Standard Operating Procedure

	University of Makati Research Ethics Committee (UMREC)
Version No: 4	**SOP No. 01** **Selection and Appointment of Members**
Date of Approval: 09.05.2025	
Date of Effectivity:09.05.2025	

Section 1. Policy Statement

The purpose of this policy is to establish guidelines for the selection of members to ensure the integrity, objectivity, and effectiveness of the ethics review process conducted by the University of Makati Research Ethics Committee.

The composition and structure of the University of Makati Research Ethics Committee (UMREC) adhere to the Philippine Health Research Ethics Board (PHREB), a national policy-making body in health research ethics in the country, created under DOST Special Order No. 091 s. 2006. PHREB ensures adherence to the universal ethical principles for the protection and promotion of the dignity of research participants.

The Ethics Committee is composed of 13 members: three (3) officers, nine (9) members, and one (1) rotating member. The officers are in charge of the review operations, classifications of review, and overseer of the review system. Then, the regular members are distributed among multidisciplinary panels, based on the consolidated research agenda of the University of Makati (UMAK).

Panel 1: Science of Technology, Engineering, and Mathematics
Panel 2: Skills Training and Education; Social Development and Economics; and Public Policy Administration, Humanities and Arts
Panel 3: Health Sciences and Its Allied Sciences
Panel 4: Officers

One reviewer is assigned as a rotating reviewer who will be review those that are with Conflict of Interest in the documents to be reviewed. The independent consultants will be open to as many specializations as may be needed for the review of specialized studies that UMAK researchers may engage in. There are also identified laypersons to check on the informed consent form.

Section 2. Objective

The primary objective for the selection of ethics reviewers is to ensure a vigorous, unbiased, and ethical review process that upholds the principles of research integrity, human subject protection, and compliance with relevant regulations.

Section 3. Selection

Ethics reviewers shall be selected based on the following criteria:

3.1 **Qualifications:** Reviewers must have at least a Master's Degree, Permanent or Casual faculty with no administrative designation or appointment, and have a research publication, preferably in an internationally refereed journal. Part-time faculty of the college may be allowed, provided that all other qualifications are satisfied.

3.2 **Training:** Reviewers must have completed the Basic Research Ethics Training (BRET).

3.3 **Expertise:** Reviewers must possess expertise in the relevant field, ensuring a comprehensive understanding of the ethical considerations associated with the research or activity under review.

3.4 **Independence:** Reviewers must demonstrate independence and objectivity, free from any conflicts of interest that could compromise the integrity of the review process.

3.5 **Professionalism:** Reviewers must demonstrate an understanding of ethical principles and guidelines.

3.6. **Special Consideration**. In exceptional cases where a faculty member has not yet published any research but has been officially nominated by their College for UMREC membership, the Committee may grant the nominee *probationary membership for one (1) year*. During this probationary period, the faculty member shall be required to fulfill the minimum qualifications prescribed for regular membership. Upon compliance within the prescribed period, the faculty member shall be endorsed to the Office of the Vice President for Planning and Research for confirmation and approval of the University President.

Failure to comply with the said qualifications within the prescribed period shall automatically result in the *termination of the probationary membership*, and the faculty member shall be deemed to have *vacated the slot*. The UMREC shall thereafter reopen the slot for new nominations.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Call for nominations of new member	Chairperson OVPPR	5 Working Days
Step 2: Submission of Application Requirement	Chairperson Vice Chairperson Secretary	5 Working Days
Step 3: Shortlisting of nominee/s	Chairperson Vice Chairperson Secretary	3 Working Days

Step 4: Confirmation of Selected Member	Chairperson Vice Chairperson Secretary OVPPR	5 Working Days
Step 5: Official approval by the President	OVPPR OVPAA President	1 Working Day
Step 6: Cascading the information	UMREC Deans New Members	1 Working Day

Section 5. Detailed Description of Procedure

Step 1 - Call for nominations of new member: The Chairperson informs the members of the need for new members. The Chairperson announces the opening of nominations through the Office of the Vice-President for Planning and Research (OVPPR). The Dean or Head of the College or Institute shall nominate a faculty to serve as a member of the Research Committee.

Step 2 – Submission of application requirements: The nominator submits the Curriculum Vitae, which includes research publications (Form 001) and the accomplished form (Form 002) to the UMREC Office. The staff checks the completeness of the nomination requirements and endorses them to the Secretariat.

Step 3 - Shortlisting of nominee/s: The Committee Secretary prepares a shortlist based on the requirements and qualifications. The Chairperson calls a special meeting with the OVPPR to present the shortlist for approval. (Form 0023)

Step 4 - Confirmation of Selected Member. The Chairperson presides over the special meeting. The Chairperson, Vice Chairperson, Secretary, and the OVPPR confirm the selected member/s based on the submitted documents.

Step 5 – Official Approval by the President: The Secretariat, through the OVPPR and OVPAA, submits the results to the President for final approval with the stipulation of the term and equivalent teaching and honorarium load.

Step 6 – Cascading the Information. The secretariat furnishes a copy of the said letter to the concerned members and their respective deans. Then, the UMREC secretariat furnishes a copy of the updated set of officers and members to the Office of the President, Vice President for Planning and Research, Vice President for Academic Affairs, and Vice President for Administration.

Section 6. Forms

Form 0001
Form 0009
Form 0023
Form 0026 Communication Logbook

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo dela Armas IV Josephine Robinos Estela De Vera-Barasi	Policy statement, Workflow, and description of procedures
3	February 13, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Merged the Selection and Appointment of Members
4	September 5, 2025	Mark Philip C. Paderan Margarette May Ga Leeland Anthony L. Dela Luna Jomariss B. Plan Rey S. Medenilla Noel A. Ybanez Maria Fay Nenette Maximo-Cariaga Lorna M. Esquivel	Special Consideration under selection Composition of Reviewers Added a process in the Cascading the Information

	University of Makati Research Ethics Committee (UMREC)
Version No: 4	**SOP No. 02** **Designation of Committee Officers**
Date of Approval: 09.05.2025	
Date of Effectivity:09.05.2025	

Section 1. Policy Statement

The purpose of this policy is to establish transparent and fair guidelines for the election of officers within the University of Makati Research Ethics Committee. This policy aims to ensure leadership positions are filled by individuals with the necessary qualifications, commitment to ethical principles, and dedication to advancing the committee's objectives.

Section 2. Objective

The objective of the Election of Ethics Committee Officers is designed to ensure an accountable, effective, and transparent leadership structure within the Ethics Committee.

Section 3. Scope

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

Section 4. Eligibility Criteria

To be eligible for election, a candidate must:

a. Be currently a member of the Research Ethics Committee.
b. Demonstrate a clear understanding of ethical principles, research regulations, and the committee's responsibilities.
c. Be a member of UMREC for a year.
d. Have a track record of active participation in REC's activities.
e. Not have any conflict of interest that may compromise the integrity task and/or the Committee.

Section 5. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Call for a special meeting	Chairperson	1 working day
Step 2: Nomination of members for election	Members	5 Working day
Step 3: Election of officers	Members	1 Working Day
Step 4: Endorsement of results	Secretariat	1 working day

	New Officer/s OVPPR	
Step 5: Issuance of Appointment Letter of new officers	UMREC Secretariat	5 Working day
Step 6: Filing of Appointment Letters	UMREC Secretariat	5 Working day

Section 6. Detailed Description of Procedure

Step 1 - Call for a special meeting: The Chairperson calls a special meeting for the purpose of electing the REC Officers. The Secretariat sends a Notice of Meeting (Form 0023) to all members.

Step 2 – Nomination: The incumbent Chairperson presides over the nomination process for the next Chairperson. In case the incumbent Chairperson is nominated for another term, an REC member may be requested to preside over the special meeting. As a matter of procedure, the newly elected Chairperson leads the nomination process for the Vice-Chairperson and Committee Secretary.

Step 3 – Election: Election of officers shall be by secret ballot and is based on the 2/3 majority rule. In case of a tie, another round of voting shall be conducted until the position is filled.

Step 4 – Endorsement: UMREC Secretariat transmits the results of the election to the President, noted by the Office of Vice President for Planning and Research (OVPPR) and Office of the Vice President for Academic Affairs (OVPAA).

Step 5 – Issuance of Appointment Letter of new officers: The office of the President issues the Appointment Letter of elected UMREC Officers that contain the role and responsibilities of the specific officers and the corresponding term of office.

Step 6 - Filing of Appointment Letters: The UMREC Secretariat files the appointment papers accordingly (refer to SOP 26: Management of Active Files).

Section 7. Filling up Vacancy

Enhancing effectiveness in the event of a vacancy.

1. **Recognition of Vacancy:** When a vacancy arises in the positions of Chairperson, Vice Chairperson or Committee Secretary due to resignation, dismissal, or any other circumstances, prompt action is taken. The REC Chairperson or designated officer notifies regular members without delay. Subsequently, a regular or special meeting is convened to formalize the assumption of office.

2. **Activation of Succession Protocol:** Following the acknowledgment of the vacancy, the Vice Chairperson seamlessly assumes the position of Chairperson. This transition ensures continuity and stability within the REC. The Vice-Chairperson

steps into the role for the remainder of the term originally held by the outgoing Chairperson, guaranteeing the fulfillment of the designated term duration of three years. This established protocol also applies to the vacant position of Vice Chairperson, providing a smooth and consistent leadership structure.

3. **Nomination and election Process:** REC members initiate an open call nomination process and elect the most suitable candidate to fill the vacant Committee Secretary position.

4. **Transition and Handover.** A smooth transition process is facilitated to ensure that the incoming officer is properly onboarded and familiarized with their responsibilities.

Section 8. Terms of Service

The duration of service of the officer shall correspond to and be coterminous with his or her term of membership in the University of Makati Research Ethics Committee (UMREC).

Section 9. Forms

Form 0023 Notice of Meeting
Form 0026 Communication Logbook

Section 9: History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo dela Armas IV Josephine Robinos Estela De Vera-Barasi	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Henry Magat Mark Philip Paderan Ferdinand Piano	Change of provision from appointment to election of officers
4	September 5, 2025	Mark Philip Paderan	Terms of Service

Section 1. Policy Statement

The purpose of this policy is to provide guidelines and transparency regarding the appointment of independent consultants by UMREC. This policy ensures that the engagement of external expertise aligns with the organization's goals, maintains ethical standards, and fosters effective collaboration.

Section 2. Objective

The appointment of independent consultants serves several key objectives, which collectively contribute to the successful execution of projects or tasks. The primary objectives of appointing independent consultants include:

2.1 **Specialized Expertise:** Engage individuals with specific knowledge, skills, and expertise that may not be readily available within the organization.

2.2 **Augment Internal Resources:** Enhance project efficiency and meet deadlines by leveraging the consultant's focused expertise.

2.3 **Efficiency and Timeliness**: Enhance project efficiency and meet deadlines by leveraging the consultant's focused expertise.

2.4 **Assessment and Recommendation**: Obtain an unbiased and objective evaluation of projects, strategies, or initiatives.

2.6 **Innovative Solutions**: Introduce fresh perspectives and innovative solutions to organizational challenges.

2.7 **Risk Mitigation**: Mitigate risks associated with specialized projects or tasks by relying on the expertise of consultants.

2.8 **Compliance and Adherence to Standards**: Compliance and Adherence to Standards - Ensure compliance with industry standards, regulations, and ethical guidelines.

Section 3. Scope

The scope of the appointment of independent consultants outlines the boundaries, responsibilities, and objectives of their engagement within a specific project or task. This scope helps to define the parameters of the consultant's work and ensures clarity for both the organization and the consultant.

Section 4. Criteria for Appointment

For the selection of External reviewers, the following criteria must be satisfied:

a. Expertise and Qualifications: Independent consultants should possess the necessary expertise, qualifications (at least with a Master's Degree), and experience relevant to the specific project or task for which they are being appointed.

b. Independence and Impartiality: Consultants must operate independently and impartially, free from any conflicts of interest that may compromise the integrity of their work or create a perception of bias.

c. Reputation and Track Record: Consideration will be given to the consultant's reputation, track record, and previous work, ensuring a high standard of professionalism and quality.

d. Compliance with Ethical Standards: Consultants must adhere to ethical standards, including confidentiality, data protection, and compliance with applicable laws and regulations.

e. Availability and Commitment: Consultants should be available and committed to fulfilling the agreed-upon scope of work within the established timelines.

Section 5. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Needs Assessment	Chairperson Vice Chairperson Secretary	1 Working Day
Step 2: Inviting Independent Consultant	Chairperson Vice Chairperson Secretary Members	5 Working Day
Step 3: Selection	Chairperson Vice Chairperson Secretary Members	5 Working Day
Step 4: Conflict of Interest Check	UMREC Members	1 Working Day
Step 5: Signing of Appointment of Agreement	Chairperson and Consultant	Confer with HR
Step 6: Stipulation of Roles and Responsibilities	Secretary	1-2 Working day
Step 7: Evaluation and Feedback of Consultants Performance	Chairperson, Vice Chairperson, Secretary, Members	1-2 Working day

Step 8: Compliance with Confidentiality and Data Protection	Chairperson, Vice Chairperson, Secretary	1-2 Working day
Step 9: Termination of Agreement	UMREC Secretariat	1-2 Working day

Section 6. Detailed Description of Procedure

Step 1 - Needs Assessment: A thorough needs assessment will be conducted to identify the specific expertise required and the scope of the consultant's engagement.

Step 2 - Invitation of Independent Consultant: The Chairperson, Vice Chairperson, and Members shall recommend an Independent Consultant that is not employed by the University of Makati for the study that needs a specialist.

Step 3 - Selection: The selection of consultants will be based on a competitive and transparent process, considering qualifications, experience, and proposed methodology.

Step 4 - Conflict of Interest Check: Prior to the appointment, a conflict-of-interest check will be conducted to ensure that the consultant does not have any conflicts that may impact the objectivity of their work.

Step 5 - Appointment Agreement: An appointment agreement, outlining the terms of engagement, deliverables, timelines, and compensation or Certificate, will be established and signed by the UMREC Chairperson and the Independent Consultant.

Step 6 - Roles and Responsibilities:

1. Collaboration - Consultants are expected to collaborate effectively with internal stakeholders, respecting the organizational culture and values.

2. Reporting - Consultants must provide regular updates and progress reports as agreed upon in the appointment agreement.

3. Ethical Conduct - Consultants are expected to adhere to the organization's ethical standards, including confidentiality and respect for privacy.

4. Review – Consultants are expected to review the assigned Protocol (use Forms 011 & 012).

Step 7 - Evaluation and Feedback: The effectiveness of consultants will be periodically evaluated based on the quality of their work, adherence to timelines, and overall contribution to the project.

Step 8 - Confidentiality and Data Protection: Consultants must comply with the organization's confidentiality and data protection policies, ensuring the secure handling of sensitive information.

Step 9 - Termination of Engagement: The organization reserves the right to terminate the engagement of a consultant if there is a breach of contract, ethical misconduct, or failure to meet agreed-upon deliverables.

Section 7. Forms

Form 0029
Form 0026 Communication Logbook

Section 8. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo, Rosalie Catanghal Emeraldo dela Armas IV Josephine Robinos Estela De Vera-Barasi	Policy statement, Workflow, and description of procedures
3	February 13, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Added details for this policy

Section 1. Policy Statement

This policy outlines the procedures and ethical principles governing the expedited review process for research projects within the University of Makati. The objective is to streamline the ethical review of low-risk projects while upholding the highest standards of participant protection and research integrity.

Expedited review is typically limited to research protocols that involve minimal risk to participants, such as surveys, interviews, observational studies, or secondary data analyses. Studies that do not meet the criteria for expedited review must undergo full review.

Section 2. Objective

The objective of expedited review in research is to facilitate the ethical review process for research protocols that involve minimal risk to participants or fall within certain predefined criteria. Expedited review allows for a quicker evaluation of research protocols by a designated panel of reviewers.

Section 3. Scope

This policy applies to research protocols that pose minimal risk to participants and meet specific criteria outlined by regulatory guidelines or institutional policies. These protocols are reviewed by a designated panel of reviewers.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment and Endorsement of Protocol to Review Panel	Secretariat Admin Staff	1 Working Day
Step 2: Review of the Assigned Protocol	UMREC Members	5 Working Days
Step 3: Consolidation and Finalization of the Review Results.	Secretariat Admin Staff	1 Working Day
Step 4: Communication of Review Results to the Researcher	Admin Staff	1 Working Day
Step 5: Issuance of the Certificate of Approval	Chairperson Admin Staff	1 Working Day
Step 6: Filing of Documents in the Protocol File.	Admin Staff	1 Working Day

Section 5. Detailed Description of Procedures

Step 1 - Assignment and Endorsement of Protocol to Review Panel: The Secretariat, in coordination with the Administrative Staff, shall assign the protocol to the appropriate review panel based on expertise, absence of conflict of interest, and workload balance. An official endorsement memo or email shall be issued to the selected reviewers, including review instructions, classification type, and submission deadlines.

Step 2 - Review of the Assigned Protocol: The designated UMREC members shall conduct a thorough ethical and scientific review of the assigned protocol within the prescribed period. Reviewers shall evaluate the study's ethical soundness, scientific validity, informed consent process, risk-benefit assessment, and data protection measures. Comments and recommendations shall be documented using the standardized UMREC review form and submitted to the Secretariat within the review period.

Step 3 - Consolidation and Finalization of the Review Results: Upon receipt of all reviewer comments, the Secretariat and Administrative Staff shall consolidate the evaluations into a single summary report. Any conflicting recommendations shall be reconciled in consultation with the Chairperson or through deliberation among the reviewers if necessary. The finalized review decision shall be recorded and prepared for communication to the researcher.

Step 4 - Communication of Review Results to the Researcher: The Administrative Staff shall formally communicate the results of the review to the researcher through email. The communication shall clearly indicate whether the protocol is Approved, Approved with Minor Revisions, Approved with Major Revisions, or Disapproved, along with corresponding comments or required modifications. All correspondence shall be logged for recordkeeping and monitoring of responses.

Step 5 - Issuance of the Certificate of Approval: Once the researcher has complied with all required revisions and the protocol has received final approval, the Chairperson and Administrative Staff shall prepare and issue the Certificate of Approval. The certificate shall include the protocol title, researcher's name, date of approval, and REC code, duly signed by the UMREC Chairperson. An electronic copy shall be emailed to the researcher, and a hard copy shall be kept in the UMREC file.

Step 6 - Filing of Documents in the Protocol File: The Administrative Staff shall systematically file all related documents—including application forms, reviewer comments, correspondence, approval certificates, and post-approval communications—into the designated protocol folder (both electronic and hard copy). Files shall be indexed and stored securely to ensure confidentiality and easy retrieval for monitoring, renewal, or audit purposes.

Section 6. Forms

Form 0011 Protocol Reviewer Worksheet

Form 0012 Informed Consent Evaluation Worksheet
Form 006 Decision letter template
Form 0026 Communication Logbook

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University research	First draft
2	January 31, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo De las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez Mark Philip Paderan	Update on the workflow and detailed description of procedure

Section 8. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 5** **Full Review**

Section 1. Policy Statement

This policy establishes the framework, procedures, and ethical principles guiding the full review process for research projects within the University of Makati. Full review is suitable for a wide range of research studies, including those involving interventions, vulnerable populations, or complex methodologies that require careful ethical consideration.

Section 2. Objective

The general objective of a full research review is to protect the rights and well-being of human participants, uphold ethical standards, and ensure the scientific integrity and regulatory compliance of research studies. By fulfilling these objectives, full research review contributes to the responsible conduct of research and the advancement of knowledge for the benefit of society.

Section 3. Scope

This policy applies to research protocols that involve greater than minimal risk to participants, complex study designs, vulnerable populations, or novel interventions. These protocols undergo a comprehensive review by the entire ethics committee during a special convened meeting.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Assignment and Endorsement of Protocol to All Reviewers	Secretariat Admin Staff	1 Working Day
Step 2: Review of the Protocol	UMREC Members	10 Working Days
Step 3: Preparation of Agenda for Full Review Meeting which includes the following: a. Call to Order b. Declaration of Quorum c. Approval of the Provisional Agenda d. Disclosure of Conflict of Interest e. Full Review f. Other Matters	Secretariat and Admin Staff	5 working days
Step 4: Reservation of venue	Admin Staff	5 working days

Step 5: Assembly of materials and documents needed for the meeting	Admin Staff	3 working days
Step 6: Preparation of presentation and recording equipment, food arrangements for the meeting (if necessary)	Admin Staff	2 working days
Step 7: Notification and Confirmation of Attendance of Members	Secretariat Admin Staff	5 working days
Step 8: Special Meeting for Full Review	Secretariat UMREC Members	1 Working Day
Step 9: Conduct of the meeting	Secretariat Admin Staff	1 Working Day
Step 10: Consolidation and Finalization of the Review Results.	Secretariat Admin Staff	1 Working Day
Step 11: Preparation of the Minutes of the Meeting	Committee Secretary	1 Working Day
Step 12: Dissemination of the Minutes of the Meeting through email	Secretariat and Admin Staff	1 Working Day
Step 13. Approval of the minutes of the meeting in the next UMREC Meeting	Secretariat All UMREC Members Admin Staff	Upon schedule
Step 14: Communication of Review Results to the Researcher	Chairperson Admin Staff	1 Working Day
Step 15: Issuance of the Certificate of Approval	Chairperson Admin Staff	1 Working Day
Step 16: Filing of Documents in the Protocol File.	Admin Staff	1 Working Day

Section 5. Description of Procedures

Step 1 - Assignment and Endorsement of Protocol to All Reviewers: The Secretariat, with assistance from the Administrative Staff, shall assign the protocol to all UMREC members for comprehensive review. A formal endorsement memo or email shall be issued, specifying the protocol title, review classification (Full Review), and submission deadlines. Reviewers shall receive electronic copies of all relevant materials.

Step 2 - Review of the Protocol: All UMREC members shall independently review the protocol, assessing its ethical soundness, scientific validity, participant protection measures, risk-benefit ratio, data privacy compliance, and consent procedures.

Reviewers shall complete and submit their evaluation forms with recommendations within ten (10) working days.

Step 3 - Preparation of Agenda for Full Review Meeting: The Secretariat and Administrative Staff shall prepare the official agenda for the Full Review meeting, ensuring it includes the following items: (a) Call to Order, (b) Declaration of Quorum, (c) Approval of Provisional Agenda, (d) Disclosure of Conflict of Interest, (e) Full Review of Protocols, and (f) Other Matters. Copies of the agenda shall be distributed to members prior to the meeting.

Step 4 - Reservation of venue: The Administrative Staff shall reserve the meeting venue in coordination with the University Facilities Management Office (UFMO) and General Services Office (GSO). The venue must be suitable for confidential discussion, with sufficient space, seating, and presentation facilities. Confirmation of the reservation shall be secured at least five working days before the meeting.

Step 5 - Assembly of materials and documents needed for the meeting: The Administrative Staff shall compile and organize all relevant documents for the Full Review meeting, including the agenda, review forms, previous minutes, and any correspondence with researchers. Materials shall be printed or electronically prepared for each member. A logbook for attendance shall also be prepared.

Step 6 - Preparation of presentation and recording equipment, food arrangements for the meeting (if necessary): The Administrative Staff shall ensure that all audiovisual and recording equipment are available and functional for the meeting. This includes setting up laptops, projectors, microphones, and attendance tracking systems. If meals or refreshments are to be provided, arrangements shall be made in coordination with the catering service.

Step 7 - Notification and Confirmation of Attendance of Members: The Secretariat shall send official meeting notices to all UMREC members, including the date, time, venue, and agenda. Members shall confirm their attendance within the prescribed timeline to ensure quorum. Reminders shall be sent as necessary.

Step 8 - Special Meeting for Full Review: A special Full Review meeting shall be convened exclusively for the deliberation of protocols classified under Full Review. The Secretariat shall ensure that only members with no conflict of interest participate in the review. The session shall be recorded for documentation, ensuring confidentiality of discussions.

Step 9 - Conduct of the meeting: The meeting shall be formally presided over by the Chairperson or Vice-Chairperson. The agenda shall be followed systematically, and members shall deliberate on each protocol. Decisions shall be made by majority vote, and the outcomes—approval, minor revision, major revision, or disapproval—shall be recorded. The Secretariat shall document all proceedings accurately.

Step 10 - Consolidation and Finalization of the Review Results: After the meeting, the Secretariat and Administrative Staff shall consolidate the reviewers' comments and

the Committee's decisions into a summary report. The final outcome shall be reviewed by the Chairperson for accuracy before being communicated to the researcher.

Step 11 - Preparation of the Minutes of the Meeting: The Committee Secretary shall prepare the detailed Minutes of the Meeting, including the list of attendees, summary of discussions, resolutions, and decisions made for each protocol. The minutes shall be reviewed and signed by the Chairperson.

Step 12 - Dissemination of the Minutes of the Meeting through email: The Secretariat shall distribute the approved minutes to all UMREC members through institutional email for their review and recordkeeping. Members shall be given the opportunity to suggest corrections prior to the next meeting.

Step 13 - Approval of the minutes of the meeting in the next UMREC Meeting: The finalized Minutes of the Meeting shall be presented for formal approval during the next regular UMREC meeting. Any amendments or corrections raised shall be incorporated into the official version, which will then be archived.

Step 14 - Communication of Review Results to the Researcher: The Administrative Staff shall prepare and send a formal communication to the researcher to set the meeting schedule with the Chairperson. The Chairperson shall explain in detail the outcome of the review to ensure that the researcher understands the scientific suggestions and ethical recommendations of the reviewers. It shall also be an avenue to inquire further both from the researcher and the chairperson, some questions relevant to the submitted protocol. The chairperson through the Admin staff sends a letter with the comments and suggestions specifying whether the protocol is approved, requires revision, or is disapproved, along with the rationale and recommendations of the committee.

Step 15 - Issuance of the Certificate of Approval: Upon compliance with all required revisions and final approval by the Committee, the Chairperson shall sign and issue the Certificate of Ethical Clearance/Approval. The certificate shall contain the protocol title, researcher's name, and date of approval.

Step 16 - Filing of Documents in the Protocol File: The Administrative Staff shall compile all documents related to the reviewed protocol—including application forms, review forms, meeting minutes, correspondence, and certificates—into the designated file folder. Both electronic and hard copies shall be securely stored in the UMREC records for future reference and audit.

Section 6. Forms

Form 0011 Protocol Reviewer Worksheet
Form 0012 Informed Consent Evaluation Worksheet
Form 006 Decision letter template
Form 0026 Communication Logbook

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University research	First draft
2	January 31, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo De las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez Mark Philip Paderan	Updating of the SOP Update on the workflow and detailed description of procedure

Section 8. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 6** **Management of Initial Submission of Protocols**

Section 1. Policy Statement

This policy underscores the procedures and principles guiding the initial submission of research protocols to the Research Ethics Committee, promoting integrity, transparency, and compliance in the ethical review process. Adherence to these guidelines fosters the protection of research participants' rights and welfare while facilitating the advancement of ethical research practices.

Section 2. Objective

The objective is to ensure a systematic, transparent, and efficient review process that upholds ethical principles and regulatory requirements.

Section 3. Scope

This policy applies to all researchers, institutions, sponsors, or entities submitting research protocols to the Research Ethics Committee for ethical review and approval.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Acceptance of Complete Documents (Hard Copy And E-Copy)	Admin Staff	1 Working Day
Step 2: Screening of the Document Submitted to Check the Completeness	Secretariat	1 Working Day
Step 3: Evaluation and Classification of submitted Protocol.	Secretariat	2 Working Days
Step 4: Preparation of Electronic Copy and Filing of Printed Copy	Admin Staff	1 Working Day

Section 5. Detailed Description of Procedures

Step 1 - Acceptance of complete documents (hard copy and e-copy): The Administrative Staff shall receive and log all submitted research protocol applications, ensuring both hard and electronic copies are provided by the researcher. The staff shall verify that the documents are submitted through the official channels and within the prescribed submission period. Upon receipt, an acknowledgment email or receipt shall be issued to the researcher as confirmation of submission.

Step 2 - Screening of the document submitted to check the completeness: The Secretariat shall review the submitted documents to ensure that all required components are included, such as the accomplished application form, research proposal, informed consent forms, data collection tools, curriculum vitae of researchers, and relevant permits. Incomplete submissions shall be returned to the researcher with a checklist of missing requirements. Only complete submissions shall proceed to evaluation.

Step 3 - Evaluation and Classification of submitted Protocol: The Secretariat shall evaluate and classify the protocol based on the level of ethical review required—either Exempted Review, Expedited Review, or Full Board Review—in accordance with PHREB guidelines. Classification is determined by factors such as the study's risk level, participant vulnerability, and research design. The Secretariat shall document the classification decision for tracking and reference.

Step 4 - Preparation of Electronic Copy and Filing of Printed Copy: The Administrative Staff shall prepare the electronic copy of the protocol for distribution to reviewers. All identifying details of the researchers (names, contact information, and affiliations) shall be redacted to maintain confidentiality and impartiality during the review. The original printed copy shall be organized and filed securely in the UMREC records for reference and audit purposes.

Section 6. Submission Requirements

4.1 Researchers must adhere to the REC's submission guidelines, including completion of the appropriate application forms and provision of all required documents and materials.

4.2 Submissions should encompass comprehensive details of the research protocol, including study objectives, methodology, participant recruitment and consent procedures, data management plans, and any relevant supporting documentation.

4.3 The researcher shall make use of the QR code or the link provided by the office for the submission of the documents.

Section 7. Administrative Review

5.1 Upon receipt, the Research Ethics Committee conducts an administrative review to ensure that the submission is complete and complies with the REC's submission requirements**.** (refer to SOP 9, 10, 11 for Classification Process)

5.2 Incomplete submissions will be returned to the researcher with a request for the necessary information or documentation.

Section 8. Workflow of Initial Submission of Protocol

6.1 Complete submissions undergo a thorough review by REC panel members to assess compliance with ethical standards, regulatory mandates, and REC policies.

6.2 The review encompasses considerations, such as the protection of participants' rights and welfare, scientific validity, potential risks and benefits, and adequacy of informed consent procedures.

Section 9. Review Results, Decisions, and Notification

7.1 Following review, the REC communicates its decision regarding the initial submission to the researcher or submitting entity.

7.2 Decisions may include approval, conditional approval contingent upon specified revisions, deferral pending additional information or clarification, or disapproval (for extreme cases).

7.3 Researchers receive written notification of the decision, along with any conditions or requirements for approval or resubmission.

Section 10. Timeliness and Communication

8.1 The Research Ethics Committee is committed to maintaining a prompt and transparent communication process throughout the submission and review stages.

8.2 Researchers are informed of the anticipated timeline for review and will receive updates on the progress of their submission as necessary.

Section 11. Forms

Form 011 Protocol Evaluation Form
Form 004 Informed Consent Assessment Form
Forms 0026 & 0027 Logbook

Section 12. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University research	First draft
2	January 31, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo De las Armas IV Josephine D. Robinos	Policy statement, Workflow, and description of procedures

		Estela De Vera-Barasi Margaret May Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez Mark Philip Paderan	Updating of the SOP Inclusion of the workflow and the detailed description of procedure

Section 13. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 7** **Management of Resubmission of Protocols**

Section 1. Policy Statement

This policy provides clear guidelines for the resubmission of research protocols to the Research Ethics Committee, emphasizing the importance of addressing feedback and implementing revisions to ensure ethical compliance and regulatory adherence. Adherence to these guidelines fosters a collaborative and iterative approach to the ethical review process, ultimately promoting the protection of research participants' rights and welfare.

Section 2. Objective

The objective is to facilitate a streamlined process for addressing feedback and implementing revisions to ensure compliance with ethical standards and regulatory requirements.

Section 3. Scope

This policy applies to all researchers, institutions, sponsors, or entities seeking to resubmit research protocols to the REC for further review and approval.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of the Resubmission Documents	Admin Staff	1 Working Day
Step 2: Endorsement of Protocol to Previously Assigned Review Panel	Secretariat Admin Staff	1 Working Day
Step 3: Review of the Assigned Protocol	UMREC Members	5 Working Days
Step 4: Consolidation and Finalization of the Review Results.	Secretariat Admin Staff	1 Working Day
Step 5: Communication of Review Results to the Researcher	Admin Staff	1 Working Day
Step 6: Issuance of the Certificate of Approval	Chairperson Admin Staff	1 Working Day
Step 7: Filing of Documents in the Protocol File.	Admin Staff	1 Working Day

Section 5. Detailed Description of Procedures

Step 1 – Receipt of the Resubmission Documents: The Administrative Staff shall receive the revised research documents from the researcher through electronic mail.

The staff shall verify that the documents correspond to the previously reviewed protocol and that all required revisions have been addressed. Each resubmission shall be logged in the UMREC logbook, indicating the protocol title, date of resubmission, and name of the researcher. An acknowledgment receipt or confirmation email shall be sent to the researcher to confirm receipt of the revised documents.

Step 2 - Endorsement of Protocol to Previously Assigned Review Panel: The Secretariat, in coordination with the Administrative Staff, shall endorse the resubmitted protocol to the same review panel that conducted the initial evaluation to maintain continuity and consistency in the review process. An official endorsement email shall be sent to the reviewers, including the revised documents, a summary of previous comments, and specific areas that were revised through the resubmission form. The endorsement shall also indicate the deadline for the completion of the re-evaluation.

Step 3 - Review of the Assigned Protocol: The assigned UMREC members shall review the revised protocol, focusing on the revisions or responses made by the researcher in accordance with the previous review comments. Reviewers shall determine whether the revisions adequately address the Committee's ethical and scientific concerns. The evaluation shall cover the ethical soundness, scientific validity, informed consent process, risk-benefit ratio, and compliance with data privacy principles. Reviewers shall record their comments and recommendations using the standardized UMREC Review Form and submit these to the Secretariat within five (5) working days.

Step 4 - Consolidation and Finalization of the Review Results: Upon receiving the reviewers' feedback, the Secretariat and Administrative Staff shall consolidate the individual evaluations into a unified summary report. Any discrepancies or conflicting recommendations shall be resolved through consultation with the Chairperson or via electronic deliberation among the reviewers if necessary. The Secretariat shall prepare the final decision document for approval by the Chairperson. The consolidated results shall form the basis of the official communication to the researcher.

Step 5 - Communication of Review Results to the Researcher: The Administrative Staff shall prepare and send the official review results to the researcher via institutional email. The communication shall clearly state the outcome of the resubmission, categorized as Approved, Approved with Minor Revisions, Approved with Major Revisions, or Disapproved. Specific reviewer comments or additional requirements shall be included to guide the researcher in making further adjustments if needed. All outgoing correspondence shall be logged for documentation and monitoring purposes.

Step 6 - Issuance of the Certificate of Approval: Once the researcher has complied with all required revisions and the protocol has received final approval, the Chairperson and Administrative Staff shall prepare and issue the Certificate of Approval. The certificate shall include the protocol title, researcher's name, date of approval, and REC code, duly signed by the UMREC Chairperson. An electronic

copy shall be emailed to the researcher, and a hard copy shall be kept in the UMREC file.

Step 7 - Filing of Documents in the Protocol File: The Administrative Staff shall systematically file all related documents—including application forms, reviewer comments, correspondence, approval certificates, and post-approval communications—into the designated protocol folder (both electronic and hard copy). Files shall be indexed and stored securely to ensure confidentiality and easy retrieval for monitoring, renewal, or audit purposes.

Section 6. Resubmission Criteria

4.1 Protocols may require resubmission following an initial review if the REC has requested revisions or clarifications to address concerns related to ethical principles, participant safety, regulatory compliance, or methodological considerations.

4.2 Researchers should carefully review the feedback provided by the REC and make necessary revisions to the protocol before resubmission.

Section 7. Revised Submission Requirements

5.1 Resubmitted protocols must include a detailed response to each comment or recommendation provided by the REC during the initial review process.

5.2 Researchers should clearly indicate how each requested revision has been addressed in the revised protocol and provide any updated or additional documentation as necessary.

Section 8. Administrative Review

6.1 Upon receipt of a resubmission, the REC conducts an administrative review to ensure that all requested revisions have been adequately addressed and that the resubmission meets the REC's submission requirements. (refer to SOP 9, 10, 11 for Classification Process)

6.2 Incomplete resubmissions will be returned to the researcher with a request for the necessary information or documentation.

Section 9. Review Results, Decisions, and Notifications

7.1 Following review, the REC communicates its decision regarding the resubmission to the researcher or submitting entity.

7.2 Decisions may include approval, conditional approval pending further revisions or clarifications, or continued deferral if additional information or clarification is still required.

7.3 Researchers receive a written notification of the decision, along with any conditions or requirements for final approval.

Section 10. Timeliness and Communication

The Research Ethics Committee is committed to maintaining clear and timely communication throughout the resubmission process, providing updates on the status of the resubmission and any additional feedback or requirements as necessary.

Section 11. Forms

Form 011 Protocol Evaluation Form
Form 004 Informed Consent Assessment Form
Forms 0026 & 0027 Logbook

Section 12. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University research	First draft
2	January 31, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo De las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez Mark Philip Paderan	Updating of the SOP Inclusion of the workflow and the detailed description of procedure

Section 11. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 8** **Review of Progress Report**

Section 1. Policy Statement

This policy provides a framework for the systematic review of progress reports submitted by researchers to ensure ongoing compliance with ethical standards and regulatory requirements.

Section 2. Objective

This policy aims to outline the procedures and criteria for the review of progress reports submitted by researchers conducting studies approved by the Research Ethics Committee.

Section 3. Scope

This policy applies to all research projects that are conducted more than one year from the date of the receipt Certificate of Approval from the Research Ethics Committee and are required to submit periodic progress reports as part of the ethical oversight process, towards the issuance of the Certificate of Ethics Clearance.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and entry into logbook of the progress report (SOP on Management of Active Files (SOP#23))	Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Staff	1-2 Working Days
Step 3: Notification of Chairperson and Primary Reviewers	Staff	1-2 Working Days
Step 4: Communication of committee action (SOP on Communication UMREC Decisions.	Chairperson	1-2 Working Days
Step 5: Filing of Progress report and decision letter and update of the protocol database. SOP on Management of Active Files.	Staff	5-10 Working Days

Section 5. Description of Procedures

Step 1 - Receipt and entry to logbook: The Staff receives Application for Review of Amendments (Form 0013) and enters the date and pertinent information in the logbook of incoming documents (See SOP 23: Management of Active files).

Step 2 - Retrieval of pertinent protocol file: After two weeks, the Staff retrieves the corresponding protocol file for reference and guidance of the Chairperson and Reviewers.

Step 3 - Notification of Chairperson and Primary Reviewers: Within two days after receipt of the Application for Review of Amendments, the Staff notifies and sends the pertinent protocol file to the Chairperson and the previously assigned Primary Reviewers.

Step 4 - Communication of committee decision: The staff communicates the committee action, The Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chairperson signs the decision letter as follows: Approval, request for additional justification/information or specific action/s.

Step 5 – Filing of Amendment documents and committee decision and update of the database: The UMREC Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent protocol database.

Section 7. Forms

Form 0013-Application for Ethical Review
Form 0013-2 Research Protocol
Form 006 Decision letter template
Forms 0026 & 0027 Logbook

Section 8. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I.	Policy statement, Workflow, and description of procedures

		Niño E. Faustino	
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez	Updating of the SOP

Section 9. References

- CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 201
- 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3	**SOP No. 9** **Review of Protocol Amendments**
Date of Approval: 02.15.2024	
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

This policy statement on the review of amendments by a Research Ethics Committee (REC) outlines the procedures and criteria for evaluating proposed changes to approved research protocols.

An amendment refers to any proposed change to the research protocol, including modifications to study procedures, recruitment methods, informed consent documents, research instruments, personnel, or any other aspect of the approved research plan.

Section 2. Objective

This policy statement outlines the procedures and criteria for the review of amendments to research protocols submitted by researchers to the Research Ethics Committee.

Section 3. Scope

This policy applies to all research projects that have received a Certificate of Approval from the Research Ethics Committee and require modifications to the approved protocol during the course of the study.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and entry into logbook of the submission of amendments (SOP # 23 Management of Active Files).	Staff	1-2 Working Days
Step 2: Retrieval of pertinent protocol file	Staff	2 Working Days
Step 3: Notification of Chairperson and Primary Reviewer	Staff	1 Working Day
Step 4: Communication of committee action	Chairperson	One month after the date of submission
Step 5: Filing of Amendments and decision letter and update of the protocol database.	Staff	5-10 Working Days

Section 5. Description of Procedures

Step 1 - Receipt and entry to logbook: The Staff receives Application for Review of Amendments (Form 0013) and enters the date and pertinent information in the logbook of incoming documents.

Step 2 - Retrieval of pertinent protocol file: After two working days, the Staff retrieves the corresponding protocol file for reference and guidance of the Chairperson and Reviewers.

Step 3 - Notification of Chairperson and Primary Reviewers: A day after receipt of the Application for Review of Amendments, the Staff notifies and sends the pertinent protocol file to the Chairperson and the previously assigned Primary Reviewers.

Step 4 - Communication of committee decision: The staff communicates the committee action. The Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chairperson signs the decision letter as follows: Approval, request for additional justification/information or specific action/s.

Step 5 – Filing of Amendment documents and committee decision and update of the database: The Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent protocol database.

Section 6. Forms

Form 0013 Amendment Form
Form 006 Decision letter template
Forms 0026 & 0027 Logbook

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano	Policy statement, Workflow, and description of procedures

		Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez	Updating of the SOP

Section 8. 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

Section 1. Policy Statement

This policy provides guidelines and procedures on managing protocol deviation and violation report. Research Ethics Committee acknowledges the importance of maintaining the integrity and ethical standards of research protocols. Protocol deviations and violations can compromise the validity of research outcomes and may also pose risks to participants, researchers, and the broader scientific community, hence this policy is formulated.

Section 2. Objective

This policy statement outlines the procedures for managing protocol deviations and violations reported by researchers conducting studies approved by the Research Ethics Committee.

Section 3. Scope

This policy applies to all research projects that have received Certificate of Approval from the Research Ethics Committee and are subject to ongoing ethical oversight.

Section 4. Definition of Protocol Deviation and Violation

4.1 Protocol Deviation: Any divergence from the approved research protocol that does not impact participant safety, welfare, or the integrity of study data.

4.2. Protocol Violation. Any breach of the approved research protocol that may pose risks to participant safety, welfare, or the integrity of study data.

Section 5. Requirements and Procedure

5.1 Reporting. Researchers are required to promptly report any protocol deviations or violations to the REC in writing. Reports should include a detailed description of the deviation or violation, the circumstances surrounding it, and any corrective actions taken or planned.

5.2 Review Process. Protocol deviation and violation reports will be reviewed by designated members of the REC or an appointed subcommittee. The review process may involve assessing the nature and severity of the deviation or violation, as well as determining the potential impact on participant rights and welfare.

5.3 Criteria for Review. Protocol deviation and violation reports will be evaluated based on the following criteria:

a. Severity and significance of the deviation or violation
b. Potential impact on participant safety, welfare, or rights
c. Adequacy of measures to address and mitigate any risks or concerns
d. Documentation and transparency of reporting

5.4 Decision Outcomes. Following the review of a protocol deviation or violation report, the REC may take one of the following actions.

a. Acknowledgment of the report and acceptance of corrective actions taken by the researcher
b. Request for additional information, clarification, or justification
c. Notification of the need for further investigation or monitoring
d. Implementation of sanctions or enforcement measures in cases of serious or repeated violations

5.5 Communicating with Researchers. Researchers will be informed of the outcome of the review process in writing. Feedback and recommendations provided by the REC will be communicated clearly, and researchers will be given an opportunity to respond to any concerns or questions raised.

5.6 Record Keeping. Records of protocol deviation and violation reports, reviews, and decisions will be maintained by the REC in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and documentation of report of protocol violations and deviations in the logbook.	Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Staff	1-2 Working Days
Step 3: Notification of Chairperson and primary reviewers.	Staff	1-2 Working Days
Step 4: Determination of type of review: exempted, expedited, or full review	Committee Secretary	3-7 Working Days
Step 5: Inclusion of report in the agenda of the next UMREC regular meeting	Secretariat	Please see the applicable SOP
Step 6: Communication of decision to the Principal Investigator/researcher	Secretariat	1-2 Working Days
Step 7: Filing of all related documents and update of the protocol database	Staff	5-10 Working Days

Section 7. Description of Procedures

Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database: The Staff receives the report on protocol deviation or violation in the appropriate report form (Form 0017) and records this in the logbook for incoming documents.

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chairperson in the selection/ designation of reviewers.

Step 3 - Notification of Chairperson and primary reviewers. The Staff notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the Chairperson and the primary reviewers.

Step 4 - Determination of type of review: expedited or full review: The Chairperson and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. See SOP 04: Expedited Review and SOP 05: Full Review.

Step 5 - Inclusion of report in the agenda of the next UMREC regular meeting. See SOP on Preparing the Meeting Agenda and SOP on Conduct of Meetings. The Chairperson 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/researcher: See SOP on Communicating UMREC Decisions. The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following: (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.

Step 7 - Filing of all related documents and update of the protocol database. See SOP on Managing Active Files (SOP#23). The Staff collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information.

Section 8. Forms

Form 0017 Protocol Deviation/Violation Report Form
Form 006 Decision Letter Template

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez	Updating of the SOP

Section 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 Health and Health-related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020

Section 1. Policy Statement

This policy statement on the review of Reportable Negative Events (RNE) reports by a Research Ethics Committee outlines the procedures and protocols for evaluating and managing adverse events and other reportable incidents occurring during the course of research studies.

Section 2. Objective

This policy statement outlines the procedures and protocols for the review of Reportable Negative Events (RNE) reports submitted by researchers conducting studies approved by the Research Ethics Committee.

Section 3. Scope

This policy applies to all research projects that have received approval from the Research Ethics Committee and are subject to ongoing ethical oversight.

Section 4. Definition of Reportable Negative Events (RNE):

Reportable Negative Events refer to any adverse events, unanticipated problems, serious adverse events, or other incidents occurring during the conduct of a research study that have the potential to impact participant safety, welfare, or the integrity of study data.

Section 5. Reporting Requirements

5.1 Reporting. Researchers are required to promptly report any RNEs to the Research Ethics Committee in accordance with the reporting requirements specified in the approved research protocol and regulatory guidelines. RNE reports should include a detailed description of the event, its severity and significance, any immediate actions taken, and plans for follow-up and resolution.

5.2 Review Process. RNE reports will be reviewed by designated members of the Research Ethics Committee or an appointed subcommittee with expertise in the relevant area(s) of research. The review process may involve assessing the nature and severity of the event, the adequacy of participant protection measures, and the researcher's response and management of the event.

5.3 Criteria for Review. RNE reports will be evaluated based on the following criteria:

a. Severity and significance of events.
b. Potential impact on participant safety, welfare, or rights
c. Adherence to reporting requirements and regulatory guidelines
d. Appropriateness of immediate actions taken to address the event
e. Plans for follow-up, resolution, and prevention of recurrence

5.4 Decision Outcomes. Following the review of an RNE report, the Research Ethics Committee may take one of the following actions:

a. Acknowledgment of the report and acceptance of the researcher's response and management plan
b. Request for additional information, clarification, or justification
c. Notification of the need for further investigation or monitoring
d. Implementation of sanctions or enforcement measures in cases of serious or repeated incidents.

5.5 Communicating with Researchers. Researchers will be informed of the outcome of the review process in writing. Feedback and recommendations provided by the Research Ethics Committee will be communicated clearly, and researchers will be given an opportunity to respond to any concerns or questions raised.

5.6 Record Keeping. Records of protocol deviation and violation reports, reviews, and decisions will be maintained by the Research Ethics Committee in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and documentation of submission of RNE report in the logbook.	Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Staff	1-2 Working Days
Step 3: Notification of Chairperson	Staff	1-2 Working Days
Step 4: Call for a Special Meeting	Chairperson	5-7 Working Days
Step 5: Deliberation on the RNE	UMREC members	2-3 Working Days
Step 6: Communication of UMREC action to the researcher (SOP # 21 on Communication of UMREC Decisions) and to the Institutional authority	Chairperson	1-2 Working Days
Step 7: Filing of all related documents (SOP # 23 Management of Active Files) and Update of the protocol database	Staff	5-10 Working Days

Section 7. Description of Procedures

Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database: The staff receives the accomplished RNE report form (Form 0018) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline which is seven (7) calendar days after the RNE.

Step 2 - Retrieval of pertinent protocol file: The staff retrieves the approved protocol file and checks the identity of the primary reviewers.

Step 3 - Notification of Chairperson: The Staff notifies and sends the report and the retrieved documents to the Chairperson who may decide to call for a special meeting.

Step 4 - Call for a Special Meeting. The staff prepares for a special meeting. The researcher and other study team members may be invited for a clarificatory meeting.

Step 5 - Conduct of the Special Meeting. The Chairperson leads the discussion of the special meeting, summarizes the RNE report, and informs the Research Ethics Committee members regarding the presence of the research team for a clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants/research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on the integrity of data, and completion of the research. The Research team is excused and the UMREC members deliberate on possible options, as follows:

a. recommend suspension of the study until the risk is resolved.
b. withdrawal of ethical clearance
c. submission of a plan to mitigate risk/harm
d. require an amendment to the protocol
e. uphold original ethical clearance

Step 6 - Communication of UMREC recommendation to the researcher: See SOP # 24 on Communicating REC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP# 26 on Management of REC Active Files.

Section 8. Forms

Form 0018 RNE Report
Form 0023 Notice of Meeting Form
006 UMREC Decision Letter

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Junlor C. Dacsa I Mark Philip C. Paderan	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado	Title, Policy Statement, Workflow, and Description of Procedures

		Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section 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 Health and Health-related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020

National Ethical Guidelines for Health and Health-related Research 2017 Philippine Health Research Ethics Board Standard Operating Procedures 2020

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity:02.15.2024	**SOP No. 11B** **Review of Serious of Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs)**

Section 1. Policy Statement

This policy statement on the review of Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) by a Research Ethics Committee (REC) outlines the procedures and protocols for evaluating and managing serious adverse events and reactions occurring during the course of research studies.

Section 2. Objective

This purpose of this policy statement is to outline the procedures and protocols for the review of Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) reported by researchers conducting studies approved by the Research Ethics Committee.

Section 3. Scope

This policy applies to all research projects that have received approval from the REC and are subject to ongoing ethical oversight.

Section 4. Definitions:

4.1 Serious Adverse Event (SAE). An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

4.2 Suspected, Unexpected, Serious Adverse Reactions (SUSARs). A SUSAR is any adverse reaction to a medicinal product that is both unexpected and serious, regardless of whether it is suspected to be related to the medicinal product.

Section 5. Reporting Requirements

5.1 Reporting. Researchers are required to promptly report any SAEs and SUSARs to the REC in accordance with the reporting requirements specified in the approved research protocol and regulatory guidelines. SAE and SUSAR reports should include a detailed description of the event, its severity and significance, any immediate actions taken, and plans for follow-up and resolution.

5.2 Review Process. SAE and SUSAR reports are reviewed by designated members of the REC or an appointed subcommittee with expertise in the relevant area(s) of research

and clinical trials. The review process may involve assessing the nature and severity of the event, the adequacy of participant protection measures, and the researcher's response and management of the event.

5.3 Criteria for Review. SAE AND SUSARs reports are evaluated based on the following criteria:

a. Severity and significance of event or reaction.
b. Potential causal relationship to the research intervention or study procedures
c. Adherence to reporting requirements and regulatory guidelines
d. Appropriateness of immediate actions taken to address the event or reaction.
e. Plans for follow-up, resolution, and prevention of recurrence.

5.4 Decision Outcomes. Following the review of an SAE or SUSAR report, the Research Ethics Committee may take one of the following actions:

a. Acknowledgment of the report and acceptance of the researcher's response and management plan
b. Request for additional information, clarification, or justification
c. Notification of the need for further investigation or monitoring
d. Implementation of sanctions or enforcement measures in cases of serious or repeated incidents.

5.5 Communicating with Researchers. Researchers will be informed of the outcome of the review process in writing. Feedback and recommendations provided by the REC will be communicated clearly, and researchers will be given an opportunity to respond to any concerns or questions raised.

5.6 Record Keeping. Records of protocol deviation and violation reports, reviews, and decisions will be maintained by the REC in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt and documentation of submission of reports of SAEs and SUSARs in the logbook.	Admin Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Admin Staff	1-2 Working Days
Step 3: Notification of Chairperson	Admin Staff	1-2 Working Days
Step 4: Submission of report to the SAE Subcommittee	Admin Staff	five (5) working Days prior to the next committee meeting
Step 5: Inclusion of report of Subcommittee in the agenda of the next regular UMREC meeting	Admin Staff Chairperson	1-2 Working Days

Step 6: Communication of committee action	Chairperson	1-2 Working Days
Step 7: Filing of all related documents and update of the protocol database	Admin Staff	1-2 Working Days

Section 7. Description of Procedures

Step 1 - Receipt and documentation of submission of the report of SAEs and SUSARs in the logbook/database: The Staff receives the accomplished SAE/SUSARs report forms (Form 0030) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the identity of the primary reviewers and a tabulation of earlier SAE/SUSAR reports.

Step 3 - Notification of Chairperson: The Staff notifies and sends the report and the retrieved documents to the Chairperson via official e-mail.

Step 4 - Submission of report to SAE Subcommittee or point person: The Chairperson forwards the report and pertinent documents to the primary reviewers for action which should not be later than five (5) working days prior to the next committee meeting.

Step 5 - Inclusion of report of SAE Subcommittee or point person in REC meeting agenda: The suggested action/decision of either the primary reviewer or the SAE/SUSAR Subcommittee is included in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda). for ratification or discussion and final decision. Possible actions include: notation with no further action required, further information or action required, or suspension of recruitment.

Step 6 - Communicating UMREC recommendation to the Principal Investigator/researcher: See SOP on Communicating UMREC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP on Managing Active Files (SOP#23).

Section 8. Forms

Form 0030 SAE/SUSAR Report
Form 0030 Evaluation of SAE/SUSAR Reports (Recommendation Section)
Form 006 UMREC Decision Letter

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Junlor C. Dacsa I Mark Philip C. Paderan	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy statement, Workflow, and description of procedures
3	February 15, 2024	Lorna, Esquivel Rey Medenilla Noel Ibanez	Updating of the SOP

Section 10. References

SUSAR/USADE Site Report, The Royal Children Hospital Melbourne, Retrieved from https://www.rch.org.au/uploadedFiles/Main/Content/ethics/SUSAR%20-%20USADE%20Site%20Report.pdf

	University of Makati Research Ethics Committee (UMREC)
Version No: 3	**SOP No. 12** **Management of Application for Continuing Review**
Date of Approval: 02.15.2024	
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

This Policy is for the management of applications for continuing review by a Research Ethics Committee, outlining the procedures and protocols for the ongoing ethical oversight of research projects that have been previously approved by the committee.

Section 2. Objective

The purpose of this policy statement is to outline the procedures and protocols for managing applications for continuing review submitted by researchers conducting studies approved by the Research Ethics Committee

Section 3. Scope

This policy applies to all research projects that have received approval from the REC and require ongoing ethical oversight to ensure the protection of human participants and the integrity of the research.

Section 4. Continuing Review Requirement

Researchers are required to submit applications for continuing review to the REC at specified intervals as determined by institutional policies, regulatory requirements, or the terms of the original approval. Continuing review is necessary to assess the ongoing conduct of the research, including participant recruitment, data collection, and any changes to the research protocol.

Section 5. Process

5.1 Submission. Researchers must submit applications for continuing review to the REC according to the specified deadlines and procedures outlined in the REC guidelines. Applications should include updated study documents, progress reports, any proposed modifications to the research protocol, and information on any adverse events or unanticipated problems that have occurred since the last review.

5.2 Review Process. Application for continuing review will be reviewed by designated members of the REC or an appointed subcommittee with expertise in the relevant area(s) of research. The review process may involve assessing the progress of the research, adherence to the approved protocol, participant safety and welfare, and compliance with ethical guidelines and regulatory requirements.

5.3 Criteria for Review. Applications for continuing review will be evaluated based on the following criteria:

a. Compliance with the approved research protocol and any regulatory requirements.
b. Adherence to ethical guidelines and principles for the protection of human participants
c. Progress of the research and achievement of study milestones
d. Any changes or amendments to the research protocol and their justification.
e. Reporting of adverse events, unanticipated problems, or protocol deviations.

5.4 Decision Outcomes. Following the review of an application for continuing review, the REC may take one of the following actions:

a. Approval of the continuation of the research without modifications
b. Conditional approval contingent upon addressing specific concerns or issues identified
c. Request for additional information, clarification, or justification
d. Notification of the need for modifications to the research protocol.

5.5 Communication with Researchers. Researchers will be informed of the outcome of the continuing review process in writing. Feedback and recommendations provided by the REC will be communicated clearly, and researchers will be given an opportunity to respond to any concerns or questions raised.

5.6 Record Keeping. Records of applications for continuing review, reviews, and decisions will be maintained by the REC in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of the application for Continuing Review and entry to log book	Staff	1 Working Day
Step 2: Retrieval of pertinent protocol files	Staff	1-2 Working Days
Step 3: Notification of Chairperson and Primary Reviewers	Staff	1-2 Working Days
Step 4: Determination of type of review: exempted, expedited or full review	Chairperson Primary Reviewers	3-7 Working Days
Step 5: Communicating of committee action	Chairperson	1-2 Working Days
Step 6: Filing of documents in the appropriate protocol folder and Update of the Protocol Database	Staff	5-10 Working Days

Section 7. Description of Procedures

Step 1 - Receipt of the application for continuing review and entry to logbook. The Staff receives, logs and enters in the protocol database the information included in the application for Continuing review (Form 0031)

Step 2 - Retrieval of pertinent protocol file: The Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.

Step 3 - Notification of Chairperson and Primary Reviewers: The Staff notifies the Chairperson 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 Chairperson 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 4: Expedited Review and SOP5: Full Review).

Step 5 - Communication of committee action: 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 Chairperson finalizes and signs the decision letter (Form 006). Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

Step 6 – Filing of documents in the appropriate protocol folder: The Staff files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder

Section 8. Forms

Form 0019 Extension
Forms 0026 & 0027 Logbook
Form 006 Decision letter template

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First Draft

2	February 2, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy Statement, Workflow, and Description of Procedures
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section 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 Health and Health-related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020

	University of Makati Research Ethics Committee (UMREC)
Version No: 3	**SOP No. 13**
Date of Approval: 02.15.2024	**Review of Final Report**
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

This policy establishes a structured framework for the thorough review of final reports submitted by researchers to uphold ethical integrity and regulatory compliance in research endeavors. The outlined procedures and criteria serve to safeguard participant welfare, maintain research quality, and foster transparency and accountability in the research process.

Section 2. Objective

This policy outlines the procedures and guidelines for the review of final reports submitted by researchers to the Research Ethics Committee. The objective is to ensure that research projects have been conducted in accordance with ethical principles, regulatory requirements, and the approved protocol.

Section 3. Scope

This policy applies to all research projects that have received a Certificate of Approval from the Research Ethics Committee and are required to submit final reports upon completion of the study.

Section 4. Submission of Final Reports

Final reports should include, but are not limited to, the following information:

a. Summary of research objectives and aims
b. Description of research methods and procedures
c. Presentation of research findings and results
d. Discussion of the implications of the findings
e. Any publications, presentations, or dissemination activities related to the research

Section 5. Process

5.1 Review. Final reports are reviewed by designated members of the Research Ethics Committee or an appointed subcommittee. The review process may involve assessing the completeness of the report, the accuracy of the findings, and adherence to ethical guidelines and regulatory requirements, as deemed applicable.

5.2 Criteria for Review. Final reports are evaluated based on the following criteria:

a. Compliance with the approved research protocol
b. Accuracy and completeness of the research findings
c. Adherence to ethical principles and participant rights

d. Transparency and honesty in reporting results
e. Appropriateness of conclusions drawn from the research.

5.3 Decision Outcomes. Following the review of a final report, the Research Ethics Committee may the following actions:

a. Acceptance of the final report as submitted
b. Request for revisions or additional information
c. Notification of concerns or discrepancies requiring clarification
d. Request for further investigation or follow-up.

5.4 Communication with Researchers. Researchers are informed of the outcome of the final report review in writing. Feedback and recommendations provided by the Research Ethics Committee shall be communicated clearly, and researchers shall be given an opportunity to respond to any concerns or questions raised.

5.5 Record Keeping. Records of applications for continuing review, reviews, and decisions is maintained by the Research Ethics Committee in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of final report and entry into logbook	Admin Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Admin Staff	1-2 Working Days
Step 3: Notification of Chairperson and Primary Reviewer	Admin Staff	1-2 Working Days
Step 4: Full review	Chairperson Panel Reviewer Committee Members	Please see the applicable SOP
Step 5: Communicating Committee action	Chairperson Admin Staff	1-2 Working Days
Step 6: Filing of the Final Report and related documents and update of the protocol files.	Admin Staff	5-10 Working Days

Section 7. Description of Procedures

Step 1 - Receipt and entry of final report into logbook: The Staff receives and enters the date of receipt of the final report into the logbook.

Step 2 - Retrieval of pertinent protocol file: The staff retrieves the corresponding protocol file as reference in the review of the Final Report.

Step 3 - Notification of Chairperson and Primary Reviewer: The staff notifies the Chairperson and the primary reviewers of the receipt of the Final Report and awaits further instructions.

Step 4 - Full review: The Chairperson instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewer is given the necessary documents so that s/he can prepare the presentation during the next meeting.

Step 5 - Communicating Committee action: The Research Ethics Committee considers the following decisions in the review of a final report: acceptance of the Final Report or to require resubmission with corrections.

Step 6 - Filing of the Final Report and related documents and update of the protocol database: The Staff files the Final Report and related documents in the designated folder and updates the protocol database.

Section 8. Forms

Form 006: Decision Letter Template

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Junlor Dacsa I	First Draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy Statement, Workflow, and Description of Procedures
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section 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 Health and Health-related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 14** **Review of Early Termination Reports (ETR)**

Section 1. Policy Statement

This Policy establishes a structured framework for the review of Early Termination Reports to ensure that premature terminations of research projects are handled ethically and appropriately. The outlined procedures and criteria aim to safeguard participant welfare, uphold research integrity, and promote transparency and accountability in research conduct.

Section 2. Objective

This policy delineates the procedures and criteria for the review of Early Termination Reports (ETR) submitted by researchers to the Research Ethics Committee. The objective is to ensure that research projects terminated prematurely are appropriately documented, and any ethical considerations are addressed.

Section 3. Scope

This policy applies to all research projects that have obtained approval from the Research Ethics Committee and have been terminated before completion, for any reason.

Section 4. Submission of Early Termination Reports

Researchers are required to submit an Early Termination Report to the Research Ethics Committee promptly upon the decision to terminate the research project. The report should provide a comprehensive explanation of the reasons for early termination, along with any relevant documentation.

Section 5. Content of Early Termination Reports

Early Termination Reports should include, but are not limited to, the following components:

a. Detailed explanation of the reasons for early termination, including any unforeseen circumstances or challenges encountered
b. Description of the steps taken to mitigate any potential risks or harm to participants or other stakeholders
c. Summary of the data collected up to the point of termination, if applicable
d. Documentation of any adverse events or incidents that contributed to the decision to terminate the project
e. Discussion of any ethical considerations or implications arising from the early termination

Section 6. Process

6.1 Review. Early Termination Reports will be reviewed by an assigned panel or any designated members of the Research Ethics Committee. The review process will involve assessing the reasons for termination, the adequacy of documentation provided, and any ethical implications associated with the decision.

6.2 Criteria for Review. Early termination Reports will be evaluated based on the following criteria:

a. Appropriateness and justification for the decision to terminate the research project early
b. Adequacy of steps taken to protect participant welfare and mitigate potential risks or harm
c. Transparency and completeness of the documentation provided in the report
d. Consideration of any ethical implications or concerns arising from the early termination

6.3 Decision Outcomes. Upon completion of the review, the Research Ethics Committee may take various actions, including:

a. Acceptance of the Early Termination Report as submitted
b. Request for additional information, clarifications, or documentation
c. Identification of any unresolved ethical concerns or implications
d. Recommendations for future actions or follow-up, if deemed necessary

6.4 Communication with Researchers. Researchers will be informed of the review outcomes in writing. Any feedback, recommendations, or requests for additional information will be clearly communicated, and researchers will be given an opportunity to respond and address any concerns raised by the Research Ethics Committee.

6.5 Record Keeping. All early Termination Reports, review outcomes, and correspondences will be meticulously documented and maintained by the Research Ethics Committee in accordance with institutional protocols and regulatory requirements.

Section 7. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of the early termination report and entry into the logbook (SOP 23 Management of Active Files)	Admin Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Admin Staff	1-2 Working Days
Step 3: Notification of Chairperson and Primary Reviewers	Admin Staff	1-2 Working Days
Step 4: Full review	Panel Reviewers Members	Refer to SOP 11

Step 5: Communicating Committee action and update of the protocol database	Chairperson Admin Staff	Refer to SOP 24 & 26

Section 8. Description of Procedures

Step 1 - Receipt and entry to the logbook and database of early termination reports, for review: The staff receives the early termination report and enters the appropriate information into the log book.

Step 2 - Retrieval of pertinent protocol file: The staff retrieves the protocol folder and summarizes the documents that have been submitted.

Step 3 - Notification of Chairperson and Primary Reviewers: The staff informs the Chairperson and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for further instructions.

Step 4 - Full review: The Chairperson instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewers are given the necessary documents so that s/he can prepare the presentation during the next meeting (SOP 05 Full Review). The review should ensure implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

Step 5 - Communication of committee action and Update of the Protocol Database: The UMREC considers the following possible decisions in the review of an early termination report: acceptance of the decision with no further action; request for additional information; or requirement for further action. The staff prepares a draft of the committee decision based on the minutes of the meeting (SOP 21 Communicating UMREC Decisions) for signature of the Chairperson. S/he updates the protocol database accordingly.

Section 9. Forms

Form 021 Early Termination Report Form
Form 006 Decision Letter Template
Forms 026 & 026 Logbook

Section 10. History of SOP

Version No.	Date	Authors	Main Change

1	January 24, 2023	Center for University Research	First Draft
2	February 01, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo De las Armas IV, Josephine D. Robinos Estela De Vera-Barasi Margaret May Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Workflow and Description of Procedures
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section 11. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 15** **Management of Appeals**

Section 1. Policy Statement

This Policy establishes the framework for managing appeals in a consistent, timely, and impartial manner. It ensures transparency, fairness, and adherence to established protocols within the University. Appeals serve as a mechanism for individuals to seek review and resolution of decisions made regarding SOPs, thereby promoting accountability and continuous improvement.

Section 2. Objective

This policy aims to provide guidelines for a clear and structured process for lodging, reviewing, and resolving appeals in Research Ethics.

Section 3. Scope

This policy applies to all employees, contractors, clients, and stakeholders who are directly affected by decisions or actions of the Research Ethics Committee and wish to seek review or redress through the appeals process.

Section 4. Submission of Appeals

Researchers or entities seeking to appeal a decision of the Research Ethics Committee must submit a written appeal to the REC Chairperson or designated appeals officer within a specified timeframe following the decision being appealed. The appeal should clearly state the grounds for the appeal and include any supporting documentation or evidence.

Section 5. Process

5.1 Review. Appeals shall be reviewed by an independent appeals panel appointed by the Research Ethics Committee. The appeals panel consists of members who were not involved in the original decision being appealed and who have relevant expertise in the area being appealed. The appeals panel shall conduct a thorough review of the grounds for appeal, as well as any supporting documentation or evidence provided.

5.2 Criteria for Review. Appeals shall be evaluated based on the following criteria:

a. Compliance with relevant regulations, guidelines, and institutional policies.
b. Adequacy of the original decision-making process by the Research Ethics Committee.
c. Presence of new evidence or information that was not available at the time of the original decision.
d. Fairness and equity in the treatment of all parties involved.

e. Potential impact on participant welfare, research integrity, or ethical standards.

5.3 Decision Outcomes. Upon completion of the review, the appeals panel may take one of the following actions:

a. Uphold the original decision of the Research Ethics Committee
b. Overturn the original decision and issue a new decision
c. Modify the original decision based on the findings of the appeal review
d. Recommend further investigation or follow-up, if deemed necessary

5.4 Communication with Researchers. The appeals panel will communicate the outcome of the appeal review to the appellant(s) in writing, providing clear reasons for the decision reached. Appellants will be given an opportunity to respond to the decision and provide feedback on the appeals process.

5.5 Record Keeping. Records of appeals, appeal reviews, and decisions will be meticulously documented and maintained by the REC in accordance with institutional policies and regulatory requirements.

Section 6. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of the early termination report and entry into the logbook (SOP 23 Management of Active Files)	Admin Staff	1 Working Day
Step 2: Retrieval of pertinent protocol file	Admin Staff	1-2 Working Days
Step 3: Notification of Chairperson and Primary Reviewers	Admin Staff	1-2 Working Days
Step 4: Full review	Primary Reviewers Members	Refer to SOP 11
Step 5: Communication of committee action and update of the protocol database	Chairperson, Admin Staff	Refer to SOP 24 & 26

Section 7. Description of Procedures

Step 1 - Receipt and entry to the logbook and database of early termination reports, for review: The staff receives the early termination report and enters the appropriate information into the log book (SOP 23 Management of Active Files)

Step 2 - Retrieval of pertinent protocol file: The staff retrieves the protocol folder and summarizes the documents that have been submitted.

Step 3 - Notification of Chairperson and Primary Reviewers: The staff informs the Chairperson and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for further instructions.

Step 4 - Full review: The Chairperson instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewers are given the necessary documents so that they can prepare the presentation for the next meeting. The review shall ensure the implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a termination package with a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

Step 5 - Communication of committee action and Update of the Protocol Database: The UMREC considers the following possible decisions in the review of an early termination report:

a. acceptance of the decision with no further action
b. request for additional information, or
c. requirement for further action.

The Committee Secretary prepares a draft of the committee decision based on the minutes of the meeting for signature of the Chairperson. The staff updates the protocol database, accordingly.

Section 8. Forms

Form 021 Early Termination Report Form
Form 006 Decision Letter Template
Forms 026 & 026 Logbook

Section 9. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First Draft
2	February 01, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosaliel. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr., Michael Gelilio Maria Fay Nenette M. Cariaga	Workflow and Description of Procedures

		Justine Marie A. Ocampo	
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section10. 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

`	**University of Makati Research Ethics Committee (UMREC)**
Version No: 3	**SOP No. 16** **Conduct of Site Visits**
Date of Approval: 02.15.2024	
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

This Policy provides a structured framework for conducting site visits by the Research Ethics Committee (REC) to ensure ongoing compliance with approved research protocols and ethical guidelines. The outlined procedures aim to promote transparency, accountability, and quality assurance in the conduct of research involving human participants.

Site visits play a crucial role in safeguarding the rights and well-being of research participants, maintaining the integrity and quality of research data, and upholding ethical standards in research conduct. They serve as a valuable tool for ensuring that research is conducted responsibly, ethically, and in accordance with regulatory requirements.

Section 2. Objective

This policy outlines the procedures and guidelines for conducting site visits by the Research Ethics Committee members to ensure compliance with approved research protocols, ethical standards, and regulatory requirements.

Section 3. Scope

This policy applies to all research projects approved by the Research Ethics Committee that involve site visits as part of the research protocol.

Section 4. Initiation of Site Visits

Site visits may be initiated by the Research Ethics Committee based on various factors, including but not limited to:

a. Random selection of projects for monitoring purposes
b. Concerns raised by REC members, researchers, participants, or other stakeholders
c. Significant deviations from approved protocols or ethical guidelines
d. Requests for clarification or additional information regarding research conduct

Section 5. Site Visit Procedures

During the site visit, representatives from the Research Ethics Committee, including designated members or appointed monitors, shall:

a. Conduct an inspection of the research site(s) to verify compliance with approved protocols, consent procedures, and ethical guidelines

b. Review research documentation, including informed consent forms, participant records, and study procedures
c. Interview research personnel, including investigators, coordinators, and other staff involved in the research
d. Assess the adequacy of facilities, equipment, and resources available for conducting the research
e. Address any questions, concerns, or issues raised by the research team or identified during the site visit

Section 6. Documentation and Reporting

The findings and observations from the site visit will be documented in a comprehensive report prepared by the REC representatives. The report will include:

a. Summary of the site visit activities and observations
b. Assessment of compliance with approved protocols and ethical guidelines
c. Identification of any deviations, deficiencies, or areas for improvement
d. Recommendation for corrective actions or follow-up measures, if applicable

Section 7. Follow-up Actions

Based on the findings of the site visit report, the REC may:

a. Issue recommendations for corrective actions or improvements to ensure compliance with approved protocols and ethical standards
b. Require additional documentation, clarifications, or modifications to the research protocol
c. Schedule further site visits or monitoring activities, if deemed necessary
d. Take enforcement actions or sanctions in cases of serious or repeated non-compliance

Section 8. Communication with Research Team

The findings and recommendations from the site visit report will be communicated to the research team in writing. The research team will be given an opportunity to respond to any concerns or issues raised and to implement any required corrective actions.

Section 9. Record Keeping

Records of site visits, including reports, findings, recommendations, and correspondence, will be meticulously documented and maintained by the Research Ethics Committee in accordance with institutional policies and regulatory requirements.

Section 10. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Selection of site to visit	UMREC SAE Subcommittee	Refer to SOP 18
Step 2: Notification of researcher	Staff	7 Working Days
Step 3: Creation of Site Visit Team	UMREC Officers	3 Working Days

Step 4: Conduct of site visit	Site Visit Team (members)	N/A
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	Site Visit Team (members)	5 Working Days
Step 6: Transmittal of Final Report and Recommendations to the researcher/investigator	Chairperson/ Staff	Refer to SOP 24
Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database	Staff	5-10 Working Days

Section 11. Description of Procedures

Step 1 - Selection of site to visit: The selection shall be based on the following criteria: high risk studies, consistent non-submission or failure to submit after-approval submission requirements, reports of major protocol noncompliance, significant number of serious adverse events, reports of complaints from study participants. The UMREC Serious Adverse Event Committee or Subcommittee shall be guided by SOP 11 SAE in fulfilling its functions.

Step 2 - Notification of researcher: The researcher shall be allowed seven (7) working days as lead time before the scheduled visit through a letter/ via email stipulating the visit details and corresponding documents needed.

Step 3 - Creation of Site Visit Team: UMREC Officers shall decide on the selection of members of the Site visit team which shall be composed by the Primary Reviewers. The team can be joined by other members as deemed necessary. They must secure the site visit form #0020 and other required documents prior to the visit.

Step 4 - Conduct of Site Visit: The site visit form shall be filled out accordingly. (Please see Site Visit Form 020). The following 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 UMREC.
- 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: The Site Visit team shall submit its report of findings to the Secretariat not more than 3 working days after the visit. Secretariat shall include this in the agenda of the next meeting (check the meeting sched). During the meeting, the

SAE committee head shall lead the presentation of their findings and recommendations. The UMREC shall deliberate and approve the decision.

Step 6 - Transmittal of the Final Report and Recommendations to the Researcher/ Investigator: The staff prepares a summary of the findings and recommendations of the UMREC based on the deliberations during the meeting. The Chairperson finalizes the draft for transmittal to the Researcher/ investigator. (SOP 21 Communicating UMREC Decisions)

Step 7 - Filing of the Site Visit documents and update of the Protocol database: The staff files the Site Visit
Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (SOP 23 Management of Active Files)

Section 12. Forms

Form 020 Site Visit Report Form

Section 13. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I Niño E. Faustino	Policy Statement, Objectives of the Activity, Workflow, and Description of the Procedures
3	February 15, 2024	Karen Gail Ibanez Junlor Dacsa I Jomariss Plan	Updating of the SOP

Section 14. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 2	**SOP No. 17** **Preparing for a Meeting**
Date of Approval:02.03.2023	
Date of Effectivity: 02.03.2023	

Section 1. Policy Statement

The UMREC shall have a regular schedule of meetings every 3rd Wednesday of the month. All meetings shall be held within the premises of the institution. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violations that impact research integrity.

Section 2. Objective of the Activity

Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings. There must be a specific intended outcome prepared before the commencement of the meeting.

Section 3. Scope

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

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Preparation of the agenda (SOP 17)	Admin Staff Secretary	First Wednesday of the month
Step 2: Coordination with the physical plant division	Admin Staff UFMO GSO	First Wednesday of the month
Step 3: Assembly of materials and documents needed for the meeting	Admin Staff	First Friday of the month
Step 4: Preparation of presentation and recording equipment, food arrangements for the meeting	Admin Staff	Second Wednesday of the month

Step 5: Notification of UMREC Members and confirmation of attendance	Secretary Admin Staff	Second Wednesday of the month

Section 5. Description of Procedures

Step 1 - Preparation of the agenda:

The preparation of the agenda must be according to SOP 18 - Preparing the Meeting Agenda

Step 2 - Coordination with the physical plant division:

The UMREC staff notifies the University Facilities Management (UFMO) for the venue reservation and the General Services Offices (GSO) for the technical needs, sound system, and projector. The reservation must be made one week before the scheduled date for the special meeting and one month before the regular monthly meeting.

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

The staff gathers the necessary documents and materials for the meeting based on the provisional agenda, provisional minutes of the previous meeting, protocols, and related documents submitted, at least 1 week before the meeting, post-approval reports, expedited review reports, administrative memos, etc.

Step 4 - Preparation of presentation and recording equipment, food arrangements for the meeting:

The staff ensures that the following are prepared and available for the meeting:

1. laptop (2),
2. projector and screen
3. microphones (3),
4. adequate food and drinks/water
5. respective honoraria of committee members (if needed)

Step 5 - Notification of UMREC Members and confirmation of attendance:

The member secretary supervises the staff in the preparation of the Notice of Meeting (Notice of Meeting, Provisional Agenda) that includes the provisional agenda. The staff sends the notice of meeting to the members of the committee at least one week before the scheduled meeting and follows up on the confirmation of attendance to ensure a quorum. In case, quorum cannot be met, the staff informs the Chair and the member secretary so that alternate members may be called in.

Section 6. Forms

The following forms and documents are needed in the implementation of this SOP 17.

1. Form of Notice of Meeting
2. Provisional Agenda
3. Minutes of the previous meeting
4. Form for Attendance Confirmation

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 28, 2023	Francisco Lambojon, Jr	First draft
2	February 3, 2023	Deborah Alejandro, Luke Ivan Moro, Rey Medenilla, Richard Rodriguez, Noel Ybanez, Wilber Sabado, Francisco Lambojon Jr. Mark Philip Paderan, henry Magat, Lorna Esquivel, Ferdinand Piano, Amante Luis Olivar, Junlor Dacsa I., Niño E. Faustino	Policy Statement, Workflow, Description of the Procedures

Section 8. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 2 Date of Approval:02.03.2023 Date of Effectivity: 02.03.2023	**SOP No. 18** **Preparing the Meeting Agenda**

Section 1. Policy Statement

The meeting agenda shall be based on the submissions received, at the latest, five (5) working days 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.

Section 2. Objective/s of the Activity

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

Section 3. Scope

This SOP describes how the UMREC 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.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Preparation of the draft meeting agenda	Admin Staff Secretary	2 Working Days
Step 2: Preparation of the provisional meeting agenda	Chairperson	2 Working Days
Step 3: Distribution of the provisional meeting agenda (SOP 17 Preparing for a Meeting)	Admin Staff	2 Working Days
Step 4: Approval of the provisional meeting agenda	UMREC Members	2 Working Days
Step 5: Filing of the final meeting agenda (SOP 23 on Management of Active Files)	Admin Staff	1-2 Working Days

Section 5. Detailed Procedures

Step 1 - Preparation of the draft meeting agenda: The staff under the supervision of the Member Secretary prepares the draft agenda two (2) weeks before the scheduled meeting, using the Meeting Agenda Template (Form 024). The agenda includes the following:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Provisional Agenda
4. Disclosure of Conflict of Interest
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes
7. New Business:
    - 7.1. Initial Review of Protocols
    - 7.2. Review of Resubmissions
    - 7.3. Review of After Approval Submissions
    - 7.4. Report on Expedited Review of Protocols
    - 7.5. Report on Expedited Review of After-Approval Submissions
    - 7.6. Report of Site Visits
8. Other Matters

Step 2 - Preparation of the provisional meeting agenda: The Chair reviews 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 provisional agenda is included in the Notice of Meeting (SOP 17 Preparing for a Meeting).

Step 4 - Approval of the provisional meeting agenda: The UMREC members approve the provisional agenda during the meeting. (SOP 19 Conduct of Meeting).

Step 5 - Filing of the final meeting agenda: The staff files the final (approved) meeting agenda in a special folder that contains all meeting agenda in a chronological order. See SOP 23 Managing Active Files).

Section 6. Forms:

Form 024 Meeting Agenda Template
Form 023 Notice of Meeting

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 26, 2023	Lorna M. Esquivel	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I Niño E. Faustino	Policy Statement, Workflow, Description of Procedures

8. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 2	**SOP No. 19** **Conduct of Meetings**
Date of Approval:02.03.2023	
Date of Effectivity: 02.03.2023	

Section 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.

Section 2. Objective/s of the Activity

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

Section 3. Scope

This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	SCHEDULE
Step 1: Distribution of meeting materials	Admin Staff	2 weeks before the meeting
Step 2: Declaration of quorum (formal start)	UMREC Member Secretary or Chair	During the meeting
Step 3: Approval of the provisional agenda	UMREC Members	During the meeting
Step 4: Declaration of conflict of interest (COI)	UMREC Members (who have COI)	During the meeting
Step 5: Approval of minutes of the previous meeting	UMREC Members	During the meeting
Step 6: Discussion of "Business arising from the minutes"	UMREC Members	During the meeting
7: Review of protocols and protocol-related submissions (SOP# 07) Full Review (SOP# 05)	UMREC Chair and Members	During the meeting

Report of results of expedited review (SOP on Expedited Review (SOP# 04)	Designated Reviewers	During the meeting
Step 9: Report of exempt from review	Chair	During the meeting
Step 10: Discussion of operations-related matters	UMREC Chair and Members	During the meeting
Step 11: Adjournment	UMREC Chair	End of the meeting
2: Collection, storage, and disposal of meeting materials	UMREC Staff	Within 1 to 2 weeks after the meeting

Section 5. Description of Procedures

Step 1 - Distribution of meeting materials:

The staff prepares and distributes the following documents to all the members of the UMREC two weeks before the scheduled date of the UMREC meeting, as directed by the chair:

1. Communication letter
2. Meeting agenda
3. Minutes of the previous meeting
4. Research protocol and corresponding forms
5. Other documents related to the other matters in the agenda

Step 2 – Declaration of quorum:

2.1. The start of the UMREC meeting shall be formally declared by the chair or designated substitute once the quorum comprising of 50% plus 1 of the number of regular members is reached, including the non-affiliated and non-scientist (lay member).

2.2. The attendees will officially register in the provided roster by affixing their signatures opposite their names, to serve as evidence of the meeting attendance.

Step 3 - Approval of the provisional agenda:

Upon presentation of the agenda and review of the body, the provisional agenda shall be approved by all the UMREC members. Any addition or deletion of items shall be included in the approval.

Step 4 - Declaration of Conflict of Interest:

4.1. Any member with COI related to the protocol shall be requested to leave the meeting room during the discussion and deliberation. He/she will be allowed to rejoin the meeting after the decision has been made by the body. The management of the COI shall be recorded in the minutes of the meeting.

4.2 In cases where the conflicted UMREC member is the researcher, his/her presence may be required for a clarificatory interview.

Step 5 - Approval of minutes of previous meeting:

All the members shall review and participate in the approval of the minutes of the previous meeting. Any questions, objections, or corrections shall be acknowledged and delivered as well. Once the body agrees, the minutes of the previous meeting shall be declared approved.

Step 6 - Discussion of "Business arising from the minutes":

The chair shall call for any member to raise matters on business arising from the minutes of the previous meeting. Any issues shall be discussed and resolved through consensus and included in the minutes of the meeting.

Step 7 - Review of protocols and protocol-related submissions:

The primary reviewers shall give a summary of the protocol and then present their findings and recommendations using the assessment forms (Protocol and ICF) as a guide.

In case an independent consultant is invited, he shall provide his expert opinion on the following, but is not limited to

1. Updates on the topic presented (SOP 03)
2. SOP 05 Full Review

The sequence of the review must proceed in the following order: technical issues, ethical issues, and informed consent process/form issues.

After the presentation of the primary reviewers, the floor shall be open for discussion with all the UMREC members.

The chair shall summarize the discussions and recommendations then the UMREC shall arrive at their decision through voting by raising hands.

Step 8 - Report of results of expedited review:

The chair reports the approved expedited review protocols.

Step 9 - Discussion of operations-related matters:

The Chair reports the exempt from review.

Step 10 - Adjournment:

Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared.

Picture taking follows for documentation purposes.

Step 11 - Collection, storage, and disposal of meeting materials:

The UMREC staff collects and sorts the documents distributed during the meeting. Extra copies of the documents shall be disposed of in compliance with the institutional policy.

The UMREC staff keeps track of meeting documents See SOPs on Managing Active Files (SOP 23) and (SOP 18) Preparation of Agenda.

Section 6. Forms

Forms referred to

Form 011 Protocol Assessment Form
Form 012 ICF Form
Form 006 UMREC Decision Form

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	2022 November 11	Francisco Lambojon,Jr. Rey Medenilla	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy Statement, Workflow, and Description of Procedures

Section 8. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 2 Date of Approval:02.03.2023 Date of Effectivity: 02.03.2023	**SOP No. 20** **Preparation of the Minutes of Meetings**

Section 1. Policy Statement

The minutes of the meeting serve as the official documentation of all the proceedings conducted by the University of Makati Research Ethics Committee in real-time. With the declaration of the meeting's quorum, the meeting shall proceed with the agenda. The minutes provide notes as actual evidence of the issues and concerns discussed during the meeting. All the decisions made by way of majority votes of the members of the UMREC, as guided by the university research agenda, **MUST** be reflected in the report.

Section 2. Objectives

The minutes of the meeting ensure the proper documentation of the procedures and decisions made by the UMREC.

Section 3. Scope

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

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Entry of preliminary information on the minutes template	Staff	1 Working day
Step 2: Preparation of the draft minutes	Staff and Secretary	3-5 Working days
Step 3: Notation of the draft minutes	Chair	Please see SOP 18
Step 4: Approval of the minutes in the next UMREC meeting	Chair and Members	Please see SOP 18
Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP 23))	Staff	1-2 Working days

Section 5. Description of Procedures

Step 1- Entry of preliminary information on the minutes template: The staff prepares the minutes based on the template of the UMREC. The member secretary supervises the staff to ensure that the relevant information is contained and included in the minutes.

Step 2 - Preparation of the draft minutes: The staff, under the supervision of the member secretary, documents the proceedings of the meeting by taking down notes real-time by flashing them on the screen and with audio/video recording. The staff validates the draft of the minutes of the meeting through the audio/video recording. The staff shall record the comments, recommendations, ethical and scientific issues, and informed consent form issues following the minute template.

Step 3 - Notation of the draft minutes: The chair checks the draft of the minutes of the meeting and notes that the following items are included:

- Date and venue of meeting
- Members attendance (members present and absent)
- Presence of Independent consultants, primary investigators, guests, and observer's attendance (if any)
- Time when the meeting was called to order
- Declaration of Quorum
- Name of Presiding officer
- Conflict of Interest (COI) declaration
- Items discussed, issues raised, and resolutions
- UMREC decisions and recommendations
- Name and signature of person who prepared the minutes
- Name and signature of the Chair and date of notation

Step 4 - Approval of the minutes in the next UMREC meeting: The approval of the minutes is done by the motion by any member of the committee and seconds accordingly.

Step 5 - Storage of the approved minutes: The hard copy shall be stored in the minutes files and the excerpts of minutes of the meeting is stored in the pertinent protocol file. The protocol files shall be stored in the secured filing cabinet of the UMREC Office. Retrieval of the file is governed by SOP on Managing Active Files (SOP 23), and Access of Confidential File (SOP 25).

Section 6. Forms

Forms referred to

Form 0025
Form 024 Meeting Agenda Template

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	November 11, 2022	Francisco Lambojon,Jr. Rey Medenilla	First draft
2	February 3, 2023	Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I. Niño E. Faustino	Policy Statement, Workflow, and Description of Procedures

Section 8. 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

Section 1. Policy Statement

This Policy establishes clear guidelines for communicating Research Ethics Committee decisions to ensure transparency, fairness, and accountability in the research review and oversight process. Effective communication of Research Ethics Committee decisions is essential for maintaining trust and confidence among stakeholders and promoting ethical conduct in research involving human participants.

Section 2. Objective

The main objective of communicating Research Ethics Committee decisions is to ensure transparency, fairness, and clarity in the review and oversight process of research involving human participants.

Section 3. Scope

This policy applies to all decisions made by the Research Ethics Committee regarding the review and oversight of research projects involving human participants.

Section 4. Types of Decisions

Research Ethics Committee decisions may include, but not limited to the following:

a. Approval of research protocols
b. Conditional approval pending revisions or clarifications
c. Request for additional information or documentation
d. Deferral of decisions pending further review or clarification
e. Disapproval or rejection of research protocols
f. Suspension or termination of approved research projects
g. Enforcement actions or sanctions for non-compliance with ethical standards or regulatory requirements

Section 5. Communication Protocols

Research Ethics Committee Chairperson or designated communications officer is responsible for communicating REC decisions to relevant parties in a timely and professional manner. Communications may be delivered via email, official letters, or other appropriate channels.

Section 6. Content of Communication

Communication regarding REC decisions should include the following information:

a. Clear and concise summary of the decision reached by the REC
b. Rationale for the decision, including any specific concerns or issues identified during the review process
c. Instructions or recommendations for next steps, if applicable (e.g., revisions required, additional documentation requested)
d. Deadline or timeframe for responding to the decision or implementing any required actions

Section 7. Confidentiality and Privacy

Research Ethics Committee decisions and communications should be treated with the utmost confidentiality and privacy, in accordance with applicable laws and regulations governing the protection of personal data and sensitive information.

Section 8. Appeals Process

Communications regarding Research Ethics Committee decisions should include information on the appeals process, including instructions for filing an appeal, relevant deadlines, and contact information for the appeals officer or designated point of contact.

Section 9. Record Keeping

Records of all communications regarding REC decisions, including copies of emails, letters, or other correspondence, will be meticulously documented and maintained by the REC in accordance with institutional policies and regulatory requirements.

Section 10. Workflow

ACTIVITY	RESPONSIBILITY	Timeline
Step 1: Finalization of recommendations of the committee (in case of full review) (SOP 05 Full Review) or Finalization of recommendations of reviewers (in case of expedited review) (SOP 04 Expedited Review)	Chairperson	1-2 Working Days
Step 2: Transfer of information from meeting minutes or reports to UMREC decision forms or templates	Admin Staff Secretary	1-2 Working Days
Step 3: Approval of the UMREC decision document	Chairperson	5 Working Days
Step 4: Transmittal of UMREC decision to researcher	Admin Staff	1-2 Working Days
Step 5: Filing of the decision document in the protocol and updating of Protocol database	Admin Staff	5-10 Working Days

Section 11. Description of Procedures

Step 1 - Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review): For finalization of Committee's Recommendations refer to SOP 11 - Full Review or for finalization of Reviewers' Recommendations, refer to SOP 10 - Expedited Review).

Step 2 - Transfer of information from meeting minutes to UMREC decision forms or templates: Upon approval of the draft minutes, or finalization of the reviewers' recommendations, the staff relays the information to the researchers using official notification letter to be sent using the official email address of UMREC. The staff drafts the said communication and the Chairperson oversees the whole process.

Step 3 - Approval of the UMREC decision document: The Chairperson reviews, approves and signs the decision documents.

Step 4 - Transmittal of UMREC decision to researcher: The researchers get the results of the review via email. Hard copies can be picked up at the UMREC office. The Chairperson oversees the whole process.

Step 5 - Filing of the decision document in the protocol file and Update of the Protocol Database: The said decision documents are filed electronically in the protocol index/ Protocol database. Hard copy is also filed in the protocol folder to facilitate retrieval.

Section 12. Forms

Form 006 Decision Form/Letter

Section 13. History of SOP

Version No.	Date	Authors	Main Change
1	January 31, 2023	Maria Fay Nenette M. Cariaga	First draft

2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosaliel. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr., Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy Statement, Objectives of the Activity, Workflow, and Description of the Procedures
3	February 15, 2024	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 14. 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

Section 1. Policy Statement

This Policy establishes guidelines for the management of incoming and outgoing communications by the Research Ethics Committee to ensure effective, transparent, and secure communication practices. Adherence to these guidelines helps to safeguard confidentiality, promote accountability, and maintain the integrity of the REC's activities.

Section 2. Objective

The main objective to ensure effective, transparent, and secure communication with stakeholders while upholding confidentiality and compliance with regulatory requirements.

Section 3. Scope

This policy applies to all incoming and outgoing communications received or generated by the Research Ethics Committee in the course of its activities, including but not limited to correspondence, emails, phone calls, and official documents.

Section 4. Incoming Communications

Research Ethics Committee decisions may include, but not limited to:

a. All incoming communications addressed to the Research Ethics Committee, including inquiries, requests, complaints, and reports, will be promptly logged and acknowledged.
b. Communications will be directed to the appropriate Research Ethics Committee personnel or designated point of contact for review and response.
c. Incoming communications will be handled with sensitivity and confidentiality, particularly those involving personal or sensitive information

Section 5. Outgoing Communications

a. Outgoing communications generated by the Research Ethics Committee, including decisions, notifications, requests for information, and official correspondence, will be drafted, reviewed, and approved by authorized personnel.
b. Communications will be clear, accurate, and professional, with due consideration for the intended audience and purpose.
c. Communications will be sent through secure channels to ensure confidentiality and integrity, particularly when transmitting sensitive information

Section 6. Confidentiality and Data Protection

a. Incoming and outgoing communications containing personal or sensitive information will be handled in accordance with applicable data protection laws and institutional policies.
b. Access to confidential communications will be restricted to authorized Research Ethics Committee personnel on a need-to-know basis.
c. Measures will be implemented to safeguard the confidentiality and integrity of electronic communications, including encryption, password protection, and secure transmission protocols.

Section 7. Timeliness and Responsiveness

a. Incoming communications will be reviewed and responded to in a timely manner, with acknowledgment of receipt provided to the sender.
b. Outgoing communications will be sent within reasonable timeframes, with due consideration for the urgency and importance of the message.
c. Where additional information or clarification is required, follow-up communications will be initiated promptly to facilitate resolution.

Section 8. Documentation and Record Keeping

a. All incoming and outgoing communications will be documented, logged, and retained in accordance with institutional policies and regulatory requirements.
b. Records of communications will be maintained in a secure and organized manner to facilitate retrieval, review, and audit as needed.

Section 9. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Sorting of incoming/outgoing communication	Admin Staff Secretary	1-2 Working Days
Step 2: Recording of incoming/outgoing communication	Admin Staff Secretary	1-2 Working Days
Step 3: Acting on incoming/ outgoing communication	UMREC Officers	1-2 Working Days
Step 4: Filing of incoming/outgoing communication and updating of database	Admin Staff	5-10 Working Days

Section 10. Description of Procedures

Step 1 - Sorting of incoming/outgoing communications: All communications (in any form) sent to UMREC through the Staff shall be organized by categories, such as protocol-related communications, process-related communications, and others.

Step 2 - Recording of incoming/outgoing communications: The Staff shall record the received communication to a logbook and in the electronic database. The record information includes the date received, source (person who sent the communication), subject, person who received the communication, and action taken. This will be supervised by the Secretariat.

Step 3 - Acting on communications: Response to communications to shall be initiated and finalized by the Secretariat. The signatory in every communication response will be the Committee Secretary and the Chairperson.

Step 4 - Storing or filing of incoming/outgoing communication: The storage of the communications received by the UMREC will be based on the communication form.

- Letters in a hard copy will be organized and stored in a secured cabinet.
- The hard copy will also be scanned and converted into PDF for the digital storage.
- Electronic communications received will be saved and converted into PDF and will be organized and stored in the digital storage.
- Files will also be tagged and organized according to the subject of the communication and the date received.
- The storing and filing will be done by the Staff and will be supervised by the Committee Secretary.

Section 11. Forms

Form 027 Logbook for Incoming Communications
Form 026 Logbook for Outgoing Communications
Form 028 Index of Protocol File

Section 12. History of SOP

Version No.	Date	Authors	Main Change
1	February 1, 2023	Gerome Abenilla	First draft

2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo RosalieI. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr., Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy Statement, Workflow, and Description of Procedures
3	February 15, 2024	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 13. 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

Section 1. Policy Statement

This Policy establishes guidelines for the management of active files by the Research Ethics Committee (REC) to ensure efficient, secure, and organized handling of documents related to ongoing REC activities. Adherence to these guidelines helps to safeguard confidentiality, promote accessibility, and maintain the integrity of REC operations.

UMREC adheres to the file management and naming convention of PHREB.

Section 2. Objective

The policy outlines the procedures for the management of active files by the Research Ethics Committee. The objective is to establish efficient practices for organizing, storing, and accessing documents related to ongoing REC activities.

Section 3. Scope

This policy applies to all active files maintained by the Research Ethics Committee, including but not limited to research protocol submissions, correspondence, meeting minutes, decision records, and regulatory documents.

Section 4. File Organization

a. Active files are organized in a systematic and logical manner to facilitate retrieval and reference. Each file is labeled with a unique identifier and categorized according to the type of document and research project

b. Digital files are stored in secure, password-protected electronic folders, while physical files are stored in locked cabinets or secure storage areas.

Section 5. File Naming

a. Digital files adhere to a standardized naming convention to ensure consistency and clarity. File names include relevant information such as the project title, document type, date, and version number.

b. File names should be descriptive and concise, allowing users to quickly identify the content of each document.

Section 6. Confidentiality and Data Protection

a. Version control measures are implemented for documents that undergo revisions or updates. Each document is assigned a version number or date to track changes and ensure that the most current version is readily available
b. Previous versions of documents are archived separately to maintain a clear audit trail of changes.

Section 7. Access Controls

a. Access to active files are restricted to authorized Research Ethics Committee personnel and individuals involved in the review and oversight of research projects. Access permissions will be granted based on the principle of least privilege, ensuring that users only have access to files necessary for their role.

b. Digital files are stored on secure servers with access controls, encryption, and regular backups to protect against unauthorized access, data loss, or corruption.

Section 8. Retention Period

a. Active files are retained for the duration of the REC's review and oversight of research projects, as well as any required retention periods specified by institutional policies or regulatory requirements.

b. At the conclusion of the retention period, active files are archived or disposed of in accordance with established procedures and retention schedules

Section 9. File Maintenance

a. Active files are regularly reviewed and updated as needed to ensure accuracy, completeness, and relevance. Outdated or redundant documents are removed, while new documents are added as necessary.

b. File maintenance tasks, such as file purging, archiving, and data migration, are conducted systematically and documented for audit purposes.

Section 10. File Maintenance

Security measures are implemented to protect the confidentiality, integrity, and availability of active files. This includes physical security measures for physical files, as well as technical safeguards for digital files, such as encryption, firewalls, and antivirus software.

Section 11. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receiving, classifying, and coding of Active Files	Committee Secretary Staff	3-5 Working Days
Step 2: Preparation of the Protocol Folder	Staff	1-2 Working Days
Step 3: Periodic updating of the Protocol File	Committee Secretary Staff	Quarterly

Section 12. Description of Procedures

Step 1. **Classification and coding of active files**: The staff under the supervision of the Committee secretary monitors the classification of active files, viz:

- 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 assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the College and Department from which the protocol was received, the year and the serial number that indicate the sequence order of receipt.

Step 2. Preparation of the Protocol Folder: The staff files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with:

- Protocol Code
- Study Title
- Proponent's Family Name
- Sponsor or Funding Agency

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 ensures that documents are filed in chronological order, such that the most recent documents are topmost. These documents include:

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

Section 13. Forms

Form 028 Index of Protocol File

Section 14. History of SOP

Version No.	Date	Authors	Main Change
1	November 11, 2022	PHREB/URC	First draft
2	November 16, 2022	PHREB/UMREC Deborah Alejandro Luke Ivan Moro Rey Medenilla Richard Rodriguez Noel Ybanez Wilber Sabado Francisco Lambojon Jr. Mark Philip Paderan Henry Magat Lorna Esquivel Ferdinand Piano Amante Luis Olivar Junlor Dacsa I Niño E. Faustino	Revised the minor contents of the SOP Revised Coding System Suggested prescribed coding of the protocol files Workflow, and Description of Procedures
3	February 3, 2023	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 15. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3	**SOP No. 24**
Date of Approval: 02.15.2024	**Archiving**
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

This establishes guidelines for the systematic archiving of documents and records by the Research Ethics Committee (REC) to ensure long-term preservation, accessibility, and compliance with regulatory requirements. Adherence to these guidelines helps to safeguard the historical integrity of Research Ethics Committee operations and facilitate future research and administrative needs

Section 2. Objective

The objective is to establish systematic processes for the long-term preservation, storage, and retrieval of historical Research Ethics Committee documents in compliance with regulatory requirements and institutional policies.

Section 3. Scope

This policy applies to all documents and records generated or received by the Research Ethics Committee in the course of its activities, including but not limited to research protocol submissions, meeting minutes, decision records, correspondence, and regulatory documents.

Section 4. Responsibilities

a. The Research Ethics Committee Chairperson or designated records manager is responsible for overseeing the archiving process and ensuring compliance with this policy.

b. Research Ethics Committee members and staff are responsible for identifying and transferring documents to be archived in accordance with established procedures.

Section 5. Archival Materials

a. Documents eligible for archiving include both physical and digital records deemed to have enduring historical, administrative, legal, or research value.

b. Example of archival materials may include approved research protocols, meeting minutes, decisions, correspondence with researchers and regulatory authorities, policy documents, and annual reports.

Section 6. Retention Period

a. The retention period for archived documents is determined based on regulatory requirements, institutional policies, and the perceived historical or administrative significance of the records.

b. Minimum retention periods is established for each category of document to ensure compliance with legal and regulatory obligations.

Section 7. Selection Criteria

a. Documents selected for archiving are evaluated based on their relevance, significance, and potential research value for future reference or historical analysis.

b. Consideration is also be given to the volume of records, available storage capacity, and resources required for long-term preservation**.**

Section 8. Format and Storage

a. Physical documents are digitized where feasible to facilitate long-term preservation and access. Original physical documents may be retained in secure, climate-controlled storage facilities.

b. Digital records are stored in secure, password-protected electronic archives with appropriate metadata and indexing to facilitate retrieval and searchability.

Section 9. Access and Retrieval

a. Access to archived documents are restricted to authorized personnel on a need-to-know basis. Access permissions are granted in accordance with institutional policies and legal requirements.

b. Procedures for requesting access to archived documents are established, including the completion of access request forms and approval by designated personnel.

Section 10. Access and Retrieval

a. Disposal of archived documents is carried out in accordance with established retention schedules and disposal procedures.

b. Documents eligible for disposal may include records that have exceeded their retention period, are duplicate copies, or are no longer deemed to have historical or administrative value.

Section 11. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE

Step 1: Acceptance of Final or Early Termination Reports	UMREC Members, Chairperson	Refer to SOP 20 & 21
Step 2: Updating of corresponding protocol folder	Admin Staff	Refer to SOP 26
Step 3: Transfer of the Protocol folder in the archives and update of the Protocol database	Admin Staff	5 Working Days

Section 12. Description of Procedures

Step 1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File: The Committee members approve or accept the final report or early termination report during a meeting. In the identification of an Inactive File, the staff informs the Committee Secretary of the failure of a concerned researcher/investigator to respond to the recommendations of UMREC in the last 3 months during which time the researcher/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the Protocol is declared inactive.

Step 2 - Updating of the corresponding active file: The staff 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.

Step 3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol Database: The staff checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Thence, the staff transfers the folder to the archive section and updates the protocol database.

Section 13. Forms

Form 026 Borrower's Log/Logbook

Section 14. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft

2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosaliel. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Workflow, and Description of Procedures
3	February 15, 2024	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 1. Policy Statement

This policy establishes guidelines for managing access to confidential files by the Research Ethics Committee (REC) to ensure the confidentiality, security, and appropriate use of sensitive information. Adherence to these guidelines helps to protect the privacy and rights of individuals, maintain trust and integrity in Research Ethics Committee operations, and mitigate risks associated with unauthorized access or disclosure of confidential information.

Section 2. Objective

The objective is to ensure the confidentiality, security, and appropriate use of sensitive information contained within Research Ethics Committee documents and records.

Section 3. Scope

This policy applies to all confidential files and records maintained by the Research Ethics Committee, including but not limited to research protocols, participant data, meeting minutes, correspondence, and regulatory documents.

Section 4. Definition of Confidential Files

Confidential files include documents containing sensitive or private information that is legally protected or subject to ethical considerations. This may include personal data, medical records, identifiable research information, proprietary information, and other privileged or confidential materials.

Section 5. Access Authorization

a. Access to confidential files is restricted to authorized personnel who have a legitimate need to access the information for official Research Ethics Committee purposes.

b. Access permission is granted based on the principle of least privilege, ensuring that individuals only have access to files necessary for their role and responsibilities.

Section 6. Access Control Measures

a. Physical access to confidential files is restricted through secure storage facilities, locked cabinets, and controlled entry points.

b. Digital access to confidential files is protected through user authentication, encryption, and access controls implemented within secure electronic systems or document management platforms.

Section 7. Access Request

a. Requests for access to confidential files must be submitted in writing to the Research Ethics Committee Chairperson or designated records manager.

b. Confidentiality agreements outlines the terms and conditions governing access to and use of confidential files, including restrictions on disclosure, copying, or unauthorized dissemination of information.

Section 8. Monitoring and Auditing

a. Access to confidential files is monitored and audited to ensure compliance with access controls, confidentiality agreements, and regulatory requirements.

b. Logs of access activities, including user authentication, file access, and modifications, are maintained and periodically reviewed for security and compliance purposes.

Section 9. Workflow

ACTIVITY	RESPONSIBILITY	TIME LINE
Step 1: Receipt and logging of request for access to confidential files	Staff	5 Working Days
Step 2: Review and approval of requests for access and retrieval of documents	Chairperson or Vice Chairperson	5 Working Days
Step 3: Supervision of the use of retrieved document	Staff	1 to 2 Working Days
Step 4: Return of document to the files	Staff	As soon as requestor is finished

Section 10. Description of Procedures

Step 1 –Receipt and logging of request for access to confidential files: The staff receives the request (Form 027) to access specific files and refers this to the Chairperson.

Step 2 - Approval of requests for access and retrieval of documents: The Chairperson or Vice Chairperson determines the validity of the reason for the request,

in which the approval or disapproval depends on. The requestor is then requests to sign the confidentiality agreement and proceeds to retrieve the pertinent document.

Step 3 - Supervision of use of retrieved document: The requestor is requested to sign the logbook, enforces the restriction to room-use of documents by the concerned researcher/ investigator. Prior approval by the officers to photocopy, scan, and/or take photos should be sought.

Step 4 - Return of document to the files: The requestor, with the assistance of the staff, returns the retrieved files to the Protocol file after its use.

Section 11. Forms

Form 026 Log of Requests

Section 12. History of SOP

Version No.	Date	Authors	Main Change
1	January 25, 2023	Esmeraldo De Las Armas IV Josephine Robiños	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosaliel. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy Statement, Workflow, and Description of Procedures
3	February 15, 2024	Carl Joseph Gading Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Policy Statement Updating of the SOP

Section 13. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 26** **Management of Queries and Complaints**

Section 1. Policy Statement

This policy establishes guidelines for the management of queries and complaints by the Research Ethics Committee (REC) to ensure that concerns raised by stakeholders are addressed promptly, fairly, and transparently. Adherence to these guidelines helps to maintain trust and confidence in Research Ethics Committee processes, uphold ethical standards, and promote accountability in research oversight.

Section 2. Objective

The objective is to ensure that queries and complaints are addressed promptly, fairly, and transparently, in accordance with established procedures and ethical principles.

Section 3. Scope

This policy applies to all queries and complaints received by the Research Ethics Committee from researchers, participants, institutions, sponsors, or other stakeholders regarding REC processes, decisions, or ethical considerations related to research projects

Section 4. Terms of Reference

4.1 Queries refer to requests for information, clarification, or guidance regarding Research Ethics Committee policies, procedures, or decisions.

4.2 Complaints refer to expressions of dissatisfaction, concerns, or grievances regarding Research Ethics Committee processes, decisions, or conduct.

Section 5. Receipt of Queries and Complaints

5.1 Queries and complaints may be received via various channels, including email, phone, written correspondence, or in-person meetings.

5.2 Research Ethics Committee personnel responsible for managing queries and complaints will promptly acknowledge receipt and initiate the appropriate response procedures.

Section 6. Response Procedures

6.1 Queries are addressed promptly and accurately by providing relevant information, clarifications, or guidance to the requester.

6.2 Complaints are investigated thoroughly and objectively to determine the nature and validity of the concerns raised.

6.3 Responses to complaints are provided in a timely manner, acknowledging the concerns raised and outlining any actions taken or recommendations for resolution.

Section 7. Confidentiality and Privacy

7.1 Queries and complaints are handled with confidentiality and discretion, with due respect for the privacy of the individuals involved.

7.2 Personal information provided in queries and complaints are treated in accordance with data protection laws and Research Ethics Committee policies on privacy and confidentiality.

Section 8. Fairness and Impartiality

8.1 Queries and complaints are addressed with fairness, impartiality, and without prejudice. Research Ethics Committee personnel involved in the response process will act objectively and refrain from conflicts of interest.

8.2 Investigations into complaints are conducted with an open mind, considering all relevant evidence and perspectives before reaching conclusions or making decisions.

Section 9. Documentation and Tracking

9.1 All queries and complaints received by the Research Ethics Committee are documented, logged, and tracked in a centralized records management system.

9.2 Records include details of the query or complaint, actions taken in response, outcomes of any investigations or resolutions, and any follow-up actions required.

Section 10. Feedback and Follow-up

10.1 Feedback on the resolution of queries and complaints are provided to the requester to ensure transparency and accountability.

10.2 Follow-up actions, such as corrective measures or preventive actions, are conducted as necessary to address systemic issues or prevent recurrence of similar concerns.

Section 11. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE

Step 1: Receiving, logging, and acknowledgement of queries and complaints	Staff	1 Working Day
Step 2: Referral of query or complaint to REC personnel 2.1 Referral of protocol-related query to primary reviewers. 2.2. Referral of all complaints to the Chairperson	Staff	1 to 2 Working Days
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 Chairperson and UMREC members	5 to 15 Working Days (may extend based on the extent of issue)
Step 4: Communicating Committee action	UMREC Staff	1-2 Working Days
Step 5: Logging of the response and inclusion in the agenda of the UMREC meeting	UMREC Staff	Refer to SOP 06 & 25

Section 12. Description of Procedures

Step 1 – Receiving of receipt, logging, and acknowledgement of queries and complaints: The Staff receives the complaint form, logs the date, time, name of concerned party, specific study, and nature of query or complaint in the logbook.

Step 2 - Referral of query or complaint to competent authority:

2.1. For queries related to specific Protocols approved by UMREC, the staff refers the query or complaint to the primary reviewers.

2.2. Also, the staff refers all complaints to the UMREC Chairperson who determines the level of risk effected by the issue.

- Minimal risk complaints are referred to the primary reviewers of the concerned protocol.
- Complaints that involve more than minimal risk are referred to the members. A special meeting that shall be called within 48 hours to discuss the Protocol that is the subject of the query or complaint.

Step 3 - Formulation of response:

1.1. For queries, the primary reviewers accomplish the Form 0016

1.2. For minimal risk complaints, the primary reviewers accomplish the same Form 0016

1.3. For more than minimal risk, the committee may choose any of the following options:
- Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.
- Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
- Formulate recommendation if there is adequate information.
  - request for explanation/justification from researcher
  - accept request/demand of participant
  - suspension of further recruitment
  - amendment of protocol and re-consent of participants
  - others

Step 4 - Communicating response:
UMREC communicates it response to the query and/or complaint through a formal letter addressed to the complainant. The letter is based on the objective data and formulated recommendation, as indicated in Step 3. The letter is prepared and signed by the Chairperson, duly noted by the Vice President for Planning and Research.

Step 5 – Logging of the response and inclusion in the agenda of the UMREC meeting:
The UMREC documents the response through a dedicated logbook, and keeps both a hardcopy and softcopy of the incoming and/or outgoing documents. Incoming and Any outgoing document is logged in a dedicated logbook.

Section 13. Forms

Form 0032 Query/Complaint Form

Section 14. History of SOP

Version No.	Date	Authors	Main Change
1	January 25, 2023	Esmeraldo De Las Armas IV Josephine Robiños	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosaliel. Catanghal Emeraldo Del Las Armas IV Josephine D. Robinos Estela De Vera-Barasi	Policy Statement, Workflow, and Description of Procedures

		Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr., Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	
3	February 15, 2024	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 15. 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 202

	University of Makati Research Ethics Committee (UMREC)
Version No: 3 Date of Approval: 02.15.2024 Date of Effectivity: 02.15.2024	**SOP No. 27** **Writing and Revising the Standard Operating Procedure (SOP)**

Section 1. Policy Statement

This policy establishes guidelines for the development, review, and revision of Standard Operating Procedures (SOP) by the Research Ethics Committee (REC) to ensure consistency, quality, and compliance in REC operations. Adherence to these guidelines helps to streamline processes, enhance efficiency, and maintain integrity in research oversight activities.

Section 2. Objective

The objective is to establish consistent, standardized processes for conducting Research Ethics Committee activities and ensuring compliance with regulatory requirements and best practices.

Section 3. Scope

This policy applies to all SOP developed and maintained by the Research Ethics Committee for its internal operations, including but not limited to review procedures, decision-making processes, administrative tasks, and quality assurance activities.

Section 4. Development of SOP

a. SOP is developed by designated Research Ethics Committee member/s with expertise in the relevant area, in consultation with stakeholders, as needed.

b. SOP is drafted in a clear, concise, and unambiguous manner, using standardized templates and formatting to enhance readability and usability.

Section 5. Review and Approval

a. Draft SOP is reviewed by the Research Ethics Committee Officers to ensure accuracy, completeness, and alignment with regulatory requirements and REC policies.

b. Reviewers provide feedback and recommendations for revisions as needed, with final approval granted by the Research Ethics Committee Chairperson or designated authority.

Section 6. Revision and Updating

a. SOP is regularly reviewed and updated as necessary to reflect changes in regulatory requirements, institutional policies, or best practices.

b. Requests for revisions of SOP may be initiated by any Research Ethics Committee member.

Section 7. Version Control

a. SOP is assigned version numbers or dates to track revisions and ensure that users are referring to the most current version.

b. Previous versions of SOPs are archived for reference and audit purposes, with clear documentation of changes and reasons for revisions.

Section 8. Documentation and Record Keeping

a. Records of SOP development, review, and revisions are maintained in a centralized document management system or repository.

b. Documentation includes details of the review process, revisions made, approvals obtained, and dates of implementation for each SOP.

Section 9. Compliance Monitoring

a. Compliance with SOP is monitored and assessed through regular internal audits, quality assurance checks, and performance evaluations.

b. Non-compliance or deviations from SOP will be investigated and addressed through a corrective action or revision of the SOP, as needed.

Section 10. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Proposal and approval for revision or writing of a new SOP	UMREC member/s Admin Staff	At least every 3 years
Step 2: Designation of the SOP Team	Chairperson	5 Working Days
Step 3: Drafting of the revision of the current or writing of new SOP	SOP Team	25 Working Days
Step 4: Review and finalization of SOP	Chairperson, Members	10 Working Days
Step 5. Preparation and submission of finalized SOP to the institutional authority	Chairperson	5 Working Days

Step 6: Inclusion of the revised or new SOP in the Manual, as well as its dissemination	UMREC Secretary Admin Staff	5 Working Days

Section 11. Description of Procedures

Step 1 - Proposal for a revision of an SOP or a new SOP and its approval: SOP is reviewed and revisited at least every three (3) years. Revision of the SOP earlier than three years must merit the necessity of the revision, and must be approved by the members in a regular or special meeting.

Any UMREC member may propose for SOP revision or writing of a new SOP, in consideration of the following:

1. There is a change in the identifier of SOP; however, correction of grammatical errors is not considered substantial.
2. When an SOP is difficult to understand or does not cover what it should.
3. When there are major changes that have substantial effect on procedures, definitions, requirements, and similar considerations.

When the need for a revision of SOP has been identified and agreed on, a draft will be written by the SOP Revision Team appointed by the Chairperson.

Any proposal for revision must be written and submitted to the Revision Committee for review, assessment, coding, and inclusion into the document. UMREC members are responsible for reviewing and approving the drafts of the revised and new SOP in a regular meeting; keeping a copy of complete proposed SOP; and performing their function according to current SOP. Chairperson submits the draft, for deliberation in a regular members meeting. The approved revised SOP version and/or new SOP is submitted to MANCOM for information, through the Office of the Vice President for Planning and Research.

Step 2 - Designation of the SOP Team: It is the responsibility of the UMREC Chairperson to appoint the SOP Team to write a new SOP or to revise the existing SOP. The Chairperson designates the members of the team, initiates approval processing of the final revision of SOP, and submits the SOP to the Management Committee for information. The SOP Team is an ad hoc committee composed of appointed UMREC members with invited resource persons. The team is responsible for proposing and writing new SOP, reviewing and revising existing SOP, if and when necessary.

Step 3 - Drafting of the revision or new SOP: The SOP Team makes a draft of the revision or new SOP based on the template detailed below:

1. **Title** – descriptive of the contents
2. **Policy Statement** – a directive or framework for decision-making
3. **Objective/s** of the activity – defines the purpose and intended outcome
4. **Scope** – defines the extent of coverage and limitations
5. **Workflow** – provides a graphical representation of the essential steps to implement the SOP, responsible person for each step, and timeline
6. **Detailed instructions** – elaborates the steps listed in workflow
7. **Forms** – documents to be accomplished by different parties
8. **History** – presents the different versions (from draft to the latest versions)
9. **References** –lists the SOP's legal bases, guidelines, or policies used in the revision of formulation of the new SOP.

Each SOP is given a code and a title, following the format:

a. UMREC-SOP-MMYY-VN where MMYY is refers to the month/year of implementation and/or circulation. VN reflects the version number (starting from 01).

b. If an SOP supersedes a previous version, a new version indicates the previous SOP version and the changes on the SOP cover, located in front of the SOP Manual (e.g. UMREC- SOP-0223-01)

Step 4 - Review and approval of SOP: Upon completion, the Chairperson submits the draft to the members for full review and deliberation. Upon approval, the Chairperson communicates the approved draft to the University President for signature.

The University President signs the approved SOP in the appropriate section on the cover page. The approved SOP takes effect after a 30-day promulgation period. Within the 30-day period, the President may provide suggestions that UMREC may take into consideration.

Step 5 - Inclusion of the revised or new SOP in the Manual, as well as its dissemination: The Committee Secretary is responsible for coordinating the writing and revising of SOP, maintaining current SOP with a complete SOP list, ensuring that all UMREC members have access to the SOP, and are working according to the current version.

The Secretariat distributes the updated version to the members; updates the electronic SOP manual, and publishes the SOP through the UMAK website (www.umak.edu.ph), and keeps all versions in the UMREC Files.

Section 12. Forms

Form 0031 Draft Resolution on Creation/Revision of an SOP

Section 13. History of SOP

Version No.	Date	Authors	Main Change
1	January 31, 2023	Estela De Vera- Barasi	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John G. Domingo Rosalie I. Catanghal Esmeraldo De Las Armas IV Josephine D. Robinos Estela De Vera-Barasi Margaret May A. Ga Myna Marie DC Nerona Gerome C. Abenilla Aldrin Mendoza John Aldred Bravo Jr. Michael Gelilio Maria Fay Nenette M. Cariaga Justine Marie A. Ocampo	Policy statement, Workflow, and Description of Procedures
3	February 15, 2024	Margaret May Ga Jefferson Marcelo Leland Anthony dela Luna	Updating of the SOP

Section 14. 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

	University of Makati Research Ethics Committee (UMREC)
Version No: 1 Date of Approval: 05.15.2023 Date of Effectivity: 05.15.2023	**SOP No. 28** **Non-Submission of Protocol for Research Ethics Review**

Section 1. Policy Statement

This policy establishes guidelines and consequences regarding the non-submission of protocols before the commencement of data gathering activities. The submission of protocols is crucial for ensuring the ethical, legal, and methodological integrity of research and data collection endeavors.

Section 2. Objective

This policy aims to uphold ethical standards, ensure compliance with regulations, and promote the integrity and credibility of research and data collection activities undertaken by at the University of Makati.

By establishing clear guidelines and consequences for the timely submission of protocols, the policy aims to:

2.1 **Promote Ethical Conduct:** By requiring the submission of protocols outlining research objectives, methodologies, participant information, and data handling procedures, the policy ensures that data gathering activities are conducted in an ethical manner, with due consideration for participant rights, confidentiality, and safety.

2.2 **Ensure Compliance:** The policy sets forth clear expectations regarding protocol submission requirements and consequences for non-compliance, thereby promoting adherence to internal policies, regulatory standards, and best practices in research and data collection.

2.3 **Protect Against Legal and Ethical Risks:** By delaying or postponing data gathering activities in cases of non-submission, the policy helps mitigate potential legal and ethical risks associated with conducting research without appropriate approvals or oversight.

2.4 **Foster Accountability:** The policy holds individuals and teams accountable for their actions by establishing consequences for non-compliance, thereby encouraging responsible behavior and adherence to established procedure.

2.5 **Enhance Data Quality and Validity:** By requiring the submission of protocols before data gathering activities commence, the policy helps ensure the methodological rigor and validity of research findings, ultimately enhancing the quality and reliability of the data collected.

Section 3. Scope

This policy applies to researchers, investigators, and collaborators engaged in data gathering activities affiliated with the University of Makati (UMAK), as well as those conducting research in collaboration with external institutions that require Ethics Clearance.

Section 4. Policy

4.1 **Submission Requirement:** All individuals or teams planning to conduct data gathering activities must submit a detailed protocol outlining the research objectives, methodology, participant information, data handling procedures, and any other relevant information to the University of Makati Research Ethics Committee (UMREC) before commencing data collection.

4.2 **Timely Submission:** Protocols must be submitted sufficiently in advance of the proposed data gathering activities to allow for thorough review and approval. The specific timeframe for submission is communicated by the Research Ethics Committee through various means (i.e., webpage, poster).

4.3 **Non-Submission Consequences:**

4.3.1 **Initial Reminder:** Individuals or teams who fail to submit their Protocol for approval before data gathering will receive a verbal and/or written reminder outlining the importance of Protocol submission and the consequences of non-compliance.

4.3.2 **Delayed Data Gathering:** Data gathering activities may be delayed or postponed until the Protocol is submitted, reviewed, and approved by the Research Ethics Committee. This delay may impact project timelines and deadlines.

4.3.3 **Non-issuance of Certificate of Approval:** Persistent non-compliance with Protocol submission requirements may result in the non-issuance of the Certificate of Approval.

4.3.4 **Liability:** Individuals or teams proceeding with data gathering activities without submitting a Protocol or obtaining necessary approvals do so at their own risk and may be personally liable for any legal or ethical implications arising from such actions.

4.4 **Appeals Process**: Individuals or teams may appeal decisions related to the submission of protocols or associated consequences through established appeal procedures outlined in another SOP.

4.5 **Awareness and Training:** UMREC shall provide training, resources, and ongoing support to ensure awareness of Protocol submission requirements and adherence to established procedures.

Section 5. History of SOP

Version No.	Date	Authors	Main Change
1	May 15, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	New SOP

Section 6. References

- National Ethical Guidelines for Health and Health-related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- World Medical Association. (2013). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Retrieved from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects

	University of Makati Research Ethics Committee (UMREC)
Version No: 1 Date of Approval: 02.12.2024 Date of Effectivity: 02.12.2024	**SOP No. 29** **Functions and Responsibilities**

Section 1. Policy Statement

This policy outlines the functions and responsibilities of the Research Ethics Committee (REC) members of the University of Makati. It aims to provide clarity and guidance to all members regarding their roles and expectations to ensure the smooth and efficient operation of the committee.

Section 2. Objective

The objective of this policy is to define the key functions and responsibilities associated with Research Ethics membership. By clearly outlining roles and expectations, this policy aims to promote accountability and ethically sound research.

Section 3. Scope

This policy applies to all Research Ethics Committee members of the University of Makati, including officers of REC.

Section 4. Description

The REC shall act in the full interest of potential research participants and affected communities, considering the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws (WHO, 2000 and 2011). The REC should be updated regarding Philippine laws and policies of regulatory agencies about possible areas or groups for research.

Section 5. REC's Key Functions and Responsibilities

1. Conduct a thorough ethical review of proposed research projects involving human subjects to ensure compliance with ethical principles and guidelines.

2. Assess the potential risks and benefits of the research to participants and other stakeholders.

3. Ensure the rights, safety, and well-being of research participants are protected throughout the research process.

4. Evaluate the informed consent process to ensure participants are adequately informed about the research and voluntarily agree to participate.

5. Evaluate the risks and potential benefits of the research to determine whether the study is ethically justifiable.

6. Ensure that the risks are reasonable in relation to anticipated benefits and that steps are taken to minimize potential harm,

7. Review and approve the informed consent documents to ensure they are clear, understandable, and provide sufficient information to participants.

8. Ensure that procedures are in place to protect the confidentiality of participant information.

9. Pay special attention to the ethical considerations when research involves vulnerable populations such as children, pregnant women, and other marginalized groups.

10. Communicate with researchers to address ethical concerns and provide guidance for compliance.

11. Prepare and submit regular reports to institutional leadership and relevant regulatory bodies.

12. Ensure compliance with relevant national and international regulations and guidelines governing the ethical conduct of research.

13. Stay informed about changes in regulations and update institutional policies accordingly.

14. Regularly review and evaluate the effectiveness of the REC's processes and procedures.

15. Implement improvements to enhance the ethical review process.

Section 6. Forms

Form 0010

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	February 12, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Additional SOP from National Ethical Guidelines 2022 pp. 41-43

	University of Makati Research Ethics Committee (UMREC)
Version No: 1	**SOP No. 30**
Date of Approval: 02.15.2024	**Administration Support**
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

The purpose of this policy is to establish guidelines and procedures for providing administrative support to ensure the effective and efficient functioning of the Research Ethics process at the University of Makati. Administrative support plays a crucial role in managing the logistical, procedural, and documentation aspects of the committee's activities.

Section 2. Objective

This policy aims to streamline administrative processes, enhance efficiency, and uphold ethical standards in research activities.

Section 3. Scope

The scope of administrative support for the Research Ethics Committee (REC) encompasses a range of responsibilities aimed at facilitating the effective functioning of the committee and ensuring compliance with ethical standards in research.

Section 4. Organizational Structure

Below is a visual representation of the Research Committee's structure and hierarchy. This clarifies reporting relationships, roles, and responsibilities, fostering transparency and facilitating effective communication within the University of Makati.

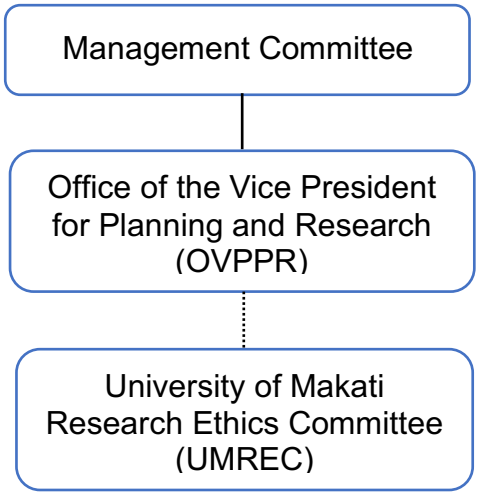

Fig. 1. UMREC Hierarchical Structure

The University of Makati Research Ethics Committee (UMREC) is composed of reviewers responsible for the comprehensive implementation of the office's functions.

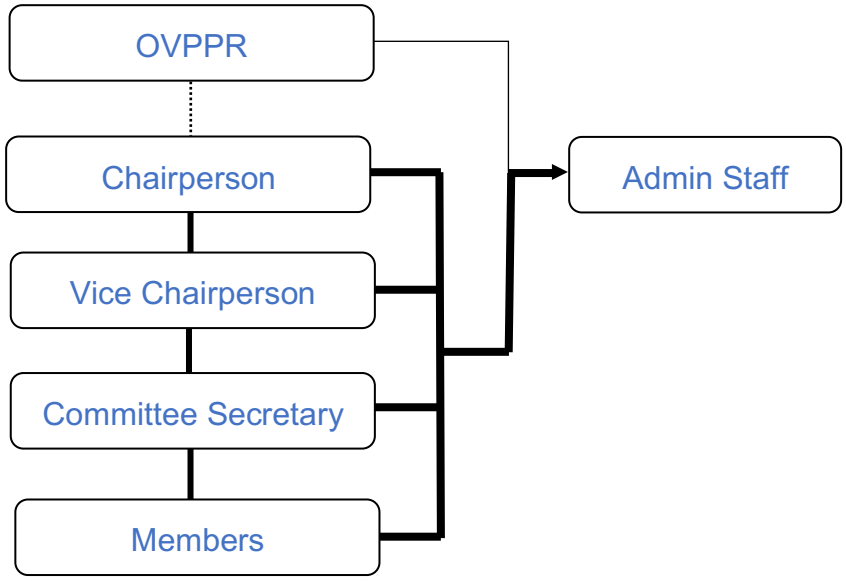

Fig. 2. UMREC International Organizational Structure

Section 5. Support Requirements

The Research Ethics Committee (REC) requires support from the University administration to effectively carry out its responsibilities in overseeing research activities involving human subjects, viz:

1. **Policy Development and Implementation**: The school administration can help develop and implement policies related to research ethics, ensuring that they align with national and international standards. This may include developing guidelines for ethical conduct in research, establishing procedures for review and approval of research protocols, and defining the scope of the REC's authority.

2. **Resource Allocation**: Providing adequate resources, both financial and human, is crucial for the functioning of the REC. This includes funding for training committee members, administrative support for managing review processes, and access to relevant literature and resources on research ethics.

3. **Training and Education**: The administration can support efforts to educate researchers, students, and faculty members about ethical principles and regulations governing research involving human subjects. This may involve supporting workshops, seminars, or training sessions on topics.

4. **Research Culture:** The administration can support UMREC in funding researchers conducted by members and officers that will help improve the systems, functions, services, practices and operations as a whole.

5. **Administrative Support**: Administrative assistance is essential for managing the day-to-day operations of the REC. This may include scheduling meetings, maintaining records of research protocols and approvals, coordinating communication with researchers, and ensuring compliance with regulatory requirements.

6. **Conflict Resolution**: The administration may be called upon to resolve conflicts or disputes that arise during the review process, particularly in cases where there are disagreements between researchers and the REC regarding ethical considerations or protocol revisions.

7. **Promotion of Ethical Culture**: School administration plays a key role in fostering a culture of research integrity and ethical conduct within the institution. This includes promoting transparency, accountability, and ethical leadership at all levels of the organization.

8. **Compliance Monitoring**: The administration can assist the REC in monitoring compliance with ethical guidelines and regulations, ensuring that researchers adhere to approved protocols and address any issues or concerns that arise during the research.

6. History of SOP

Version No.	Date	Authors	Main Change
1	February 15, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	New SOP Research Culture under Section 5

	University of Makati Research Ethics Committee (UMREC)
Version No: 2 Date of Approval: 05.15.2024 Date of Effectivity: 05.15.2024	**SOP No. 31** **Special Meeting**

Section 1. Policy Statement

This policy establishes the guidelines for the planning, execution, and documentation of special meetings. The Research Ethics shall meet as a committee on a schedule determined based on the research cycle of the UMAK. This provision is for holding special meetings to consider urgent matters as decided by the officers. All meetings shall be held within the premises of the University.

Section 2. Objective

The objective of this policy is to bring together the members of the Research Ethics Committee with a specific purpose which is to converse and decide on urgent matters, encourage collaboration, communication, and decision-making.

Section 3. Scope

This SOP covers all activities before, during, and after the conduct of an UMREC special meeting. A special meeting may be called according to need. This also refers to the range and extent of topics, issues, or activities that the meeting aims to cover.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Preparation of agenda which includes the following: 1. Call to Order 2. Declaration of Quorum 3. Approval of the Provisional Agenda 4. Disclosure of Conflict of Interest 5. Review and Approval of the Minutes of the Previous Meeting 6. Business Arising from the Minutes 7. New Business 8. Full Review, Expedited, Exempted, Resubmission, and Site Visit. 9. Other Matters	Secretary Admin Staff	3 working days
Step 2: Reservation of venue	Admin Staff UFMO	3 working days

	GSO	
Step 3: Assembly of materials and documents needed for the meeting	Admin Staff	2 working days
Step 4: Preparation of presentation and recording equipment, food arrangements for the meeting (if necessary)	Admin Staff	2 working days
Step 5: Notification of and confirmation of attendance for the Members and confirmation of attendance	Member Secretary Admin Staff	2 working days
Step 6: Conduct of the meeting	Chairperson	1 working day
Step 7: Preparation of the Minutes of the Meeting	Secretary	3 working days
Step 8: Dissemination of the Minutes of the Meeting through email	Secretary Admin Staff	2 working day
Step 9. Approval of the minutes of the meeting in the next UMREC Meeting	UMREC Members	5 working day

Section 5. Detailed Description of Meeting

Step 1 - Preparation of the Agenda: The Committee Secretary shall prepare the draft agenda for the meeting. The agenda shall include the date, time, and venue of the meeting; a list of topics for discussion; reports or updates from subcommittees; and any other matters arising from previous meetings. The Chairperson shall review and approve the draft agenda before dissemination. Once finalized, the Secretariat shall circulate the approved agenda to all UMREC members at least one week prior to the meeting to allow members sufficient time to prepare for deliberations and to propose additional agenda items, if necessary.

Step 2 - Reservation of the Venue: The Administrative Staff shall be responsible for securing the meeting venue in coordination with the University Facilities Management Office (UFMO) and the General Services Office (GSO). A reservation shall be made at least one week before the scheduled meeting to ensure availability and proper setup of the venue. The staff shall confirm that the venue meets the requirements for capacity, accessibility, and necessary facilities (such as audio-visual equipment, tables, and seating arrangements). For online or hybrid meetings, the Secretariat shall prepare the official meeting link and ensure that technical support is available on the day of the meeting.

Step 3 - Assembly of materials and documents needed for the meeting: Prior to the meeting, the Administrative Staff and the Committee Secretary shall prepare and compile all necessary documents and materials, including the finalized agenda, previous minutes of the meeting, reports, proposals, and supporting reference documents.

Copies of these materials shall be printed and distributed to the UMREC members during the meeting. Upon arrival, each member shall sign the attendance logbook for proper documentation of participation. The Secretariat shall also prepare extra copies of materials for guests or observers, if applicable.

Step 4 - Preparation of presentation and recording equipment, food arrangements for the meeting (if necessary): The Admin Staff shall ensure that all necessary audiovisual equipment, such as laptops, projectors, microphones, and recording devices, is properly set up and tested for functionality before the start of the meeting. Backup devices should be available to prevent technical disruptions. The meeting venue shall be arranged to accommodate all participants comfortably, ensuring visibility of presentations and accessibility of materials. If food or refreshments are to be provided, coordination with the catering service shall be made in advance to ensure timely delivery and appropriate quantity based on confirmed attendees.

Step 5 - Notification of and confirmation of attendance for the Members and confirmation of attendance: The Admin staff and Committee Secretary shall issue an official meeting notice to all UMREC members and relevant participants at two working days prior to the scheduled meeting date. The notice shall include the date, time, venue (or online meeting link, if applicable), and agenda. Members shall be required to confirm their attendance within the specified deadline to facilitate logistical and quorum preparations. Follow-up reminders may be sent to those who have not yet confirmed to ensure full participation.

Step 6 - Conduct of the meeting: The meeting shall be presided over by the UMREC Chairperson or, in his/her absence, the designated Vice-Chairperson. The meeting shall follow the approved agenda, ensuring that discussions are organized and time-bound. Attendance shall be recorded at the start of the meeting to determine the quorum. Each agenda item shall be presented, deliberated upon, and resolved as necessary. The Secretariat shall document the proceedings accurately, including key points of discussion, decisions, and action items. Any confidential matters shall be handled in accordance with institutional and ethical standards.

Step 7 - Preparation of the Minutes of the Meeting: Following the meeting, the Secretariat shall prepare the official Minutes of the Meeting, summarizing the attendance, agenda items, deliberations, decisions, and agreed-upon actions or follow-ups. The minutes should be clear, concise, and factual, ensuring that each action point is assigned to a responsible person or committee with a target completion date. The draft minutes shall be reviewed by the UMREC Chairperson for accuracy prior to dissemination.

Step 8 - Dissemination of the Minutes of the Meeting through email: Once approved by the UMREC Chairperson, the Secretariat shall distribute the Minutes of the Meeting to all members via official institutional email. The email shall include the minutes as an attachment or embedded document, along with a cover message indicating that members are requested to review and provide any comments or corrections before the next scheduled meeting. Proper document control measures should be observed, including labeling the file with the meeting date and version number.

Step 9 - Approval of the minutes of the meeting in the next UMREC Meeting: At the beginning of the subsequent UMREC meeting, the Chairperson shall present the Minutes of the previous meeting for review and formal approval by the members. Any amendments or corrections raised shall be duly noted and incorporated into the final version. Once approved, the minutes shall be officially adopted as a true and accurate record of the proceedings and archived accordingly by the Secretariat for institutional documentation.

Section 6. Regular Meeting Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Call the meeting to order and establish the ground rules.	Staff	2 working days before or during the meeting
Step 2: Declaration of a quorum (formal start)	Member Secretary	During the meeting
Step 3: Approval of the provisional agenda	Members	During the meeting
Step 4: Declaration of conflict of interest (COI)	Members (who have COI)	During the meeting
Step 5: Approval of minutes of the previous meeting	Members	During the meeting
Step 6: Discussion of "Business arising from the minutes"	Members	During the meeting
Step 7: Discussion of New Business	Vice Chairperson Members	During the meeting
Step 8: Discussion of Other Matters (if there is any)	Designated	During the meeting
Step 9: Adjournment	Chairperson	During the meeting

Section 7: Detailed Description of the Regular Meeting

Step 1 - Call to Order. Begin the meeting with a welcome and opening remarks, followed by the call to order. Review the ground rules for the meeting, including guidelines for participation, timekeeping, and respectful communication.

Step 2 - Declaration of a Quorum. Declare the presence or the absence of a quorum after the roll call. Proceed if a quorum is reached. Adjourn the meeting if a quorum is not present.

Step 3 - Approval of the Provisional Agenda. Present the provisional agenda for approval of the members. Once moved for adoption, followed by a motion to second, declare the adoption of the agenda as official.

Step 4 - Declaration of Conflict of Interest (COI). Invite members to voluntarily declare their Conflict of Interest (COI) by raising of hand. Once recognized, the member explains the ground for inhibition in the discussion.

Step 5 - Approval of the Minutes of the Previous Meeting. After pointing out corrections in form and substance, offer the approval of the minutes of the previous meeting, followed by a second to the motion.

Step 6 - Business Arising from the Minutes of the Previous Meeting. Invite members to raise points of action from the previous meeting.

Step 7 - Discussion of New Business. Present new items for discussion. Set action points for each item.

Step 8 - Discussion of Other Matters. Discuss all other matters that are added to the regular agenda.

Step 9 - Adjournment. After discussing all relevant concerns, call for adjournment of the meeting, followed by a second to the motion.

Section 6. Forms

Form 0024 Meeting Agenda Template
Form 0023 Notice of Meeting
Form 0026 Communication Logbook

Section 7. History of SOP

Version No.	Date	Authors	Main Change
1	January 24, 2023	Center for University Research	First draft
2	February 1, 2023	Florante Delos Santos Mark Vincent Valerio Carl Joseph Gading Anthony John Domingo Rosalie Catanghal Emeraldo dela Armas IV Josephine Robinos Estela De Vera-Barasi	Policy statement, Workflow, and Description of procedures
3	February 13, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Combined the SOP No. 17 Preparing for a Meeting, SOP No. 18 Preparing the Meeting Agenda, SOP No. 19 Conduct of the

			Meeting, SOP No. 20 preparation of the Minutes of the Meeting Specific mention of the Full revision, expedited, exempted, resubmission and site visit in the Step 1 of the activity Inclusion of the Detailed Description of the Meeting preparation and flow Creating a separate section for the Detailed Description of the Regular Meeting flow

	University of Makati Research Ethics Committee (UMREC)
Version No: 1	**SOP No. 32**
Date of Approval: 02.15.2024	**Training**
Date of Effectivity: 02.15.2024	

Section 1. Policy Statement

The purpose of this policy is to establish guidelines for the training and continuous professional development of members serving on the Research Ethics Committee (REC). This policy aims to ensure that committee members are well-equipped with the necessary knowledge, skills, and ethical understanding to fulfill their responsibilities effectively.

Section 2. Objective

This policy aims to ensure that committee members are well-equipped with the necessary knowledge, skills, and ethical understanding to fulfill their responsibilities effectively.

Section 3. Scope

The scope of Research Ethics Committee (REC) training should cover a broad range of topics to ensure that committee members are well-informed, skilled, and up-to-date with ethical principles, regulations, and best practices.

Section 4: Training Requirements

Members of the REC shall undergo initial and continuing training on the ethics and science of biomedical, socio-behavioral, and other research, and applicable laws such as the Philippine National Health Research System (PNHRS) Act, Indigenous Peoples Rights Act (IPRA), and Data Privacy Act of 2012 (DPA), pertinent to the types of protocols reviewed by the REC.

1.1 **Initial training shall be required of new members**. Newly appointed UMREC members must undergo an orientation before they can participate in the review process. This ensures that they are well-versed in the Committee's mandate, functions, and standard operating procedures. The training introduces members to the basic ethical principles—respect for persons, beneficence, and justice—as well as international and national ethical guidelines such as the Declaration of Helsinki**,** CIOMS Guidelines**,** and PHREB National Ethical Guidelines for Health and Health-Related Research.

In cases where a formal Basic Research Ethics Training is not immediately available, the UMREC Chairperson must ensure that an internal orientation is conducted to equip new members with essential knowledge prior to active service. This guarantees that all reviewers act with competence, objectivity, and accountability from the outset.

1.2 **UMREC Institutional Training.** Institutional training familiarizes the faculty members, researchers, advisers, panel members, and other individuals associated with the research activities with the organizational context, policies, and procedures specific to the University of Makati. It highlights the UMREC's structure, the responsibilities of members and administrative staff, and institutional expectations on confidentiality, documentation, and communication.
This training ensures alignment between UMREC operations and the University's overall research governance system, strengthening institutional compliance with ethical, administrative, and legal standards.

1.3 **Basic Research Ethics Training (BRET).** This training provides the **foundational knowledge** necessary for understanding research ethics and the ethical review process. It covers the core ethical principles governing research involving human participants, risk-benefit assessment, participant protection, informed consent, and the roles of ethics committees.
Completion of BRET is a **minimum requirement** set by the **Philippine Health Research Ethics Board (PHREB)** for all REC members. It ensures that reviewers are capable of identifying ethical issues in biomedical, behavioral, and social research protocols and of applying ethical reasoning in their deliberations.

1.4 **Good Research Practice (GRP).** Training in Good Research Practice emphasizes **integrity, transparency, and accountability** in the conduct and review of research. It reinforces understanding of responsible authorship, data management, record keeping, and avoidance of research misconduct such as plagiarism, falsification, and fabrication.
For REC members, GRP training ensures that the evaluation of research protocols includes consideration of research integrity, promoting a culture of ethical conduct among investigators and institutions.

1.5 **Advanced/Focused Workshops.** These specialized workshops deepen the knowledge and skills of REC members in handling complex ethical issues that go beyond basic training. Each module addresses specific competencies required for effective ethical review:

- **a. Standard Operating Procedures (SOPs):** Ensures that all REC members understand and uniformly implement approved SOPs for reviewing, documenting, and communicating decisions.
- b. **Conflict of Interest (COI):** Trains members to identify, declare, and manage potential conflicts to maintain impartiality and credibility in the review process.
- c. **Informed Consent:** Strengthens understanding of ethical and legal requirements in obtaining voluntary, informed participation, including considerations for vulnerable populations.
- d. **Ethics Review Committees (ERCs):** Provides insights on committee management, review processes, and harmonization with PHREB standards for effective functioning.
- e. **Training of Trainers (ToT):** Builds internal capacity by preparing qualified members to conduct local training sessions, ensuring sustainability of ethics education within the institution.

f. **Training for Evaluators:** Prepares members to assess and monitor the performance and compliance of the REC through internal or external evaluations, maintaining PHREB accreditation standards.

These workshops enhance the technical proficiency of members and strengthen UMREC's institutional capacity for ethical governance.

1.6 Continuing Education Activities on Research Ethics. Continuing education ensures that REC members remain updated on emerging ethical issues**,** evolving research methodologies, and new regulations such as amendments to the Data Privacy Act**,** IPRA**,** and PNHRS policies**.**

Regular participation in seminars, conferences, webinars, or refresher courses reinforces the culture of lifelong learning and ethical vigilance. This ongoing training requirement upholds the quality and credibility of UMREC's review process and supports PHREB's requirement **for** continuous professional development **of** ethics committee members.

Section 5: Collaboration with External Entities

a. The REC may collaborate with external organizations, national and/or international experts, and institutions to enhance the training program.
b. Participation in external conferences, webinars, and workshops related to research ethics is highly encouraged.

Section 6: Continuing Professional Development

a. Members are encouraged to pursue additional professional development opportunities in the national or international settings, such as certifications, workshops, and conferences, to enhance their expertise in research ethics.

b. The REC will recognize and support members' efforts in continuing professional development.

Section 7: Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Training proposal during regular meeting	Secretariat Members	1 Working Day
Step 2: Request for Training Schedule with PHREB	Secretariat	1 Working Day
Step 3: Approval of the Proposal from OVPPR	Secretariat VPPR	1 Working Day
Step 4: Training Preparation	Secretariat Members Admin Staff	One month before the event

Step 5: Training proper	Secretariat UMREC Members Admin Staff	During the training
Step 6: Post-Activity Report	Secretariat Admin Staff	Within one week after the event
Step 7: Submission of Documents for Honorarium/Honoraria for Speaker	Secretariat Admin Staff	During the meeting

Section 8: Detailed Description of the Procedure

Step 1 - Training proposal during regular meeting: During the regular UMREC meeting, the Secretariat presents the proposal for a training activity in coordination with the Committee Members. The proposal shall include the training objectives, topics, resource persons, budget estimates, and intended participants. The members may provide suggestions or modifications to ensure the activity addresses current needs or compliance requirements. Once finalized, the Committee shall endorse the proposal for further approval.

Step 2 - Request for Training Schedule with PHREB: After the internal approval of the training proposal, the Secretariat shall formally communicate with the Philippine Health Research Ethics Board (PHREB) or its designated training division to request the training schedule. The request shall include the proposed date, type of training (e.g., Basic Research Ethics Training, SOP Workshop), expected number of participants, and institutional endorsement. The Secretariat shall await confirmation of schedule and trainer availability before proceeding to logistical preparations.

Step 3 - Approval of the Proposal from OVPPR: Once the training schedule from PHREB is tentatively set, the Secretariat shall forward the training proposal, along with supporting documents, to the OVPPR for review and approval. The OVPPR shall assess the proposal in terms of institutional alignment, budget allocation, and compliance with university procedures. The Secretariat shall secure written approval or endorsement before proceeding with any financial or logistical arrangements.

Step 4 - Training Preparation: The Secretariat, together with the UMREC Members and Administrative Staff, shall begin preparations at least one month prior to the scheduled training. Preparations include confirming the venue, arranging equipment and materials, finalizing participant lists, coordinating with speakers and PHREB representatives, and ensuring compliance with institutional procurement and finance procedures. Publicity materials and communication advisories (e.g., invitations, registration forms, and announcements) shall also be prepared during this phase. A letter of endorsement for the call for participants from each college shall be sent to the OVPAA, noted by the OVPRR. The enlisted participants shall be provided by each college to UMREC office for proper documentation.

Step 5 - Training proper: The training shall be conducted according to the approved program of activities. The Secretariat and Administrative Staff shall manage on-site logistics, including registration, documentation, attendance monitoring, and distribution

of training materials. The UMREC Members shall actively participate in the sessions, workshops, and discussions. The Secretariat shall also ensure that evaluation forms are distributed and collected at the end of the training to assess participant satisfaction and learning outcomes.

Step 6 - Post-Activity Report: Within one week after the completion of the training, the Secretariat and Administrative Staff shall prepare a Post-Activity Report. The report shall include a summary of the activity, participant attendance, evaluation results, documentation of expenses, photos, and recommendations for future training improvement. The report shall be submitted to the UMREC Chairperson and the OVPPR for recordkeeping and institutional reporting.

Step 7 - Submission of Documents for Honorarium/Honoraria for Speaker: The Secretariat and Administrative Staff shall prepare and submit the necessary documentation for the processing of honoraria for invited speakers or facilitators. Required documents typically include the approved program of activities, attendance sheet, proof of conduct (photos, certificates), and speaker's billing statement or acknowledgment receipt. Submission should ideally coincide with or immediately follow the next UMREC meeting to ensure timely processing of payments in accordance with university financial policies.

Section 9:

Form 0026 Communication Logbook

Section 10: History of SOP

Version No.	Date	Authors	Main Change
1	February 15, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Creation of a new SOP Inclusion of an improved Training requirements that each member should undergo, workflow, and detailed description of procedure Inclusion of Form 026 under forms

	University of Makati Research Ethics Committee (UMREC)
Version No: 1	**SOP No. 33** **Accreditation**
Date of Approval: 05.15.2024	
Date of Effectivity: 05.15.2024	

Section 1. Policy Statement

The purpose of this policy is to outline the principles and procedures governing the accreditation process for the Research Ethics Committee (REC). Accreditation ensures that the REC operates at the highest standards, adhering to ethical principles, regulations, and best practices in the review and oversight of research involving human participants.

All RECs shall apply for PHREB accreditation that shall indicate the nature of research that it can review (See PHREB Policies and Requirements for Accreditation, Appendix G)

Section 2. Objective

The primary objective of accrediting a Research Ethics Committee (REC) is to ensure that it operates at the highest standards of ethical review, safeguarding the well-being and rights of research participants.

Accreditation aims to:

a. **Enhance credibility:** Establish the REC as a credible and trustworthy entity committed to ethical conduct in the review of research protocols.

b. **Adherence to Standards:** Ensure that the REC adheres to established ethical standards, guidelines, and regulations governing research involving human participants.

c. **Continuous Improvement:** Encourage continuous improvement in the REC's processes, procedures, and expertise in response to evolving ethical challenges and regulatory changes.

d. **Public Trust and Transparency:** Build public trust by demonstrating transparency in the ethical review process, contributing to a positive perception of research within the community.

e. **Quality Assurance:** Provide assurance to researchers, institutions, and sponsors that the REC maintains a high level of quality and competence in its ethical oversight.

f. **International Recognition:** Facilitate international recognition, promoting collaboration and harmonization of ethical standards with other accredited committees globally.

g. **Accountability:** Encourage ongoing professional development of REC members, fostering expertise and competence in research ethics.

h. **Professional Development:** Encourage ongoing professional development of REC members, fostering expertise and competence in research ethics.

Section 3. Scope

The scope of accrediting a Research Ethics Committee encompasses various dimensions, ensuring a comprehensive evaluation of its structure, processes, and ethical oversight. Accreditation of a Research Ethics Committee is a multifaceted process aimed at ensuring that the committee meets and sustains the highest ethical standards in the review and oversight of research involving human participants.

Section 4. Workflow

Activity	Responsibility	Timeline
Step 1: Evaluation of the UMREC Requirements	Chairperson Vice-Chairperson Secretary	1 working day
Step 2: Meeting With UMREC members	Secretariat UMREC Members	1 working day
Step 3: Distribution of Assignments	Secretariat Admin Staff	1 working day
Step 4: Compliance of Requirements	Secretariat UMREC Members	1 working day
Step 5: Request for Accreditation Schedule	Secretariat	1 working day
Step 6: Approval from OVPPR	Secretariat Admin Staff	1 working day
Step 7: Request for Accreditation Funding	Secretariat Admin Staff	1 working day
Step 8: Accreditation	Secretariat UMREC Members Admin Staff	1 working day
Step 9: Request for Honorarium of Accreditors	Secretariat Admin Staff	1 working day
Step 10: Post-Activity Report	Secretariat Admin Staff	1 working day
Step 11: Post Accreditation Meeting	Secretariat Admin Staff	1 working day

Section 5. Detailed Description of Procedure

Step 1 - Evaluation of the UMREC Requirements: The Chairperson, Vice-Chairperson, and Secretary shall conduct an initial evaluation of the committee's readiness for accreditation. This involves reviewing the completeness and compliance of all documentary requirements, such as organizational structure, membership credentials, standard operating procedures (SOPs), training certificates, and previous reports. Gaps or deficiencies identified during this assessment shall be documented, and corrective actions shall be planned accordingly.

Step 2 - Meeting With UMREC members: The Secretariat shall convene a meeting with all UMREC members to discuss the findings of the initial evaluation and outline the accreditation process. During this meeting, the Secretariat shall present the checklist of requirements, timelines, and individual assignments. Members may provide inputs, clarifications, or updates on documents under their responsibility to ensure alignment and cooperation.

Step 3 - Distribution of Assignments: The Secretariat, in coordination with the Administrative Staff, shall distribute specific tasks among members and staff. Tasks may include document preparation, verification of training certificates, compilation of minutes, or updating of SOPs. Clear deadlines and submission formats shall be provided to ensure orderly collection and compliance. The Secretariat shall maintain a tracking system to monitor the status of each assigned task.

Step 4 - Compliance of Requirements: UMREC members and the Secretariat shall complete their assigned tasks and submit the required documents within the prescribed timeline. The Secretariat shall review each submission for completeness and accuracy before compiling them into the final accreditation portfolio. Coordination with the PHREB Secretariat may be initiated for clarifications or to confirm document formats.

Step 5 - Request for Accreditation Schedule: Once all requirements have been prepared, the Secretariat shall formally submit a request to the Philippine Health Research Ethics Board (PHREB) for the scheduling of the accreditation visit or evaluation. The request shall include the updated UMREC profile, list of members, and confirmation that all documentary requirements are complete. The Secretariat shall coordinate with PHREB regarding the proposed date and logistics of the accreditation activity.

Step 6 - Approval from OVPPR: The Secretariat and Administrative Staff shall forward the finalized accreditation documents and the PHREB communication to the OVPPR for official approval. The OVPPR shall review the materials to ensure compliance with institutional policies and alignment with the University's research governance framework. Written approval from the OVPPR must be secured prior to any financial or logistical arrangements.

Step 7 - Request for Accreditation Funding: Following OVPPR approval, the Secretariat and Administrative Staff shall prepare and submit a budget request to cover expenses related to the accreditation activity, such as materials, logistics, and honoraria for accreditors. All funding requests shall follow the University's financial procedures and be accompanied by the approved proposal, program of activities, and budget breakdown.

Step 8 - Accreditation: On the scheduled day, the UMREC shall undergo the accreditation process conducted by PHREB representatives. The Secretariat, Members, and Administrative Staff shall ensure that all required documents and records are properly organized and accessible for review. The team shall assist accreditors during interviews, document validation, and facility inspection, ensuring a smooth and transparent process.

Step 9 - Request for Honorarium of Accreditors: After the accreditation activity, the Secretariat and Administrative Staff shall process the documents for the release of honoraria to the PHREB accreditors. This includes the attendance sheet, approved program, photos, and acknowledgment receipts or billing statements. The request shall be submitted to the OVPPR or concerned finance office for appropriate processing and payment in accordance with university policies.

Step 10 - Post-Activity Report: The Secretariat and Administrative Staff shall prepare a Post-Activity Report summarizing the accreditation proceedings, key findings, recommendations, and observations from the PHREB team. The report shall also include supporting documentation such as photos, evaluation forms, and participant attendance. This report will be submitted to the UMREC Chairperson and OVPPR for review, recordkeeping, and follow-up action planning.

Step 11 - Post Accreditation Meeting: The Secretariat shall convene a post-accreditation meeting with the UMREC members and administrative staff to discuss the PHREB's feedback, commendations, and areas for improvement. Action plans shall be formulated to address any deficiencies or recommendations identified during accreditation. This ensures continuous improvement and preparedness for future evaluations.

Section 5. Forms

Form 0026 Communication Logbook

Section 6. History of SOP

Version No.	Date	Authors	Main Change
1	February 15, 2024	Henry G. Magat Mark Philip C. Paderan Ferdinand J. Piano	Created a new SOP as part of the revision Inclusion of the workflow and the detailed description of procedure