies who intend to conduct clinical trials in our institution.

The ethical and scientific standards set forth in this manual are anchored on international guidelines formulated and established for biomedical research for human subjects throughout the years. It is specifically based on the World Medical Association Declaration of Helsinki (2013), the Belmont Report, The Nuremberg Code, the WHO/ CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, the WHO and ICH Guidelines for Good Clinical Practice, the WHO Operational Guidelines for Ethics Review Committee, the Western Pacific Region (WPRO) Ethics Review Committee Standard Operating Procedure, and the Philippine National Health Research System National Ethical Research Guidelines. Compliance with the above guidelines is necessary and imperative to ensure the safety, dignity and well-being of the subjects with the utmost respect for the rights of the subjects.

I hereby submit this Revised Manual (Version 5, 2022 Edition) of University of the East Ramon Magsaysay Memorial Medical Center Research Institute for Health Sciences - Ethics Review Committee Standard Operating Procedures to be the official guide of the institutional Ethics Review Committee of UERMMMCI.

Maria Milagros U. Magat, MD
Chairman
UERM RIHS Ethics Review Committee

This Revised Manual (Version 5, 2022 Edition) of UE Ramon Magsaysay Memorial Medical Center Research Institute for Health Sciences-Ethics Review Committee Standard Operating Procedures is hereby officially accepted to serve as a guide of the Institutional Ethics Review Committee of UERMMMCI.

JENNIFER M. NAILES, MD, MSPH
Vice President for Research
UERM Research Institute for Health Sciences

DOCUMENT HISTORY

VERSION NO.	DATE	PREPARATION /REVISION	REASON FOR REVISION	APPROVED BY
1	2013	UERM RIHS ERC en banc	First Draft	ISAAC DAVID AMPIL II, MD, MSC VICE PRESIDENT FOR RESEARCH
2	AUGUST 1, 2014	JOSE RONILO G. JUANGCO, MD, MPH ERC CHAIR	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS	ISAAC DAVID AMPIL II, MD, MSC VICE PRESIDENT FOR RESEARCH
3	NOVEMBER 3, 2017	MARIA MILAGROS U. MAGAT, MD, MEM	FOR REACCREDITATION APPLICATION	JENNIFER M. NAILES, MD, MSPH VICE PRESIDENT FOR RESEARCH
4	JANUARY 12, 2021	MARIA MILAGROS U. MAGAT, MD, MEM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES	JENNIFER M. NAILES, MD, MSPH VICE PRESIDENT FOR RESEARCH
5	MAY 15, 2022	MARIA MILAGROS U. MAGAT, MD, MEM	FOR REACCREDITATION APPLICATION (Revised format using PHREB template)	JENNIFER M. NAILES, MD, MSPH VICE PRESIDENT FOR RESEARCH

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5	**TABLE OF CONTENTS**
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PREFACE

This Standard Operating Procedure (SOP) Manual of the UERMMMC Research Institute of Health Sciences – Ethics Review Committee (RIHS-ERC) was written to guide the activities, provide rationale, and inform the decisions of the Institution's ERC. The members of the ERC and principal investigators, sponsors and regulatory authorities will be directed to relevant information regarding the process of ethical review in UERMMMCI.

This Manual is largely based on historical landmark documents, national guidelines and updated legislation to uphold ethics in health and health-related research. These documents include the Declaration of Helsinki (2013) from the World Medical Association, the Belmont Report, The Nuremberg Code, the World Health Organization – Council for International Organizations of Medical Sciences (WHO-CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016, the WHO and International Conference on Harmonization - Good Clinical Practice (ICH-GCP E6 R2 2016) guidelines, the WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011, the Western Pacific Region (WPRO) Ethics Review Committee Standard Operating Procedures 2011, and the National Ethical Guidelines for Research involving Human Participants 2022. Foremost among our aims is compliance with the guidelines, upholding supreme respect for study participants and ensuring their safety, dignity and well-being.

A BRIEF HISTORY OF ETHICS REVIEW COMMITTEE (UERMMMCI RIHS ERC)

In 1997, the University of the East Ramon Magsaysay Memorial Medical Center, Inc. (UERMMMCI) established an ethics review committee, which functioned under the Office of Research Education and Development. In 2004, the Research Development Office was expanded and renamed Research Institute for Health Sciences with Dr. Fernando S. Sanchez, Jr. as Director. Two years later, the Ethics Review Committee (ERC) and the Technical Review Committee were created, paving the way for what would be later formalized as the institution's answer to competent ethical practice in research.

In 2014, the Ethics Review Committee (ERC) was officially granted the highest level of accreditation - Level 3 - by the Philippine Health Research Ethics Board (PHREB) and international recognition by the Forum for Ethical Review Committees in the Asian and Western Pacific Regions (FERCAP). Valid for a period of three years, the certificates were officially awarded on November 25, 2014, at the 14th Forum for Ethical Review Committees in Asia and the Western Pacific at the Taal Vista Hotel, Tagaytay City. The Chair of the ERC, then Dr. Jennifer M. Nailes, Secretary Dr. Jose Ronilo Juangco, and three members of the Committee, received the certificates.

Currently, many of the former members of the original 2012-2014 ERC still serve on the Committee, even as other members have been added. There are now 16 individuals composing the ERC, varied across age, gender, specialty and affiliation.

1. ERC STRUCTURE AND COMPOSITION

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 1.1** **SELECTION AND APPOINTMENT OF MEMBERS**

1. **Policy Statement**
   The structure and composition of the University of the East- Ramon Magsaysay Memorial Medical Center, Inc. Research Institute for the Health Sciences Ethics Review Committee (UERMMMCI RIHS ERC) shall pursue the provisions of the Philippine National Health Research System (PNHRS) Law of 2013 and in recognition of international standards and guidelines in ethical research. The selection of ERC members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists, medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution. Members shall be classified as regular or alternate members. The regular and alternate members shall serve for a period of 3 years but may be renewed for a number of terms. The alternate members shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.

2. **Objectives of the Activity**
   This activity aims to ensure that the selection of members complies with the international and national guidelines and who have the appropriate expertise is taken into consideration.

3. **Scope**
   This SOP shall provide the terms of reference (TOR) that describe the framework for the constitution of the UERMMMCI RIHS ERC guided by the fundamental ethical standards

4. **Workflow**

Activity	Responsibility
Step 1: Appoint ERC Chair and ERC Members	President of the Medical Center
Step 2: Nominate ERC Chair	VP for Research
Step 3: Nominate ERC members, appoint ERC Member Secretary, SAE subcommittee chair and SAE subcommittee members	ERC Chair

Step 4: Signing of conflict-of-interest disclosure and confidentiality agreement	New ERC members
Step 5: Filing of appointment documents and CVs in membership file.	Staff Secretary

5. Description of the Procedures

5.1. Step 1 – Appoint ERC Chair and ERC members

5.1.1. The ERC Chair and ERC members shall be appointed by the President of the Medical Center for a three-year renewable term, upon the recommendation of the Vice President for Research (RIHS). Members shall be appointed based on but not limited to:

5.1.1.1. Their willingness to commit the time required for their duties on the Committee.

5.1.1.2. Their expert knowledge in medicine, science, or another field, as appropriate.

5.1.1.3. Their willingness to acquire knowledge of research ethics through appropriate training and education within two months of beginning service on the Committee.

5.1.2. To ensure the independence of the ERC and the ability of its members to exercise their judgment concerning matters coming before the ERC, they may be removed from the ERC by the Vice President for Research

5.1.2.1. Failure to attend three consecutive meetings for which they had previously committed, without informing the Staff Secretary in advance of the meetings.

5.1.2.2. Failure to attend at least 40% of the ERC meetings in any given year.

5.1.2.3. Failure to perform the functions expected of ERC members, including serving as primary reviewer of assigned research proposals.

5.1.2.4. Flagrant departure from ERC SOP

5.1.2.5. Conduct unbecoming for a member of the ERC

5.1.3. In case of vacancy or resignation or termination of any member of the RIHS ERC:

5.1.3.1. The ERC Chair shall recommend to the Vice President for Research for an advertisement to be placed in the UERM portal for the said vacancy.

5.1.3.2. The ERC chair may admit recommendations from other members of any potential ERC member. The ERC chair will review the curriculum vitae and conduct an interview of the applicant for the position. The ERC chair will then recommend to the Vice president for Research all qualified applicants for the position.

5.1.3.3. Upon the recommendation of the Vice President for Research, the new ERC member/s shall be appointed by the President of the Medical Center.

5.2. Step 2 – Nominate ERC Chair

5.2.1. The Vice President for Research of the UERMMMCI shall nominate the ERC Chair.

5.3. Step 3 – Nominate ERC members, appoint ERC member secretary, SAE subcommittee chair and SAE subcommittee members

5.3.1. The ERC Chair shall nominate the members of the ERC, including the SAE subcommittee Chair and its members.

5.4. Step 4 – Signing of conflict-of-interest disclosure and confidentiality agreement

5.4.1. The newly appointed members shall sign a conflict-of-interest disclosure and confidentiality agreement upon their appointment to the ERC.

5.5. Step 5 – Filing of appointment documents and CVs in the membership file

5.5.1. The Staff Secretary shall file all appointment documents and CVs, signed and dated, of the newly appointed ERC members in their membership files.

6. Glossary

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

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

Medical Members – are individuals with academic degrees in the medical profession and a master's in the nursing profession.

Non-medical members - are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

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

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

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

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

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

Staff Secretary – institutional personnel assigned to assist in the operations of the ERC.

7. Forms

ERC Form 1A: Curriculum Vitae V4.0
ERC Form 1B: Confidentiality Agreement V4.0
ERC Form 1C: Training Record V4.0

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	Jose Ronilo G. Juangco, MD, MPH	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	UERM RIHS ERC en banc	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	UERM RIHS ERC en banc	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	Maria Milagros U. Magat, MD	Removed responsibilities of members and replaced with workflow, added glossary, history of SOP and updated references following the format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
N National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

1. ERC STRUCTURE AND COMPOSITION

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 1.2** **STRUCTURE AND COMPOSITION OF THE ERC**

The University of the East Ramon Magsaysay Memorial Medical Center, an academic health institution has Research as one of its three general line functions. This function is the responsibility of the Research Institute for Health Sciences.

The Research Institute for Health Sciences is established to strengthen research in the Medical Center and to develop a research culture in all its units. It evolved from the Research Section of the Office of Research and Educational Development, a unit under the Vice President for Academic Affairs. The Research Institute's strengthening and expansion plan creating sections in the organization of the RIHS began in 2007. The plan was approved by the Board of Trustees in the same year.

1. Policy Statement

The University of the East Ramon Magsaysay Memorial Medical Center recognizes that research is a primary function of a higher education institution, that it has a responsibility to contribute to the fund of knowledge so essential to the development of health and medical sciences. Research is a priority of the Medical Center. It rededicates and commits itself to the strengthening of its research capability and the expansion of its research program. The Board of Trustees fully supports this vision-mission.

The structure and composition of the University of the East Ramon Magsaysay Memorial Medical Center, Inc. Research Institute for the Health Sciences Ethics Review Committee (UERMMMCI RIHS ERC) shall pursue the provisions of the Philippine National Health Research System (PNHRS) Law of 2013 and in recognition of international standards and guidelines in ethical research. There shall at least be technical review, ethics review, and dissemination and publication committees. The hospital shall have a clinical epidemiology unit which shall supervise its R & D activities.

2. Objectives of the Activity

This activity aims to ensure that the selection of members complies with the international and national guidelines and who have the appropriate expertise is taken into consideration.

- All research projects to be undertaken in the Medical Center shall be reviewed and approved by the Research Institute. They shall conform to the National Ethics Guidelines.

- All researches to be conducted in the medical center and those to be conducted by faculty, students and other UERM personnel shall first be reviewed and approved by the Ethics Review Committee.

3. Scope

This SOP shall provide the terms of reference (TOR) that describe the framework for the constitution of the UERMMMCI RIHS ERC guided by the fundamental ethical standards.

4. Organizational Structure

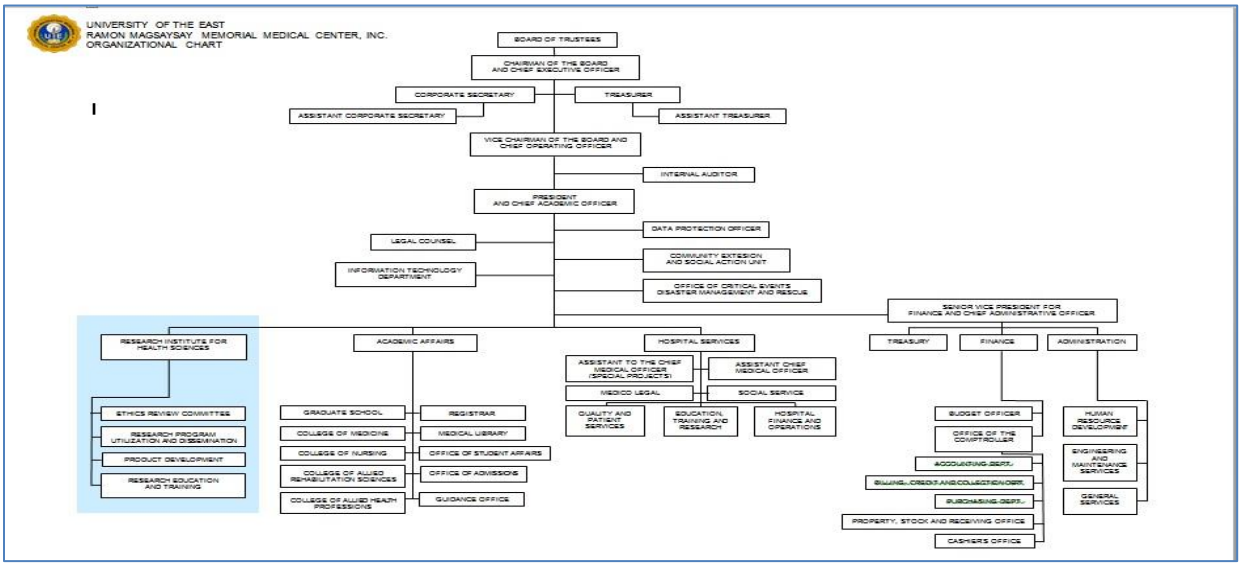
The need for an ever increasing research services in UERMMMCI prompted the proposal for the creation of committees which serve the Research Institute in the performance of its functions, namely:

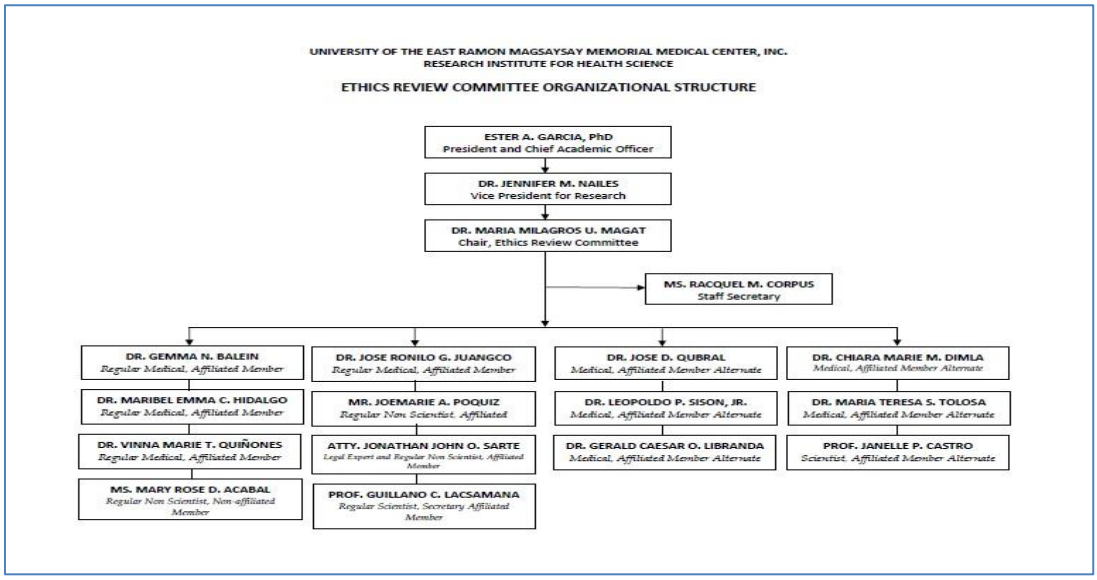
- Ethics Review
- Publication

The Research Institute for Health Sciences is directly under the President of the Medical Center. It has an office with support staff. It is linked with the other units with research activities. The Research Institute has overall supervision of the research activities of the various units of the Medical Center through the research coordinators.

On January 4, 2022, a new organizational structure was drafted (see Figure 1 below) which shows the Ethics Review Committee and other sections under the Research Institute for Health Sciences. Its organization enables the Medical Center to efficiently function as a research center for the academe and hospital.

Figure 1.





5. Composition

5.1. The ERC will be multidisciplinary and multi-sectoral in composition. The committee is composed of 9 regular members and 8 alternate members. The members have an equitable representation of the different units in the institution. It includes clinicians and non - clinicians, epidemiologist / research methodology experts, academicians, a lawyer, and a social worker / layperson / patient representative to represent different points of view. At least one member will come from outside of the Institution and will be identified as an independent / non-affiliated member. The members will be invited alternately depending on the protocol submitted for review.

5.2. The committee should have adequate representation in terms of age, gender, community, etc., to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism. The members should have varied backgrounds to promote complete and adequate review of research activities commonly conducted in the Medical Center.

6. Glossary

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

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

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

Staff Secretary – affiliated personnel assigned to assist in the operations of the ERC.

7. Forms
N/A

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft

2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM	Removed the term "two panels/panel" following the format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

1. ERC STRUCTURE AND COMPOSITION

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5	**SOP No. 1.3**
Date of Approval: May 15, 2022	**GENERAL AND SPECIFIC DUTIES OF ERC OFFICERS AND MEMBERS**
Date of Effectivity: May 15, 2022	

1. Policy Statement

The general and specific duties of the ERC members shall be in accordance with the Philippine National Health Research System (PNHRS) Law of 2013.

2. Objectives of the Activity

This activity aims to ensure that the duties of members comply with the international and national guidelines and who have the appropriate expertise is taken into consideration.

3. Scope

This SOP provides a reference for the duties of the ERC members and is specific for the Ethics Review Committee of the Institution.

4. General Duties of ERC members

4.1. ERC members shall submit their respective updated and signed curriculum vitae and **ERC Form 1A: Curriculum Vitae** together with Good Clinical Practice (GCP) certificates and other related certificates if available. This will be filed in the ERC Membership File (contains CV, Terms of Appointment and copies of Training Certificates of each member). If necessary, the newly appointed members should be willing to attend the required ethics training during the course of his/her appointment.

4.2. Members are required to sign **ERC Form 1B: Confidentiality Agreement** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the ERC in the course of its work.

4.3. Members should be willing to publicize their full name, profession, and affiliation to the ERC upon request.

4.4. Members must commit to record and make available upon request, all financial relationships, and any conflict of interest within or related to the ERC.

5. Specific Duties and Functions of ERC

5.1. **ERC Chair**

5.1.1. Represents the ERC in the research organizational structure of RIHS.

5.1.2. Recommends policy amendments and changes.

5.1.3. Presides over meetings of the Ethics Review Committee.

5.1.4. Prepares the budget and proposes membership.
5.1.5. Represents the RIHS in national and international ethics fora.
5.1.6. Oversees the operations of the ERC members and subcommittee/s.
5.1.7. Supervises the management of the ERC Office.
5.1.8. Acts on suggestions, complaints and queries from stakeholders.
5.1.9. Initiates and schedules site visits as needed
5.1.10. Ensures updated member files (contains CV, Terms of Appointment and copies of Training Certificates of each member).

5.2. **ERC Member Secretary**

5.2.1. Oversees ERC protocols reviewed by the ERC and assigns primary reviewers to review protocols submitted to the ERC.
5.2.2. Oversees preparation of the notice of meeting and its agenda, minutes of the previous meeting, approval of protocols, and other pertinent documents necessary for the function of the ERC.
5.2.3. Supervises the preparation of communication pertinent to protocol review-related actions to the principal investigator.
5.2.4. Maintains all records of the ERC including the protocols submitted according to the SOP on record keeping
5.2.5. Presides over the ERC meeting in the absence of the ERC Chair.
5.2.6. Ensures that member files (contains CV, Terms of Appointment and copies of Training Certificates of each member) are updated
5.2.7. Performs other ERC-related tasks that may be assigned to him/her by the ERC Chair

5.3. **ERC Members**

5.3.1. The role of the **scientist and/or medical member** is to focus on the review of the study protocol while the role of the **non-scientist or lay member** is to focus on the review of the informed consent process and form
5.3.2. The roles of the **affiliated and non-affiliated members** in terms of the review are similar, however, the non-affiliated member/s is/are expected to provide an external perspective to ensure the independence of the position of the UERM RIHS Ethics Review Committee, even from possible bias posed by its own institution that may the impact rights, safety, and well-being of human subjects in research
5.3.3. Makes a timely and thorough review and decision regarding protocols given to him/her for evaluation
5.3.4. Familiarizes him/herself with the UERMMMCI SOP of the ERC, his/her terms of reference, and the international and national guidelines on research ethics.
5.3.5. Participates actively in the ERC meetings. It is expected that a member will have at least 80% attendance during the period of appointment because attendance is integral to the effectiveness of the ERC as a review board
5.3.6. Recommends appropriate action on adverse events based on monitoring reports from SAE Subcommittee.
5.3.7. Participates in the review of the progress reports, final reports, and other amendments presented during the ERC meeting.
5.3.8. Participates in Site Visits and similar activities as needed.

5.3.9. Maintains confidentiality of the documents and deliberations of ERC meetings.
5.3.10. Declares any conflict of interest in general and for specific protocols for review.
5.3.11. Participates in required training with proof of attendance in such training activity submitted to the RIHS ERC.
5.3.12. Submits an updated and signed CV at the start of each calendar year.
5.3.13. Refers to the ERC Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors before acting on them.
5.3.14. Performs other ERC-related duties that may be requested of him/her by the ERC Chair.

5.4. **ERC Non-affiliated / Independent member/s**

5.4.1. Represent members (scientific and non-scientific) not affiliated with the institution or trial site, who undertake review free from bias and influence and provide advice to the Principal Investigators on all aspects of welfare and safety on research participants. It shall be the duty of the independent member/s to assist the committee in the assessment of the ethical issues surrounding specific researches particularly with emphasis on the following:

5.4.1.1. Consider the ethical implications of all proposed research projects involving humans and determine whether or not they are acceptable on ethical grounds;
5.4.1.2. Consider the ethical suitability of all projects, particularly areas of the project that impact or affect account of local cultural and social attitudes in making decisions;
5.4.1.3. Ensure that appropriate procedures relating to obtaining consent are observed;
5.4.1.4. Maintain confidentiality on all materials, discussions and issues that arise within the ethical review process.
5.4.1.5. Review the proposal keeping in mind the participants (vulnerability, etc.), the process (informed consent, requirements for privacy and confidentiality etc.), the study requirements (risks/benefits) as well seek and obtain clarifications, if necessary.

5.5. **ERC Legal Expert Member**

5.5.1. Ascertains the acceptability of research in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice and provides guidance regarding the interpretation of regulations, laws and policies to Principal Investigators.

5.6. **Staff Secretary**

5.6.1. Manages protocol submissions.
5.6.2. Organizes an effective and efficient tracking procedure for each protocol received.
5.6.3. Prepares and distributes protocol files for review.
5.6.4. Informs ERC members and personnel about training workshops and arranges for the latter's participation in such workshops.
5.6.5. Organizes the preparation, review, revision, and distribution of SOPs and guidelines.
5.6.6. Provides the necessary secretarial support for ERC-related activities like site visits and communicating decisions to the principal investigator.

5.6.7. Maintains the ERC Active Files and Archives, **electronic submissions logs**, references and other document files, especially their security and confidentiality.

5.7. **Serious Adverse Events (SAE) Subcommittee Chair**

5.7.1. Presides over SAE Subcommittee meetings.
5.7.2. Liaises directly with other ERC personnel.
5.7.3. Invites Independent Consultants to provide special expertise for specific serious adverse events reports, as necessary.
5.7.4. Performs other ERC-related tasks that may be assigned to him/her by the ERC Chair.

5.8. **SAE Subcommittee Members**

5.8.1. Familiarize him/herself with the UERM RIHS ERC SOP on Post-Approval Review and his/her terms of reference.
5.8.2. Participate actively in the SAE Subcommittee meetings.
5.8.3. Recommend appropriate action on serious adverse events reports.
5.8.4. Participate in site visits and similar activities as needed.
5.8.5. Maintain confidentiality of the documents and deliberations of SAE Subcommittee meetings.
5.8.6. Declare any conflict of interest in general and for specific protocols for review.
5.8.7. Perform other SAE Subcommittee-related duties that may be requested of him/her by the SAE Subcommittee Chair.

6. Glossary

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

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

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

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

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

Staff Secretary – affiliated personnel assigned to assist in the operations of the ERC.

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

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

7. Forms

ERC Form 1A: Curriculum Vitae V4.0
ERC Form 1B: Confidentiality Agreement V4.0

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
			INCLUSION OF PHREB GUIDELINES ON

4	2021 JANUARY 12	MUM	COVID-19 VACCINES
5	2022 MAY 15	MUM	Changed the term "scientific" and "non-scientific" to "scientist" and "non-scientist", "Independent Lay Member" to "Non-affiliated / Independent member/s", "Secretariat Staff" to "Staff Secretary"

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

1. ERC STRUCTURE AND COMPOSITION

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 1.4** **APPOINTMENT OF INDEPENDENT CONSULTANT**

1. Policy Statement

The ERC may call upon, or maintain a list of independent consultants who may provide special expertise to the ERC on proposed research protocols, when the Chairperson/Member Secretary or the ERC members determine that a study will involve procedures or information that is not within the area of expertise of the ERC members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g., genetic disorders, stem cell research, etc.) or they may be representatives of communities, patients, or special interest groups. These consultants or subject experts cannot vote for a decision.

2. Objectives of the Activity

This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the ERC.

3. Scope

This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols for the ERC.

4. Workflow

Activity	Responsibility
Step 1: Identification of the study that requires an independent consultant	ERC Chair Primary Reviewer
Step 2: Invitation to the independent consultant	ERC Chair
Step 3: Appointment of independent consultant	Independent Consultants
Step 4: Receipt of the signed ERC Form 1B Confidentiality Agreement	Staff Secretary

Step 5: Stores roster of Independent Consultants in the Independent Consultants File	Staff Secretary

5. Description of Procedures

Step 1 - Identification of the study that requires an independent consultant
Determine if the study involves procedures or information that is not within the area of expertise of the ERC members: Either the primary reviewer or Chair identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of the ERC.

Step 2 - Invitation to the independent consultant
Sends invitations to various professionals with specific scientific expertise to be part of the ERC roster of independent consultants representing expertise not present in the existing ERC members. S/he instructs the Staff Secretary to prepare the **ERC Form 1D Independent Consultant Appointment** for signature of the Chair**.**

Step 3 - Appointment of independent consultant
Upon acceptance of the invitation, the Staff Secretary sends the appointment signed by the Chair to the independent consultant together with the **ERC Form 1B: Confidentiality Agreement** and asks for submission of **Curriculum Vitae.** The independent consultant accomplishes and signs a copy of **ERC Form 1B: Confidentiality Agreement** and **Curriculum Vitae.**

The duties and responsibilities of the **Independent Consultants** are:

- Review assigned protocols along his/her specialty/expertise;
- Attend the ERC meeting when invited and where deliberations on said protocols will be made; and
- Submit a signed and updated CV.

Step 4 – Receipt of the signed conflict of disclosure and confidentiality agreement
The staff secretary receives the accomplished and signed copy of **Curriculum Vitae** and **ERC Form 1B: Confidentiality Agreement** and files this in the appropriate folder.

Step 5 - Inclusion in the pool of independent consultants:
The Staff Secretary enters the name of the new independent consultants in the appropriate database containing name, date joined, expertise and status.

6. Glossary

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

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

Database – a structured/organized collection of information so that the data can easily be accessed, managed and updated.

7. Forms

ERC Form 1A: Curriculum Vitae
ERC Form 1B: Confidentiality Agreement
ERC Form 1D Independent Consultant Appointment

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Added description of procedures following the format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

2. PROTOCOL REVIEW

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 2.1** **MANAGEMENT OF INITIAL SUBMISSIONS**

1. Policy Statement

The ERC receives applications for ethical review through several modes online (email, google drive), courier or hand-carried by the principal investigator. The ERC shall require the submission of a set of pertinent documents 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 *NEGRIHP 2022*, The Research Ethics Review Process Guideline 3.1. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be "exempted from review".

2. Objectives of the Activity

To describe the procedure for initial review of the ERC from receipt of protocol and related documents until the approval letter is released by the ERC to the principal investigator (PI).

3. Scope

The UERMMMCI RIHS ERC shall review all research protocols submitted for review from within the institution and from outside institutions and investigators as well. Protocols from within the institution include those from the following: consultants of the hospital, trainees (fellows and residents), faculty, employees and students of the Center.

Industry-sponsored clinical trials and other protocols (bioavailability / bioequivalence) as well as investigator-initiated trials from other institutions with no PHREB accredited ethics committees (ECs) may be accepted for ethics approval as well, with the following conditions:

- Protocols which are industry-sponsored and investigator-initiated should have a memorandum of agreement (MOA) accomplished between the industry sponsor or outside institutions to establish UERMMMCI RIHS ERC's scope of authority.
- Investigator-initiated protocols must be minimal risk in nature. The description of minimal risk shall comply with the *National Ethical Guidelines for Research involving Human Participants 2022*.

Industry – sponsored protocols with ethics approval from the Single Joint Research Ethics Board (SJREB) may be accepted for ethics approval as long as a MOA is likewise accomplished. This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database.

4. Workflow

Activity	Responsibility
Step 1: Receipt of study documents for initial review and determination of completeness of submission	Staff Secretary
Step 2: Coding	Staff Secretary
Step 3: Entry into the database	Staff Secretary
Step 4: Determination of type of Action/ Type of Review and Communication of Decision. *a. Exemption from Review* *b. Expedited Review (SOP No. 2.4 Expedited Review)* *c. Full Review (SOP No. 2.5 Full Review)*	Chair
Step 5: Preparation of a protocol folder	Staff Secretary

5. Description of Procedures

Step 1 - Receipt of study documents for initial review and determination of completeness of submission:
The Staff Secretary accepts study protocol documents for review at the ERC office during office hours. Both electronic and hard copy submissions of documents are required. The Staff Secretary checks completeness of submitted forms and documents using **ERC Form 2B Requirement Checklist V4.0**. Incomplete submissions will not be accepted. Submissions should include signed and accomplished forms and study-related documents as follows:

Basic Documents (must submit) (*to be checked and verified by the ERC Secretariat*)**:**
ERC Form 2B Requirement Checklist V4.0
ERC Form 2C Registration and Application V4.0
ERC Form 2D Study Protocol Assessment V4.0
ERC Form 2E Informed Consent Assessment V4.0 (for studies with human participants)
ERC Form Waiver of Informed Consent Assessment
ERC Form 2J Review of Resubmitted Protocol V4.0
Study Protocol
Study Protocol Synopsis

Data Collection Forms (including CRFs)
CV of PI and study team members
Informed consent form in English (for studies with human participants)
Informed consent form in local language (for studies with human participants)
Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
Electronic copy of study protocol, **RIHS ERC FORM 2(B), RIHS ERC FORM 2(C), RIHS ERC FORM 2(D),** and **RIHS ERC FORM 2(E)** for initial submission
Electronic copy of study protocol and **RIHS ERC FORM 2(J)** for resubmission

Study-specific Documents (submit as needed):

Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV) and other clinical trials outside of Phase 1 - 4
Summary of all safety, pharmacological, pharmaceutical, and toxicological data (for study product such as pharmaceutical or device under investigation)
Recruitment advertisements (as needed by the study protocol)
Other information or documents for participants (such as diaries, etc.)
Material Transfer Agreement (for any research involving transfer of biological specimens)
Memorandum of Agreement (for collaborative studies)
ERC Form 2F Site Resources Checklist V4.0 for Clinical Trial Outside UERMMMCI-By-UERMMMCI Personnel
ERC Form 2G Site Resources Checklist Non UERM PI V4.0 for Clinical Trial Outside UERMMMCI By non-UERMMMCI Personnel
Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
Disclosure of previous ethical and/or scientific board reviews (with attached copy of conclusions, recommendations and incorporated changes)
National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while RIHS ERC review is on-going)
Declaration of Conflict of Interest of the Principal Investigator/Co-investigators
Disclosure of funding sources, sponsors, institutional affiliations and other possible sources of conflicts of interest
Any additional materials submitted for approval (pls. specify)

Step 2 – Coding of study protocol

If the documents are determined to be complete, the Staff Secretary assigns a protocol code (UERM RIHS ERC Code) to the protocol package and will be labeled on all forms and documents submitted. UERM RIHS ERC will use a code that includes information on the year of submission and series number.

The protocol file is coded as "running number / hospital, college or graduate school, pharmaceutical-sponsored, external / year of submission / series number". For example, 1198 / H / 2022 / 008 will indicate – 1198 as running number of research accepted in UERM, H is for Hospital, 2022 for year of submission and 008 is the serial number that indicates the sequence order of receipt for the year 2022. (This coding system will be maintained on the database (inventory of researches) and also labeled on each protocol file.

Legend:

H – Hospital (e.g.; resident/consultant)
G – Graduate School
P – Pharmaceutical-sponsored
E – External research papers
C - Colleges

Step 3 – Entry into the database

The Staff Secretary enters in the database the following information (1) date received, (2) UERM RIHS ERC Code, (3) title of the study, (4) name of principal investigator, (5) Institution/Department/College, (5) type of research, and (6) classification of review. In the latter case, there will be a need for subsequent entries in a database as described in SOP # Managing Active Files.

Step 4 – Determination of type of Review/Action

4.1 The Staff Secretary informs the ERC Chair regarding the new study protocol for classification (full board, expedited, or exempted).

4.2 If the Chair decides that the protocol is **exempted from review**, s/he directs the Staff Secretary to follow the procedure in communicating the decision to the Principal Investigator. Subsequently, the decision shall be documented in the database. Exempted from review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by the ERC Chair. NEGHHRR 2022 lists the following as criteria for exemption from review:

4.2.1 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.

4.2.2 Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the ERC for exemption from review:

4.2.2.1 Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

4.2.2.2 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:

4.2.2.2.1 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

4.2.2.2.2 The 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.

4.2.2.3 Protocols that involve the use of publicly available data or information.

4.2.3 The ERC, in its annual report submitted to the PHREB, shall include a list of all proposals or protocols that were exempted from review.

4.3 If the Chair determines that the protocol should undergo either **full or expedited review**, then he/she shall assign the primary reviewers and instruct the Staff Secretary to proceed in accordance with either **SOP No. 2.3 Expedited Review** or **SOP No. 2.4 Full Review**.

4.3.1 An expedited review may be conducted, only if the protocols involve:

- Revised proposal previously approved through full review by the ERC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis or health record research
- Anonymous surveys and retrospective chart reviews
- Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers
- Proposals involving previously banked materials and/or tissues as per policies of respective authorities like – tumor tissue repository,
    - Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes
- Other documents which would be considered for expedited review are as follows but may not restrict to:
    - Minor deviations from originally approved research during the period of approval (usually of one year duration)
    - Change in the name/ address of sponsor
    - Change in contact details of Principal Investigator
    - Change in Principal Investigator or hand over of trials or projects
    - Inclusion or deletion of name/s of Co-Investigator/s
    - Request for change in Principal Investigator, Co-Investigator, change in any member involved in the research
    - Minor amendments in the protocol, CRF
    - Minor corrections in budget
    - Other administrative changes in the IB, ICF, etc.
    - addition of provision to include compliance with data privacy law in the study protocol

The Staff Secretary will then send the complete study protocol package to the assigned primary reviewers.

Step 5 – Preparation of a Protocol Folder

The staff files the protocol documents in a protocol folder and labels it accordingly.

6. Glossary

Initial Submission – a set of documents consisting of the full proposal and other study- related documents that need to be submitted so that review can be conducted.

Study Protocol Documents / Protocol File - include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the ERC for review.

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

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

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually an electronic platform used for tracking and monitoring the implementation of a study.
Exemption from Review – a decision made by the ERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1.

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

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

7. Forms

ERC Form 2B Requirement Checklist V4.0
ERC Form 2C Registration and Application V4.0
ERC Form 2D Study Protocol Assessment V4.0
ERC Form 2E Informed Consent Assessment V4.0 (for studies with human participants)
ERC Form Waiver of Informed Consent Assessment
ERC Form 2J Review of Resubmitted Protocol V4.0
ERC Form 2F Site Resources Checklist V4.0 for Clinical Trial outside UERMMMCI By UERMMMCI Personnel
ERC Form 2G Site Resources Checklist Non UERM PI V4.0 for Clinical Trial outside UERMMMCI By non-UERMMMCI Personnel

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Added checklist requirements and information in the coding system following the format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Research involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

2. PROTOCOL REVIEW

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 2.2** **MANAGEMENT OF RESUBMISSIONS**

1. Policy Statement

The ERC shall require a resubmission of a protocol that requires either minor or major modification/s not later than 90 days after receipt of the Action Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review.

2. Objectives of the Activity

Management of resubmissions ensures that the principal investigator addressed the required modifications before approval of the protocol.

3. Scope

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

4. Workflow

Activity	Responsibility
Step 1: Receipt and Update of the database	Staff Secretary
Step 2: Notification of Primary Reviewers	Staff Secretary
Step 3: Review of the Resubmission *a. Expedited Review (SOP No. 2.4 Expedited Review)* *b. Full Review (SOP No. 2.5 Full Review)*	Primary Reviewers
Step 4: Communication of Decision	Staff Secretary

5. Description of Procedures

Step 1 - Receipt and Update of the database
The Staff Secretary receives study documents related to resubmission (revised protocol and ICF, ERC form on review of resubmitted protocol, cover letter with table of summary of changes), ensures that the submission is complete and enters the relevant information on resubmission in the database. Electronic submissions of documents are also considered.

Step 2 – Notification of Primary Reviewers
The Staff Secretary informs the primary reviewers concerned and forwards to them the documents for resubmission.

Step 3 – Review of the Resubmission
The primary reviewers conduct review of the resubmitted protocol by referring to the resubmission form noting the different recommendations made by the ERC and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit their recommendation report to the Chair for inclusion in the next regular meeting.

Step 4 – Communication of Decision
For resubmissions approved at the level of the Chair: The Chair dictates his/her decision to the Staff Secretary for preparation of the approval letter and sending to the principal investigator. For the resubmissions that underwent full review, see *SOP No. 4.5 Communicating ERC Decisions*.

6. Glossary

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

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

Database – Significant information about protocols that are organized systematically so that these can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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

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

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

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

7. Forms

ERC Form 2J Review of Resubmitted Protocol V4.0
ERC Form 6B Protocol Approval Template
ERC Form 6C Letter for Modification Template V4.0

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2022 MAY 15	MUM / RMC	First Draft based on PHREB template 2020

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

2. PROTOCOL REVIEW

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 2.3** **MANAGEMENT OF PROTOCOLS FROM SINGLE JOINT RESEARCH ETHICS BOARD (SJREB)**

1. Policy Statement

The UERM RIHS ERC will review protocols for Single Joint Ethics review (SJREB), focusing on site-specific issues, and follow the decision of the SJREB on the approval of the submitted protocol.

2. Objective of the Activity

To describe the procedure of the ERC in reviewing and managing proposals submitted to the DOH Single Joint Research Ethics Board (SJREB) for review ensuring that the proposals are processed expeditiously.

3. Scope

This SOP applies to the ERC procedure for the review and approval of study protocols submitted to SJREB for joint review

4. Workflow

Activity	Responsibility
Step 1: Receipt of study documents for initial review and determination of completeness of submission	Staff Secretary
Step 2: Coding	Staff Secretary
Step 3: Determination of type of Action/ Type of Review and Communication of Decision. *a. Expedited Review (SOP No. 2.4 Expedited Review)* *b. Full Review (SOP No. 2.5 Full Review)*	Chair
Step 4: Assignment of Reviewers	Chair / Member Secretary

Step 5: Provision of documents and assessment forms to reviewers	Staff Secretary
Step 6: Accomplishment and submission of assessment forms	Primary Reviewers
Step 7: Follow the procedure for expedited review (SOP No. 2.4) or full review (SOP No. 2.5), as applicable	Chair
Step 8: Attend the SJREB meeting	Chair / ERC representative / Primary Reviewer/s
Step 9: Communication of review results to the Principal Investigator	Staff Secretary
Step 10: Filing of documents in the protocol file and update database	Staff Secretary

5. Description of Procedures

Step 1 – Receipt of study documents for initial review and determination of completeness of submission
The Staff Secretary accepts study protocol documents for review at the ERC office during office hours. Electronic submissions of documents are also considered. The Staff Secretary checks completeness of submitted forms and documents. Incomplete submissions will not be accepted, see *SOP NO. 2.1 MANAGEMENT OF INITIAL SUBMISSIONS*.

Step 2 – Coding of study protocol
If the documents are determined to be complete, the Staff Secretary assigns a protocol code (UERM RIHS ERC Code) to the protocol package and will be labeled on all forms and documents submitted. UERM RIHS ERC will include the **SJREB-assigned code** in labeling the protocol package and entry in the database, s*ee SOP NO. 2.1 MANAGEMENT OF INITIAL SUBMISSIONS*.

Step 3 – Determination of type of review/action
The Staff Secretary informs the ERC Chair regarding the new study protocol for classification (full board or expedited).

Step 4 – Assignment of reviewers
The Chair assigns two ERC members (one scientific and one nonscientific) for expedited study protocols with an ICF. If protocol is a retrospective study, the reviewers should be scientific members. The Chair may designate an additional independent consultant should none of the ERC members have the expertise needed for a particular protocol for review.

Step 5 – Provision of documents and evaluation form to reviewers
The Staff Secretary prepares all pertinent documents for protocol review and sends via email or courier. The study documents may be the complete submission package if protocol is for initial review and the pertinent information from the retrieved protocol and the report itself for post approval submissions.

Step 6 – Accomplishment and submission of assessment forms
The primary reviewers read the study protocol and related documents, submit their findings and recommendations and accomplish the assessment forms. The primary reviewers present these during the actual meeting (for full review of study protocol).

Step 7 – Follow the procedure for expedited review (SOP No. 2.4) or full review (SOP No. 2.5), as applicable
The ERC waits for the decision of SJREB before communicating the decision to the PI

Step 8 – Attend the SJREB meeting
The Chair attends or assigns the primary medical/scientist reviewer or a member to attend the SJREB meeting. The Chair or ERC representative takes note of the discussions in the SJREB meeting.

Step 9 – Communication of review results to the principal investigator
The decision of the ERC, incorporating the points in the SJREB decision and the preliminary review of the primary reviewer, is communicated to the PI within seven days of receipt of the SJREB decision.

Step 10 – Filing of documents in the protocol file and update database
All protocol-related documents are filed in a protocol folder and updates the protocol database.

6. Glossary

SJREB – a group of experts organized by the DOH who shall facilitate and provide oversight to the overall operations of the joint review process

Single Joint Ethics Review – review for the purpose of approving multi-site research that will be conducted within the purview of the Department of Health

Multi-site Research – researches that will be conducted in three or more sites utilizing the same study protocol

7. Forms

ERC Form 2B Requirement Checklist V4.0
ERC Form 2C Registration and Application V4.0
ERC Form 2D Study Protocol Assessment V4.0
ERC Form 2E Informed Consent Assessment V4.0 (for studies with human participants)

ERC Form Waiver of Informed Consent Assessment
ERC Form 2J Review of Resubmitted Protocol V4.0
ERC Form 2F Site Resources Checklist V4.0 for clinical trial outside UERMMMCI by UERMMMCI Personnel
ERC Form 2G Site Resources Checklist Non UERM PI V4.0 for clinical trial outside UERMMMCI by non-UERMMMCI Personnel

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1		En banc	No SOP on SJREB
2		En banc	No SOP on SJREB
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised based on the format using PHREB template

9. References

DOH AO 2017-0021 dated October 3, 2017
Single Joint Research Ethics Board SOP 2021

2. PROTOCOL REVIEW

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 2.4** **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 four weeks after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

2. Objective of the Activity

Expedited review aims to demonstrate due diligence and high standards in the system of protection of human participants. An expedited review will reduce the turn-around time for review, thereby, allowing conduct of research to begin.

3. Scope

This SOP applies to initial review of protocols and post-approval submissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise. This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting.

4. Workflow

Activity	Responsibility
Step 1: Assignment of Reviewers or Independent Consultant/s *(SOP No. 1.4 Appointment of Independent Consultants)*	Chair / Member Secretary
Step 2: Notification of Reviewers or Independent Consultant/s	Staff Secretary

Step 3: Provision of study documents and assessment forms to reviewers	Staff Secretary
Step 4: Accomplishment and submission of assessment forms	Primary Reviewers
Step 5: Finalization of review results	Chair
Step 6: Communication of review results to the Principal Investigator *(SOP No. 4.5 Communicating ERC Decisions)*	Chair and Staff Secretary
Step 7: Filing of documents in the protocol file (SOP No. 5.2 Management of Active Files)	Staff Secretary
Step 8: Inclusion of the Review in the Agenda of the next meeting (SOP No. 4.2 Preparing the Meeting Agenda)	Chair and Staff Secretary

5. Description of Procedures

Step 1 - Assignment of Reviewers or Independent Consultant/s
The Chair assigns two ERC members (one scientific and one nonscientific) for expedited study protocols with an ICF. If protocol is a retrospective study, the reviewers should be scientific members. The Chair may designate an additional independent consultant should none of the ERC members have the expertise needed for a particular protocol for review.

Step 2 – Notification of Reviewers or Independent Consultant/s
The Staff Secretary informs the reviewers and/or independent consultant as soon as possible. Reviewers or independent consultants notify the Staff Secretary within two days after receipt of information if there would be conflict of interest, availability, suitability, or acceptance of review.

Step 3 - Provision of documents and evaluation form to reviewers
The Staff Secretary prepares all pertinent documents for protocol review and sends via email or courier. The study documents may be the complete submission package if protocol is for initial review and the pertinent information from the retrieved protocol and the report itself for post approval submissions.

Step 4 - Accomplishment and Submission of Assessment forms
The primary reviewers read the study protocol and related documents and accomplish the assessment forms. Reviewers are given 10 working days to review and return accomplished assessment forms and submit it via email or courier to the Staff Secretary.

The primary reviewers will review the technical and ethical aspects of the protocol (as listed below) and related documents using the assessment forms:

Study Protocol Assessment

Scientific issues

- *Clarity of study objectives/expected output*
- *Sufficiency of review of literature*
- *Appropriateness of research design to objectives*
- *Appropriateness of sampling design and sample size*
- *Appropriateness of data analysis plan for quantitative and qualitative methods*
- *Appropriateness of inclusion, exclusion, and withdrawal criteria, especially in vulnerable groups*

Conduct of the Study

- *Clarity and confidentiality of procedure on the data/ specimen collection, storage, access, and disposal*
- *Suitability of PI qualifications*
- *Management of COI*
- *Rationalization for choice of study site*

Ethical Issues

- *Adequacy of discussion on the significance of the study*
- *Protection of privacy and confidentiality of research information including data protection plan*
- *Vulnerability of research participants*
- *Equity of the participant selection*
- *Non-coerciveness of recruitment*
- *Risk benefit ratio of study to participant and/or community*
- *Appropriateness of compensation/reimbursements*
- *Appropriateness and comprehensiveness of recruitment and informed consent (assent) process and documents*

Informed Consent Form Assessment

- *Introduction*
- *Purpose of the Research*
- *Type of Research Intervention*
- *Participant Selection*
- *Voluntary participation*
- *Information on trial drug (if study is clinical trial)*
- *Procedures*
- *Duration of Participant involvement*
- *Foreseeable risks*
- *Benefits to participants, community and society*
- *Confidentiality*
- *Compensation/Reimbursements*

- *Right to refuse or withdraw*
- *Sharing of Results*

The following are the possible actions of the primary reviewers on a specific protocol submission:

- Approve
  - when no further modification is required
- Major Modification
  - Any revision of the Informed Consent Form (ICF) except typographical and administrative revisions
  - Any change in study design
  - Change in sample size
  - Adding or removing procedures to improve study methods
- Minor Modification
  - Any revision not included as major revision
  - Any clarification
- Disapprove
  - due to ethical or legal concerns
  - If a study protocol is disapproved, a justification is provided and it is automatically elevated in the next full board meeting
- Deferred, if major clarifications are required before a decision can be made

Step 5 - Finalization of review results
The Staff Secretary checks completeness of the assessment forms and consolidates the review results. The Staff Secretary will draft the decision letter for expedited protocols based on the returned review forms and send it to the Chair for harmonization of differing opinions and finalizing the review results. If needed, the Chair will discuss the decision with the primary reviewers.

Step 6 - Communication of review results to the Principal Investigator
The Staff Secretary prepares the decision letter, **ERC Form 6C Letter for Modification Template** or **ERC Form 6B Protocol Approval Template** for signature of the Chair and sends the communication to the PI within 5 working days see *SOP No. 4.5 Communicating ERC Decisions.*

Step 7 - Filing of documents in the protocol file
All protocol-related documents are filed in a protocol folder including the ERC forms, protocol, and communications, see *SOP No. 5.2 Management of Active Files*.

Step 8 - Inclusion of the Review in the Agenda of the next ERC regular meeting
Once the protocol is approved, it will be reported in the agenda for the next regular meeting, see *SOP No. 4.2 Preparing the Meeting Agenda*.

6. Glossary

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

Exempt from Review - a decision made by the ERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.

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

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

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

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

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

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

Independent Consultant - resource person who is not a member of the Ethics Review Committee, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but is non-voting during the deliberations.

7. Forms

ERC Form 2D Study Protocol Assessment V4.0
ERC Form 2E Informed Consent Assessment V4.0
ERC Form 6B Protocol Approval Template
ERC Form 6C Letter for Modification Template V4.0

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included list of types of studies that may fall under expedited review, detailed description of procedures, defined Major and Minor Modifications and cited SOP numbers.

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

2. PROTOCOL REVIEW

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 2.5** **FULL REVIEW**

1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants; when study participants belong to vulnerable groups; or when a study generates vulnerability to participants. Such a protocol shall be deliberated and decided upon during a regular meeting. Only protocols submitted for, at least two weeks before the 2nd Tuesday of the next 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 proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within one week after the full board meeting.

2. Objective of the Activity

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

3. Scope

This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents and updating of the database.

4. Workflow

Activity	Responsibility
Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP No. 1.4 Appointment of Independent Consultants)	Chair / Member Secretary
Step 2: Notification of primary reviewers or Independent Consultants	Staff Secretary

Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	Staff Secretary
Step 4: Provision of protocol and protocol-related documents to the rest of the committee members	Staff Secretary
Step 5: Presentation of review findings and recommendations during a committee meeting (SOP No. 4.3 on Conduct of Meeting)	Primary Reviewers
Step 6: Discussion of technical and ethical issues	Committee members
Step 7: Summary of issues and resolutions	Chair
Step 8: Committee action	Committee members and Chair
Step 9: Documentation of Committee deliberation and action (SOP No. 4.4 Preparing the Meeting Minutes)	Staff Secretary and Member Secretary
Step 10: Communication of Committee Action to the Principal Investigator *(SOP No. 4.5 Communicating ERC Decisions)*	Chair and Staff Secretary
Step 11: Filing of protocol-related documents and Updating of the Protocol Database	Staff Secretary

5. Description of Procedures

Step 1 - Assignment of primary reviewers or Independent Consultant/s
The Chair assigns members who have the necessary expertise as primary reviewers for the protocol (designates an independent consultant in case such expertise is not present among the members) including a non-scientist member to review the Informed Consent Process and Form.

Step 2 – Notification of Reviewers or Independent Consultant/s
The Staff Secretary informs the assigned primary reviewers and/or independent consultants about their assignment (by text messages, Viber or email) with a request that they confirm their acceptance and availability within 3 days. Reviewers or independent consultant notify (by text messages or email) the Staff Secretary if there would be conflict of interest, availability, suitability, or acceptance of review.

Step 3 - Provision of protocol and protocol-related documents and assessment forms to reviewers

Upon receipt of confirmation/acceptance, the Staff Secretary prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery to the primary reviewers and/or independent consultants via email/google docs or courier. Using the study protocol assessment form (**ERC Form 2D Study Protocol Assessment**) and ICF assessment form (**ERC Form 2E Informed Consent Assessment**), the primary reviewers and /or Independent Consultant/s conduct a thorough review of the ethical and technical aspects of the study protocol and related documents and Informed Consent and give recommendations. They must submit the duly accomplished assessment forms for each study protocol reviewed three days before the scheduled board meeting.

Step 4 - Provision of protocol and protocol-related documents to the rest of the committee members

The Staff Secretary provides the rest of the members of the ERC with an executive summary (synopsis) of the study protocol (included among the submitted documents in the Study Protocol package) three (3) days before the committee meeting, at the latest.

Step 5 - Presentation of review findings and recommendations during a committee meeting

The primary reviewers submit their findings and recommendations (**ERC Form 2D Study Protocol Assessment** and **ERC Form 2E Informed Consent Assessment**) to the Staff Secretary 3 days before the meeting and present these during the actual meeting. If a primary reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

If needed, The ERC may allow or invite the proponent /PI to attend the meeting for clarificatory interview. Principal investigators may be requested to present their study protocol briefly and help clarify any questions of the ERC. Other members of the board may ask for clarifications and are expected to give recommendations and participate in the discussion and decision making of the protocols reviewed.

Step 6 - Discussion of technical and ethical issues

The Chair leads the discussion of the technical and ethical issues using the study protocol assessment form (**ERC Form 2D Study Protocol Assessment**) and ICF assessment form (**ERC Form 2E Informed Consent Assessment**) and the assessment of the primary reviewers as guide to evaluate the following listed below for an orderly exchange of ideas.

Study Protocol Assessment

Scientific issues

- *Clarity of study objectives/expected output*
- *Sufficiency of review of literature*
- *Appropriateness of research design to objectives*
- *Appropriateness of sampling design and sample size*
- *Appropriateness of data analysis plan for quantitative and qualitative methods*
- *Appropriateness of inclusion, exclusion, and withdrawal criteria, especially in vulnerable groups*

Conduct of the Study

- *Clarity and confidentiality of procedure on the data/ specimen collection, storage, access, and disposal*
- *Suitability of PI qualifications*
- *Management of COI*
- *Rationalization for choice of study site*

Ethical Issues

- *Adequacy of discussion on the significance of the study*
- *Protection of privacy and confidentiality of research information including data protection plan*
- *Vulnerability of research participants*
- *Equity of the participant selection*
- *Non-coerciveness of recruitment*
- *Risk benefit ratio of study to participant and/or community*
- *Appropriateness of compensation/reimbursements*
- *Appropriateness and comprehensiveness of recruitment and informed consent (assent) process and documents*

Informed Consent Form Assessment

- *Introduction*
- *Purpose of the Research*
- *Type of Research Intervention*
- *Participant Selection*
- *Voluntary participation*
- *Information on trial drug (if study is clinical trial)*
- *Procedures*
- *Duration of Participant involvement*
- *Foreseeable risks*
- *Benefits to participants, community and society*
- *Confidentiality*
- *Compensation/Reimbursements*
- *Right to refuse or withdraw*
- *Sharing of Results*
- *Who to Contact*

Step 7 - Summary of issues and resolutions

The Chair summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved. The Chair then leads the board to a recommendation regarding the protocol.

Step 8 - Committee action

The following are the possible actions of the ERC on a specific protocol submission:

- Approve
  - when no further modification is required

- Major Modification
  - Any revision of the Informed Consent Form (ICF) except typographical and administrative revisions
  - Any change in study design
  - Change in sample size
  - Adding or removing procedures to improve study methods
- Minor Modification
  - Any revision not included as major revision
  - Any clarification
- Disapprove
  - due to ethical or legal concerns
- Deferred, if major clarifications are required before a decision can be made

The ERC decides by voting by raising hands. The majority decision is adopted.

Step 9 - Documentation of committee deliberation and action
Throughout the meeting, the Member Secretary documents in real time (by entering in the agenda of meeting template on a projector or share screen via ZOOM the details of deliberation and decision of the committee for specific protocol).

Step 10 - Communication of Committee Action to the Principal Investigator
The Staff Secretary prepares the decision letter, **ERC Form 6C Letter for Modification** or **ERC Form 6B Protocol Approval** for signature of the Chair and sends it to the PI within 5 working days.

If a study protocol is for modification or is disapproved, an action letter is forwarded by the Staff Secretary to the PI detailing the recommended revisions or the reasons for the disapproval.

If the study protocol is approved, the ERC stipulates the frequency of continuing review relative to risks for participants. The Staff Secretary sends the approval letter indicating the list of approved document versions to the principal investigator. The approval expires one (1) year after the approval date, after which, an application for continuing review should be submitted to the ERC before the expiry date.

The letter should also contain obligations and expectations from the principal investigator throughout the course of the study including submission of amendments, SAE and SUSAR reports, protocol deviations, progress report or continuing review, end of study in the site and final report, see *SOP No. 4.5 Communicating ERC Decisions*.

Step 11 - Filing of protocol-related documents and Updating of the database
The Staff Secretary files the pertinent documents in the respective study folder and updates the database (See SOP on Managing Active Files (SOP #).

6. Glossary

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

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

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

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

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

Primary Reviewers – are members of the Ethics Review Committee (usually a medical/scientist and a non-medical/non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee. The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

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

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

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

Protocol-related Documents – consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., informed consent form, survey questionnaire, CV of proponent, advertisements, interview guide questions

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

Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

Consensus – a collective agreement.

Clarificatory Interview/meeting – is a consultation between the ERC and the principal investigator (face-to-face or via ZOOM) for the purpose of obtaining explanations or clarity regarding some research issues identified by the ERC to make these issues less confusing or more comprehensible

7. Forms

ERC Form 2D Study Protocol Assessment V4.0
ERC Form 2E Informed Consent Assessment V4.0
ERC Form 6B Protocol Approval Template
ERC Form 6C Letter for Modification Template V4.0

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included detailed description of procedures, defined Major and Minor Modifications and cited SOP numbers.

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Health and Health-related Research 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.1** **REVIEW OF PROGRESS REPORT**

1. Policy Statement

The ERC shall require the submission of progress reports at a frequency based on the level of risk of the study. This is required for studies given ethical clearance or approval which are approaching the one-year expiry date and requiring a renewal or extension. This requirement shall be explicitly stated in the Approval Letter.

2. Objectives of the Activity

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

3. Scope

This SOP applies to the management and review of progress submitted by the proponent while the study is on-going or has ended. This SOP begins with the receipt and entry to electronic submissions log of incoming documents and the protocol database and ends with filing of progress report / continuing review application and committee decision in the protocol file.

4. Workflow

Activity	Responsibility
Step 1: Receipt and entry into electronic submissions log / database of the progress report (SOP No. 5.2 Management of Active Files)	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary
Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers

Step 5: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 6: Filing of Progress report and decision letter and update of the protocol database. SOP No. 5.2 Management of Active Files)	Staff Secretary

5. Description of Procedures

Step 1 - Receipt and entry to electronic submissions log / database
The staff secretary retrieves the corresponding protocol file for reference and guidance of the Chair and reviewers and enters the date and pertinent information in the electronic submissions log of incoming documents and the database immediately upon receipt.

Step 2 – Retrieval of pertinent protocol file
The Staff secretary retrieves the corresponding protocol file for reference and guidance of the Chair and reviewers.

Step 3 – Notification of Chair and Primary Reviewers
Within two days after receipt of the progress report, the staff secretary notifies and sends the pertinent protocol file to the Chair and the previously assigned primary reviewers.

Step 4 – Determination of type of review
The Chair and the primary reviewers, together, decide the type of review and proceed accordingly. For expedited review, see *SOP No. 2.4 Expedited Review* and for full review, see *SOP No. 2.5 Full Review*. A full review is necessary if the submitted protocol progress report increases risk to study participants, as assessed by the ERC Chair.

Step 5 – Communication of committee decision
The ERC communicates the committee decision, see *SOP No. 4.5 Communicating ERC Decisions*. The Staff Secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a full board meeting. The Chair signs the decision letter which may be:

- Approval
- Request for additional information or specific action/s.
- Submission of an explanation for failure to submit required reports or
- Disapproval

The decision letter is forwarded to the principal investigator within five (5) working days.

Step 6 – Filing of Progress Report and committee decision and update of the database

The Staff Secretary files the progress report and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.

6. Glossary

Progress Report – description of how the implementation of the study is moving forward. This is done by submitting a Progress Report. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the ERC based on the level of risk.

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

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

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

Database – a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

7. Forms

ERC Form 4B Continuing Review Application
ERC Form 6H SAE / Deviation / Site Visit / Continuing Review Approval Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION

4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.2** **REVIEW OF AMENDMENTS**

1. Policy Statement

The ERC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter. The type of review of amendments shall be based on whether the amendment is minor or major. An expedited review shall be done on minor amendments and a full review for major amendments.

2. Objectives of the Activity

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

3. Scope

This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is on-going. This SOP begins with the receipt and entry of the submission of amendment to electronic submissions log of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

4. Workflow

Activity	Responsibility
Step 1: Receipt and entry into electronic submissions log / database of the submission of amendments (*ERC Form 4A Study Protocol Amendment) (SOP No. 5.2 Management of Active Files)*	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary

Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers
Step 5: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 6: Filing of Amendments and decision letter and update of the protocol database. SOP No. 5.2 Management of Active Files)	Staff Secretary

5. Description of Procedures

Step 1 - Receipt and entry to electronic submissions log / database
The Staff Secretary receives Study Protocol Amendment Form (**ERC Form 4A Study Protocol Amendment)** and enters the date and pertinent information in the electronic submissions log of incoming documents and database immediately upon receipt.

Step 2 – Retrieval of pertinent protocol file
The Staff secretary retrieves the corresponding protocol file for reference and guidance of the Chair and reviewers.

Step 3 – Notification of Chair and Primary Reviewers
Within two days after receipt of the Study Protocol Amendment Form (**ERC Form 4A Study Protocol Amendment)**, the Staff Secretary notifies and sends the pertinent protocol file to the Chair and the previously assigned primary reviewers.

Step 4 – Determination of type of review
The Chair and the primary reviewers, together, decide the type of review and proceed accordingly. For Expedited review, see *SOP No. 2.4 Expedited Review* and for full review, see *SOP No. 2.5 Full Review*.

A full review is necessary if the proposed study protocol amendment increases risk to study participants, as assessed by the ERC Chair, such as a change in study design, which may include but is not limited to:

- 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

Step 5 – Communication of committee decision
The ERC communicates the committee decision, see *SOP No. 4.5 Communicating ERC Decisions*. The Staff Secretary prepares a draft of the committee decision based on either an expedited

review report or minutes of a full board meeting. The Chair signs the decision letter which may be any of the following:

- Approval
- Additional justification/information required.
- Re Consent required
- Disapproval

The decision letter is forwarded to the Principal Investigator within five (5) working days.

Step 6 – Filing of Amendment documents and committee decision and update of the database

The Staff Secretary files the amendment report and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent database.

6. Glossary

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

Primary Reviewer – a member of the Ethics Review Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

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

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

Database– a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually an electronic platform used for tracking and monitoring the implementation of a study.

7. Forms

ERC Form 4A Study Protocol Amendment
ERC Form 6E Protocol Amendment Approval Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE

1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Health and Health-related Research 2017
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.3** **MANAGEMENT OF PROTOCOL DEVIATION AND VIOLATION REPORT**

1. Policy Statement

Protocol deviations and violations impact safety and welfare of the research participants and integrity of data. In sponsored clinical trials, the ICH-GCP guidelines shall be followed in reporting protocol deviations and violations which are usually done by clinical monitors and auditors. However, in Principal Investigator-initiated studies, principal investigators shall report protocol deviations and violations in the conduct of approved researches within a week from the occurrence of the event, or knowledge thereof, whichever is earlier. Major protocol violations shall undergo full review.

2. Objectives of the Activity

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

3. Scope

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the electronic submissions log and ends with the filing of all related documents and update of the database.

4. Workflow

Activity	Responsibility
Step 1: Receipt and documentation of report of protocol violations and deviations in the electronic submissions log and database	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary

Step 3: Notification of Chair and Primary Reviewers	Staff Secretary
Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers
Step 5: Inclusion of report in the agenda of the next ERC regular meeting (SOP No. 4.2 Preparing the Meeting Agenda); SOP No. 4.3 Conduct of Meeting)	Chair and Staff Secretary
Step 6: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair and Staff Secretary
Step 7: Filing of all related documents and decision letter and update of the protocol database (SOP No. 5.2 Management of Active Files)	Staff Secretary

5. Description of Procedures

Step 1 - Receipt and documentation of report of protocol violations and deviations in the electronic submissions log / database
The Staff Secretary receives the report on protocol deviation or violation in the **ERC Form 4D Protocol Deviation** and records the submissions in the electronic submissions log of incoming documents and the database immediately upon receipt.

Step 2 – Retrieval of pertinent protocol file
The Staff Secretary retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair.

Step 3 – Notification of Chair and Primary Reviewers
The Staff Secretary notifies (by text messages or email) and sends the protocol deviation or violation report together with the retrieved pertinent documents to the Chair and the primary reviewers.

Step 4 – Determination of type of review
The Chair and primary reviewers determine whether the deviation is major or minor based on the submitted form. If it is a major protocol violation, full review is required. Otherwise, the protocol deviation undergoes expedited review, see SOP No. 2.4 Expedited Review and SOP No. 2.5 Full Review.

The ERC based its decision depending on the seriousness of the violation, based but not limited to the following:

- MINOR PROTOCOL DEVIATION - (non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature).
- MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION - (persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk).

Step 5 – Inclusion of report in the agenda of the next ERC regular meeting
The Chair includes the report on protocol deviation and violation in the agenda of the next meeting if it is for full review or the decision report if expedited review.

Step 6 – Communication of Decision to the Principal Investigator
The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair signs the decision letter which may include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance. The decision letter is sent to the Principal Investigator.

Step 7 – Filing of all related documents and committee decision and update of the database
The staff secretary collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information.

6. Glossary

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

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

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

Sponsored Clinical Trials – are clinical studies on investigational drugs.

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

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

Regular Meeting – a periodically scheduled assembly of the ERC.

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

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

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

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

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

Clarificatory Interview/meeting – is a meeting or consultation of the ERC with the Principal Investigator for the purpose of obtaining explanations or clarity regarding some research issues identified by the ERC.

7. Forms

ERC Form 4D Protocol Deviation
ERC Form 6H SAE / Deviation / Site Visit / Continuing Review Approval

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES

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5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.4** **REVIEW OF SAEs AND SUSARs**

1. Policy Statement

Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) are important issues in sponsored clinical trials. Reporting SAEs and SUSARs is the responsibility of the sponsor who collects such reports from all its study sites. This report is sent to the individual principal investigators for submission to their institutional ERC. Review of these reports is an important function of Level 3 ERCs.

The principal investigator must report to the ERC all SAEs according to the following timelines consistent with FDA Guidelines on Safety Reporting (FDA Circular 2012-007, adopted from ICH GCP E2A).

The ERC shall require the submission of reports of SAEs and SUSARs within 4 weeks after the event has come to the attention of the principal investigator. The evaluation of the SAEs and SUSARs shall be conducted by the Subcommittee on SAEs and SUSARs whose recommendation shall be submitted to the ERC for final action.

2. Objectives of the Activity

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

3. Scope

This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. It begins with the receipt and documentation of submission of reports of SAEs and SUSARs in the electronic submissions log and database and is completed upon the filing of all related documents and update of the protocol database.

Serious adverse events are events temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)

- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

4. Workflow

Activity	Responsibility
Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the electronic submissions log and database	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair	Staff Secretary
Step 4: Submission of report to the SAE Subcommittee	Staff Secretary
Step 5: Inclusion of report of Subcommittee in the agenda of the next regular ERC meeting	Chair and Staff Secretary
Step 5: Communication of ERC action to the Principal Investigator (SOP No. 4.5 Communicating ERC Decisions)	Chair and Staff Secretary
Step 7: Filing of all related documents (SOP No. 5.2 Management of Active Files)	Staff Secretary

5. Description of Procedures

Step 1 - Receipt and documentation of submission of report of SAEs and SUSARs in the electronic submissions log / database

The Staff Secretary receives and checks the completeness of the SAE/SUSARs report forms (**ERC Form 4G Serious Adverse Event Report Form**) and enters the submission in the electronic submissions log and database. The Staff Secretary notes whether the submission is within the required timeline consistent with FDA Guidelines on Safety Reporting (FDA Circular 2012-007, adopted from ICH GCP E2A):

1.1 Safety Reporting

1.1.1 Suspected Unexpected Serious Adverse Drug Reactions

- Fatal or Life-Threatening Unexpected ADRs occurring in clinical investigations qualify for very rapid reporting. ERC should be notified in writing (thru email or physical copies) as soon as possible but not later than 7 working days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar medicinal products.
- All Other Unexpected Serious, ADRs
  Serious, unexpected reactions (ADRs) that are not fatal or life-threatening whether onsite or offsite must be filed as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

1.1.2 Expected Adverse Drug Reactions

- Serious adverse drug reactions which are expected based on information from the Investigators Brochure will be reported in the regular progress report and final report.
- Adverse drug reactions which are not serious will also be reported in the regular progress report and final report.

1.2 The Staff Secretary collates all the serious adverse event/s reports and encodes data in the Serious Adverse Events Database and **ERC Form 4J Serious Adverse Event Summary Report Form**.

Step 2 – Retrieval of pertinent protocol file
The Staff Secretary retrieves pertinent study documents such as identity of primary reviewers, approved protocol and earlier SAE and SUSAR report form (**ERC Form 4G Serious Adverse Event Report Form**) and all other related submissions.

Step 3 – Notification of Chair and primary reviewers
The Staff Secretary notifies (through text messages or email) the Chair regarding the SAE and/or SUSAR report form (**ERC Form 4G Serious Adverse Event Report Form**) within 48 hours of receipt and all the study documents are retrieved.

Step 4 – Submission of report to SAE Subcommittee or point person
The Chair forwards the report form (**ERC Form 4G Serious Adverse Event Report Form**) and pertinent documents to the point person or to the SAE/SUSAR Subcommittee for action which should not be later than 3 days prior to the next committee meeting. The SAE Subcommittee or point person will classify the SAEs as onsite or offsite; related vs not related to the intervention and expected or unexpected. The review of offsite reports may be expedited but if SAE occurred onsite, then the report will undergo full review in the next board meeting.

Step 5 – Inclusion of report of SAE Subcommittee or point person in ERC meeting agenda

The suggested action/decision of either the point person or the SAE/SUSAR Subcommittee is included by the Staff Secretary in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda) for ratification, discussion and final decision. Possible actions include:

- Notation with no further action required
- Request further information or action required
- Suspension of recruitment

Step 6 – Communication of decision to the principal investigator
The Staff Secretary prepares the draft decision based on the minutes of the meeting. The Chair signs the decision letter which may include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance. The decision letter is sent to the principal investigator.

Step 7 – Filing of all related documents and update of the protocol database
The Staff Secretary collates and files the retrieved protocol documents, the SAEs and SUSARs reports and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information; see *SOP No. 5.2 Management of Active Files*.

6. Glossary

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

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

SUSAR (Suspected Unexpected Serious Adverse Reactions)- is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.

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

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

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

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

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

7. Forms

ERC Form 4G Serious Adverse Event Report Form
ERC Form 4J Serious Adverse Event Summary Report Form
ERC Form 6H SAE / Deviation / Site Visit / Continuing Review Approval

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.5** **MANAGEMENT OF AN APPLICATION FOR CONTINUING REVIEW**

1. Policy Statement

The ERC shall require the submission of an application for Continuing Review at least 4 weeks before the expiration of the ethical clearance of a protocol. This is required for studies given ethical clearance or approval which are approaching the one-year expiry date and requiring a renewal or extension. Protocols that underwent full review in its initial submission shall undergo full review in its application for continuing review. Similarly, protocols that underwent expedited review shall undergo expedited review in its application for continuing review.

2. Objectives of the Activity

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

3. Scope

This SOP applies to the management of an application for continuing review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the entry in the electronic submissions log and protocol database.

4. Workflow

Activity	Responsibility
Step 1: Receipt of the application for Continuing Review and entry in the electronic submissions log (SOP No. 5.2 Management of Active Files)	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary

Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers
Step 5: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 6: Filing of all related documents (SOP No. 5.2 Management of Active Files)	Staff Secretary

5. Description of Procedures

Step 1 - Receipt of the application for continuing review and entry in the electronic submissions log / database
The Staff Secretary receives, logs and enters in the protocol database the information included in the application for continuing review (ERC Form 4B Continuing Review Application)

Step 2 – Retrieval of pertinent protocol file
The Staff Secretary retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance

Step 3 – Notification of Chair and primary reviewers
The Staff Secretary notifies the Chair and the primary reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance

Step 4 – Determination of type of review: expedited or full review
The Chair shall determine the type of review based on the policy that protocols that underwent full review in its initial submission shall undergo full review in its application for continuing review. Similarly, protocols underwent expedited review shall undergo expedited review in its application for continuing review, see *SOP No. 2.4 Expedited Review* or *SOP No. 2.5 Full Review*

Step 5 – Communication of committee action
The Staff Secretary prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter. Possible decisions include the following: (1) approval, (2) additional information required, (3) submission of an explanation for failure to submit required reports or (4) disapproval

Step 6 – Communication of decision to the principal investigator
The Staff Secretary files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder.

6. Glossary

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

Progress Report – A description of how the implementation of the study is moving forward. This is done by submitting a Progress Report. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the ERC based on the level of risk.

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

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

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

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

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

SUSAR – Suspected Unexpected Serious Adverse Reaction – is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert

Primary Reviewers – are members of the Ethics Review Committee (usually a medical/scientist and a non-medical/non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

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

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

Electronic Submissions Log – a real-time, chronological record of incoming documents (study protocol-related) that includes the Date of Receipt, RIHS ERC Code, Title of the Study Protocol, Name of the Proponent, Contents of submission and Action done (review status).

Database – a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually an electronic platform used for tracking and monitoring the implementation of a study.

7. Forms

ERC Form 4B Continuing Review Application
ERC Form 6J Reminder Letter for Continuing Report Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.6** **REVIEW OF FINAL REPORT**

1. **Policy Statement**
   Submission and review of final reports signal the completion of the study and its acceptance by the ERC This is an important step in the timeline of the study, on which will depend other principal investigator/institutional/funding agency decisions regarding the study, e.g., student/trainee graduation, publication/ release of final funding tranche. The Final Report Form is useful in checking the consistency of study implementation with the approved protocol and the knowledge gained from the endeavor.

   The ERC shall require the submission of the final report not later than eight weeks after the end of the study. Final reports shall undergo either expedited or full review.

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

3. **Scope**
   This SOP applies to the management and review of final reports submitted by proponents at the end of the study. This SOP begins with the receipt of **ERC Form 4C Final Report** and entry of the final report in the submissions log and ends with an update of the protocol database.

4. **Responsibility**
   4.1 Upon completion of the study, the investigator should provide the ERC with a summary of the outcome of the study, especially of the human participants who were involved, in a form of an end of study report.
   4.2 The Staff Secretary looks through the Study Protocol Database for the titles of study protocols that are due for final report at the end of the month.
   4.3 The Staff Secretary informs the respective principal investigators of study protocols whose ethical clearances have expired to submit a final report at least one month in advance of the due date of review by e-mail using **ERC Form 6J Reminder Letter for Continuing Report Template** and keeps a receiving copy of the communication.

5. Workflow

Activity	Responsibility
Step 1: Receipt of final report and entry in the electronic submissions log (SOP No. 5.2 Management of Active Files)	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary
Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers
Step 5: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 6: Filing of the Final Report and related documents and update of the protocol files	Staff Secretary

6. Description of Procedures

Step 1 - Receipt and entry of final report in the electronic submissions log

The Staff Secretary receives and enters the date of receipt of the final report (**ERC Form 4C Final Report**) in the electronic submissions log / database within one working day.

Step 2 – Retrieval of pertinent protocol file

The Staff Secretary retrieves the corresponding protocol file as reference in the review of the final report.

Step 3 – Notification of Chair and primary reviewers

The Staff Secretary notifies (by text messages or email) the Chair and the primary reviewers of the receipt of the final report and awaits further instructions.

Step 4 – Determination of type of review

The Chair and primary reviewers decide the type of review and proceed accordingly. For expedited review, see *SOP No. 2.4 Expedited Review* and for Full Review, see *SOP No. 2.5 Full Review*.

Step 5 – Communication of committee action

The Staff Secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a full board meeting. The Chair signs the decision letter which may be any of the following: acceptance of the final report or to require resubmission with corrections. The Staff Secretary forwards the decision letter to the principal investigator.

If the final report is approved, the principal investigator is informed of the following: (1) the study protocol is reclassified as INACTIVE, (2) ethical clearance automatically expired effective on the date of the approval and (3) the protocol records will be made available for three (3) years after the expiration date, see *SOP No. 5.3 Archiving.*

Step 6 – Filing of the final report and related documents and update of the protocol database

The Staff Secretary files the Final Report and related documents in the appropriate folder and updates the protocol database.

7. Glossary

Final Report – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The ERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Primary Reviewers – are members of the Ethics Review Committee (usually a medical/scientist and a non-medical/non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

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

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

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

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

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

Electronic Submissions Log – a real-time, chronological record of incoming documents (study protocol-related) that includes the date of receipt, RIHS ERC Code, title of the study protocol, name of the proponent, contents of submission and action done (review status).

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

8. Forms

ERC Form 4C Final Report
ERC Form 6G Final Report Approval Template
ERC Form 6J Reminder Letter for Continuing Report Template

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
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10. References

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3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.7** **REVIEW OF EARLY TERMINATION REPORTS**

1. Policy Statement

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

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

2. Objectives of the Activity

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

3. Scope

This SOP begins with the receipt of **ERC Form 4E Early Termination** and entry to electronic submissions log of the early termination reports and is completed upon the communication of committee action to the principal investigator and updating of the protocol database.

4. Responsibility

4.1 The PI submits **ERC Form 4E Early Termination**, together with documents deemed relevant by the investigator to support or clarify information indicated in the application.

5. Workflow

Activity	Responsibility
Step 1: Receipt of the Early Termination Report and entry in the electronic submissions log (SOP No. 5.2 Management of Active Files)	Staff Secretary

Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary
Step 4: Determination of type of review: expedited (SOP No. 2.4 Expedited Review) or full review (SOP No. 2.5 Full Review)	Chair and Primary Reviewers
Step 5: Inclusion of report in the agenda of the next ERC regular meeting	Staff Secretary
Step 6: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 6: Filing of the Early Termination Report and related documents and update of the protocol files	Staff Secretary

6. Description of Procedures

Step 1 - Receipt and entry of early termination report in the electronic submissions log

The Staff Secretary receives and enters the date of receipt of the early termination report (**ERC Form 4E Early Termination**) in the electronic submissions log/database within one working day.

Step 2 – Retrieval of pertinent protocol file

The Staff Secretary retrieves the corresponding protocol file as reference in the review of the Early Termination Report.

Step 3 – Notification of Chair and primary reviewers

The Staff Secretary notifies (by text messages or email) the Chair and the primary reviewers of the receipt of the early termination report and the summary of documents. The Staff Secretary awaits further instructions.

Step 4 – Determination of type of review

The Chair and primary reviewers decide the type of review and proceed accordingly. For expedited review, see *SOP No. 2.4 Expedited Review* and for Full Review, see *SOP No. 2.5 Full Review*.

Step 5 – Inclusion of report in the agenda of the next ERC regular meeting

The Chair includes the report on early termination in the agenda of the next meeting if it is for full review or the decision report if expedited review. The ERC deliberates on the implications of the application on the rights, safety and welfare of the study participants including adapting specific provisions for continued protection and dissemination of specific information to the study

participants. The ERC may request the information from the principal investigator or invite the principal investigator for clarificatory interview.

Step 6 – Communication of committee action
The ERC considers the following possible decisions in the review of an early termination report: (1) acceptance of the decision with no further action; (2) request for additional information; or (3) requirement for further action. The Staff Secretary prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review for signature of the Chair, see *SOP No. 4.5 Communicating ERC Decisions*.

Step 7 – Filing of the early termination report and related documents and update of the protocol database
The Staff Secretary files the Early Termination Report and related documents in the appropriate folder and updates the protocol database.

7. Glossary

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

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

Primary Reviewers – are members of the Ethics Review Committee (usually a medical/scientist and a non-medical/non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

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

Electronic Submissions Log – a real-time, chronological record of incoming documents (study protocol-related) that includes the Date of Receipt, RIHS ERC Code, Title of the Study Protocol, Name of the Proponent, Contents of submission and Action done (review status).

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

8. Forms

ERC Form 4E Early Termination
ERC Form 6G Final Report / Early Termination Report Approval Template

9. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

10. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.8** **MANAGEMENT OF APPEALS**

1. Policy Statement

Appeals are requests from principal investigators (sometimes, from sponsors or funding agencies) for reconsideration of a decision or action of the research ethics committee with regard to the protocol or related documents. Consideration of appeals is a reflection of the open-mindedness of ERC members and their adherence to the principles of transparency and fairness. The ERC shall consider the perspective of the principal investigator regarding the feasibility and acceptability of ERC recommendations including its disapproval. Appeals of principal investigators shall undergo full review and shall be resolved within six weeks (24 working days) upon receipt of the fully documented appeal.

2. Objectives of the Activity

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

3. Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee's action to the Principal Investigator and updating of the protocol

4. Workflow

Activity	Responsibility
Step 1: Receipt of an appeal	Staff Secretary
Step 2: Retrieval of pertinent protocol file	Staff Secretary
Step 3: Notification of Chair and Primary Reviewers	Staff Secretary
Step 4: Inclusion in Agenda of the next regular meeting	Chair and Primary Reviewers

Step 5: Discussion of and deliberation on the appeal	Chair and ERC Members
Step 6: Communication of committee action (SOP No. 4.5 Communicating ERC Decisions)	Chair
Step 7: Filing of documents and updating of the protocol database	Staff Secretary

5. Description of Procedures

Step 1 - Receipt of an appeal

The staff receives the letter of appeal and enters the pertinent information in the electronic submissions log / database.

Step 2 – Retrieval of pertinent protocol file

The Staff Secretary retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

Step 3 – Notification of chair and primary reviewers

The Staff Secretary notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.

Step 4 – Inclusion in agenda of the next regular meeting

The Chair instructs the staff to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the principal investigator to be available on the scheduled meeting in case there is a need for further clarification

Step 5 – Discussion of and Deliberation on the Appeal

The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The principal investigator may be called in for further clarification of issues. The principal investigator is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.

Step 6 – Communication of committee action

Based on the deliberations, the Chair summarizes the decision points and instructs the Staff Secretary to prepare the draft decision letter for his/her finalization and forwarding to the principal investigator, see *SOP No. 4.5 Communicating ERC Decisions.*

Step 7 – Filing of documents and update of protocol database

The Staff Secretary files all the documents into the appropriate folder and updates the protocol database accordingly.

6. Glossary

Appeal – a request of a principal investigator for a reconsideration of the ERC recommendation.

Primary reviewer – is a member of the ERC who is assigned to do an in-depth evaluation of research-related documents using technical and ethical criteria established by the committee.

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

Electronic Submissions Log – a real-time, chronological record of incoming documents (study protocol-related) that includes the date of receipt, rihs erc code, title of the study protocol, name of the proponent, contents of submission and action done (review status).

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

7. Forms

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2022 MAY 15	MUM / RMC	First Draft based on PHREB template 2020 Revised form numbers and cited SOP numbers

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

3. REVIEW OF POST APPROVAL SUBMISSIONS

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 3.9** **CONDUCT OF SITE VISITS**

1. Policy Statement

The ERC shall designate a site visit team to conduct visits of selected sites of approved protocols that fall within the following established criteria: (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 principal investigator; and (e) multiple studies conducted by a principal investigator.

2. Objectives of the Activity

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

3. Scope

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

4. Workflow

Activity	Responsibility
Step 1: Selection of site to visit	ERC Members
Step 2: Notification of Principal Investigator	Chair and Staff Secretary
Step 3: Creation of Site Visit Team	Chair
Step 4: Conduct of site visit	Site Visit Team Members
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team Members

Step 6: Transmittal of Final Report and Recommendations to the Principal Investigator	Chair and Staff Secretary
Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database	Staff Secretary

5. Description of Procedures

Step 1 - Selection of site to visit

Part of the post review process is to ensure that the protocol and good clinical practice is being followed by the research team. This will necessitate a site visit by the ERC to the research site and interview the research team **on-site or via the online platform (e.g. Zoom)**.

5.1 Reasons/criteria for site visit

5.1.1 Routine:

- Initial site visit for studies to be conducted outside of UERMMMCI to determine suitability of site.
- Once a year for studies which last more than one year.

5.1.2 for cause:

- High risk studies
- The principal investigator/research team's track record/past performance as researcher
- Track record of study site for compliance with approved research protocols
- High number of active protocols approved under one PI
- Report of complaints from study participants
- Significant number of SAEs
- Reports of protocol deviation/ violation when decided by the full board
- Frequent non-submission or failure to submit progress reports
- Upon recommendation of the primary reviewer(s)
- Other criteria as determined by the ERC

Step 2 – Notification of principal investigator

Upon instructions of Chair, the Staff Secretary sends a letter together with the site visit resource checklist, **ERC Form 2F Site Resources Checklist or ERC Form 2G Site Resources Checklist Non UERM PI** which the PI needs to fill up to inform the PI of the visit at least two weeks before the scheduled date of visit. The notification letter should provide information on visit details and documents to prepare.

Step 3 – - Creation of site visit team

The Chair will appoint the members of the site visit team composed of at least three members who would preferably include the primary reviewers (1 scientific and 1 non-scientific) of the study. If the primary reviewers are not available, the Chair appoints or asks for volunteers among the ERC members. The site visit team should review the **ERC Form 2F Site Resources Checklist or ERC Form 2G Site Resources Checklist Non UERM PI,** all documents in the study folder and other reports associated with reason for site visit.

The Staff Secretary will inform the members of the site visit team of the time and date of the site visit and send the site visit package which will include the **ERC Form 2F Site Resources Checklist or ERC Form 2G Site Resources Checklist Non UERM PI** or the Site Visit Report Form (**ERC Form 4F Site Visit Report**) and all pertinent documents needed for the team to conduct the site visit properly.

Step 4 – Conduct of site visit
On the day of the visit, the site visit team will introduce themselves to the Research team and conduct the site visit in accordance with the checklist provided in the site visit report form. Typically, important points to cover during the site visit include:

- Study protocol version
- Informed consent documents: verify if the site is using the most recently approved version
- Post-approval documents: verify if these have been submitted to and approved by the ERC.
- Security, privacy, and confidentiality of the documents at the study site
- Facilities in the study site
- Determination of the protection of the rights, safety, and welfare of human participants in the study

Step 5 – Draft of report and presentation of report during meeting and discussion for recommendations
Upon completion of the site visit, the team will discuss to the PI and the research team the initial result of their site visit for clarification and feedback of the study team.

The Site visit team will submit a unified consensus of the site visit report form and submit the same to the Staff Secretary not later than seven days from the scheduled site visit. The Staff Secretary will schedule the deliberation of the results of the site visit on the agenda of the next full board meeting.

The ERC will be informed of the site visit findings in the next meeting by one of the members of the site visit team. The ERC will discuss the results of the site visit and make a decision thereon in accordance with the result of the site visit.

Step 6 – Transmittal of the Final report and recommendations to the principal investigator
The Staff Secretary prepares a summary of the findings and recommendations of the ERC based on the deliberations during the meeting. The Chair finalizes the draft for transmittal to the principal investigator; see *SOP No. 4.5 Communicating ERC Decisions*.

The Staff Secretary informs the PI of the decision of the board with regards to the site visit through a decision letter. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

Step 7 – Filing of the site visit documents and update of the protocol database
The Staff Secretary files the Early Termination Report and related documents in the appropriate folder and updates the protocol database. The staff files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly; see *SOP No. 5.2 Management of Active Files*.

6. Glossary

Site Visit – is an action of the ERC (based on established criteria) in which an assigned team goes to the research site or office (or conducts a virtual inspection) for specific monitoring purposes.

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

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

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

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

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

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

Protocol Database – a collection of information regarding protocols that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

7. Forms

ERC Form 2F Site Resources Checklist
ERC Form 2G Site Resources Checklist Non UERM PI
ERC Form 4F Site Visit Report

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

4. MEETING PROCEDURES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectively: May 15, 2022	**SOP No. 4.1** **PREPARING FOR A MEETING**

1. Policy Statement

The ERC shall have a regular schedule of meetings every 2nd Tuesday of the month. Meetings can be held face-to-face or via online platforms. All face-to-face meetings shall be held within the premises of the institution, while online meetings will be conducted using the official online media platform (e.g., Zoom account) of the Ethics Review Committee. Special meetings shall be held to resolve issues that require immediate attention and action.

2. Objective of the Activity

Preparing for a meeting aims to determine the necessary actions that will ensure the efficient and orderly conduct of ERC meetings.

3. Scope

This SOP covers all activities prior to the conduct of an ERC meeting. This SOP provides descriptions related to identifying the agenda of the regular and special meetings as well as determining members who will attend the meeting.

Only the members of the ERC and the Staff Secretary are allowed to attend the meetings unless otherwise specified (independent consultants) as permitted under these rules to be present for a particular meeting or a portion thereof.

4. Workflow

Activity	Responsibility
Step 1: Setting the schedule for regular and/or special meeting	ERC Chair and Staff Secretary
Step 2: Preparation and Distribution of Meeting Agenda	ERC Member Secretary and Staff Secretary
Step 3: Confirmation of attendance and determination of quorum	Staff Secretary

Step 4: Assembly and preparation of materials and documents needed for the meeting	Staff Secretary

5. Description of the Procedures

Step 1 – Setting the schedule for regular meeting

The ERC Chair will ensure that an ERC meeting will be held regularly every 2nd Tuesday of the month. The Staff Secretary will send a notice of meeting to the members of the ERC at least a week prior to the meeting.

Special meetings may be scheduled when:

a. The industry partners requests for one because they cannot wait for the next scheduled full board meeting
b. There are numerous protocol submissions that cannot be accommodated during the regular meeting
c. There is no quorum on the day of the full board meeting

In case a special meeting is needed, the ERC Chair will determine the date and time of the meeting. The Staff Secretary will coordinate with the ERC Chair regarding the members of the ERC who will be requested to attend the special meeting. Once the date and members are ascertained, the Staff Secretary will send a formal notice of meeting to the members at least one week before the special meeting.

Step 2 – Preparation and distribution of meeting agenda

The Staff Secretary, under the supervision of the Member Secretary prepares the agenda at least three days before the scheduled meeting using the Notice of Meeting template (**ERC Form 2A Notice of Meeting Template**). The agenda includes the following:

a. Call to order
b. Declaration of quorum
c. Disclosure of conflict of interest
d. Reading and approval of the agenda
e. Reading and approval of the minutes of the last meeting
f. Business arising from the minutes of the last meeting
g. Protocol review
- Full review - study protocols for initial review
- Resubmissions or study protocols for modification

- Study protocols for clarificatory interview
- Withdrawal of study protocol application
- Study protocol amendment application
- Continuing review applications/ progress report
- Final reports
- SAE and SUSAR reports
- Site visit reports
- Study protocol non-compliance (deviation or violation) reports
- Early study termination applications
- Queries or complaints

h. Other matters

The protocols received by the Staff Secretary two weeks before the 2nd Tuesday scheduled meeting shall be included in the agenda of the meeting for the month. The ERC Chair reviews the draft agenda within two days and signals its distribution to the ERC members.

The Staff Secretary distributes the Notice of Meeting (**ERC Form 2A Notice of Meeting Template**) and the Minutes of the Previous Meeting (ERC Form 6A) and study protocol synopses of the studies for review to ERC members and independent consultants (if any). The primary mode of distribution of these materials is via email. Physical copies may be given to the ERC member upon request, and that member is responsible for checking the completeness of the documents received. He/she is required to return the documents to the Staff Secretary upon the adjournment of the meeting.

Step 3 – Confirmation of attendance and determination of quorum

The Staff Secretary sends meeting reminders to ERC members through a phone message and email a day before the meeting. The ERC members notify the Staff Secretary of their availability to attend the meeting. The principal investigator or an authorized representative may attend the meeting to give clarifications on the protocol under review upon the invitation of the ERC chair.

At least five members, including the ERC Chair or Member Secretary, must be present to constitute a quorum. A meeting can only commence once a quorum is obtained. If at any time during the meeting the quorum is lost, the meeting must be concluded. The Staff Secretary and other experts or observers do not count in the determination of quorum. No quorum should consist entirely of members of one sector or one gender. At all times, the meeting must include at least one member whose primary area of interest/specialization is nonscientific (lay person) and at least one member who is independent of the institution.

In case a quorum cannot be met, the Staff Secretary informs the ERC Chair and the Member Secretary to determine the need to call in alternate members or to schedule a special meeting instead.

Step 4 – Assembly and preparation
The Staff Secretary ensures that the following are prepared and available during the meeting:

For face-to-face meetings: Protocols for review, laptop, LCD projector, screen, food and drinks, and honoraria of the committee members

For online meetings: protocols for review, Zoom link, laptop and/or desktop with webcam and microphone, and honoraria of committee members

6. Glossary

Quorum – presence of the majority of the ERC members including the non-affiliated and the non-scientist members. At least five members, including the ERC Chair or Member Secretary, a non-scientist member and a non-affiliated member must be present

Staff Secretary – affiliated personnel assigned by administration to assist in the operations of the ERC.

Regular Meeting - a periodically scheduled assembly of the ERC

Special Meeting - a meeting held over and above the regular full board meeting to accommodate numerous protocols, or when a regular full board cannot be held on its regular schedule due to lack of quorum

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

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

7. Forms

ERC Form 2A Notice of Meeting Template
ERC Form 6A Minutes of Meeting Template

8. History of SOP

VERSION	DATE	AUTHORS	MAIN CHANGE

NO.			
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	JPC	Revised format using PHREB template including detailed procedures on special meeting and face-to-face or via online platforms

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

4. MEETING PROCEDURES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 4.2** **PREPARING THE MEETING AGENDA**

1. Policy statement

The meeting agenda is the guide in the conduct of a meeting. It ensures order and completeness of topics for discussion. It is recommended that the agenda template includes the following: date, time, and venue of the meeting; titles of protocols for full review; titles of protocols that underwent expedited review, after approval reports, administrative issuances and operations.

The meeting agenda shall be based on the submissions received, at the latest, two weeks before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

2. Objective of the Activity

This SOP aims to ensure a smooth, orderly, inclusive, and efficient conduct of regular and special meetings.

3. Scope

This SOP describes how the ERC determines what items are to be included in the agenda of regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

4. Workflow

Activity	Responsibility
Step 1: Preparation of the draft meeting agenda	Staff Secretary and Member Secretary
Step 2: Preparation of the provisional meeting agenda	Chair
Step 3: Distribution of the provisional meeting agenda	Staff Secretary
Step 4: Approval of the provisional meeting agenda	ERC members

Step 5: Filing of the final meeting agenda	Staff Secretary

5. Description of the Procedures

Step 1 - Preparation of the draft meeting agenda
The Staff Secretary in collaboration with Member Secretary prepares the draft agenda using the Meeting Agenda Template (**ERC Form 2A Notice of Meeting Template**) for approval of the Chair. The agenda includes the following:

- Call to Order
- Determination of quorum
- Disclosure of Conflict of interest
- Reading and approval of the agenda
- Reading and Approval of the Minutes of the last meeting
- Business arising from the Minutes of the last meeting
- Protocol review:
  - Study Protocols for Initial Review
  - Resubmissions or Study Protocols for Modification
  - Study protocols for clarificatory interview
  - Withdrawal of study protocol application
  - Study protocol amendment application
  - Continuing review applications/ progress report
  - Final reports
  - SAE and SUSAR reports
  - Study protocol non-compliance (deviation or violation) reports
  - Early study termination applications
  - Queries or complaints
  - Report on Expedited Review of Protocols
  - Report on Expedited Review of Post Approval Submissions
  - Report of Site Visits
- Other Matters
- Adjournment

Step 2 – Preparation of the provisional meeting agenda
The chair reviews and approves the draft agenda (within 2 days) as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting

Step 3 – Distribution of the provisional meeting agenda
The Staff Secretary shall furnish each ERC Member a copy of the Notice of the Meeting (with date, time and venue) via electronic mail, at least one week prior to the meeting. The provisional agenda is included in the Notice of Meeting (*SOP No. 4.1 Preparing for a Meeting*).

Step 4 – Approval of the provisional meeting agenda

The ERC members approve the provisional agenda during the meeting (*SOP No. 4.3 Conduct of Meeting*).

Step 5 - Filing of the final meeting agenda
The Staff Secretary files the final (approved) meeting agenda in a special folder that contains all meeting agenda in a chronological order, *see SOP No. 5.2 Management of Active Files*.

6. Glossary

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

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

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

Quorum – the minimum number (i.e., majority of the members) and type of members of the ERC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.

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

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

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

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

Post-approval Reports – are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required be submitted by the Principal Investigator to the ERC for monitoring purposes.

Administrative Issuance – official communications or announcements from institutional authorities.

7. Forms

ERC Form 2A Notice of Meeting Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included description of procedures, glossary and cited SOP numbers.

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

4. MEETING PROCEDURES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 4.3** **CONDUCT OF MEETING**

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.

2. Objective of the Activity

Meetings are conducted to provide an opportunity for the ERC to arrive at collegial decisions regarding study protocols and ERC operations and to be informed of pertinent administrative matters. It is also ensuring that meetings are conducted in an organized manner; guided by the approved agenda.

3. Scope

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

4. Workflow

Activity	Responsibility
Step 1: Distribution of meeting materials	Staff Secretary
Step 2: Declaration of quorum (formal start)	Chair or ERC Member Secretary
Step 3: Approval of the provisional agenda	ERC members
Step 4: Declaration of conflict of interest	ERC members (who have COI)
Step 5: Reading of the previous minutes of the meeting and approval of the agenda	ERC members

Step 6: Discussion of "business arising from the minutes"	ERC members
Step 7: Review of protocols and protocol-related submissions (SOP No. 2.5 Full Review)	Chair and members
Step 8: Report of results of expedited review (SOP No. 2.4 Expedited Review)	Chair
Step 9: Discussion of operations-related matters	Chair and Members
Step 10: Adjournment	Chair
Step 11: Collection, storage, and disposal of meeting materials	Staff Secretary

5. Description of the Procedures

Step 1 - Distribution of meeting materials
The Staff Secretary prepares and makes available the protocols to be reviewed in a full board meeting based on the number of ERC members who confirmed their attendance for the said meeting.

Step 2 – Declaration of quorum
The ERC Chair, or the member secretary in the absence of the Chair, or a scientific member in the capacity of Acting Chairperson in the absence of the two aforementioned, shall preside over the meeting and call the meeting to order.

The ERC Member Secretary shall determine if quorum is present and if there is a non-affiliated member present. Only upon the declaration of both shall the meeting be officially declared open.

Step 3 – Approval of the provisional agenda
The Chair invites the members to examine the provisional agenda and for them to propose changes and/or approve it as the final agenda.

Step 4 – Declaration of conflict of interest
The Chair calls for declaration of conflict of interest (COI) involving any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretary. The ERC Chair instructs the members who declared COI to recuse themselves from the deliberation of the study protocol for which the COI declaration was made.

Step 5 – Reading of the previous minutes of the meeting and approval of the agenda

The ERC Member Secretary presides over the review of the Minutes of the previous meeting. Any corrections to the minutes of the previous meeting shall be noted by the Member Secretary and incorporated as corrections of the minutes. Any member who was present during the previous meeting can declare a motion for approval, which any member who should also be present during the previous meeting can second. The Chair then declares approval of the Minutes of the previous meeting.

Step 6 - Discussion of "business arising from the minutes"
The Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Member Secretary for inclusion in the minutes of the current meeting

Step 7 - Review of protocols and protocol-related submissions
The ERC chair proceeds with the discussion of protocols submitted for full board review. After all the protocols for full board review have been tackled and decided upon, the ERC Chair will proceed to report on protocols submissions for expedited review and full board protocols with modification expedited at the level of the chair which consist of the following:

- Approved protocols
- Study Protocols for Initial Review
- Resubmissions (study protocols for modification)
- Study Protocol Amendments
- Continuing Review Applications
- Final Reports
- Study Protocol Non-Compliance (Deviation or Violation) Reports
- Early Study Termination Applications
- Queries or Complaints

Step 8 - Report of results of expedited review
The Chair goes through the results of review of expedited protocols, which are included in the meeting agenda. Members who wish to raise concerns are entertained, however, reports of expedited review results are for information of the board and for documentation purposes only.

Step 9 - Discussion of operations-related matters
When all the protocols have been deliberated upon and decision made, the ERC chair proceeds to discuss other matters that the ERC needs to decide upon such as operations-related matters.

Step 10 – Adjournment
If there are no other matters left to discuss, the ERC Chair then adjourns the meeting.

Step 11 - Collection, storage, and disposal of meeting materials
The meeting folders containing all documents used during the meeting are collected and properly filed in corresponding folders by the Staff Secretary at the end of the meeting. Extra copies of documents are disposed of by shredding.

6. Glossary

Quorum – the minimum number (i.e., majority of the members) and type of members of the ERC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.

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

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

Adjournment – formal closure of the meeting; motion for adjournment and record of the time are recorded.

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

Meeting Minutes – the official narration and record of the proceedings of the assembly of ERC members, based on the agenda.

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

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

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

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

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

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

7. Forms

ERC Form 2A Notice of Meeting Template
ERC Form 6A Minutes of Meeting Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included description of procedures, glossary and cited SOP numbers

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

4. MEETING PROCEDURES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 4.4** **PREPARATION OF THE MINUTES OF MEETINGS**

1. Policy statement

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

2. Objective of the Activity

The preparation of the minutes of the meeting ensures that there is proper documentation of the deliberation done by the ERC members on study protocols, protocol-related matters and operations-related matters.

3. Scope

This SOP covers all ERC actions related to the documentation of a full board meeting which is the minutes of the meeting.

4. Workflow

Activity	Responsibility
Step 1: Entry of preliminary information on the minutes template	Staff Secretary
Step 2: Preparation of the draft minutes	Staff Secretary and Member Secretary
Step 3: Notation of the draft minutes	Chair
Step 4: Approval of the minutes in the next ERC meeting	Chair and Members
Step 5: Filing of the approved minutes (SOP No. Managing Active Files (SOP#))	Staff Secretary

5. Description of the Procedures

Step 1 – Entry of preliminary information on the minutes template
The Staff Secretary enters the preliminary information which shall include: names and designation of the members who attended to ensure diversity of the membership, the names and designation of those who are absent, the date of the meeting, the title of the protocols reviewed and the agenda of the meeting.

Step 2 – Preparation of the draft minutes
During the meeting, the Member Secretary documents the proceedings of the meeting by doing a real-time note taking into the **ERC Form 2A Notice of Meeting Template**. This template is projected on screen using an LCD projector or screen shared via ZOOM platform and is being updated as the discussion about the agenda is developed. The subsequent discussion, which includes comments and recommendations on scientific issues, ethical issues and informed consent form issues, are directly entered into the minutes of the meeting.

Step 3 – Notation of the draft minutes
The Staff Secretary shall complete the minutes of the meeting within a week after the full board meeting.
The Staff Secretary, Member Secretary and the Chair shall sign the minutes of the meeting. The date of notation shall be indicated as well. The final draft of the minutes of the meeting shall include the following items:

- Date and venue of meeting
- Members attendance (present and absent)
- Independent consultants, principal investigators, guests, and observers' attendance (if any)
- Time when the meeting was called to order
- Conflict of interest declaration
- Items discussed, issues raised and resolutions
- ERC decisions and recommendations

Step 4 – Approval of the minutes in the next ERC meeting
In the next ERC meeting, the ERC members approve the minutes of the meeting through a formal motion from any member and are seconded by any member accordingly.

Step 5 – Storage of the approved minutes
After the ERC meeting, the Staff Secretary files the original copy of the approved minutes of meeting in the ERC Meeting Minutes Folder that is labeled by year for easy retrieval. A copy of the minutes of the meeting will also be filed in the specified folder in the ERC computer and corresponding research protocol file.

6. Glossary

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

Draft Meeting Minutes – proceedings of the meeting prepared by the Staff Secretary under the supervision of the Member-Secretary.

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

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

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

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

7. Forms

ERC Form 6A Minutes of Meeting Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
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5	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included description of procedures, glossary and cited SOP numbers.

9. References

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4. MEETING PROCEDURES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 4.5** **COMMUNICATING ERC DECISIONS**

1. Policy Statement

The outcome of a review shall be communicated by the Staff Secretary to the principal investigator preferably within one week after the ERC meeting when the decision was made.

2. Objective of the Activity

The management of communicating ERC decisions ensures that all stakeholders are appropriately informed of the results of the deliberations made by the ERC board through a decision document in the form of an action letter.

3. Scope

This SOP covers all ERC actions related to communicating ERC decisions on protocols it has reviewed.

The communication of the decision shall include, but is not limited, to the following:

- The exact title of the research proposal reviewed
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable). The names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form
- The name and title of the principal investigator
- The date and place of the decision
- The names of the ERC members who participated in the deliberation
- A clear statement of the decision reached
- Any suggestions of the ERC
- Validity of approval usually will be yearly for multi year projects, however, may change on a case-to-case basis.

4. Workflow

Activity	Responsibility

Step 1: Finalization of recommendations of the committee (full board review) or reviewers (expedited review)	Chair
Step 2: Transfer of information from minutes or reports to ERC decision letter or template	Staff Secretary and Member Secretary
Step 3: Approval of the ERC decision letter	Chair
Step 4: Send the ERC decision letter	Staff Secretary
Step 5: Storage of the decision letter in the protocol file	Staff Secretary

5. Description of the Procedures

Step 1 – Finalization of recommendations of the ERC committee or primary reviewers

The ERC Chair finalizes the recommendations of the ERC committee (see SOP No. 2.5 Full Review) or the recommendations of the primary reviewers (see SOP No. 2.4 Expedited Review).

Step 2 – Transfer of information from minutes or reviewer's reports to the ERC decision letter template

The Staff Secretary transfers the decisions made by the ERC members in a full board meeting or the primary reviewers' reports in an expedited review to the action letter template, which is the decision document of the ERC. The decision can be any of as follows:

- A conditional decision (i.e., approval with recommendations or modifications, suggestions for revision and the procedure or any other requirements by the ERC (***please see below***), will be valid only for six months from the date of issue of letter. If the Principal Investigator does not comply with the ERC suggestions during these three months, a reminder will be issued. The modifications will be re-reviewed by Member Secretary, ERC Members or primary reviewer/s and /or may be referred for full board review.

    - **The principal investigator may be required to provide additional information or additional documents.**
    - **Primary reviewers can likewise recommend clarificatory interviews with principal investigator/s (and Faculty adviser/s in cases of student-initiated protocols).**
        - **Principal investigator/s (and faculty adviser/s in cases of student-initiated protocols) may seek a clarificatory interview with the primary reviewer/s**

- A positive decision, wherein the Principal Investigator is notified through an approval letter of the following requirements:
  - A statement of the responsibilities of the Principal Investigator; for example, confirmation of the acceptance of any requirements recommended by the ERC
  - Submission of progress report(s) decided on case-to-case basis, usually yearly
  - The need to notify the ERC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study)
  - The need to notify the ERC in the case of amendments to the recruitment material like the potential research participant information, or the informed consent form or the need to report serious and unexpected adverse events related to the conduct of the study
  - The need to report unforeseen circumstances, the termination of the study, or significant decisions by other ERC
  - The information the ERC expects to receive in order to perform ongoing review
  - The final summary or final report
  - The schedule/plan of ongoing review of sponsored trials
- A negative decision, in which the ERC will state the reasons of disapproval of a study protocol, and that which will be communicated to the principal investigator

Step 3 – Approval of the ERC decision letter
The Chair approves of the ERC decision through signing the decision letter after the Staff Secretary has finished drafting this document.

Step 4 – Send the ERC decision letter to the principal investigator
The Staff Secretary will then communicate to the Principal Investigator by sending the decision letter that was signed by the Chair within 5 working days.

Step 5 – Storage of the decision letter in the protocol file
The Staff Secretary will store the decision letter in the protocol file which will be kept in secured in the ERC office.

6. Glossary

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

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

Database - a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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

7. Forms

ERC Form 6C Letter for Modification Template
ERC Form 6B Protocol Approval Template

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
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5	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included description of procedures, glossary and cited SOP numbers.

9. References

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National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.1** **MANAGEMENT OF INCOMING AND OUTGOING COMMUNICATIONS**

1. Policy Statement

All communications shall be recorded accurately and appropriately saved in the database and electronic submissions log. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

2. Objective of the Activity

This SOP aims to establish accountability and an efficient and effective tracking system of all communications such as proper sorting, response/action, distribution and filing of study-protocol or administrative-related communications

3. Scope

This SOP covers ERC actions in the management of incoming and outgoing documents and ensuring an appropriate ERC response. This SOP begins with sorting of incoming/outgoing communications and is completed upon the proper storing or filing of the incoming/outgoing communications.

4. Workflow

Activity	Responsibility
Step 1: Sorting of incoming/outgoing communications	Staff Secretary
Step 2: Recording of incoming/outgoing communications	Staff Secretary
Step 3: Acting on incoming communications	Chair or Member Secretary
Step 4: Filing of incoming/outgoing communications and updating of database	Staff Secretary

5. Description of the Procedures

Step 1 – Sorting of incoming/outgoing communications
The Staff Secretary, under the supervision of Member Secretary, organizes and sorts all communications (communications can come in the form of letters, official memoranda, or emails.) received, and prepares them for recording. Unclaimed decision letters will be filed in the respective study protocol folders.

Step 2 – Recording of incoming/outgoing communications
The Staff Secretary records all study protocol-related communications received in the ERC database and electronic submissions log. The Staff Secretary records in the database system and electronic submissions and logs the following information: date received, assigned code, protocol title, principal investigator, contents of submission, action taken. The Member Secretary oversees this activity. This is updated as each submission is received.

Step 3 – Acting on incoming communications
The Staff Secretary, under the guidance of the Member Secretary and/or the Chair, gives timely and relevant responses to all communications received. The Staff Secretary drafts a letter of response to be reviewed and signed by the Chair.

Step 4 – Filing of incoming/outgoing communications and updating of database
The Staff Secretary files incoming /outgoing protocol related communications in the study protocol file. The Staff Secretary then writes in the protocol folder contents index as each communication is filed in a timely manner, while non protocol related incoming and outgoing communications are filed in an Administrative Communication folder with appropriate indexing as needed. The Member Secretary oversees this activity.

6. Glossary

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

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

Administrative Communications - documents that pertain to the operations of the ERC and are not directly related to a study or protocol. Examples include the SOPs, membership files, agenda and minutes files, administrative issuances.

Protocol-related Communications - consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., informed consent form, survey questionnaire, CV of proponent, advertisements, Interview guide questions, indexing system.

7. Forms
ERC Form 6I Online Initial Submissions / Resubmissions Log

ERC Form 6I Online Post-approval Submissions Log

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2022 MAY 15	MUM / RMC	Revised format using PHREB template, included detailed workflow, description of procedures, glossary

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
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5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.2** **MANAGEMENT OF ACTIVE FILES**

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 No. 5.4 Management of Access to Confidential Files.

2. Objective of the Activity

This SOP aims to describe how the ERC ensures accessibility, easy retrieval of active files and protection of confidentiality of all study protocol related documents.

3. Scope

This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the ERC. This SOP begins with the classification and coding of active files and ends upon the maintenance of the file.

4. Workflow

Activity	Responsibility
Step 1: Classification and coding of Active Files	Member Secretary and Staff Secretary
Step 2: Preparation of the Protocol Folder	Staff Secretary
Step 3: Periodic updating of the Protocol File	Member Secretary and Staff Secretary

5. Description of the Procedures

Step 1 – Classification and coding of active files

The Staff Secretary under the supervision of the member secretary classifies active files as follows:

- Initial Submission
- Resubmission

- Progress Report
- Amendment
- Protocol Deviation
- Protocol Violation
- SAE Serious Adverse Event (SAE
- SUSAR – Suspected Unexpected Serious Adverse Reaction –
- Early Termination –
- Continuing Review
- Final Report/ Close Out Report

The Staff Secretary assigns a code to the initial submission and indicates the same for the rest of the submissions related to the initial submission. The study files are assigned unique identifiers (RIHS ERC Code).

The protocol file is coded as "running number / hospital, college or graduate school, pharmaceutical-sponsored, external / year of submission / series number". For example, 1198 / H / 2022 / 008 will indicate – 1198 as running number of research accepted in UERM, H is for Hospital, 2022 for year of submission and 008 is the serial number that indicates the sequence order of receipt for the year 2022. (This coding system will be maintained on the database (inventory of researches) and also labeled on each protocol file.

Legend:

H – Hospital (e.g.; resident/consultant)
G – Graduate School
P – Drug-sponsored/Industry-sponsored clinical trials
E – External research papers
C - Colleges

Step 2 – Preparation of the protocol folder

The Staff Secretary files all documents pertaining to a study in a sturdy folder that is labeled on the front cover with: running number/department, college or institution/year of submission/series number. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.

Step 3 – Periodic updating of the protocol file

The Staff Secretary ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:

- Protocol (original and revised) versions
- Informed consent (original and revised) versions
- Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment,
- Early Termination, Site Visit Reports
- Assessment Forms for each of the submitted and reviewed reports which should be signed and dated

- Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
- Decision and Approval Letters
- Communications

The Staff Secretary updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

6. Glossary

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

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

Progress Report - a systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 4K. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the ERC based on the level of risk.

Amendment - a change in or revision of the protocol made after it has been approved.
Protocol Deviation– non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

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

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

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

Suspected Unexpected Serious Adverse Reaction (SUSAR) - is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.

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

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

Final Reports/ Close Out Reports – is a summary of the outputs and outcomes of the study upon its completion. The ERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

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

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

7. Forms

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES

5	2022 MAY 15	MUM	Revised format using PHREB template, included detailed workflow, description of procedures, glossary

9. References

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5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.3** **ARCHIVING**

1. Policy statement

Protocols for archiving include those (a) with approved/ accepted final reports, (b) with approved early termination reports and (c) whose principal investigator has not submitted a response to the ERC recommendation after three months from receipt of the **ERC Form 6C Letter for Modification** and those approved protocols that do not have any report submitted to the ERC within one year shall be considered inactive.

The ERC follows a uniform process for archiving terminated, inactive, and completed study protocols and maintaining security of these files. Study protocol files which have been terminated or completed or declared inactive are kept in a separate secure storage for at least three years after the study closure. It considers study-protocol-related documents as confidential. Only the Staff Secretary can retrieve documents from the archives. Requests to access files and all other files deemed confidential by the ERC must undergo a process for viewing which is compliant with the WHO Operational Guidelines, CIOMS Guidelines, ICH GCP Guidelines, National Ethical Guidelines 2017 and the Data Privacy Act 2012.

2. Objective of the Activity

The aim of this SOP is to outline the process of archiving of terminated, inactive or completed files in order to ensure efficient and effective retrieval of information from the files for reference and compliance with national and international guidelines.

3. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

4. Workflow

Activity	Responsibility

Step 1: Acceptance of Final or Early Termination Reports (SOP No. 3.6 Review of Final Reports, SOP No. 3.7 Review of Early Termination Reports, and Identification of a Protocol as Inactive)	Chair and Members
Step 2: Updating of corresponding protocol folder	Staff Secretary
Step 3: Transfer of the protocol folder in the archives and Update of the Database	Staff Secretary

5. Description of the Procedures

Step 1 – Acceptance of Final or Early Termination Reports and Identification of an Inactive File

The ERC members approve or accept the final report or early termination report during a meeting (*SOP No. 3.6 Review of Final Reports; SOP No. 3.7 Review of Early Termination Reports*. In the identification of an inactive file, the Staff Secretary informs the Member Secretary of the failure of a concerned principal investigator to respond to the recommendations of the ERC in the last 3 months during which time the principal investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.

Archived study protocol files are classified as either:

- Study protocols with approved final or early termination reports, or
- Approved study protocols declared INACTIVE by the ERC if no communication is received from the study team for a period of twelve (12) months
- Study protocols for initial review with resubmissions beyond 90 days from date of action letter

Step 2 – Updating of the corresponding active file

The Staff Secretary files the final or early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive in the protocol folder. Likewise, the Staff Secretary shall update the database of the corresponding protocol.

Step 3 – Transfer of the protocol folder to the archives and update of the database

The Staff Secretary checks whether the documents listed in the protocol file index are complete and the archived folder is transferred to the designated archive cabinet. The study file will be archived for three (3) years. Only one copy of the protocols and other related materials will be archived. Unnecessary copies are disposed of accordingly. Also, the staff secretary updates the database.

After completion of the archival period, the closed files will be shredded and disposed of.

6. Glossary

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

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

Inactive Study – a study whose proponent has not communicated with the ERC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the ERC.

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

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

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

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

7. Forms

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION

4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM	Revised format using PHREB template, included detailed workflow, description of procedures, glossary

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.4** **MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES**

1. Policy statement

It is the responsibility of the ERC to keep particular protocol related documents (meeting minutes, decisions, decision letters/notification of committee decision, approval letters, and study protocol-related communications) in its custody confidential. Access to the ERC confidential files shall be regulated and limited to ERC members and Staff Secretary. 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. Principal Investigators shall be allowed access only to their own protocol files subject to the approval of the Chair. The provisions of WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011, *CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*, ICH GCP Guidelines E6 R2 (2016) and the National Ethical Guidelines (2022) will be followed for security, storage and access of files

2. Objective of the Activity

The aim of this SOP is to outline the specific process in order to protect the intellectual property rights of principal investigators and maintain the integrity of the credibility and integrity of ERC.

3. Scope

This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

4. Workflow

Activity	Responsibility
Step 1: Receipt and logging of request for access to confidential files	Staff Secretary
Step 2: Approval of requests for access and retrieval of documents	Member Secretary or Chair

Step 3: Supervision of use of retrieved document	Staff Secretary
Step 4: Return of document to the files	Staff Secretary

5. Description of the Procedures

Step 1 – Receipt and logging of request for access to confidential files
The Staff Secretary receives the request letter to access specific files and refers this to the Chair or Member Secretary.

Step 2 – Approval of requests for access and retrieval of documents
The Chair or Member Secretary considers the indicated reason for the request and when found satisfactory approves it. The Staff Secretary asks the individual requesting to sign the confidentiality agreement and proceeds to retrieve the pertinent document.

Step 3 – Supervision of use of retrieved document
The staff secretary asks the requesting party to sign in a logbook listing persons accessing confidential ERC files dated by the requesting individual and countersigned by the Staff Secretary. The ERC enforces the restriction to "room-use only" of documents and limits photocopying to concerned principal investigators. Otherwise, a reproduced copy can be provided once suitably justified by the requesting party and approved by the Chair. Moreover, regulatory authorities such as PHREB, FDA, FERCAP, and others will be provided a reproduced copy of the requested documents as endorsed by the Chair. If necessary, the requested document may be anonymized by erasing all identifiers.

Step 4 – Return of document to the files
The requesting party will log out in a logbook listing persons accessing confidential ERC files and the staff secretary returns the retrieved files to the protocol file.

6. Glossary

Confidentiality - is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.

Protocol-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the ERC and the principal investigator.

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

Intellectual property – refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

Meeting Minutes – narration of the proceedings of the assembly of ERC members.

Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration

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

Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.

Room-use Restriction – the rule that limits the use of a document within the designated premises.

7. Forms

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM	Revised format using PHREB template, included detailed workflow, description of

			procedures, glossary

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.5** **MANAGEMENT OF QUERIES AND COMPLAINTS**

1. Policy statement

Queries and complaints may come from various stakeholders but the responsibility of the ERC is highest for those coming from research participants and their families. Nevertheless, all queries and complaints must be addressed as promptly, diligently, and appropriately as possible. 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 Staff Secretary or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

2. Objective of the Activity

This SOP for the management of queries and complaints, especially from research participants, aims to promote public trust and confidence in the ERC and its institution and to ensure that the rights and well-being of participants are attended to. It aims to provide a mechanism through which feedback from stakeholders can be heard and managed.

3. Scope

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the ERC. 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 ERC meeting.

4. Workflow

Activity	Responsibility

Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP No. 5.1 Management of Incoming and Outgoing Communications)	Staff Secretary
Step 2: Referral of query or complaint to competent authority *2.1 Referral of protocol-related query to primary reviewers.* *2.2. Referral of all complaints to the ERC Chair*	Staff Secretary
Step 3: Formulation of response *3.1. Protocol-related queries* *3.2. Minimal-risk complaints* *3.3. More than minimal risk complaints: en-banc committee*	 Primary Reviewers Primary Reviewers Chair and ERC members
Step 4: Communication of response (SOP No. 4.5 Communicating ERC Decisions)	Staff Secretary
Step 5: Logging of the response (SOP No. 5.1 Management of Incoming and Outgoing Communications) and inclusion in the agenda of the ERC meeting (SOP No. 4.2 Preparing the Meeting Agenda)	Staff Secretary

5. Description of the Procedures

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

The Staff Secretary receives queries and complaints through letters and phone calls from the study participants and/or their families. The Staff Secretary records in a logbook dedicated to queries and complaints the details namely: name of concerned party, date, time, contact information, title of study protocol, specific request, issues and/or concerns.

Step 2 – Referral of query or complaint to competent authority

2.1. The Staff Secretary retrieves the study folder and refers queries related to specific protocols approved by the ERC to the primary reviewers.

2.2. On the other hand, the Staff Secretary refers all complaints to the Chair who determines the level of risk affected by the issue.

2.2.1. Minimal risk complaints are referred to the primary reviewers of the concerned protocol.

2.2.2. Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The Staff Secretary notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

Step 3 – Formulation of response

3.1. For queries, the primary reviewers accomplish the **ERC Form 4I Queries or Complaint**.

3.2. For minimal risk complaints, the primary reviewers accomplish **ERC Form 4I Queries or Complaint**

3.3. For more than minimal risk, the committee may choose any of the following options:

3.3.1. Constitute a site visit team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

3.3.2. Designate the primary reviewers to meet with the complainants and the Principal Investigator (preferably separately) for clarification of issues and obtain suggestions for resolution.

3.3.3. Formulate recommendation if satisfied with the adequacy of information –

- request for explanation/justification from Principal Investigator
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- others

Depending on the urgency of the matter, the queries may be taken up in the next ERC meeting or a special meeting may be called for urgent cases.

Step 4 – Communication of response

The Staff Secretary with assistance of Member Secretary prepares the letter based on the result of the investigation and discussion, forwards it to the Chair for approval and signature and sends the communication to the complainant (*see SOP No. 4.5 Communicating ERC Decisions*).

Step 5 – Logging of the response and inclusion in the agenda of the ERC meeting

The response is logged in and filed copy of the response letter in the study protocol file by the staff secretary. The ERC will be updated on all actions and follow-up activities during the regular meeting (*see SOP No. 5.1 Management of Incoming and Outgoing Communications* and *SOP No. 4.2 Preparing the Meeting Agenda*).

6. Glossary

Query – the act of asking for information or clarification about a study.

Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Regular Meeting – a periodically scheduled assembly of the ERC.

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose.

Competent Authority – designated officer or member of the ERC with the authority to respond to queries and complaints regarding studies approved by the ERC.

Primary Reviewers – are members of the Ethics Review Committee (usually a medical/scientist and a non-medical/non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

Site Visit Team – members/staff of the ERC (2-3 members) assigned by the ERC Chair to formally go to the research site (or conduct a virtual inspection), meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

7. Forms

ERC Form 4I Queries or Complaint

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
4	2021 JANUARY 12	MUM	INCLUSION OF PHREB GUIDELINES ON COVID-19 VACCINES
5	2022 MAY 15	MUM	Revised format using PHREB template, included detailed workflow, description of procedures, glossary

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

5. DOCUMENTATION AND MANAGEMENT OF FILES

UERM Memorial Medical Center, Inc.	**UERMMMCI RIHS** ETHICS REVIEW COMMITTEE
Version No.: 5 Date of Approval: May 15, 2022 Date of Effectivity: May 15, 2022	**SOP No. 5.6** **WRITING AND REVISING SOPs**

1. Policy statement

The ERC shall designate a team to periodically review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

2. Objective of the Activity

The objective of writing and revising SOPs ensures continuing quality assurance of ERC functions.

3. Scope

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the UERMMMCI RIHS ERC. It begins with the proposal and approval for revision or writing of a new SOP and is completed upon the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

4. Workflow

Activity	Responsibility
Step 1: Proposal and approval for revision or writing of a new SOP	Any member or Staff Secretary
Step 2: Designation of the SOP Team	Chair
Step 3: Drafting of the revision or new SOP	SOP Team
Step 4: Review and finalization of SOP	Members
Step 5: Submission of finalized SOP to the institutional authority	Chair
Step 6: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	Staff Secretary

5. Description of the Procedures

Step 1 – Proposal and approval for revision or writing of a new SOP
Any member of the ERC can propose to (a) draft and write a new SOP; or (b) revise an existing SOP, when regulations and guidelines on which the SOPs are based have been changed significantly. The proposal may be discussed and approved in a regular or special meeting.

Step 2 – Designation of the SOP Team
The Chair designates the SOP Team from the ERC members.

Step 3 – Drafting of the revision or new SOP
The SOP Team will use the latest PHREB SOP template to prepare the draft of revision or new SOP with the following recommended contents:

a. Title, which is descriptive of contents
b. Policy statement
c. Objective/s of the activity, which defines the purpose and intended outcome
d. Scope, which defines the extent of coverage of the SOP and its limitations
e. Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.
f. Detailed instructions, which elaborates the steps listed in workflow
g. Glossary – acronyms and terms which need to be defined
h. Forms, documents to be accomplished by different parties as required by the SOP,
i. Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
j. References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

The following components are arranged and laid out in the page of the SOP:

- Institutional seal or logo
- Name of Institution
- SOP No.
- SOP /Title
- SOP Version No.
- Date of Approval
- Date of Effectivity
- Page number
- SOP content and a footer indicating file name, directory and path included, of the corresponding electronic document, if the file can be accessed through the ERC website.

Step 4 – Review and finalization of SOP
The designated SOP team will present the draft of newly prepared and/or revised SOP in a regular or special meeting. The Committee will collect comments, discuss and deliberate on the SOP draft until a decision by consensus is reached and the draft is approved.

Step 5 – Submission of finalized SOP to the institutional authority

Step 6 – Inclusion of the new or revised SOP in the SOP Manual and its dissemination

The Staff Secretary incorporates the signed copy of the revised SOP or the new SOP into the existing SOP manual. The e-copy of the ERC SOP will also be updated by the Staff Secretary. The final approved SOP should be disseminated to ERC members and other stakeholders immediately for e-copies and within thirty (30) days for paper copies. The latest approved version is filed in the existing manual and superseded version is stored separately in specified folders.

6. Glossary

Standard Operating Procedures – are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

Coding – unique set of letters and numbers assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.

Format – general style or layout of the document

Date of Effectivity – date when the guidelines shall be enforced.

7. Forms

N/A

8. History of SOP

VERSION NO.	DATE	AUTHORS	MAIN CHANGE
1	2013	UERM RIHS ERC en banc	First Draft
2	2014 AUGUST 1	JRJ	FOR COMPLIANCE WITH PHREB FERCAP SUGGESTIONS
3	2017 NOVEMBER 3	MUM	FOR REACCREDITATION APPLICATION
			INCLUSION OF PHREB GUIDELINES ON

4	2021 JANUARY 12	MUM	COVID-19 VACCINES
5	2022 MAY 15	MUM / RMC	Revised the layout/format of SOP using PHREB template, included description of procedures, corrected glossary, change in numbers, updated history of SOP and references

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
National Ethical Guidelines for Research involving Human Participants 2022
Philippine Health Research Ethics Board Standard Operating Procedures 2020

GLOSSARY

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

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

Adjournment – formal closure of the meeting; motion for adjournment and record of the time are recorded.

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

Administrative Issuance – official communications or announcements from institutional authorities

After-approval reports – are reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the ERC for submission by the Principal Investigator after the study has been approved for implementation.

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

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

Amendment – a change in or revision of the protocol made after it has been approved.

Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.

Appeal – a request of a principal investigator for a reconsideration of ERC recommendation.

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

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

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

Ballot – voting (indicating a choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.

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

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

Clarificatory Interview/meeting – is a face-to-face consultation between the ERC and the principal investigator for the purpose of obtaining explanations or clarity regarding some research issues identified by the ERC.

Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period as a significant step in quality control.

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

Clinical Trial – a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers in order to discover or verify the effects of and/or identify and adverse reactions to investigational products with the object of ascertaining their efficacy and safety.

Coding - a unique set of letters and numbers assigned to a document. A protocol code indicates the year and order of receipt. The SOP code indicates its serial position among the other SOPs and its version number.

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

Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.

Confidentiality – is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.

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

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

Conforme - an indication of acceptance of or agreement to an assignment or designation

Consensus – a collective agreement; the process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objections are registered.

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

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

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

Date of Effectivity – date when the guidelines shall be enforced.

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

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

Draft Meeting Minutes – proceedings of the meeting prepared by the Staff Secretary

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

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

Exempt from Review – a decision made by the ERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2022. The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.

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

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

Expedited Review Reports – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review presented during a regular ERC meeting for information of the ERC members and for record purposes.

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

Final Meeting Minutes – proceedings of the meeting that have been approved by the ERC members.

Final Reports/ Close Out Reports – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The ERC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Format - general style or layout of the document

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

Honorarium - monetary payment for a specific professional service.

Inactive Study – a study whose proponent has not communicated with the ERC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the ERC.

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

Independent consultants - individuals who are not members of the Ethics Review Committee, but whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberation.

Initial Review – the ethical assessment of the first complete set of study documents submitted to the ERC for assessment that can be expedited or full review

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

Intellectual property – refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

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

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

Meeting Minutes – the official narration and record of the proceedings of the assembly of ERC Members, based on the agenda.

Medical Members – are individuals with academic degrees in the medical profession and a master's in the nursing profession.

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

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

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

Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution since they do not receive regular salary or stipend from the institution.

Non-medical members - are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

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

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

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

Physical Plant Division – unit within the institution that is in charge of the maintenance and use of physical facilities.

Post-approval Reports – are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required to be submitted by the principal investigator to the ERC for monitoring purposes.

Primary Reviewers – are members of the Ethics Review Committee *(usually a medical/scientist and a non-medical/non-scientist)* assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee. The non-scientist member shall focus on the review of the informed consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The primary reviewers shall present their findings and recommendations during the meeting for discussion.

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

Progress Report – a systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form 4K. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the ERC based on the level of risk.

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

Protocol database - a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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

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

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

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

Protocol-related Documents - consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., informed consent form, survey questionnaire, CV of proponent, advertisements, interview guide questions.

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

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

Provisional Meeting Minutes – proceedings of the meeting that have been noted or approved by the presiding officer.

Query – the act of asking for information or clarification about a study.

Quorum – the minimum number (i.e., majority of the members) and type of members of the ERC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.

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

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

Regular Meeting – a periodically scheduled assembly of the ERC.

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

Regulatory Authorities – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration

Principal Investigator-Initiated Studies – are research activities whose conceptualization, protocol development and implementation are done by a principal investigator or group of individuals who may request for external funding support.

Resubmissions – the revised study proposals that are forwarded to the ERC in response to the recommendations given during the initial review.

Reviewer – a regular member of the Ethics Review Committee who is assigned to assess a research protocol, the informed consent, and other research-related submissions based on technical and ethical criteria established by the committee.

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

Room-use Restriction – the rule that limits the use of a document within the designated premises.

Secret Ballot – is a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

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

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

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

Site Visit – is an action of the ERC (based on established criteria) in which an assigned team goes to the research site or office or conducts a virtual inspection for specific monitoring purposes.

Site Visit Team – members/staff of the ERC (2-4 members) assigned by the ERC Chair to formally go to the research site (or conduct a virtual inspection), meet with the research team and evaluate compliance with the approved protocol and informed consent form and process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

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

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

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

Standard Operating Procedures – are the step-by-step description of the different procedures done to accomplish the objective of an activity.

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

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

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the ERC and the principal investigator.

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

SUSAR – Suspected Unexpected Serious Adverse Reaction – is a noxious response to a drug that is not described in the investigator's brochure nor in the drug insert.

SAE Subcommittee – a group of experts designated to analyze SAE/SUSAR reports and make the necessary recommendations to the ERC. The experts may or may not be members of the ERC.

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

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

Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

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

UERM RIHS ERC FORMS

FORMS	ERC Code
CURRICULUM VITAE	ERC FORM 1A
CONFIDENTIALITY AGREEMENT	ERC FORM 1B
TRAINING RECORD	ERC FORM 1C
INDEPENDENT CONSULTANT APPOINTMENT	ERC FORM 1D
NOTICE OF MEETING	ERC FORM 2A
REQUIREMENT CHECKLIST	ERC FORM 2B
REGISTRATION AND APPLICATION	ERC FORM 2C
STUDY PROTOCOL ASSESSMENT	ERC FORM 2D
INFORMED CONSENT ASSESSMENT	ERC FORM 2E
SITE RESOURCES CHECKLIST	ERC FORM 2F
SITE RESOURCES CHECKLIST NON UERM PI	ERC FORM 2G
PRIMARY REVIEWER APPOINTMENT	ERC FORM 2I
REVIEW OF RESUBMITTED PROTOCOL	ERC FORM 2J
CHECKLIST FOR EXEMPTION FROM REVIEW	ERC FORM 2K
WAIVER OF INFORMED CONSENT ASSESSMENT	ERC FORM 2L
STUDY PROTOCOL AMENDMENT	ERC FORM 4A
CONTINUING REVIEW APPLICATION	ERC FORM 4B
FINAL REPORT	ERC FORM 4C
PROTOCOL DEVIATION	ERC FORM 4D
EARLY TERMINATION	ERC FORM 4E
SITE VISIT REPORT	ERC FORM 4F
SERIOUS ADVERSE EVENT REPORT FORM	ERC FORM 4G
ASSIGNMENT OF SITE VISIT	ERC FORM 4H

QUERIES OR COMPLAINTS	ERC FORM 4I
SAE SUMMARY REPORT	ERC FORM 4J
PROGRESS REPORT	ERC FORM 4K
MINUTES OF MEETING	ERC FORM 6A
PROTOCOL APPROVAL TEMPLATE	ERC FORM 6B
LETTER FOR MODIFICATION TEMPLATE	ERC FORM 6C
LETTER FOR PI CLARIFICATION OR INTERVIEW	ERC FORM 6D
PROTOCOL AMENDMENT APPROVAL	ERC FORM 6E
NOTIFICATION LETTER REQUEST FOR INFORMATION TEMPLATE	ERC FORM 6F
FINAL REPORT APPROVAL TEMPLATE	ERC FORM 6G
SAE/DEVIATION/SITE VISIT/CONTINUING REVIEW APPROVAL TEMPLATE	ERC FORM 6H
SUBMISSIONS LOG	ERC FORM 6I
REMINDER LETTER FOR CONTINUING REVIEW/REPORT	ERC FORM 6J
CERTIFICATE OF EXEMPTION FROM REVIEW	ERC FORM 6K