DDOSC

RESEARCH ETHICS MANUAL

2026

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INTRODUCTION

DDOSC Vision and Mission statements

Vision: A proactive academic pillar of development in the ASEAN region.

Mission: DDOSC shall provide golden opportunities to its stakeholders towards producing globally competent graduates, relevant and responsive research, extension, and production services anchored on good governance.

Goals:

KRA: 1: Quality Instruction - produce globally competitive and morally upright graduates

KRA 2: Relevant and Responsive Research, Extension, and Production - develop, transfer, and adopt knowledge and technology toward socioeconomic development

KRA 3: Effective and Efficient Resource Management - generate, allocate, and utilize resources with optimum participation, accountability, transparency, and adherence to the rule of law

Core Values: DDOSC is a trailblazer of learned individuals that values the culture of **EXCELLENCE**, **INTEGRITY**, and **SOLIDARITY.**

History and Mandate of DDOSC-REC

Arising from the need to establish an efficient system of knowledge production that will complement the present directions of the College towards integrated training programs for human resources, gave birth to DDOSC-Research Ethics Committee (DDOSC-REC) on March 22, 2018, through Memorandum Order No. 041, series of 2018.

As defined in the order, the DDOSC-REC is the working group that is duly tasked to plan, implement, monitor, and evaluate programs and activities that will strengthen the role of research in the training of human resources in all campuses of the College.

Review Scope of Authority

The DDOSC-REC reviews and monitors research involving human subjects and includes research on identifiable human material and data that are proposed to be done or conducted by faculty, staff, and students at the College. The committee may also review and monitor community-based researches that seek endorsement from the College, as well as research done in other institutions that do not have ethics review committees.

Functions of the DDOSC-REC

The following are the functions of the DDOSC-REC:

1. To determine that all proposed interventions, particularly the administration of devices or procedures under development, are acceptably safe to be undertaken in humans or to verify that another competent Research Ethics Committee has done so;

2. To determine that the proposed research is scientifically sound or to verify that another competent Research Ethics Committee has done so;

3. To ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and in practice;

4. To consider the qualifications of the investigators, including education in the principles of research practice and the conditions of the research site, with a view to ensuring the safe conduct of data gathering; and

5. To keep records of decisions and to take measures to follow up on the conduct of ongoing research projects.

LIST OF ACRONYMS

AE	Adverse Effects
AO	Administrative Order
CHED	Commission on Higher Education
COI	Conflict of Interest
CV	Curriculum Vitae
DA	Department of Agriculture
DDOSC	Davao de Oro State College
DOST	Department of Science and Technology
DSWD	Department of Social Welfare and Development
FGD	Focus Group Discussion
IB	Investigator Brochure
ICC	Indigenous Cultural Communities
ICD	Informed Consent Document
ICF	Informed Consent Form
IP	Indigenous Peoples
IPRA	Indigenous Peoples' Rights Act
IRR	Implementing Rules and Regulations
MOA	Memorandum of Agreement MOU Memorandum of Understanding
NCIP	National Commission on Indigenous Peoples
NEC	National Ethics Committee
PCHRD	Philippine Council for Health Research and Development
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
REC	Research Ethics Committee
REMB	Regional Ethics Monitoring Board
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reactions
TOR	Terms of Reference
TWG	Technical Working Group

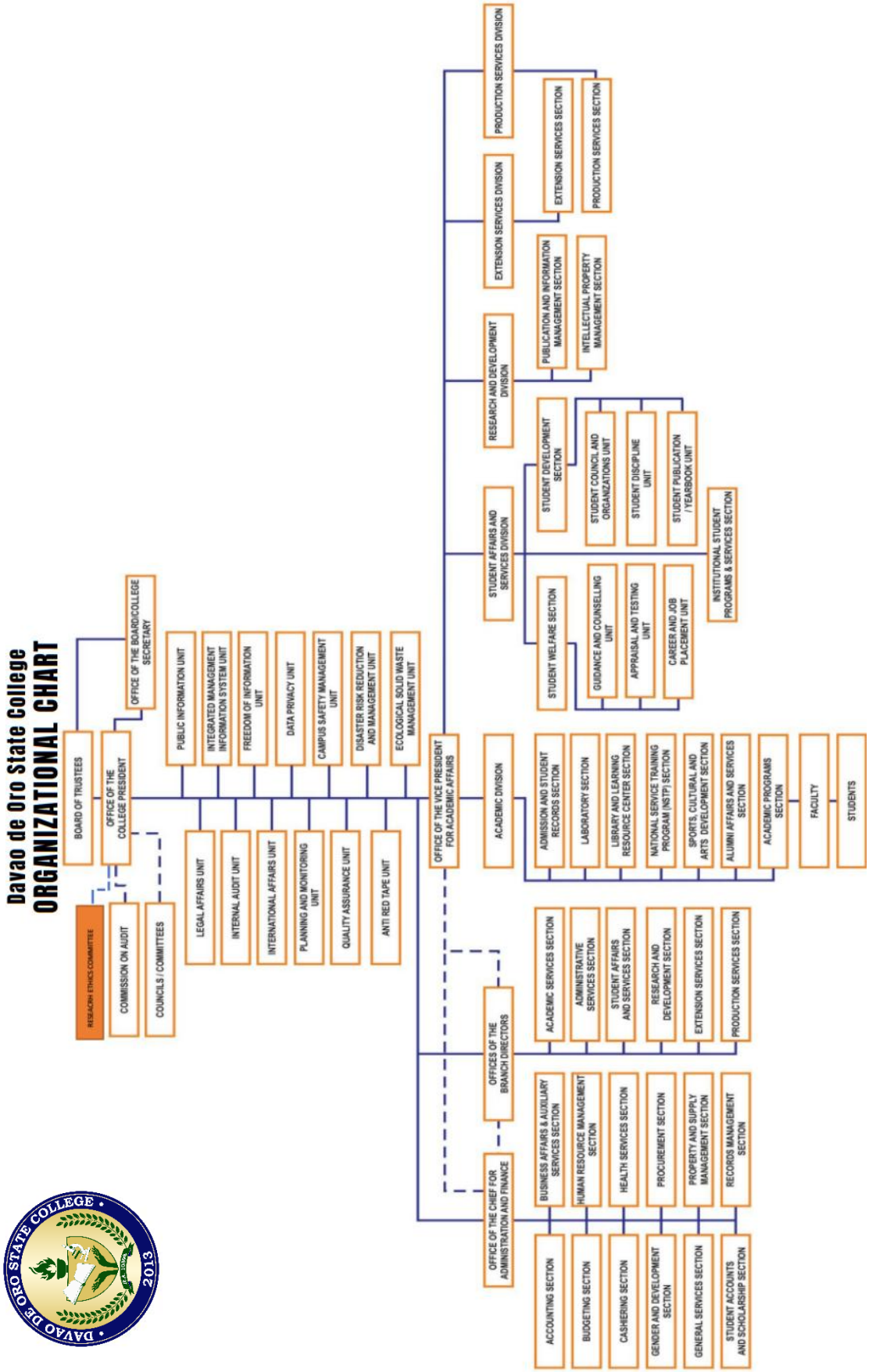


Figure 1. DDOSC Institutional Organizational Structure

Figure 2. DDOSC-REC Organizational Structure

REPUBLIC OF THE PHILIPPINES
DAVAO DE ORO STATE COLLEGE
COMPOSTELA, DAVAO DE ORO

RESEARCH ETHICS COMMITTEE
SOP TEAM

JUANITA C. LEOPOLDO, DBA
Leader

KENNY JIM M. GAMBONG, LPT
Member

LILYBETH M. MATUNHAY, PhD
Member

JERRY JAKE B. HANGGAM
Member

Figure 3. SOP Team

Figure 4. **DDOSC-REC Process Flow**

STANDARD OPERATING PROCEDURES

STATEMENT OF POLICY

The establishment of the DDOSC-REC and the recent recognition for PHREB Level 2 accreditation will streamline and harmonize the process of ethics review in the College, on all campuses. This strategic move provides a strongly supportive and enabling environment for research. In addition, it will maximize the utilization of its human and institutional resources and ensure that all types of protocols are reviewed in accordance with international and national requirements. This document constitutes the formal statement of the DDOSC-REC applicable to faculty, personnel, and students within the oversight of the Office of the College President. This is designed to provide an ethical framework and guidance to the conduct of this oversight and anticipates the variety of situations that can occur in the conduct of research.

PURPOSE

To ensure the protection of the rights, well-being, and safety of human participants in research, and ensure satisfactory review of submitted research protocols by following standard operating procedures.

SCOPE

The DDOSC-REC implements a policy of oversight of institutional research. Institutional research includes any research conducted by faculty members, staff, and students. All institutional research protocols must undergo ethics review as stipulated.

GENERAL POLICIES AND GUIDELINES FOR ETHICS REVIEW:

1. All research proposals/protocols shall be submitted for ethics review.
2. All research protocols must undergo technical review prior to submission to DDOSC-REC.
3. Protocols carrying technical approvals must be endorsed by the department /unit through the respective research advisers to DDOSC-REC for ethics review.
4. Investigators must submit evidence of technical review. Applications for ethical approval without prior technical review will not be processed and will be returned to the researcher.
5. All research protocols should include a section on Ethical Considerations that details the ethical issues and corresponding measures to reduce the risks to human participants.

On Mandatory Registration:

Mandatory registration of research within the college is an expression of the College's rights to:

1. Monitor and regulate the utilization of its facilities
2. Monitor and regulate the use of its name
3. Protect its intellectual property

Registration of research is a college requirement, and noncompliance is subject to college rules and regulations.

Submission requirements for continuing review:

1. No amendments in an approved protocol shall be implemented without prior approval by the DDOSC-REC; and
2. Operational definitions of revisions, amendments, and resubmissions will follow existing DDOSC-REC SOPs on continuing review.

Review and Approval of Study Protocols

1. Research protocols will be reviewed based on the following elements:
    - Completeness of documentation requirements
    - Scientific soundness
    - Ethical considerations
    - Conflict of interest
    - Informed consent
2. Review procedure will be in accordance with the REC-approved SOP;
3. A protocol submission package shall be accomplished by the investigator/researcher and submitted to the research adviser.
4. The research adviser shall process the submitted documents and forward the submission package to REC.
5. The REC Secretariat shall screen the protocol and assign the protocol package to the members of the appropriate Review Panel.
6. The Review Panel may request additional information to be included in the study protocol and related documents, such as the informed consent form, to ensure the protection of the rights, safety, and well-being of the study participants.
7. Approved protocols duly signed by the Panel Chair shall be submitted to the research adviser by the REC Secretariat for release to the Researcher.
8. The conduct of approved research protocols is subject to monitoring by the DDOSC REC.
9. Responsible and ethical conduct of approved research is the shared responsibility of the investigator/researcher, the research adviser, and the DDOSC-REC to promote and protect the safety and well-being of the research participants.
10. Monitoring is done through various activities initiated by the DDOSC-REC panel that approved the implementation of the research protocol in accordance with DDOSC-REC SOP, such as:
    10.1. Continuing review, including review of interval/progress report, incident report, or proposed amendment;
    10.2. Site visit;
    10.3. Review of reports on protocol non-compliance;
    10.4. Review of completion/final report;
    10.5. Review of requests for early termination;
    10.6. Review of adverse events, as applicable.
11. Ethical clearance can be suspended or withdrawn from studies found to be noncompliant or in violation of the REC terms of approval upon determination of non-compliance or violation by the approving REC Review Panel.

DDOSC-REC SPECIAL GUIDELINES

1. All undergraduate student research must be conducted under the supervision of a faculty member/research adviser.

2. Undergraduate students shall ONLY be allowed to do the following types of research:
   2.1 Research that is of minimal risk
   2.2 Research that fulfills the criteria for an expedited review
   2.3 Non-therapeutic or non-interventional
   2.4 Research that will compromise the security, safety, and well-being of students shall not be allowed.

3. Student research can be discontinued at any time by the faculty adviser or the DDOSC-REC if deemed harmful to the study participants.

4. Research involving vulnerable populations must have the following minimal requirements:
   4.1 The purpose of the research is to obtain knowledge relevant to the particular health needs of the vulnerable subject population
   4.2 The assent of each subject has been obtained to the extent of his or her capabilities, and a prospective participant's refusal to participate is always respected
   4.3 In the case of incompetent participants, informed consent is obtained from the legal guardian or a duly authorized person
   4.4 The degree of risk attached to interventions that are not intended to benefit the individual participant is low and commensurate with the importance of the knowledge to be gained.

5. Vulnerable populations are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. These include, but are not limited to, the following:
   5.1 Children and the elderly
   5.2 Persons suffering from mental or behavioral disorders
   5.3 Pregnant and breastfeeding women
   5.4 Prisoners and drug users
   5.5 Persons being recruited by those who teach, treat, or employ them
   5.6 Very sick and desperate patients
   5.7 Underdeveloped communities, including Indigenous communities

6. Human participants in research are entitled to lodge their complaints or grievances related to research protocols approved by DDOSC-REC Panels. Examples are:
   6.1. Research misconduct (dishonesty, disrespect, coercion, physical "abuse" not in keeping with research procedures, breach of privacy, etc.);
   6.2. Deviation from procedures enunciated in the informed consent;
   6.3. Misinformation; and
   6.4. Injuries (physical, psychological, mental) perceived to be due to the study procedures.

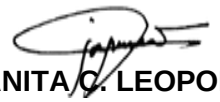
7. The DDOSC-REC does not have police powers, but in view of its oversight functions, it can directly receive complaints or grievances relevant to research protocols approved by DDOSC-REC Panels and address such complaints from participants in coordination with the approving panel.

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval Section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval Section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

All activities of the REC should have corresponding standard operating procedures (SOPs) that cover all its operations. These SOPs shall be regularly reviewed for possible revision every three (3) years or as the need arises. SOPs deemed inefficient, irrelevant, or unimplementable shall be revised upon recommendation of the REC Chair or any REC member and staff.

PURPOSE

The purpose of this SOP is to provide clear instructions for the process of writing, reviewing, amending, and distributing SOPs of REC, and to provide for continuous quality improvement of the research review process per national and international standards.

SCOPE

This set of instructions applies to the creation of the SOPs of the REC. It starts with the selection and appointment of members of the SOP team and ends with the filing and uploading to the RECs website and other platforms of the newly revised/created SOPs.

WORKFLOW CHART

Step	Activity	Person Responsible	Timeline
1	Appointing the SOP Team	College President	Every three (3) Years
2	Request for Creation of New SOP	SOP Team	
3	Assessing and Approving the Request for Creation of SOP	REC Chair	
4	Drafting New/Revising SOP	SOP Team	One (1) Month
5	Reviewing and Approving the Draft SOPs	College Academic Council & College President	One (1) Month

DETAILED INSTRUCTIONS

1. **Appointing the SOP Team**
   The College President appoints qualified individuals to be members of the Standard Operating Procedures (SOP) Team. REC Admin Staff prepares the Office Order that authorizes the SOP Team to periodically review the SOPs.

2. **Request for Creation of New SOP**

All SOPs of the REC are subject to review every three (3) years by the DdOSC- SOP Team. But anytime a REC Member or Administrative Staff sees the need to create a:

2.1. List all procedures in the operations of the DdOSC - Research Ethics Committee (REC). Write down all the important procedures in the operations of the DdOSC Research Ethics Committee (REC), from submission of protocol for review up to post-review processes and filing of protocol and protocol-related documents, and other REC files, and updating of the website of the REC and its e-databases.

2.2. Based on Section 2.1, make a list of SOPs and determine which ones exist and which ones have to be created.

3. Assessing and Approving the Request for Creation/Revision of SOP

3.1. The SOP creation was discussed during the Research and Extension Coordinators' Meeting (interim SOP and REC Team) with the Regional Ethics Monitoring Board, chaired by Dr. Alvin Concha, on February 14, 2018, held at Southern Philippines Medical Center, REMB Conference Room, Bajada, Davao City. The team drafted/created the SOP for presentation to the College President for approval by the Board of Trustees (BOT) of the College.

3.2. For proposed SOP creations/revisions once approved by the DdOSC-Research Ethics Committee (REC), the SOP Team Leader, as the initiator, prepares the DdOSC-REC Form 4.5-Document Creation/Revision Request Form (DCRR) to be created or revised. The DCRR forms are endorsed by the REC Chair and forwarded to the College President for final approval by the College's Governing Board.

4. Drafting New SOP/Revising Existing SOPs

4.1. The REC Chair meets with the SOP Team for discussion and assignment of tasks. SOP Team Members revise the SOPs assigned to them and create the SOPs that are not in the list identified in Step 2.2.

4.2. Coding, Format, and Layout of SOPs

To harmonize the coding of DdOSC-Research Ethics Committee (REC) SOPs, Q (for Quality) is added to SOP. QSOP stands for Quality Standard Operating Procedure. Each SOP should be given a number and a title that is self-explanatory and easily understood. The SOP Team will assign a unique code number with the format SOP XX/YY.W to each SOP item. XX is a two-digit number assigned specifically to the SOP. YY is a two-digit number identifying the version of the SOP, and W is a one-digit number identifying the version of the SOP with minor changes. The number of versions should start from 01, and the W should start with 0, for example, SOP 01/01. 1 is the SOP number 01 version 01 with one minor revision, ie, 01.1.

A. An SOP is written according to the following format (Standard Operating Procedure Template):
   - Header
   - Statement of Policy
   - Purpose of the SOP
   - Scope
   - Procedure Flowchart which describes the steps/tasks in the procedure, the person/s responsible, and the documentary evidence of the action taken

- Detailed Instructions – describes the steps/tasks in the procedure in more detail. The steps in the Detailed Instructions must be in harmony with or correspond to the steps in the Procedure Flowchart
- Forms/Templates/Checklists Related to the SOP – form/template/checklists used in performing the tasks that are described in the SOP
- SOP Document History – which describes the changes from the original version to the next (Note: The SOP Document History is included only in the master copy, not in the reproduced copies or those uploaded on the website.)
- Footer

The list of Acronyms will be unified and placed at the front of the Manual of SOPs, while the unified Glossary and the List of References used in writing/revising all SOPs will be placed at the back of the manual.

B. The header has the following elements:
- Institutional seal or logo
- Name of Ethics Review Committee
- SOP title
- SOP identifier/code number
- Effectivity date

C. The footer has the following elements:
- Version that was superseded by the newly revised version
- Version date of the superseded SOP
- Page in relation to the total number of pages in the Manual of SOPs
- Title of the Manual

4.3 The draft of the newly created or revised SOPs will be discussed with the rest of the SOP Team before these are presented to the REC for further comments. If an SOP supersedes a previous version, the previous SOP version and date, plus the main changes in the SOP, shall be described in the section on SOP Document History and in the Document Creation/Revision Request form.

5. Reviewing and Approving the Draft SOPs

5.1. The final draft will be submitted to the SOP Team Leader for review. If the SOP Team Leader is the one who revised/created the SOP, another member of the SOP Team reviews it.

5.2. After the completion of the final review, the SOP Team Leader informs the REC Admin Staff to include the presentation of the newly created or revised SOPs in the agenda of the DdOSC-REC Meeting.

5.3. Draft SOPs are presented to the DdOSC-REC Members for deliberation and approval. Further revision of the draft SOPs is made during the meeting until the final form meets the approval of the members.

5.4. The REC Admin Staff prepares a clean copy of the final version of the SOP approved by the REC for the signature of the person who prepared the SOP, the SOP Team Leader who reviewed the SOP, and the REC Chair who endorses the SOP for approval.

5.5. The aforementioned copy of the final version of the SOP is presented to the College President for final approval.

5.6. The Effectivity Date of the SOP is based on the date of approval of the College President.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DdOSC-REC Form 4.5 - Document Creation/Revision Request Form (DCRR)

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	Omitted the BOT as one of the approving bodies of the SOP. Changed the term “noted“ to “Approved“ in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	• Revised timeline for steps 4 and 5. • Added “Title of the Manual“in section 4. C of the detailed instructions.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

The REC must be constituted in accordance with the national and international ethical guidelines on the composition of the Research Ethics Committee – multidisciplinary and multi-sectoral membership, representation from both genders and across the College's campuses, and the inclusion of persons with backgrounds appropriate to the nature of the research it reviews.

PURPOSE

The purpose of this SOP is to describe the selection and appointment of the members and officers of REC to ensure that these comply with DDOSC standards, and to describe the responsibilities of its members, officers, and staff in their appointment documents.

SCOPE

This set of instructions applies to the selection and appointment of members and officers of the REC, the description of their qualifications, and their responsibilities. It starts with the identification of Members of the REC and ends with the completion and organization of the documents in the Membership File.

WORKFLOW CHART

Step	Activity	Responsible Person	Timeline
1	Identification of Members of the REC	REC Chair and Members	1 month
2	Nomination of REC New Members & Officers	REC Chair and members	
3	Final Approval of the Appointment of REC Members	College President	
4	Completion and Organization of the Documents in the Membership File	REC Staff	

DETAILED INSTRUCTIONS

1. **Identification of Members of the REC**

1.1. REC Members are selected by their interest and/or scientific knowledge and expertise, as well as by their willingness to volunteer the necessary time and effort required of them.

1.1.1. The membership shall include persons whose primary concerns are in the natural sciences, teacher education, business, agriculture, entrepreneurship, and social sciences areas. At least one member who is non-affiliated with

Davao de Oro State College (DdOSC) and at least one non-scientist who does not have an academic function.

1.1.2. It is recommended that the REC include a person who will represent the interests and concerns of the community. There should also be a good representation of both genders to promote gender sensitivity in its review procedures.

1.1.3. Any one of the REC members can nominate a new member. The members submit the name of their nominee to the REC Chair, who presents it during the REC meeting for discussion and recommendation. The REC Chair presents the nominees to the Executive Committee meeting and recommends the same to the College President for approval. Once the appointment is approved, the REC Admin Staff files the documents.

1.2. **Types of Membership**

1.2.1. **Regular Members**

The DDOSC-Research Ethics Committee review panel has at least seven (7) regular members, at least one layperson or non-scientist, and at least one non-institutional member. Regular members are required to attend at least 50% of the meetings in a year.

1.2.2. **Alternate Members**

Alternate members are individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to meet the quorum requirement when the latter cannot attend. Like the regular members, the term of appointment of the members is three (3) years, renewable upon the recommendation of the REC Chairperson and the approval of the College President.

1.2.2.1. Alternate members are pooled. They attend Full-board meetings of the REC to replace a regular member who cannot attend or when expertise is needed. Alternate members may be requested to be the primary reviewer of the protocol for the full panel or expedited review.

1.2.2.2. When designated as the primary reviewer, an alternate member, like a regular member, has to attend the review panel meeting where the protocol is assigned to undergo initial review. And like a regular member, the alternate member can vote during deliberation of a protocol and is also responsible for reviewing the resubmitted protocol, protocol amendment, continuing review, and the final report of the protocol that was initially reviewed as the primary reviewer.

2. Nomination of REC Members and Officers

2.1. REC Members

2.1.1. The DDOSC Executive Committee is responsible for the final recommendation of prospective members of the REC.

2.1.2. The REC Chair shall appoint a member secretary in conformance with the other members.

2.2. REC Chair

The REC Chair should be a highly respected individual within or outside the institution, fully capable of managing the REC and matters brought before it with fairness and impartiality.

2.2.1. The REC Chair shall be appointed by the college president based on the fitness and competency requirements, as outlined in the PHREB guidelines for the establishment of the Research Ethics Committee.

1.1.2. The REC Chair must have the following qualifications:
- 1.1.2.1. Good personal standing;
- 1.1.2.2. An affiliated member of REC;
- 1.1.2.3. Researcher of at least one (1) research project conducted in the past five (5) years;
- 1.1.2.4. Has training in Basic Research Ethics and the advanced course in Research Ethics in the past three (3) years; and
- 1.1.2.5. Must be a member of a Research Ethics Committee for at least three (3) years.

3. Final Approval of the Appointment of REC Members

3.1. The REC Admin Staff prepares the Appointment Letter of the selected member using the standard DDOSC-REC Form 1.1 – Letter of Appointment. Each appointment letter specifies the responsibilities of the DDOSC-REC members and Officers. The term of appointment of the members is three (3) years, renewable upon the recommendation of the REC Chairperson and the approval of the College President.

3.2. The REC Staff transmits the appointment letters to the College President for approval and facilitates the filing and furnishes copies to the appointed members. In the appointment letter preparation, the REC Admin Staff shall be guided by the following responsibilities of the members and officers:

3.3. Responsibilities of the REC Members:

- 3.3.1. Serve as Primary Reviewers for research protocol within their area of expertise and as General Reviewers of all research (students, faculty, and staff research) deliberated at the Full Panel/Technical Review of each college in all campuses;
- 3.3.2. Review and assess research protocol and informed consent document using the Protocol and ICF Assessment form.
- 3.3.3. Submit on time the completed Protocol and ICF Assessment Forms, and Individual Reviewer Decision form relative to the review of the research protocol;
- 3.3.4. Participate in REC review meetings, and vote for full approval, suspend approval pending compliance with suggested revisions, or disapproval of the research protocols;
- 3.3.5. Conduct expedited reviews on behalf of the REC when so designated by the REC Chair;
- 3.3.6. Perform post-approval review procedures relative to the review of research protocol or protocol-related documents where they are the primary reviewers (whether by expedited or full-board review), such as – application for Protocol Amendment, Protocol Deviation/Violation report,

Study Site Monitoring Visit for protocols of more than minimal risk, RNE Reports, Closure/Final Report;

3.3.7. Monitor serious adverse event reports related to protocols where they are the primary reviewers and recommend appropriate action(s);
3.3.8. Confirm at all times to the legal and ethical principles accepted by the REC;
3.3.9. Attend basic and continuing education on Research Ethics;
3.3.10. Perform other tasks requested by the REC Chair,
3.3.11. The lay members of REC shall focus on the subject recruitment process, the informed consent process, and the informed consent document to ensure that there is no undue influence on the research subject, especially by their health care provider. Lay members should ask themselves if they would give consent to participate if they or close members of their families are recruited as research subjects;
3.3.12. The Primary Reviewer is responsible for the intensive review of the protocol and informed consent document (ICD) assigned to him/her, including protocol-related documents such as recruitment materials, case record forms, etc. The Primary Reviewer is also responsible for the review of resubmitted documents, for pre-approval review, and for review of post-approval submissions; and
3.3.13. The REC alternate members have the same responsibilities as the regular members.

3.4. Responsibilities of REC Chair:

3.4.1. Sets agenda and presides over REC meetings;
3.4.2. Designates the REC member to be the primary reviewer of a protocol where the member has the related expertise (whether by the full board or expedited review), and ensures that the aforementioned REC member does not have a conflict of interest;
3.4.3. Does oversight review of the initial review decision of the review panels and emails back concurrence or comments, if any, to the REC Admin Staff;
3.4.4. Designates REC Member to act on behalf of the REC Chair on particular REC matters where the Chair has COI;
3.4.5. Manages complaints from study participants, authorities, or the general public;
3.4.6. Ensures that all REC Members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter;
3.4.7. Obtains administrative and logistics support for the sustained operations of the REC, submits the annual report on the accomplishments of REC to the Research Extension and Development Office and the Office of the College President;
3.4.8. Ensures that the REC is perceived as fair and impartial, immune from pressure either by the institution's management, the investigators whose protocols are brought before it, or other professional and nonprofessional groups;
3.4.9. Represents the REC in various fora;
3.4.10. Does oversight review of the results of protocol/protocol-related review by members of the REC and emails concurrence or comments back to REC Staff; and

3.4.11. Manages review panel and the matters brought before it according to the regulations pertaining to the rights and welfare of research subjects and the REC's related SOPs.

3.5. Responsibilities of DDOSC-REC Member Secretary:

3.5.1. Prepares provisional meeting agenda in coordination with the DDOSC-REC Staff;
3.5.2. Ensures that panel members completely fill out necessary forms used for the review of submissions;
3.5.3. Finalizes the meeting minutes in coordination with the REC Staff; and
3.5.4. Performs internal quality audit of the Review Panel's protocol files, meeting agenda, and minutes.

4. Completion and Organization of the Documents in the Membership File

4.1. When the Appointment Letter is already approved by the College President, the REC Member is requested to complete the Membership File.

4.2. Membership Requirements

4.2.1. Upon the acceptance of the appointment, and before assuming the responsibilities as a REC Member, the new member shall sign and date the appointment letter indicating his/her willingness to assume his/her responsibilities, and the confidentiality and disclosure of the conflict-of-interest agreement related to the review of a research protocol where the member is involved. The member must disclose in writing any interest or involvement – financial, professional, or otherwise in a research proposal under review.

4.2.2. The REC Member is also required to submit an updated, signed, and dated curriculum vitae using the prescribed format, and the completed Training Record, including a photocopy of relevant training certificates.

4.3. Content of Membership File

4.3.1. The Membership File contains:

4.3.1.1. Appointment letter signed and dated by the appointee
4.3.1.2. Updated curriculum vitae that is signed and dated by the member
4.3.1.3. The CV is updated every time the appointment is renewed.
4.3.1.4. DDOSC-REC Form 1.4 – Training Record Form and related Certificates of Training
4.3.1.5. DDOSC-REC Form 1.3 - Confidentiality and Disclosure of Conflict-of-Interest Agreement signed and dated by the member.

4.4. The REC Staff creates one membership file for each member and files the abovementioned documents in each member's membership file.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 1.1 Letter of Appointment/Statement of Responsibilities of REC Member
2. DDOSC-REC Form 1.2 Curriculum Vitae
3. DDOSC-REC Form 1.3 Confidentiality and Disclosure of Conflict of Interest Agreement

4. DDOSC-REC Form 1.4 Training Record Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2019 May 17	Lilybeth M. Matunhay and other REC members	Revised the Policy statement by ensuring its consistency with the present constitution of the REC.
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Changed the responsible people in step 1; • Added provisions in the selection and nomination process. • Added definition of an alternate member; and • Change the term “noted“ to Approved“ in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	• Changed the final recommending body from the Academic Council to the Executive Committee; • Indicated the duration of the appointment of the members in the detailed instructions.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

The REC Administrative Staff must have an academic background appropriate to the nature of their work.

PURPOSE

The purpose of this SOP is to describe the selection and appointment of the Administrative Staff of DDOSC-REC to ensure that these comply with DDOSC standards, and to describe the responsibilities of individual staff.

SCOPE

This set of instructions applies to the selection and appointment of staff of DDOSC-REC, the description of their qualifications, and their responsibilities. This begins with the initial screening and ends with filing of administrative staff files.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Initial Screening	REC Chair	1 week
2	Appointment	College President	
3	Responsibilities	REC Admin Staff	
4	Filing of administrative staff files	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Initial Screening**
   Upon vacancy of the Admin Staff or the Admin Staff position, the REC Chair shall facilitate the initial screening process consistent with the procedures adopted by the Davao de Oro State College – Human Resource Management Office and the minimum requirements and qualifications for the REC Administrative Staff.
   1.1 The REC Admin Staff shall have the following qualifications:
   - be a graduate of a relevant college course;
   - be proficient in using Word, spreadsheet, database, and email applications;
   - be proficient in communication, writing, and note-taking;
   - be proficient in writing, assessing, and editing research-related documents;
   - have a certificate in the Basic Research Ethics course; and
   - have at least one year of relevant experience in organizing, filing, and archiving research hardcopy and softcopy files.

2. **Appointment**
   After thorough review and consideration, the College President signs the appointment of the administrative staff upon recommendation of the Personnel Selection Board, and the staff shall undergo the basic orientation for newly hired personnel.

3. Responsibilities

3.1. The REC Admin Staff shall have the following responsibilities:

3.1.1. Determines review category under the supervision of the REC Chair;
3.1.2. Assists investigators in accomplishing complete related requirements and the application submission process;
3.1.3. Coordinates meetings for the REC, prepares agenda in consultation with the REC Chair, and ensures there is an appropriate composition of members to make a quorum according to national and international requirements;
3.1.4. Maintains electronic database of REC Members;
3.1.5. Prepares and edits abstracts from research protocol or reports;
3.1.6. Performs various clerical duties, including typing, answering phones, and preparing correspondence, and among others. Writes, reviews, and edits communications, announcements, issuances, and documents of the REC;
3.1.7. Attends and participates in research conferences, scientific symposia, and other meetings;
3.1.8. Generates reminder notices to principal investigators to ensure that they are aware of timelines/deadlines; and
3.1.9. Performs other tasks assigned by the REC Chair;
3.1.10. Organizes and schedules REC meetings and makes reservations for conference rooms and prepares resources needed for the meetings;
3.1.11. Monitors and orders supplies for the office and for training events, orders food and beverages for meetings and training events, and creates invoices and payment vouchers for community members;
3.1.12. Prepares and distributes research protocols/protocol-related documents to REC Members and/or independent consultants for review;
3.1.13. Routes documents for signatures;
3.1.14. Checks the submitted research and facilitates completion by communicating with investigators, REC members, and independent consultants;
3.1.15. Organizes an effective and efficient tracking procedure for each proposal received;
3.1.16. Keep, organize, and file hard copies of documents submitted to the REC;
3.1.17. Keeps and updates an electronic database of submission details and revisions;
3.1.18. Maintains REC office research files and performs routing and filing of daily REC correspondence and related attachments, creates new files and labels;
3.1.19. Coordinates schedules, logistics, and participants of meetings and trainings;
3.1.20. Schedules regular cleaning of the research office; and
3.1.21. Performs other tasks assigned by the REC Chair.

4. Filing of Administrative Staff Files

4.1 Identifying and managing the Administrative Staff files

a. Administrative staff signed and dated the Appointment Letter and Terms of References (DDOSC-REC Form 1.1);
b. Signed and dated Curriculum Vitae (DDOSC-REC Form 1.2), and the signed and dated Confidentiality and Declaration of COI Agreement (DDOSC-REC Form 1.3) in the file, and Training Record Form (DDOSC-REC Form 1.4).
c. The REC Secretariat shall see to it that their records are updated at least every three (3 years).

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

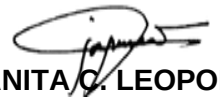
1. DDOSC-REC Form 1.1 - Letter of Appointment/Statement of Responsibilities of REC Admin Staff
2. DDOSC-REC Form 1.2 - Curriculum Vitae
3. DDOSC-REC Form 1.3 - Confidentiality and Disclosure of Conflict-of-Interest Agreement
4. DDOSC-REC Form 1.4 - Training Record Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Changed the responsible people in step 1; • Edited the Forms/Template associated with this SOP's section; and; • Change the term "Noted" to Approved" in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Conflict of interest shall be managed in the selection and appointment of the REC Chair and Members, in assigning primary reviewers, and during full panel meetings. REC Chair, Members, and Staff shall remove themselves from the review process when they or close family members have a conflict of interest.
2. The REC Chair, Members, and Staff shall not divulge sensitive information regarding protocols, meeting deliberations, and related matters.

PURPOSE

The purpose of this SOP is to provide instructions to REC members and other concerned parties on complying with confidentiality and conflict-of-interest requirements.

SCOPE

This set of instructions applies to persons involved in protocol review or attending review meetings, or allowed to peruse protocol and protocol-related documents of the REC, and to all those who are required to accomplish the document on Confidentiality and Disclosure of Conflict-of-Interest Agreement

WORKFLOW CHART

Step	Activities	Responsible Person	Timeline
1	Completing the Confidentiality and Disclosure of Conflict-of-Interest Agreement Template	REC Admin Staff	1 day during the REC meetings
2	Clarifying the Contents and Signing of the Confidentiality and Disclosure of Conflict-of-Interest Agreement	REC Chair and REC Member	
3	Filing the Documents	REC Admin Staff	Within 1 day after signing the COI

DETAILED INSTRUCTIONS

1. **Completing the Confidentiality and Disclosure of Conflict-of-Interest Agreement Template**

1.1 Confidentiality Agreement

1.1.1 REC Members and Staff and anybody who participates in the review and deliberation of study protocols (e.g., consultants and guests) shall sign a DDOSC-REC Form 1.3 - Confidentiality and Conflict of Interest Agreement for the following reasons:

- To protect against the misuse of confidential information, particularly that which is proprietary and discriminatory in nature; and

- To protect and maintain the integrity of the REC.

1.1.2 To ensure the maintenance of confidentiality of information, the following must be observed:

- All REC Members and Staff shall sign the Confidentiality Agreement upon receipt of their appointment papers and before they start their work reviewing study protocols.
- All REC Members who receive copies of the study protocol and related documents must return these to the REC Admin Staff right after the review.
- The REC Admin Staff keeps a log of members who received and returned the documents, and the kind of documents that they received or returned.
- The REC keeps only one copy of each study protocol and related documents. The remaining copies should be returned to the proponent/principal investigator or shredded.
- Non-REC members, except regulatory or accreditation officers, are not allowed access to study protocols and related documents without the written approval of the REC Chair.
- Requests for observation and attendance in review panel meetings by non-REC members are reviewed and approved by the REC Chair. The principal investigator/s whose protocol will be reviewed have to approve the request as well. Should the request be approved by both the REC Chair and the principal investigator, the guest signs and dates the DDOSC-REC Form 1.6 Confidentiality Agreement for Guest/Observers.
- Consultants sign the Confidentiality Agreement before they are allowed access to study documents for review, or before the start of the meeting.
- If the investigator submitting the study protocol for review feels that a REC Member has a potential conflict, the REC Member is encouraged to write the REC Chair requesting that the member be excluded.
- The REC Office is always locked. Only REC Admin Staff and REC Members are allowed access to the office.
- Only the REC Chair and the REC Admin Staff know the password to the computer, and are allowed to use the computer in the REC office.

1.2 Disclosure of Conflict-of-Interest Agreement

1.2.1 In externally-funded studies, no REC member may participate in the review of a protocol in which the member has a COI – real or perceived, except to provide the information requested by the REC.

1.2.2 For investigator-initiated studies, REC Members who are also the Research Coordinators of the same college/campus may be allowed to participate in the deliberation with majority approval of the REC. But these members cannot participate in the review decision-making. Said approval shall be documented in the minutes of the meeting.

1.2.3 In order to avoid real or perceived COI, the following are observed:

- No participating REC member may hold an equity interest (partnership, stocks, profit-sharing) in the organization requesting the review.
- No participating REC member may be paid more than reasonable compensation or receive more than reasonable benefits for REC-related activities.

- No REC member may receive compensation or benefits under the arrangements that could impede or discourage objective decision-making on behalf of the human study participants.
- COI may also include a faculty advisor or member of a student's dissertation committee; a REC member involved in an independent and potentially competing research program, cases where access to funding or intellectual information may provide uncompetitive advantage, or cases where the member's personal biases/strong beliefs may interfere with his or her impartial judgment.

1.2.4 When the REC Chair has a COI related to a particular protocol, s/he designates the REC Secretary or any Member of the REC to determine the review category and the primary reviewers. The REC Chair shall always consider COI in selecting primary reviewers.

1.2.5 During full panel meetings, the REC Chair routinely asks for the presence of COI among reviewers before starting the review procedure. The REC will decide on the extent to which members with a conflict of interest may participate in the review or deliberation of the said research protocol, depending on the nature of the COI. Such should be noted in the minutes of the REC meeting.

2. Clarifying the Contents and Signing of the Confidentiality and Disclosure of Conflict-of-Interest Agreement

2.1 Members direct questions to the REC Chair or Administrative Staff if any part of the document is not clear. The REC Chair or REC Admin Staff explains or clarifies the contents of the document.

2.2 Members sign and date both copies of the document before the Administrative Staff. They return one copy of the form to the Administrative Staff and keep the other copy for their file.

3. Filing the Documents

3.1 The REC Admin Staff files a copy of the signed Confidentiality and Disclosure of COI Agreement in the Member's Membership File.

3.2 The Confidentiality and Declaration of COI Agreement signed and dated by the Independent Consultants shall be kept in their respective file together with their appointment letter and updated CV.

3.3 Documents in the file of an Independent Consultant who has been dropped from the roster are scanned and stored in the e-folder for inactive Independent Consultants. The hard copy is transferred to the archive and retained for 3 years. After 3 years, the file is logged (in the Log of Files for Shredding) and shredded.

3.4 The DDOSC-REC Form 1.6 Confidentiality Agreement for Guest/Observer Attendees during review meetings shall be kept in one appropriately labeled folder – 1 folder per year. The said folder is transferred to the archive at the end of the year and retained in the archive for 3 years. After 3 years, the file is logged out and shredded.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 1.3 - Confidentiality and Conflict of Interest Agreement
2. DDOSC-REC Form 1.6 -Confidentiality Agreement for Guest/Observer Attendees

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Changed the responsible people in step 1; • Added provisions in the selection and nomination process and • Change the term “noted“ to Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
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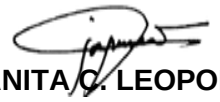
APPROVAL

Prepared by:



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Approved by:

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	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-05/01.4
	TRAINING OF MEMBERS AND STAFF	Revision No.	3
		Effectivity:	02/13/2026

STATEMENT OF POLICY

Training on research ethics, ethical considerations in different types of research methodologies, and the REC's ethical review process shall be provided to REC Members and Staff when they join the Committee and periodically thereafter.

PURPOSE

The purpose of this SOP is to make REC Members and Staff aware that attendance in basic and continuing training is part of their responsibilities.

SCOPE

This set of instructions applies to the training requirements for REC Members and Staff and to how the REC can ensure they are provided.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Requiring REC Members and Staff's Attendance in Basic Research Ethics Training REC Members and Staff	REC Chair through the Learning and Development Unit	(depends on schedules/ per invitation as scheduled)
2	Recommending Continuing Professional Education for both regular and alternate REC Members and Staff through participation in meetings, conferences, and training courses	REC Chair	
3	Documenting REC Members' and Staff's Participation in Continuing Professional Education and Filing the Documents in the Membership File	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Requiring REC Members and Staff's Attendance in Basic Research Ethics Training REC Members and Staff**

   1.1. New REC Members and Staff

   Upon appointment to the REC, a new Member (whether regular or alternate) or Staff member undergoes an orientation process, either individually or as a group. The REC Chair may issue travel orders to committee members for training, seminars, and orientations.

   1.1.1 The orientation covers the following topics:

   - REC Members'/Staff's responsibilities;
   - Confidentiality and disclosure of no Conflict-of-Interest agreement;
   - REC review process and use of Protocol and ICF Assessment forms; and

- All SOPs in the Manual of SOPs of the REC, especially those on the review procedures.

1.1.2 All regular and alternate REC Members and Staff shall attend the Basic Course on Research Ethics.

1.1.3 The new member/staff receives CDs or internet links that contain, at a minimum, the following materials:

- National Ethical Guidelines for Health Research (PNHRS, 2011);
- Standards and Operational Guidelines for Ethics Review of Health-Related Research with Human Participants, (WHO, 2011);
- Declaration of Helsinki (WMA, 2013);
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002);
- International Ethical Guidelines for Epidemiological Studies (CIOMS, 2009);
- ICH Topic 6: Guidelines for Good Clinical Practice (GCP) (European Agency for the Evaluation of Medicinal Products, 1997).

1.2 All Regular and Alternate REC Members and Staff

1.2.1 Educational Sessions

Periodically, the REC Chair organizes brief education sessions held at the beginning of scheduled meeting. Relevant information can also be emailed to REC Members.

1.2.2 Attendance in training courses

In addition, opportunities to attend relevant local and national workshops and conferences are also offered.

2. Providing Continuing Professional Education for both regular and alternate REC Members and Staff through participation in meetings, conferences, and training courses

2.1. The REC Chair endeavors to send its members/staff to participate in local and national research ethics seminars, conferences, and workshops by allocating office funds for this purpose.

2.2. The REC Chair coordinates with other agencies in the conduct of an annual research ethics forum for purposes of updating REC Members/Staff on current issues and concerns in the conduct of research involving human subjects

2.3. The REC Members/Staff are encouraged to do their own readings or internet searches in the field of research ethics. They are encouraged to share this information with the other members.

2.4. The REC Chair identifies training/continuing education opportunities for REC members/staff. This may be sourced from other RECs, Research Ethics Networks, and other channels.

2.5. The REC Members who participate in research ethics training courses or seminar workshops, either through personal or through REC efforts, are encouraged to:

- Share information with other members during REC meetings; and
- Distribute photocopies/e-copies of relevant materials to the other members.

2.6. Should there be CHED-recognized research organizations that organize advanced courses on Research Ethics. REC Members are encouraged to attend these courses.

3. Documenting REC Members' and Staff's Participation in Continuing Professional Education and Filing the Documents in the Membership File

3.1. All regular and alternate REC Members/Staff regularly update their Training Records. They should submit proof of attendance in these training or continuing professional education sessions – e.g., certificates of training to the REC Staff for filing.

3.2. All regular and alternate REC Members/Staff:

- Fill in DDOSC-REC Form 1.4 - Training Record of REC Member to record the training course, workshop/conference activities that they attended in chronological order;
- Make a copy of the form;
- Keep the original form as their record; and
- Give the duplicate copy to the REC Staff to keep in the REC Membership File.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

DDOSC-REC Form 1.4 - Training Record of REC Member

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Changed the responsible people in step 1. • Changed the term “noted“to Approved“ in the approval section.
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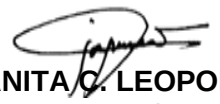
APPROVAL

Prepared by:



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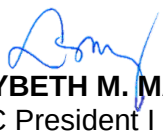
Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Selected primary reviewers shall have expertise related to the nature of the study protocol. When none of the REC members has the required expertise, the REC shall engage an independent consultant to clarify technical and specialized aspects of the protocol. Independent consultants shall possess both subject-matter expertise relevant to the protocol and adequate familiarity with ethical principles governing research involving human participants, consistent with NEGRIHP standards.
2. The REC shall maintain a pool of independent consultants whose specialty corresponds with the nature of protocols received for review and which the REC membership lacks. These consultants may be affiliated or non-affiliated.
3. There shall be written procedures requiring terms of reference for and the signing of confidentiality and declaration of Conflict-of-Interest agreements by the consultants. Conflict of Interest shall also be managed in the selection of consultant/s needed to facilitate the review of the protocol.

PURPOSE

The purpose of this SOP is to describe the procedures for engaging the services of an independent consultant to ensure compliance with accepted standards.

SCOPE

This set of instructions pertains to the selection, appointment, and engagement of independent consultants to review research protocols when REC membership lacks the relevant expertise. This begins with assessing the need for an Independent Consultant and ends with requesting the services of the Independent Consultant.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Assessing the Need for Independent Consultants and Seeking Approval for Contracting Their Services	REC Chair	7 days
2	Inviting Independent Consultants	REC Admin Staff	
3	Appointing an Independent Consultant	College President	
4	Sign and Secure Confidentiality and Conflict of Interest Agreement for Independent Consultants	Independent Consultant	
5	Filling of Appointment and Related Documents	REC Admin Staff	
6	Requesting an Independent Consultant's Services	REC Admin Staff	

7	Using the Consultant's Protocol Assessment Report during Deliberation on the Research Protocol	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Assessing the Need for Independent Consultants and Seeking Approval for Contracting Their Services**
   1.1. Considering the nature of the protocol/s for review, the REC Chair scouts for independent consultants.

   1.2. Independent consultants engaged by the REC shall meet the following minimum qualifications:
      1.2.1. Demonstrated academic, professional, or technical expertise relevant to the nature of the research protocol under review;
      1.2.2. Prior experience in research, protocol review, or REC-related activities, or completion of recognized training in research ethics (e.g., Basic Research Ethics Training or equivalent);
      1.2.3. Familiarity with national and international ethical guidelines for research involving human participants, including but not limited to the NEGRIHP.

   1.3. The REC Chair, based on the needs of the office for an independent consultant, identifies and presents the need for contracting the services of an independent consultant to the College President and requests approval. The honorarium for the independent consultant shall be paid by the College.

2. **Inviting Independent Consultants**
   2.1. After obtaining the College President's approval to seek the services of independent consultant/s, the REC Chair instructs the REC Admin Staff to prepare the DDOSC-REC Form 1.5 – Invitation to Independent Consultant.

   2.2. The letter of invitation includes the following:
      - Terms of Reference (TOR) – duration of consultancy, general overview of deliverables;
      - Honorarium;
      - Request for a copy of the consultant's DDOSC-REC Form 1.2 Curriculum Vitae (CV);
      - Secure Confidentiality and Conflict of Interest Agreement with signature and date signed.

   2.3. The REC Chair signs and dates the letter of invitation.

   2.4. The REC Admin Staff sends the letter by email and/or courier, and follows up on the response from the addressee.

3. **Appointing an Independent Consultant**
   3.1. The REC Admin Staff prepares the Appointment Letter, presents this to the REC Chair for review, and endorses this to the College President for approval and signature.

3.2. The REC Admin Staff sends the Appointment Letter to the consultant for a signature, together with the Confidentiality and Declaration of Conflict-of-Interest Agreement form for filling up and for a dated signature.

3.3. The REC Admin Staff maintains the list of the pool of independent consultants with their expertise and dates of appointments (as consultants-on-call) and ensures that all the necessary documents for the contracting of their services are on file.

4. Sign and Secure the Confidentiality and Conflict of Interest Agreement

The REC Admin Staff prepares DDOSC-REC Form 1.3 – Confidentiality and Conflict of Interest Agreement to be signed by the Independent Consultants during the appointment and before the meeting review begins, and the DDOSC-REC Admin Staff secures the DDOSC-REC Form 1.3 for filling and furnishes one (1) copy of DDOSC-REC Form 1.3 to the Independent Consultant.

5. Filing of Appointment and Related Documents

5.1. The REC Admin Staff files the independent consultant's signed and dated Appointment Letter, signed and dated CV, and the signed and dated Confidentiality and Declaration of COI Agreement on file.

5.2. The REC Admin Staff shall see to it that the independent consultant's CV is updated at least every three (3) years.

6. Requesting an Independent Consultant's Services

6.1. If the consultant agrees to assist in the review, the REC Admin Staff emails the Notice of Review and sends a text message to alert the latter of the said email.

6.2. Notice of Review reminds the consultant when the accomplished Protocol Assessment & ICF Forms are to be emailed back to the REC Admin Staff, and that his/her presence during the review meeting is requested. The Notice of Review also contains a reminder of the deliverables:

- Mode of presenting the report – written report only, or written report and oral presentation and discussion during a REC meeting; and
- Date, time, and venue of the REC meeting, if the consultant is required to present the report.

6.3. The REC Admin Staff provides the consultant with the protocol package for review and the Protocol and ICF Assessment Forms at least two (2) weeks before the review meeting. The REC Admin Staff must ensure that the documents do not contain the names of the researchers and the sponsor.

7. Using the Consultant's Protocol Assessment Report during Deliberation on the Research Protocol

7.2 The REC Admin Staff follows up on the consultant's report as per the TOR. If the consultant is not required to present his/her assessment report, the concerned Review Panel Chair will present the report and initiate discussion. The concerned Review Panel will decide if the information provided by the consultant is adequate for it to decide on the protocol. If the information is adequate, the Review Panel decides on the protocol. If the information is inadequate, the Review Panel lists the information items it still requires to come up with a decision, and the REC Admin

Staff sends this list to the consultant, or, depending on the availability of the consultant, it may require the latter's presence in the next Review Panel's meeting.

7.3 If the TOR requires the consultant's presence during the meeting, the presentation of the consultant's evaluation report must be included in the agenda of the concerned Review Panel's Meeting. The consultant can participate in the discussion but cannot vote.

7.4 The minutes of the meeting where the consultant's protocol assessment report was presented should be explicit in documenting the decision on the report – whether it was adequate and was accepted, or more information is needed, or whether the services of another consultant are required.

7.5 The REC Admin Staff ensures that the consultant's protocol assessment report becomes a permanent part of the research protocol file.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 1.2 Curriculum Vitae (CV)
2. DDOSC-REC Form 1.3 Confidentiality and Conflict of Interest Agreement
3. DDOSC-REC Form 1.5 Invitation to Independent Consultants

HISTORY OF SOP

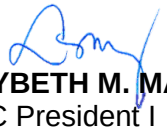
Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2018 Dec 03	Lilybeth M. Matunhay and other REC members	Added step 4 in the Workflow and in the Detailed Instruction.
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Change the term "noted"to "Approved" in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	Clarified that the Chair will identify the independent consultant.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval Section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Added the specific criteria for selecting an Independent Consultant in section 1 of the Statement of Policy and section 1.2 of the Detailed Instructions. • Updated the signatories in the Approval Section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Application for ethical review of a protocol shall be standardized, transparent, facilitated, and accepted only when all required documents are complete and appropriate. The REC shall comply with the prescribed timelines for ethics review and shall not exceed four weeks from receiving the complete submission to the initial review. In cases where submissions are found to be incomplete, the REC Staff shall formally notify the researcher of the deficiencies and require the submission of the missing or incomplete documents within seven (7) working days from receipt of the notification.

PURPOSE

This SOP describes the procedure for how REC manages study initial protocol submission packages, including REC actions, review classifications, and panel review assignments, to ensure timely responses and actions.

SCOPE

This set of instructions applies to the submission of protocol and protocol-related documents for review by the REC. This begins with receiving the Protocol Package for Initial Review and ends with distributing the protocol package for review by the Review Panel Members and/or Independent Consultants.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving the Protocol Package for Initial Review	REC Admin Staff	1-2 days from the receipt of the protocol
2	Verifying Completeness of Protocol Package	REC Admin Staff	
3	Assigning Protocol Code Number if Submitted for the First Time and Recording in the Log of Incoming Documents and the Protocol Database	REC Admin Staff	
4	Determining the Type of Review, Review Panel, and Primary Reviewers	REC Chair	1-3 days
5	Filing the Document in the Protocol Folder and Updating the Protocol Database and Protocol File Index	REC Admin Staff	1-2 days
6	Distributing the protocol or protocol-related document to Review Panel Members and/or Independent Consultant, if applicable	REC Admin Staff	1 week before the meeting

DETAILED INSTRUCTIONS

1. **Receiving the Protocol Package for Initial Review**
   The REC Admin Staff receives the protocol submission for initial review from the researcher or representative.

2. **Verifying Completeness of Protocol Package**
   2.1 The REC Admin Staff ensures completeness of submitted forms and documents using the DDOSC-REC Form 2.1 Application Form (Page 2-*submission checklist*) by marking missing items with a “check”.

   2.2 If the submission checklist is complete, proceed to 3.

   2.3 If the submission checklist is incomplete, the REC Secretariat shall make a photocopy of the accomplished Submission Checklist and return the incomplete documents, together with the copy of the Submission Checklist, to the Researcher or his/her authorized representative. The Researcher shall be formally notified of the deficiencies through email and/or other official communication channels of the REC and shall be given a specified period of seven (7) working days from receipt of the notification to submit the missing or incomplete documents. Resubmission of the required documents may be done in person or through the official REC email address, following the prescribed submission requirements.

   2.4 The original Submission Checklist, signed and dated by the applicant, shall be retained by the REC Secretariat for reference when the complete protocol package is resubmitted, whether submitted physically or electronically. Failure to submit the required documents within the prescribed timeframe shall result in the protocol being considered withdrawn from the review process, without prejudice to resubmission as a new application.

3. **Assigning Protocol Code Number if Submitted for the First Time and Recording in Log of Incoming Documents and Protocol Database**
   3.1 On the same day, upon receipt of the complete submission, the administrative staff checks if the protocol has the version number and date in the footer. If none, the Staff stamps the version number and date on the protocol and ICF and other protocol-related documents; and assigns the REC protocol code no. as follows and stamps this on the protocol and all related documents:
      3.1.1 REC Protocol Code no. stands for “SSS-MM-YYYY”, it will start with three digits for the sequence number (which starts at 001) of the protocol received for the day, followed by two digits for MM (e.g., 11 for November), and four digits stand for YY (e.g., the year 2012), which shall be reset annually.

   3.2 The REC Admin staff writes the REC Protocol Code No. and the date of submission in the space provided in the Review Application Form, and the Submission Receipt.

   3.3 The REC Admin Staff creates a new entry in the Protocol Database for the initial protocol submission using the new Protocol Number.

   3.4 The REC Admin Staff records the submission in the Log of Incoming Protocols.

3.5 The REC Admin staff requests that the researcher send an electronic copy of their completed submission package to the REC members.

4. Determining the Type of Review, Review Panel, and Primary Reviewers

4.1 Within two (2) weeks from the assignment of the REC protocol code number, the REC Chair then determines the type of review (whether exempt from review, expedited review, or full board review). The REC Chair or the designee, provided that they do not declare any conflict of interest, is the main person responsible for determining the type of review.

4.2 **EXEMPT**

4.2.1. Exempt from Review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by a designated member of the REC. “Exempt from Review” is a decision made by the REC.

4.2.2. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

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

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

4.2.3.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

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

4.2.3.2.2. The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

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

4.3 **EXPEDITED**

4.3.1. minimal/low-risk research that requires personal information;
4.3.2. about a topic that should not result in causing social stigma;
4.3.3. does not involve vulnerable populations;
4.3.4. retrospective studies using data from medical records;
4.3.5. studies using simple questionnaires without identifiers; and
4.3.6. laboratory research that uses anonymized human tissue/specimen

4.4 **FULL BOARD**

4.4.1. human health research involving medium to high risks to human participants;
4.4.2. intervention studies involving experimental treatments;
4.4.3. may involve vulnerable populations who should be protected; and

4.4.4. involves private information that may cause stigma

4.5 The REC Admin Staff assigns the protocol to the Review Panel on deck.

4.6 The REC Admin Staff provides the REC Chair with the names of suitable Primary Reviewers, including their availability to review. The REC Chair finalizes the choice of Primary Reviewers for the protocol.

5. **Filing the Document in the Protocol Folder and Updating the Protocol Database and Protocol File Index**
   Refer to QSOP27 Management of Active Files

6. **Distributing the protocol or protocol-related document to Review Panel Members and to the Independent Consultant**, if applicable
   The REC Admin Staff records the protocol/protocol-related document for distribution to members of the Review Panel and Independent Consultant in the Log for Outgoing Documents.

   6.1 If exempt, please refer to QSOP08 Exempt from Review.

   6.2 The REC Admin Staff emails the protocol/protocol-related document for review, a blank copy of the DDOSC-REC Form 2.3 – Protocol Evaluation Form, and DDOSC-REC Form 2.4 Informed Consent Evaluation Form at least one to two (2) weeks before the review meeting date.

   6.3 The REC Admin Staff also distributes print copies of protocol/protocol-related documents for review, blank Form 2.3 – Protocol Evaluation Form, and DDOSC-REC Form 2.4 – Informed Consent Evaluation Form to all members of the Review Panel and Independent Consultant (if one is called) at least one (1) week before the review meeting date.

   6.4 If for expedited review, refer to QSOP 09 Expedited Review.

   6.5 If for Full Panel review, refer to QSOP 10 Full Board Review.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 2.1 – Application Form
2. DDOSC-REC Form 2.2 – Summary Sheet
3. DDOSC-REC Form 2.3 – Protocol Evaluation Form
4. DDOSC-REC Form 2.4 – Informed Consent Assessment
5. DDOSC-REC Form 5.1 – Informed Consent Form
6. Log of Incoming Documents

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo,	First draft

		Rona C. Apolinario, and Rholey R. Picaza	
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Updated criteria for Exempt From Review. • Revised the statement policy. • Change the term "noted" to "Approved" in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	Revised the timeline for steps 1-5.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Clarified paragraph 3.1.1 to state that the protocol code sequence will be reset annually. • Revised the Statement of Policy to specify a timeframe for researchers to submit any missing documents; consequently, revised paragraphs 2.3-2.4 of the Detailed Instruction. • Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

All research directly involving human participants or the collection of private identifiable data pertaining to human participants shall be subject to REC review. There are researches, however, that have no to very low risk or have no direct interaction with human participants or data from human participants that can be exempted from review. The principal investigator shall not at any time decide if the study protocol should be exempted. As such, research protocols of this nature should be forwarded to the REC to get a certificate of exemption prior to commencing such.

PURPOSE

The purpose of this SOP is to describe research protocols that are exempt from review and outline the process for the determination of exemption.

SCOPE

This SOP applies to all research protocols that will satisfy the criteria for Exempt from Review. The SOP begins by reviewing study protocols applying for Exempt from Review and ends by filing the relevant documents in the Exempt for Review File and the e-Folder for that particular protocol.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Reviewing the study protocols applying for Exempt from Review	REC Chair	3-5 days
2	Issuing a Certificate of Exemption/Recommendation for Review	REC Chair	2 weeks after the application
3	Filing the relevant documents in the Exempt for Review File and e-Folder for that particular protocol	REC Admin Staff	1 week after the decision

DETAILED INSTRUCTIONS

1. **Reviewing the Study Protocols Applying for Exempt from Review**

   1.1. After the Admin Staff received and verified the completeness of the protocol documents as stated in the QSOP 07 Management of Initial Submissions, the REC Chair or the assigned reviewer, provided that they do not declare any conflict of interest, reviews the study protocol for exemption.

   1.2. The REC Chair or the assigned reviewer shall then evaluate the study protocol using DDOSC-REC Form 2.9 Exempt Reviewer Checklist before making a final decision.

1.2.1. If the assessment is exempt, there is no further action to be taken by the REC Chair or the assigned Reviewer, and the certificate of exemption will be issued.

1.2.2. If the assessment of the assigned reviewer is not for exemption, the latter makes a decision together with the REC Chair to reclassify the type of review as expedited or full board.

2. Issuing a Certificate of Exemption/Recommendation for review

2.1. The REC Chair or the assigned reviewer will be given two (2) weeks to recommend whether the study protocol can be exempted from review to the REC Administrative Staff. The Chair also reports this decision at the next Full Board meeting.

2.2. The REC Admin Staff shall prepare DDOSC-REC Form 2.7 Certificate of Exemption from Ethics Review, signed and dated by the REC Chair.

2.3. The REC Admin Staff shall ensure that the Certificate of Exemption is given to the principal investigator.

3. Filing the relevant documents in the Exempt for Review File and e-Folder for that particular protocol

The REC Admin Staff shall secure copies of the related documents filed in the Exempt for Review Files and update the e-database.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 2.7 Certificate of Exemption from Ethics Review
2. DDOSC-REC Form 2.9 Exempt Reviewer Checklist

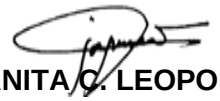
HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2018 Dec 03	Lilybeth M. Matunhay and other REC members	Indicated that the exemption does not need further action and need not be renewed.
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	• Added a second sentence in the Scope section to complete the information.

			• Revised paragraph 1.1 in the Detailed Instruction to refer to the QSOP 07Management of Initial Submissions. • Updated the signatories in the Approval section.

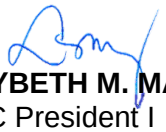
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Expedited review shall be applied to all study protocols that (1) involve human participants, (2) do not impose more than minimal risks or the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life, (3) do not have study participants belonging to a vulnerable group, (4) the study procedures do not generate vulnerability, (5) and are not exempt from review as determined by the REC Chair/Admin Staff.
2. The expertise of the reviewers shall match the nature of the protocol to be reviewed.
3. The presence of COI shall be considered in the selection of primary reviewers.
4. The REC shall comply with the College's prescribed timelines for ethics review and shall not exceed 2 weeks from the review of protocol to communication of the decision.

PURPOSE

This SOP provides instructions on the management, review, and approval of the expedited protocols.

SCOPE

This set of instructions applies to research protocols or other research-related documents submitted to the REC for expedited review. The SOP begins with the assignment of Reviewers or an Independent Consultant and ends with the inclusion of the Decision in the Meeting Agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Assignment of Reviewers or Independent Consultant/s	REC Chair	Within the day of receipt
2	Notification of Reviewers or Independent Consultant/s	Admin Staff	Within two (2) days
3	Provision of study documents and evaluation forms to the primary reviewers	Admin Staff	3-10 days upon receipt
4	Accomplishment and submission of evaluation forms	Primary Reviewers	
5	Consolidation and Finalization of review results	REC Chair	1-2 days
6	Communication of the review results to the researcher	REC Chair and Staff	
7	Filing of documents in the protocol file	Admin Staff	Within the day of communicating results/decisions
8	Inclusion of the Decision in the Meeting Agenda	REC Chair and Staff	

DETAILED INSTRUCTIONS

1. **Assignment of Reviewers or Independent Consultant/s**
   After the Admin Staff received and verified the completeness of the protocol documents as stated in the QSOP 07 Management of Initial Submissions, the Chair assigns members with the necessary expertise as primary reviewers (designating an independent consultant if such expertise is not present among the members), including a non-scientist member, to review the Informed Consent Process and Form.

2. **Notification of Reviewers or Independent Consultant/s**
   The Staff notifies the assigned primary reviewers and/or independent consultants of their assignment by email, requesting that they confirm their acceptance and availability within two (2) days.

3. **Provision of study documents and evaluation forms to the primary reviewers**
   The REC Staff gathers the pertinent documents for both the initial submission package and the post-approval submission packages. The documents, upon receipt of the acceptance/confirmation, will be sent to the primary reviewers and/ or independent consultants via email.

4. **Accomplishment and submission of evaluation forms**
   The primary reviewers and/ or independent consultants will be given a maximum of ten (10) days to review and fill out the evaluation forms comprehensively. The reviewers will submit the completed forms to the REC Staff via email.

5. **Consolidation and Finalization of review results**
   The Chair, with the help of the REC Staff, will consolidate and finalize the results of the review. In the event of differing opinions among the reviewers, the Chair has the final say on the review results.

6. **Communication of the review results to the researcher**
   (Refer to DDOSC-REC QSOP26 Communicating Decision)

7. **Filing of documents in the protocol file**
   (Refer to DDOSC- REC QSOP27 Management of Active Files)

8. **Inclusion of the Decision in the Meeting Agenda**
   The REC Member Secretary confers with the REC Admin Staff to include the decision of the expedited reviews in the meeting agenda for the presentation of the information to the Full Board Meetings

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 2.3 Protocol Evaluation Form
2. DDOSC-REC Form 2.4 Informed Consent Evaluation Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change

1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Change the term "noted" to "Approved" in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	Revised the timeline; and Added provisions for steps 1-5.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Revised section 1 of the Statement of Policy to define the term "Minimal Risk". • Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Full Board review shall be applied to all initial protocol submissions, to resubmissions of protocols/protocol-related documents that pose more than minimal risks to those conducted among vulnerable populations (e.g., children, indigenous people, differently-abled persons, institutionalized individuals, and those in marginalized communities), and post-approval submissions for major protocol amendments, major protocol violation report and RNE report as determined by the REC Chair or any REC Member designated by the REC Chair.
2. Quorum in a REC meeting is operationally defined as the presence of 50% + 1 of the REC Members. Quorum also requires the presence of at least one Non-scientist/Lay member and a non-affiliated member. In the absence of these required members, there is no quorum.
3. Presence of COI shall be considered in the selection of primary reviewers.
4. The REC shall comply with prescribed timelines for ethics review and shall not exceed two (2) weeks from review of protocol to communication of the decision.

PURPOSE

This SOP describes the procedure for the REC to review protocols and protocol-related documents by full board review to ensure compliance with technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.

SCOPE

This set of instructions applies to protocol and protocol-related documents submitted to the REC for full-board review. This starts with the assignment of reviewers or an independent consultant and ends with the filing of the protocol and protocol-related documents and the updating of the electronic protocol database.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Assignment of Reviewers or Independent Consultant/s	REC Chair	Within the day of receipt
2	Notification of Reviewers or Independent Consultant/s	Admin Staff	Within two (2) days
3	Provision of Study Protocol and Protocol-related Documents and Assessment Forms to Reviewers/Independent Consultants	Admin Staff	Upon receipt of confirmation/ acceptance
4	Provision of Protocol and Protocol-related documents to the rest of the committee members	Admin Staff	Three (3) days before the meeting

5	Managing Disclosed COI of Reviewer/s	REC members /Review Chair and Presiding Member	On the day of the meeting
6	Presenting the Protocol Summary	Principal Investigator	
7	Presenting the Collated Review Findings of the Primary Reviewers	Primary Reviewers	
8	Discussing Technical and Ethical Issues	REC members & REC Chair	
9	Summarizing Discussion Points and Recommendations	REC Chair	
10	Decision making	REC members & REC Chair	
11	Communicating the Decision and Recommendations	Admin Staff	Within three (3) days after the meeting
12	Retrieving Protocol and Protocol-related Documents from Reviewers	Admin Staff	Within 1 day of communicating with the Researcher
13	Filing the Protocol Package and Updating the Protocol Database and protocol-related documents	Admin Staff	

DETAILED INSTRUCTIONS

1. **Assignment of Reviewers or Independent Consultant/s**
   After the Admin Staff received and verified the completeness of the protocol documents as stated in the QSOP 07 Management of Initial Submissions, the Chair assigns members who have the necessary expertise as primary reviewers (designates an independent consultant in case such expertise is not present among members), including a non-scientist member, to review the Informed Consent Process and Form.

2. **Notification of Reviewers or Independent Consultant/s**
   The Staff notifies the assigned primary reviewers and/ or independent consultants about their assignment by email with the request that they confirm their acceptance and availability within two (2) days.

3. **Provision of Study Protocol and Protocol-related Documents and Assessment forms to Reviewers/Independent Consultants**
   Upon receipt of confirmation/acceptance, the Admin Staff prepares copies of the protocol and/or protocol-related documents, as well as assessment forms, for delivery to the primary reviewers and/or independent consultants via email.

4. **Provision of Protocol and Protocol-related documents to the rest of the committee members**
   The Admin Staff provides the rest of the members of the REC with an executive summary of the study proposal (included among the submitted documents in the application package) three (3) days before the committee meeting, at the latest.

5. **Managing Disclosed COI of the Reviewer**

5.1. Using the prepared script, the REC Chair/Presiding Member declares the start of the REC meeting.

5.2. If a REC Member discloses COI relative to the protocol on deck for review, the REC Chair asks the committee whether the said Member shall be allowed to participate in the discussion or not.

5.3. Generally, in sponsor-initiated studies, the REC Member is not allowed to participate in the deliberation and is requested to leave the meeting room.

5.4. In an individual-initiated study, COI may arise when the REC Member is the Research Coordinator of the college/campus where the researcher belongs. In this case, subject to the decision of the committee, the REC Member may participate in deliberations but shall not participate in decision-making. This should be noted in the meeting minutes.

6. Presenting the Protocol Summary

6.1. When the Researcher is Faculty or staff, the faculty/staff presents a brief summary of the study using the guidelines for summary presentation.

6.2. In cases where the Researcher from external agencies cannot come to present the protocol summary, the Primary Reviewer will present the protocol summary.

6.3. The REC Chair asks the REC members if they wish to ask clarificatory questions to the researcher.

6.4. After the clarificatory questions are answered, the Researcher/s are requested to leave the room while the reviewers discuss the protocol.

7. Presenting the Collated Review Findings of the Primary Reviewers

7.1. The Primary Reviewer presents a summary of their assessment (based on the collated review findings from the completed DDOSC-REC Form 2.3 - Protocol Evaluation Form and DDOSC-REC Form 2.4 Informed Consent Assessment Form submitted before the meeting). In a protocol where an independent consultant was called in, the Independent presents the protocol assessment.

7.2. The flow of the discussion follows the review elements cited in the DDOSC-REC Form 2.3 - Protocol Evaluation Form and DDOSC-REC Form 2.4 - Informed Consent Assessment Form. In addition to these elements, the primary reviewers should ensure the study protocol's compliance:

- Facilities and infrastructure of participating sites
- Community involvement and benefits from the study, and if relevant, to consider – community consultation; involvement of local researchers and institutions in the study protocol design, analysis, and publication of the results; contribution to the development of local capacity for research and treatment; feedback of the results of the study; and benefit sharing.

7.3. After the presentation of the Primary Reviewer, the REC Chair asks the lay member to present the assessment of the ICF in terms of the language of the ICF – no jargon, simple, and easy to understand.

8. Discussing Technical and Ethical Issues

After the presentation of the Primary Reviewers, the REC Chair and other members weigh their opinion for or against the issues raised by the Primary Reviewers. The other REC members may also raise technical and ethical issues that are not included in the Primary Reviewers' presentation.

9. Summarizing Discussion Points and Recommendations

When all issues raised have been discussed and resolved, the REC Chair/designee summarizes the discussion points and the recommendations using the encoded minutes projected on the screen.

10. Decision making

10.1. The REC Chair/designee checks for a quorum before every decision-making. The voting will start if there is a quorum. Only qualified panel members can vote. Consultants and observers cannot vote.

10.2. All REC Members, including the REC Chair, tick the Individual Reviewer's Decision Form with any one of the following decisions:

10.2.1. Protocol Amendments, Continuing Review, and Study Closure/Final Report

- Approve
- Clarification/Additional documents required
- Disapprove

10.2.2. Protocol Deviation/Violation Report

- Acknowledged
- Additional information required
- Corrective action required

10.2.3. SAE Report

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

10.2.4. Early Study Termination

- Approve
- Request further information
- Recommend further action
- Pending, if major clarifications are required before a decision can be made

10.3. The REC Admin Staff collects the completed Protocol Evaluation Forms from the REC Members.

10.4. The REC Chair/designee counts the votes per decision category and notes the decision made by the panel. The number of votes per decision category shall be reflected in the meeting minutes.

11. Communicating the Decision and Recommendations

(Refer to DDOSC-REC QSOP26 Communicating Decision)

12. Retrieving Protocol and Protocol-related Documents from Reviewers

12.1. REC Admin Staff retrieves protocol/s and protocol-related documents from the reviewers.

12.2. REC Admin Staff shreds the extra copies of protocol packages or protocol-related documents in investigator-initiated studies. For externally-funded-initiated studies, the extra copies of the protocol package/Investigator's Brochure are returned to the PI. If these are not picked up from the REC office within a month, the documents are shredded.

13. Filing the Protocol Package and Updating the Protocol Database and protocol-related documents.

13.1. For active protocol filing, please refer to QSOP 27 Management of Active Files.

13.2. For updating database entries, see QSOP 30 on Maintenance of Protocol Database.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

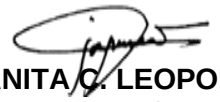
1. DDOC-REC Form 2.3 Protocol Evaluation Form
2. DDOC-REC Form 2.4 Informed Consent Evaluation Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Change the term FULL PANEL into FULL BOARD. • Change the term "noted" to "Approved" in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members and staff	• Added provision no. 2 on the Statement of Policy. • Revised and added provisions for steps 1-4.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-11/01.3
	REVIEW OF RESUBMITTED PROTOCOL	Revision No.	3
		Effectivity:	02/13/2026

STATEMENT OF POLICY

1. Application for ethical review of a protocol shall be standardized, transparent, and accepted only when documents are complete.
2. Resubmission of the revised protocol shall be accepted for review, provided all the recommended revisions have been complied with.
3. The REC shall comply with DDOSC-prescribed timelines for ethics review and shall not exceed 2 weeks from resubmission of protocol to communication of the decision.

PURPOSE

This SOP provides instructions for managing and re-reviewing resubmitted research protocols by the REC.

SCOPE

This set of instructions covers the review of resubmitted protocols that were initially reviewed by the REC and begins by determining the due date of the resubmitted protocol and ends by including the review decision for the Final Study Reports in the Meeting Agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Determining the Due Date of Resubmitted Protocol	Primary Reviewer	20 days after receiving the notification
2	Receiving Resubmission	REC Admin Staff	3-5 days upon resubmission
3	Verifying Completeness of Protocol Package	REC Admin Staff	
4	Reviewing Resubmission by Full Board or Expedited Review and Communicating the Decision to the Researcher	Primary Reviewer	
5	Filing the documents	REC Admin Staff	Within 1 day after the review
6	Including the Review Decision in the Meeting Agenda	REC Chair	

DETAILED INSTRUCTIONS

1. **Determining the Due Date of Resubmitted Protocol**
   1.1. The researcher will be given twenty (20) days to comply with the necessary recommendations given by the Panel. Protocols that are not resubmitted within

twenty (20) days of the date of notification following the initial review shall be dropped from the review process and archived. (Refer to QSOP 28 Archiving of Terminated, Inactive, and Completed Files.)

2. Receiving of Resubmission

2.1. The REC Admin Staff receives the submission for resubmission from the Researcher or representative.

3. Verifying Completeness of Protocol Package

3.1. REC Admin Staff reviews resubmitted protocol and protocol-related documents for completeness. The Admin Staff ensures the completeness of submitted forms and documents using the Submission Checklist.

3.2. For resubmitted protocol (after revision as per REC recommendations) or protocol-related document (Protocol Resubmission Form, Informed Consent Form, Informed Assent form, Case Report Form, recruitment materials, etc.), the REC Admin Staff must ensure that the version number and date are indicated in the footer and the revised parts of the document are highlighted.

3.3. If the submission is incomplete, make a photocopy of the accomplished Submission Checklist and give it to the principal investigator or his/her representative, together with the incomplete documents.

3.4. If resubmitted protocol and protocol-related documents are complete, REC Admin Staff logs the document in Log of Incoming Document/Communications and creates a new resubmission entry within the protocol details entry of the original protocol. (For updating of database entries, see QSOP 30 on Maintenance of Protocol Database.)

3.5. The type of re-review for resubmitted protocols (expedited or full board review) is determined during the REC meeting or Expedited Review Meeting of the initial protocol.

3.6. Administrative Staff forwards the resubmitted protocol and protocol-related documents to the REC Chair and Primary Reviewers.

4. Reviewing Resubmission by Full-board or Expedited Review and Communicating the Decision to the Researcher

4.1. The Primary Reviewers and the concerned REC review documents under consideration.

4.1.1. For Full Board Review, refer to DDOSC-REC QSOP 10 Full Board Review

4.1.2. For Expedited Review, refer to DDOSC-REC QSOP 09 Expedited Review

4.1.3. For the communication of the decision, please refer to DDOSC-REC QSOP 26 Communicating Decisions.

5. Filing the documents

Please refer to QSOP 27 – Management of Active Files.

6. Including the Review Decision in the Meeting Agenda

Please refer to QSOP 12 – Preparation of Meetings.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 2.8 Protocol Resubmission Form

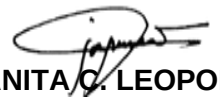
2. Other pertinent documents/Forms.

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. For the efficiency and effectiveness of DDOSC-REC operations, preparation for REC meetings shall be standardized and systematized.
2. Notice of the meeting shall include the agenda and shall be distributed to all concerned at least three (3) working days prior to the date of the meeting.

PURPOSE

This SOP describes the procedure for preparing for a REC meeting to ensure quorum and conduct a quality protocol review.

SCOPE

This set of instructions applies to the preparation of the meeting agenda and the conduct of all DDOSC-REC meetings – whether regular or special to ensure efficient and effective meetings. This starts with the REC Chair & Members' determination of the Type of Meeting and ends with the filing of the meeting agenda. This begins with the determination of the Type of Meeting and ends with the filing of the Meeting Agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Determination of the Type of Meeting	REC Chair & Members	1 week before the meeting review
2	Preparation of the Draft Meeting Agenda	REC Admin Staff	
3	Finalization of the Provisional Meeting Agenda	REC Chair & Admin Staff	1 day
4	Arrangements for the REC Meetings	REC Admin Staff	At least three (3) days before the meeting date
5	Distribution of Notice of Meeting	REC Admin Staff	
6	Filing of the Meeting Agenda	REC Admin Staff	Within 1 day after the scheduled meeting

DETAILED INSTRUCTIONS

1. **Determination of the Type of Meeting**
   - 1.1. **Regular Meeting**
     - 1.1.1. A regular meeting is conducted every last Friday of the month.
     - 1.1.2. The following submissions and matters shall be discussed during a Regular Meeting, as applicable:
       - 1.1.3. Initial protocol submissions requiring Full Board Review

1.1.4. Resubmissions of protocols previously reviewed by the Full Board, including those requiring major revisions
1.1.5. Continuing review submissions, including annual progress reports
1.1.6. Final reports of completed studies
1.1.7. Amendments that do not qualify for expedited review
1.1.8. Reports of deviations, violations, and non-compliance requiring Full Board deliberation
1.1.9. Appeals of REC decisions
1.1.10. Results from the Expedited Review (for information)
1.1.11. Protocols that were granted exemption from review (for information)
1.1.12. Operations-related matters, for information or approval, as necessary.

1.2. **Special/Emergency Meeting**

1.2.1. This meeting is called by the REC Chair in consultation with the REC members if there is an increase in the number of protocols that need to be reviewed, or if there is an urgent concern that needs to be acted upon, like a related to intervention, an urgent complaint from study participants, or notice of early study termination, and similar concerns.

1.2.2. For the REC Special or Emergency Meeting, this meeting is also called outside the regular meetings by the REC Chair to discuss urgent administrative matters or other purposes deemed urgent by the Chair.

1.3. **Full Board Review Meeting**

1.3.1. A full board review meeting is called upon when there is/are protocol/s submitted that need/s immediate review, which meets the expedited review category.

1.3.2. The following types of submissions shall be reviewed during a Full Board Review Meeting:
1.3.2.1. Initial protocol submissions requiring Full Board Review
1.3.2.2. Resubmissions of protocols previously reviewed under Full Board Review that:
1.3.2.2.1. Required major revisions, or
1.3.2.2.2. Were disapproved and subsequently appealed or revised
1.3.2.3. Protocol amendments that involve:
1.3.2.3.1. Increased risk to participants
1.3.2.3.2. Significant changes in study design, population, or procedures
1.3.2.4. Continuing review submissions that raise ethical or compliance concerns
1.3.2.5. Final reports that require Full Board assessment
1.3.2.6. Other submissions as determined by the REC Chair to require Full Board deliberation

2. Preparation of the Draft Meeting Agenda

2.1. One (1) week before the scheduled meeting date, the Administrative Staff reviews the Log for Incoming Protocols submitted during the month and lists the documents for review. Documents for full-board review are identified, and the meeting agenda is drafted following the prescribed format for DDOSC-REC Form 4.1 Meeting Agenda

2.2. One (1) week before the scheduled meeting date, and in consultation with the REC Chair, the REC Admin Staff prepares the draft of the meeting agenda following the prescribed format for the DDOSC-REC Form 4.1 Meeting Agenda.

3. Finalization of the Provisional Meeting Agenda

3.1. The REC Admin Staff emails the draft meeting agenda to the REC Member Secretary for review. The REC Member Secretary reviews the draft meeting agenda and, if needed, makes any necessary changes.

3.2. The REC Admin Staff emails the draft meeting agenda to the REC Chair for review. The REC Chair reviews the draft meeting agenda and, if needed, makes changes to produce the provisional meeting agenda.

3.3. The provisional meeting agenda shall be approved during the meeting. If this is approved without any changes, the provisional agenda becomes the approved agenda. If there are changes, the provisional meeting agenda is revised. This becomes the approved meeting agenda. Printed and digital copies of the provisional and approved meeting agenda are kept in their respective folders by year.

4. Arrangements for the REC Meetings

The following steps are followed by the REC Admin Staff to prepare for the meeting:

4.1. The REC Admin Staff makes a room reservation on the scheduled meeting date and time.

4.2. The REC Admin Staff makes arrangements for the logistics of the meeting attendees.

4.3. For REC Meetings:

4.3.1. REC Admin Staff verifies if REC Members received the protocols and protocol-related documents for full-board review.

4.3.2. Copies of protocol-related documents for full review, like the RNE Report, application for major Protocol Amendment, Major Protocol Deviation Report, Notice of Early Study Termination, and the like, are forwarded to the Primary Reviewers who did the initial review.

4.3.3. At least three (3) days before the meeting date, the REC Admin Staff reminds the Primary Reviewers/Independent Consultant to email their completed Protocol and ICF Assessment forms if they have not done so.

4.3.4. The REC Admin Staff prepares the REC Chair's (or Presiding Officer's) summary of discussion points and the Protocol Review kit containing extra copies of the Protocol and ICF Assessment Forms, the Individual Review Decision forms, the Initial Review Announcement form, and the attendance sheet.

4.4. The REC Admin Staff checks the room to make sure that the room is clean and that the digital light projector and projector screen are available and in good running condition.

4.5. The REC Admin Staff also checks the digital voice recorder to ensure that it is functional and the battery is fully charged.

4.6. If the REC meeting is conducted through an online platform, the REC Admin Staff ensures that the chosen virtual meeting platform is accessible to all REC Members and invited participants. The REC Admin Staff schedules the online meeting, generates the meeting link, and disseminates it to the REC Members, along with the agenda and relevant meeting materials, in advance.

4.7. Prior to the meeting, the REC Admin Staff verifies the functionality of the audio and video features, screen-sharing capability, and recording function of the platform, if applicable. During the meeting, the REC Admin Staff provides technical assistance as needed, ensures attendance is properly documented, and secures the electronic recording and meeting files for proper documentation and archiving.

5. Distribution of Notice of Meeting Agenda

The REC Admin Staff distributes the Notice of Meeting with the provisional meeting Agenda for the REC or for the REC Members at least three (3) working days before the scheduled meeting date. Text messages shall also be sent to the concerned REC Members for them to check their emails to ensure the attainment of a quorum

6. Filing of the Notice Meeting Agenda

6.1 The REC Admin Staff keeps e-copies of the provisional meeting agenda in separate e-folders intended for the Meeting Agenda. The REC Admin Staff also keeps an e-copy of the approved Meeting Agenda.

6.2 The REC Admin Staff files a paper copy of the approved meeting agenda in separate REC administrative files per year.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 4.1 Meeting Agenda.
2. Log of Incoming Documents

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Revised the Policy statement; • Finalized the definition of the Type of Meeting; • Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Amended Step 1. Added paragraph 1.1.2 & 1.3.2 to include the type of

			submissions that will be discussed during a meeting. • Added paragraphs 4.6 and 4.7 to include the procedure for online conduct of the meeting. • Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-13/01.2
	PREPARING THE MEETING AGENDA	Revision No.	2
		Effectivity:	02/13/2026

STATEMENT OF POLICY

The meeting agenda shall be based on the submissions received, at the latest, two (2) weeks before the scheduled regular meeting. Submissions received after the prescribed deadline of two (2) weeks before the scheduled regular meeting shall be considered late submissions and shall not be included in the agenda of the scheduled regular meeting. All late submissions shall be deferred and reviewed during the next scheduled regular meeting of the REC. Only in exceptional cases, where the REC Chair determines that the submission involves urgent ethical, safety, or regulatory concerns, may a late submission be acted upon outside the regular meeting schedule through a Special or Emergency Meeting.

It shall follow an established template for the meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

PURPOSE

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

SCOPE

This SOP describes how the REC determines what items should be included in the agenda of regular and special meetings. This SOP begins with preparing the draft meeting agenda and ends with filing the final meeting agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Preparation of the draft meeting agenda	Staff and Member Secretary	Two weeks before the Meeting
2	Preparation of the provisional meeting agenda	REC Chair	Within two days
3	Distribution of the provisional meeting agenda (QSOP12 Preparing for a Meeting)	Admin Staff	
4	Approval of the provisional meeting agenda	REC Members	On the day of the Meeting
5	Filing of the final meeting agenda (QSOP 27 on Management of Active Files)	Admin Staff	

DETAILED INSTRUCTIONS

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 meeting, using the Meeting Agenda Template (DDOSC-REC Form 4.1). The agenda includes the following:

   1.1. Call to Order
   1.2. Roll Call
   1.3. Declaration of Quorum
   1.4. Review and Approval of the Provisional Agenda
   1.5. Disclosure of Conflict of Interest
   1.6. Reading and Approval of the Minutes of the Previous Meeting
   1.7. Business Arising from the Minutes
   1.8. Business Agenda:
      1.8.1. PROTOCOLS FOR REVIEW
         - *New Protocols*
         - *Resubmitted Protocols*
         - *Protocols for Modifications*
         - *Protocols for Amendments*
         - *Progress Reports*
         - *Continuing Review*
         - *Final Reports*
         - *Protocol Deviations*
         - *Early Study Termination*
         - *Site Visit Reports*
         - *SAE/SUSAR Reports*
         - *Queries for Complaints*

      1.8.2. REPORTS FROM THE RESULTS OF EXPEDITED REVIEW
         - *New Protocols*
         - *Resubmitted Protocols*
         - *Protocols for Modifications*
         - *Protocols for Amendments*
         - *Progress Reports*
         - *Continuing Review*
         - *Final Reports*
         - *Protocol Deviations*
         - *Early Study Termination*
         - *Site Visit Reports*
         - *Queries for Complaints*

      1.8.3. REPORTS OF EXEMPT FROM REVIEW

   1.9. Other Matters

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.

3. **Distribution of the provisional meeting agenda**
   The provisional agenda is included in the Notice of Meeting (QSOP13 Preparing for a Meeting).

4. **Approval of the provisional meeting agenda**
   The REC members approve the provisional agenda during the meeting. See QSOP14 Conduct of Meeting.

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 chronological order. See QSOP27 Managing Active Files.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

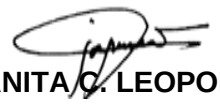
DDOSC-REC Form 4.1 Meeting Agenda Template

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2022 Oct 10	Lilybeth M. Matunhay, Kenny Jim M. Gambong	First draft
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Amended the Statement of Policy to include policy in handling late submissions.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. For the efficiency and effectiveness of REC operations, preparation for REC meetings shall be standardized and systematized.
2. REC meetings shall be conducted monthly on a fixed schedule (except for special meetings).
3. Special meetings shall be conducted to address the exigencies of service.
4. The REC should make its decisions at announced meetings at which at least a quorum, as stipulated in its SOP, is present.

PURPOSE

The purpose of this SOP is to describe the procedure for the conduct of meetings (both regular and special) of the REC.

SCOPE

This set of instructions applies to the conduct of meetings of the REC, beginning with the determination of quorum and ending with the time the meeting is adjourned.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Determining the Status of Quorum	REC Chair/Presiding Officer	1 day
2	Approving the Provisional Meeting Agenda	REC Chair/Presiding Officer	
3	Approving Minutes of the Previous Meeting and Discussing Business arising from the Minutes	REC Chair/Presiding Officer	
4	Disclosing Conflict of Interest	REC Chair/Presiding Officer	
5	Proceeding with the Meeting Following the Approved Agenda	REC Chair/Presiding Officer	
6	Reporting of Results of Expedited Review	Member Secretary	
7	Discussing Operations-Related Matters	REC Chair/Presiding	
8	Adjourning the meeting	REC Chair/Presiding Officer	

DETAILED INSTRUCTIONS

In a REC meeting, if the REC Chair has a conflict of interest relative to any one of the protocols that are up for deliberation, the REC Member Secretary presides over the meeting. If both the REC Chair and Member Secretary have a conflict of interest, any of the members is designated to preside over the meeting.

In the REC meetings, the REC Admin Staff takes the minutes of the meeting in real-time. Minutes taken are projected on the screen. In the case of a Full board meeting, the REC Member Secretary also takes the minutes of the meeting and is responsible for finalizing them.

1. Determining the Status of the Quorum

1.1. Quorum in a REC meeting is operationally defined as the presence of 50% + 1 of the REC Members. Quorum also requires the presence of at least one Non-scientist/Lay member and a non-affiliated member. In the absence of these required members, there is no quorum.

1.2. REC Admin Staff routes the attendance sheet for the REC Members' signature.

1.3. For the Regular meeting, the REC Admin Staff, based on the signed names in the attendance sheet, declares whether there is a quorum or not.

1.4. For the REC Full board meeting, the REC Member Secretary, based on the signed names in the attendance sheet, declares if a quorum is met.

1.5. The REC Chair declares that there is a quorum based on the presence of members at the meeting table.

2. Approving the Provisional Meeting Agenda

2.1 REC Chair (in the case of Regular meetings) or (in the case of REC Full board meetings) requests members to review the provisional agenda emailed to them earlier, a copy of which is projected on the screen to determine if modification is required.

2.2 If no addition, deletion, or modification is raised, the REC Chair requests a motion to approve the meeting agenda.

3. Approving Minutes of the Previous Meeting and Discussing Business arising from the Minutes

3.1. The REC Chair asks for any corrections in the minutes of the previous meeting that were emailed to all Panel Members earlier, a copy of which is projected on the screen.

3.2. If nobody raised any corrections, the REC Chair requests a motion to approve the minutes of the previous meeting.

3.3. The REC Chair asks members for issues related to the minutes of the previous meeting that they would like to raise.

3.4. In a REC meeting, information on the status of protocols for revision and requests for further information from the researcher related to RNE or Protocol Deviation

Reports discussed during the previous meeting. Protocols where the review decision was a major modification may be shared during this time.

4. Disclosing Conflict of Interest

4.1. In a REC meeting, if the approved agenda includes issues related to protocol review, the REC Chair asks members to disclose conflicts of interest. If the agenda does not include matters relating to protocol review, this task/step is omitted.

4.2. The REC Chair always asks the members to disclose conflicts of interest.

4.3. If the member discloses COI relative to a sponsor-initiated study, the said member is not allowed to participate in the deliberation and is requested to leave the room when the protocol is up for discussion.

4.4. If the member discloses COI relative to a researcher-initiated study as a mentor/adviser or as the research coordinator, the REC deliberates whether to allow the said member to participate in the discussion as a content expert. However, a said member cannot be the primary reviewer and is not allowed to vote or participate in the decision-making.

5. Proceeding with the Meeting Following the Approved Agenda

5.1. The meeting proceeds following the approved agenda.

5.2. The review of research protocols and protocol-related submissions shall be conducted in accordance with QSOP 10 – Full Board Review.

5.3. In REC meetings, decision-making is by a simple majority through open voting.

5.4. The REC Chair can also vote.

5.5. In a REC Meeting, decision-making is by a simple majority through closed voting (member ticks the review decision using the Individual Review Decision form). The REC Chair, who also votes, then counts the votes by decision category and announces the distribution of the votes by decision category.

6. Reporting of Results of Expedited Review

6.1. The results of expedited reviews shall be reported during the REC meeting for the information of the REC members only.

6.2. The report shall include a summary of the research protocols or protocol-related submissions reviewed under expedited review, the corresponding review decisions, and any conditions or recommendations imposed.

6.3. Expedited review results shall not be subjected to further deliberation or voting by the REC, unless a member formally raises ethical concerns warranting referral to Full Board Review, in accordance with SOP 10.

6.4. The primary purpose of reporting expedited review results is to ensure transparency, institutional awareness, and proper documentation of review actions taken between REC meetings.

7. Discussing Operations-Related Matters

7.1. Operations-related matters refer to administrative, procedural, and logistical concerns necessary for the effective, efficient, and compliant functioning of the REC.

7.2. Operations-related matters that may be presented during REC meetings include, but are not limited to, the following:
   a. Updates on REC workload, including the number of protocols received, reviewed, approved, deferred, or disapproved;
   b. Status of pending reviews, continuing reviews, amendments, serious adverse events, and protocol deviations;
   c. Scheduling of REC meetings, submission deadlines, and review timelines;
   d. Updates on REC membership, including appointment, reappointment, resignation, or replacement of members;
   e. Training, capacity-building activities, and accreditation-related matters of REC members and staff;
   f. Revisions or proposed changes to REC policies, SOPs, forms, and templates:
   g. Resource and administrative concerns, including staffing, budgetary requirements, equipment, and records management;
   h. Compliance monitoring activities, audits, and external communications with oversight bodies (e.g., PHREB, REMB).

7.3. The following operations-related matters shall require deliberation and approval by the REC members:
   a. Adoption, revision, or retirement of REC SOPs, policies, and official forms;
   b. Decisions affecting REC structure, membership composition, or quorum requirements;
   c. Endorsement of accreditation-related submissions, corrective action plans, and responses to audit findings;
   d. Approval of operational procedures that may affect the ethical review process, timelines, or researcher obligations.

7.4. The following operations-related matters are for information only and shall not require deliberation or voting, unless a member raises concerns requiring further action:
   a. Routine administrative updates and status reports;
   b. Notifications of completed trainings and seminars;
   c. Information on external communications, circulars, or advisories received from oversight agencies;
   d. Progress updates on previously approved actions or operational plans.

7.5. All operations-related matters discussed during the meeting shall be properly documented in the Minutes of the Meeting, indicating whether the item was for information, for deliberation, or for approval, and reflecting the corresponding action taken, if any.

8. Adjourning the meeting

8.1. When all items on the agenda have been discussed, the REC Chair or the REC Chair announces the adjournment of the meeting. The REC Member Secretary or the REC Admin Staff takes note of the time of adjournment.

8.2. The REC Admin Staff retrieves all protocol and protocol-related documents from the reviewers (REC Members and/or Independent Consultants).

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

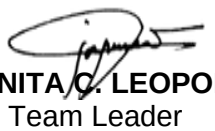
1. DDOSC-REC Form 4.1 – Meeting Agenda
2. DDOSC-REC Form 4.2 – Meeting Minutes

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2019 May 17	Lilybeth M. Matunhay and other REC members	Included the presence of non-affiliated members to complete the quorum.
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Added a paragraph (par. 5.2) in section 5 of QSOP 14 that references QSOP 10 for a detailed discussion. • Added 2 steps to the Workflow Chart, along with their corresponding detailed instructions. • Updated the signatories in the Approval section.

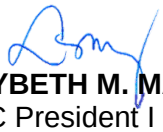
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Minutes of the meeting should be written in sufficient detail to record all the items described in this SOP.
2. The Research Ethics Committee should maintain the minutes of its meetings.
3. For accuracy of the information, the provisional minutes of the meeting shall be prepared within a week after the date of the meeting and circulated to all concerned before the next meeting.
4. Minutes of the meeting shall be approved and properly filed to facilitate retrieval.

PURPOSE

This SOP describes the procedure for preparing the meeting minutes such that deliberations on protocol and protocol-related documents and other vital actions taken by the DDOSC-REC are accurately recorded.

SCOPE

This set of instructions applies to the preparation of the minutes of the meetings of the REC using the prescribed template. This starts with preparing the draft meeting minutes and ends with distributing and filing the Meeting Minutes.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Preparing the Draft Meeting Minutes	REC Admin Staff	1 day
2	Preparing for the Provisional Meeting Minutes	REC Admin Staff	
3	Distributing and Filing the Meeting Minutes	REC Admin Staff	Within 10 days after the meeting review

DETAILED INSTRUCTIONS

1. **Preparing the Draft Meeting Minutes**
   1.1. The REC Admin Staff is responsible for taking the minutes of the meeting for both REC Regular and REC Special meetings.
      1.1.1. For the REC Regular Meetings, the REC Administrative Staff uses the DDOSC-REC Form 4.2 Meeting Minutes template to organize the minutes. The REC Administrative Staff fills up the first 10 rows of the box for each protocol submission for review ahead of the meeting date.

1.1.2. As the REC meeting proceeds, the Administrative Staff takes minutes in real-time according to the prescribed format DDOSC-REC Form 2.4 Meeting Minutes and projects this on the multimedia screen to enable the DDOSC-REC Members to closely follow the proceedings and to facilitate the recapitulation of discussion points by the REC Chair.

1.1.3. The REC meeting minutes should include the following items:

- ➢ Date and venue of the meeting
- ➢ Members attendance
- ➢ Attendance of Researchers/PI, Independent Consultant, and guest or observer, if any
- ➢ Time when the meeting was called to order
- ➢ Presiding officer
- ➢ Status of a quorum at the start of the meeting and before every decision-making
- ➢ Members who declared COI and the protocol concerned
- ➢ Protocols for Review:
  - ○ New Protocols
    - ■ Summary of technical and ethical discussion points and recommendations
    - ■ REC decision and voting results by decision categories and members abstaining (listed by name).
    - ■ If the review decision is “approved as is”, the duration of the approval (start and end dates) and the frequency of submission of the progress report are decided upon.
    - ■ If the review decision is disapproved, the reason for the disapproval is stated.
  - ○ Resubmitted Protocols
  - ○ Protocols for Modifications
  - ○ Protocols for Amendments
  - ○ Progress Reports
  - ○ Continuing Report
  - ○ Final Report
  - ○ Protocol Deviations
  - ○ Early Study Termination
  - ○ Site Visit Reports
  - ○ Reportable Negative Events Reports
  - ○ Queries for Complaints
- ➢ Report on protocols or protocol-related documents approved by an expedited procedure, such as:
  - ○ New Protocols
  - ○ Resubmitted Protocols
  - ○ Protocols for Modifications
  - ○ Protocols for Amendments
  - ○ Progress Reports
  - ○ Continuing Report
  - ○ Final Report
  - ○ Protocol Deviations
  - ○ Early Study Termination

- Site Visit Reports
- Queries for Complaints

➢ Name and signature of the person who prepared the minutes, Date of completion.
➢ Name and signature of the Panel Secretary to indicate that the contents have been verified and corrected
➢ Name and signature of the person who approved the minutes, and Date of approval

1.1.4. After the meeting, the Administrative Staff prepares the draft of the meeting minutes and emails this to the REC Member Secretary for corrections within one (1) week from the review meeting date.

1.1.5. For REC Special/Emergency Meetings, as the REC meeting proceeds, the REC Admin Staff takes minutes in real-time according to the prescribed format DDOSC-REC Form 4.2 Meeting Minutes and projects it on the screen to enable the members to closely follow the proceedings

1.1.6. After the meeting, the Administrative Staff prepares the draft of the meeting minutes and emails this to the REC Chair for corrections within one (1) week from the meeting date.

2. Preparing for the Provisional Meeting Minutes

2.1. The REC Member Secretary finalizes the draft minutes of the REC meeting and emails the provisional meeting minutes to the REC Admin Staff for distribution to all the members who attended the meeting.

2.2. The REC Chair reviews the draft minutes of the REC Special/Emergency meetings.

2.2.1. The REC Admin Staff copy-pastes the content of the Recommendation and/or Decision sections to the Notification Letter to the Researcher.

3. Distributing and Filing the Meeting Minutes

3.1. The REC Admin Staff sends a copy of the provisional meeting minutes to the concerned REC Members through email for their review and comments within ten (10) days from the meeting date. REC Members are expected to email their corrections to the rest of the concerned group (DDOSC-REC).

3.2. A review of the meeting minutes is done through email exchanges. After three (3) days from the date of posting, the meeting minutes of the REC are further finalized by the REC Member Secretary with the assistance of the REC Admin Staff.

3.3. In filing the documents, please refer to QSOP 27 Management of Active Files.

FORMS/TEMPLATE ASSOCIATED WITH THIS SOP

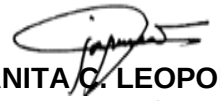
1. DDOSC -REC Form 4.2 Meeting Minutes

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	Change the term “noted“ to “Approved“ in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	Edited the detailed instructions for step 1 (items present in the Meeting Agenda).
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

In the interest of improving the quality of services through research, a principal investigator receiving a review decision letter advising disapproval may appeal the decision by writing a letter to the REC Chair justifying the request for re-review and supplying additional information for consideration.

PURPOSE

This SOP describes how an appeal for reconsideration of the disapproved study protocol is managed.

SCOPE

This set of instructions applies to study protocols disapproved by the REC and starts with the Inclusion of the Appeal in the Meeting Agenda, followed by the process of reviewing the appeal, and ends with the REC Chair or Review Panel Chair providing the outcome of the appeal.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Inclusion of the Appeal in the Meeting Agenda	REC Chair	30 days after receipt of the REC decision
2	Reviewing the appeal	Review Panel Chair	1 week after the appeal
3	Communicating the Decision to the Researcher	REC Admin Staff	1 week after the review of the appeal
4	Filing the Protocol Package	REC Admin Staff	Within 1 day after communicating the decision of the appeal
5	Inclusion of the Decision in the Meeting Agenda and the Review Panel that Initially Disapproved the Protocol	Review Panel and REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Inclusion of the Appeal in the Meeting Agenda**
   1.1. If a researcher disagrees with the revisions suggested or the decision made by the REC to disapprove a study, the researcher may submit a written appeal for reconsideration of the decision addressed to the REC Chair.

1.2. The appeal should include the reason for requesting reconsideration and should contain supplemental documentation in support of the arguments made in the appeal.

1.3. The REC Chair will then review the appeal, the minutes of the concerned Review Panel meeting, the protocol, and related documents. The REC Chair will determine whether there is a sufficient basis for the appeal to be heard by the Review Panel.

1.4. If the date of the regular REC meeting is earlier than the date of the concerned Review Panel meeting, the REC Chair may decide to include the deliberation on the appeal in the meeting agenda of the REC meeting.

Note: The right to an appeal or re-review lapses 30 calendar days after receipt of the REC decision.

2. Reviewing the appeal

2.1. The review decision of disapproval can only be given during a full board review and not during an expedited review.

2.2. The deliberation on whether to consider the appeal will be reviewed and voted upon during either a REC Regular meeting or during the Full board review chaired by the REC Chair, whichever comes earlier, in the presence of one or both Primary Reviewers of the protocol.

2.3. The principal investigator may be requested to appear before the Review Panel Meeting to present his or her appeal and any supporting material or newly obtained documentation, but then s/he cannot be present during the vote on the REC's decision on whether to reconsider the protocol for re-review with the assistance of an expert if deemed necessary.

2.4. The REC Chair may also consult the REC members in a meeting or through documented email exchanges regarding the need for a consultant during the review of the appeal, regardless of whether the appeal will be heard by the Review Panel chaired by the REC Chair.

3. Communicating the Decision to the Researcher

(Refer to QSOP26 – Communicating Decision)

4. Filing the Protocol Package

4.1. The REC Admin Staff files the minutes of the meeting containing the discussion points of the deliberation on the appeal, the completed Reviewer Decision forms, the Letter of Appeal from the PI, and other protocol-related documents in the appropriate folder of the protocol file, and updates the Protocol File Index. The Staff also saves any newly emailed soft copy of protocol-related documents in the appropriate e-folder for this particular protocol.

4.2. Letter of Appeal from the researcher and other protocol-related documents in the appropriate folder of the protocol file and updates the Protocol File Index. The Staff also saves any newly emailed soft copy of protocol-related documents in the appropriate e-folder for this particular protocol.

5. **Inclusion of the Decision in the Meeting Agenda and the Review Panel that Initially Disapproved the Protocol**
   5.1. If the review of the appeal was done, the REC Admin Staff includes the decision of the review in the next meeting agenda of the Review Panel that initially disapproved the protocol and the reasons for the decision.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

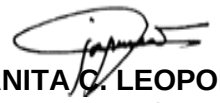
DDOSC-REC Form 3.10 Appeal Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 09	Lilybeth M. Matunhay and other REC members	• Realigned the Scope with the Workflow; and • Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-17/01.4
	REVIEW OF PROTOCOL AMENDMENTS	Revision No.	3
		Effectivity:	02/13/2026

STATEMENT OF POLICY

All post-approval changes of the protocol shall only be initiated after written approval by a Research Ethics Committee, except when necessary to eliminate immediate danger to the research participants.

PURPOSE

This SOP provides instructions on how amendments to previously approved protocols are reviewed by the REC.

SCOPE

This set of instructions applies to all applications for post-approval protocol amendments and starts with the receiving application for protocol amendment and ends with including the decision in the meeting agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving application for protocol amendment	REC Admin Staff	1 day, upon submission of protocol amendments
2	Verifying Completeness of Protocol Package	REC Admin Staff	
3	Assessing whether the amendment is major or minor	REC Chair	
4	Forwarding Protocol Amendment Package to REC & Primary Reviewers	REC Admin Staff	1 week before the meeting review
5	Reviewing Protocol Amendment by Full-board or Expedited Review and	Panel Reviewer	7 days after the meeting review
	Communicating the Decision to the Researcher	REC Admin Staff	
6	Filing the documents	REC Admin Staff	Within a day after the review of an amendment
7	Including the Protocol Amendment Review in the Meeting Agenda	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Receiving application for protocol amendment**

   The REC Admin Staff receives the submission for the protocol amendment application from the researcher or representative.

2. Verifying Completeness of Protocol Package

2.1. REC Admin Staff reviews protocol amendment package for completeness. The REC Admin Staff ensures completeness of submitted forms, such as DDOSC-REC Form 3.1 Amendment Application Form and other pertinent documents, using the Submission Checklist.

2.2. If the protocol amendment package is complete, Admin Staff logs the document in the Log of Incoming Documents and creates a new amendment entry within the protocol details entry of the original protocol. (For updating database entries, see QSOP 30 on Maintenance of Protocol Database.)

2.3. REC Admin Staff forwards the protocol amendment package to the REC Chair.

2.4. If the submission is incomplete, make a photocopy of the accomplished Submission Checklist and give it to the principal investigator or his/her representative, together with the incomplete documents.

3. Assessing whether the amendment is major or minor

3.1. The REC Chair reviews the document to determine whether an amendment is major or minor.

3.2. Protocol amendments that increase the risk to study participants require full board review. These include, but are not limited to, the following:

3.2.1. Modification of treatment – addition or reduction of treatments;
3.2.2. Any changes in inclusion/exclusion criteria;
3.2.3. Change in research methodology;
3.2.4. Significant change in the number of subjects/respondents; and
3.2.5. Any other changes that will entail more than minimal risk.

3.3. Protocol amendments that are considered minor are those that are unlikely to compromise the integrity of the research or the safety and rights of the participants and present no new ethical issues. The review for these can be expedited.

4. Forwarding Protocol Amendment Package to REC & Primary Reviewers

4.1. REC Admin Staff identifies the Primary Reviewers who did the initial review and verifies REC approval, photocopies relevant documents of the previous review/s of the protocol that will provide the Primary Reviewers with background information that will facilitate the assessment of the proposed amendment/s. Better still, the Primary Reviewers should go to the REC office to review the pertinent documents in the protocol file and determine whether the proposed changes in the protocol will cause a change in the risk-benefit ratio.

4.2. REC Admin Staff sends the protocol amendment package and relevant documents of the previous review/s to the Primary Reviewers within a week from the date of submission. If Primary Reviewers are not available to do the review, the REC Chair and/or Secretary will do the review, provided they do not have a COI. Otherwise, the REC Chair designates a qualified member of the same REC to do the review.

5. Reviewing Protocol Amendment by Full Panel or Expedited Review and Communicating the Decision to the Researcher

5.1. Reviewing Protocol Amendment by Full Panel or Expedited Review.

5.1.1. The Primary Reviewers and the concerned REC members review the documents under consideration.
5.1.2. For Full Board Review, refer to DDOSC-REC QSOP 10 Full Board Review
5.1.3. For Expedited Review, refer to DDOSC-REC QSOP 09 Expedited Review

5.2. Communicating the Decision to the Researcher.
For the communication of decisions, please refer to DDOSC-REC QSOP 26 Communicating Decisions.

6. Filing the documents
Please refer to DDOSC-REC QSOP 27 Management of Active Files.

7. Including the Protocol Amendment Review in the Meeting Agenda
Please refer to DDOSC-REC QSOP 12 Preparation for Meetings.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

DDOSC-REC Form 3.1 Amendment Application Form

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Realigned the Scope with the Workflow; • Revised Step 5; and change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. The REC shall require the submission of progress reports at a frequency based on the level of risk of the study, as determined during ethical review and in accordance with the National Ethical Guidelines for Health and Health-Related Research (NEGRIHP).
2. For purposes of continuing review, studies shall be categorized as follows:
   - *No more than minimal risk* – studies in which the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests;
   - *Greater than minimal risk* – studies in which the probability and/or magnitude of harm or discomfort exceeds that ordinarily encountered in daily life; and
   - *High-risk studies* – studies involving vulnerable populations, invasive procedures, sensitive data, or interventions with a higher likelihood of serious adverse events.
3. Progress reporting frequencies shall be defined as follows:
   - Studies involving no more than minimal risk shall submit progress reports at least annually;
   - Studies involving greater than minimal risk shall submit progress reports every six (6) months; and
   - High-risk studies shall submit progress reports every three (3) months, or more frequently as may be required by the REC.
4. The assigned risk category and corresponding progress report submission schedule shall be explicitly stated in the Approval Letter and may be reviewed and modified by the REC as necessary to ensure the ongoing protection of research participants.

PURPOSE

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

SCOPE

This SOP applies to the management and review of progress submitted by the proponent while the study is ongoing or has ended. This SOP begins with receipt and entry into the Logbook of Incoming Documents and the protocol database, and ends with the filing of the progress report and the committee decision in the protocol file.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receipt and entry into the logbook of the progress report (SOP on Management of Active Files (QSOP27))	Admin Staff	1-2 days from the date of submission
2	Retrieval of pertinent protocol file	Admin Staff	

3	Notification of Chair and Primary Reviewers	Admin Staff	1-2 days from the receipt of the Progress Report
4	Determination of the type of review: Expedited (SOP on Expedited Review (QSOP09)) or Full Review (SOP on Full Review (QSOP10))	REC Chair and Primary Reviewers	
5	Communication of committee action (SOP on Communicating Decisions (QSOP26))	Admin Staff	1-3 days from the review of the protocol
6	Filing of the Progress report, the decision letter, and updating of the protocol database. SOP on Management of Active Files (QSOP27) and SOP on Management of Protocol Database (QSOP30)	Admin Staff	Within the day of communicating the decision

DETAILED INSTRUCTIONS

1. **Receipt and Entry into the Logbook of the Progress Report**
   The Staff receives the progress report from the Progress Report Form 3.2 and enters the date and pertinent information in the logbook for incoming documents (See SOP 27: Management of Active files).

2. **Retrieval of Pertinent Protocol File**
   The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.

3. **Notification of Chair and Primary Reviewers**
   Within 2 days of receipt of the progress report, the Staff notifies the Chair and the previously assigned Primary Reviewers and sends the pertinent protocol file via email.

4. **Determination of the Type of Review: Expedited or Full Review**
   The Chair, together with the Primary Reviewers, decides the type of review and proceeds accordingly. For Expedited review, see QSOP09; for Full review, see SOP10.

5. **Communication of Committee Action**
   The staff prepares a draft of the committee decision based on either an expedited review report or meeting minutes. The Chair signs the decision letter as follows: Approval, request for additional information, or specific action/s.

6. **Filing of Progress Report and Decision Letter, and Updating of the Protocol Database**
   The Staff files the progress report and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 3.2 Progress Report

HISTORY OF SOP

Version No.	Date	Authors	Main Change

1	2022 Oct 10	Lilybeth M. Matunhay, Kenny Jim M. Gambong	First draft
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	• Revised the Statement of Policy to define risk categories and specify corresponding submission intervals. • Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Application for continuing review shall be required if the research needs to be extended beyond the period covered by the initial ethical clearance. Therefore, REC conducts a continuing review of the research protocol that goes beyond the period of effectivity of the initial ethical clearance for the renewal of ethical approval.

PURPOSE

This SOP provides instructions for continuing the review of previously approved protocols by the DDOSC-REC.

SCOPE

This set of instructions applies to the review of progress reports of protocol implementation in cases where the required frequency of submission is more than once a year, or to review applications for renewal/extension of REC approval. This starts with reminding the Researcher of the submission date of the progress report/renewal of approval, and ends with handling Late Submissions.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Reminding the Researcher of the submission date for the renewal of approval	REC Admin Staff	Within 2 months before the expiration
2	Receiving application for continuing review	REC Admin Staff	1 day upon submission
3	Verifying Completeness of Protocol Package	REC Admin Staff	
4	Distributing the Continuing Review Application Package to REC or to Researcher	REC Admin Staff	1 week before the meeting review
5	Reviewing the Continuing Review Application Package by Full Board Review or by Expedited Review	REC Review Panel	1 day during the REC meeting
6	Communicating the Decision to the Researcher	REC Admin Staff	Within 1 day after the full review
7	Filing the Continuing Review Package	REC Admin Staff	Within 1 day of communicating the decision

8	Handling Late Submissions	REC Admin Staff	Within 1 month after the expiration

DETAILED INSTRUCTIONS

1. **Reminding the Researcher of the submission date of the progress report/renewal of approval**
   1.1. The frequency of continuing review is stated in the REC Approval Letter.

   1.2. The computer system sends reminder letters to the researcher/principal investigator one and two months before the due date of the expiration date of the REC approval through an automatically generated email. The Admin Staff keeps a copy of the emailed notice in the e-folder for this particular protocol.

   1.3. Ethical clearance or approval is typically granted for a period of one year. After approval, a continuing review is required to be done at least once a year, depending on the risk assessment of the study protocol, as determined during the initial review. This is facilitated through the submission of DDOSC-REC Form 3.2 Progress Report and DDOSC-REC Form 3.9 Continuing Review Application.

   1.4. For ethical approvals approaching the one-year expiry date and requiring renewal or extension of approval, it is advisable to submit DDOSC-REC Form 3.2 Progress Report and DDOSC-REC Form 3.9 Continuing Review Application 60 days before the expiry date.

2. **Receiving application for progress report/continuing review**
   2.1. The REC Admin Staff receives the submission of the progress report/continuing review application from the principal investigator or representative using DDOSC-REC Form 3.2 Progress Report and DDOSC-REC Form 3.9 Continuing Review Application.

3. **Verifying Completeness of Protocol Package**
   3.1. Admin Staff reviews progress report/continuing review package for completeness. The Admin Staff ensures the completeness of submitted forms and documents using the Log Document Submission Checklist.

   3.2. If the progress report/continuing review package is complete, Admin Staff logs the document in the Log of Incoming Documents/Communications and creates a new progress report/continuing review entry within the protocol details entry of the original protocol. (For updating database entries, see QSOP 30 on Management of Protocol Database.

   3.3. REC Admin Staff forwards the progress report/continuing review package to the REC Chair and Primary Reviewers.

   3.4. If the submission is incomplete, make a photocopy of the accomplished Log Document Submission Checklist and give it to the principal investigator or his/her representative, together with the incomplete documents.

4. **Distributing the Continuing Review Application Package to REC or to Primary Reviewers**

4.1. Admin Staff identifies the REC and the Primary Reviewers who did the initial review and the type of review of the initial submission – whether full-board review or expedited.

4.2. The type of review of the continuing review of the protocol is the same as that of the initial review. If the initial review was by full-board review, the continuing review shall also be a full board review.

4.3. The REC Admin Staff makes sufficient copies (either for Primary Reviewers only in the case of an expedited review or for all members of the REC in the case of full board review) of the Continuing Review Application Package.

4.4. The REC Admin Staff distributes the continuing review application package to the Primary Reviewers who did the initial review of the protocol and also to the rest of the REC members if the continuing review is by full-board review.

4.5. As in resubmitted protocol for re-review or other post-approval reviews by expedited review procedure, the Primary Reviewers may decide to have the continuing review package reviewed by full-board review.

5. Reviewing the Continuing Review Application Package by Full Board Review or by Expedited Review

5.1. The Primary Reviewers and the concerned REC Members review the documents under consideration.

5.1.1. For Full Board Review, refer to DDOSC-REC QSOP 10 Full-board Review

5.1.2. For Expedited Review, refer to DDOSC-REC QSOP 09 Expedited Review

6. Communicating the Decision to the Researcher

6.1. For the communication of the decision, please refer to DDOSC-REC QSOP 24 Communication of REC Decision.

7. Filing the Continuing Review Package

7.1. Please refer to DDOSC-REC QSOP 25 Management of Active Files.

8. Handling Late Submissions

8.1. If the required submission is not received thirty (30) days before the approval expiration date, the REC Administrative Staff shall issue a first reminder to the Researcher through the official REC communication channels.

8.2. If no submission is received fifteen (15) days before the approval expiration date, a second and final reminder shall be issued, informing the Principal Investigator of the impending expiration and the consequences of late or non-submission.

8.3. Submissions received after the approval expiration date but within thirty (30) calendar days shall be accepted for processing; however, the study shall be placed on temporary hold, and no research-related activities involving human participants shall be conducted until continuing approval is granted.

8.4. Submissions received more than thirty (30) calendar days after the approval expiration date shall result in the automatic suspension of the ethics approval. Such

submissions shall not be accepted as continuing review and shall be processed as a new application, subject to full board review.

8.5. The REC Chair shall be informed of all cases of late submission, temporary hold, and automatic suspension. These cases shall be reported to the REC during the next scheduled meeting for information and appropriate action.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

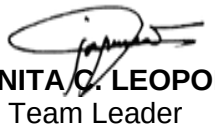
1. DDOSC-REC Form 3.2 Progress Report
2. DDOSC-REC Form 3.9 Continuing Review Application
3. Log of Incoming Documents/Communications

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2019 May 17	Lilybeth M. Matunhay and other REC members	Revise the Policy Statement.
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Realigned the Scope, Workflow, and Detailed Instructions; and Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	Added a Step 8 in the Workflow Chart and in the Detailed Instruction to include handling late submissions.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

For a research protocol to be declared closed, the following criteria must be met:

1. Data collection is complete;
2. There is no more participant contact, including phone calls, long-term follow-up, observation visits, and surveys;
3. The only research activity that may be going on is the analysis of anonymized data.

The REC shall require the submission of the Final Paper (PDF), along with the corresponding forms and any other supplementary documents, for review of the final report.

PURPOSE

This SOP provides instructions on the review of the final/closure report of research protocols approved by the REC.

SCOPE

This set of instructions applies to the procedure for reviewing the Study Final Report of a research protocol approved or endorsed by the REC. It begins with determining the due date for the final study report and ends with including the review results in the REC meeting agenda.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Determining the Due Date of the Final Study Report and Reminding the Researcher	REC Admin Staff	20 days before the due date
2	Receiving application for study closure/final report	REC Admin Staff	7 days from receiving the application for study closure/final report
3	Verifying Completeness of Protocol Package	REC Admin Staff	
4	Distributing the Documents for Review to the Primary Reviewers	REC Admin Staff	
5	Reviewing the Final Report by Full-board or Expedited Review	REC Chair/Member	
	Communicating the Decision to the Researcher	REC Admin Staff	
6	Filing the documents	REC Admin Staff	Within 1 day after the review
7	Including the Review Decision of the Final Study Reports in the Meeting Agenda	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Determining the Due Date of the Final Study Report and Reminding the Researcher**

1.1 The REC Admin Staff reviews the electronic database of approved protocols weekly to determine the due date for the submission of the final study report.

1.2 The Admin Staff sends automatically generated email reminders to the researcher about the submission of the final study report or the study closure form (if the study is already closed, but there is no final study report yet) at least two months before the expiration of the approval. The official email address of the REC is copy-furnished with every email reminder sent.

1.1.1. The email reminder also informs the researcher to submit the progress report and the continuing review application form for renewal of approval if the data collection part of the research study or the analysis data is still going on.

1.1.2. In multicenter studies, where the data collection and analysis of data on the site are already completed, but not on the other sites, the researcher is reminded to submit the Study Final Report Form.

1.2. Another computer-generated reminder is sent to the researcher one month before the due date, and on the date of expiration of the approval.

1.2.1. If the final study report is not submitted after the expiration date of the approval, the Admin Staff calls the researcher to verify if data collection or analysis of data is still ongoing. If the researcher does not respond, a site monitoring visit is scheduled (Refer to QSOP 23 Site Monitoring Visit). REC Admin Staff logs the call in the Communication Logbook – a print copy of the log is filed with the protocol file, and a scanned copy is in the e-folder for that particular protocol.

1.2.2. If the researcher is found to be enrolling research participants, collecting data, analyzing data, or following up with participants beyond the approval period, the REC Chair is informed so that the procedure for suspension of the study can be formalized.

2. **Receiving application for study closure/final report**

2.1. The Admin Staff receives the submission for study closure/final report application from the principal investigator or representative.

3. **Verifying Completeness of Protocol Package**

3.1. REC Admin Staff reviews study closure/final report package for completeness. The REC Admin Staff ensures the completeness of submitted forms and documents using the Submission Checklist.

3.2. If the study closure/final report package is complete, Admin Staff logs the document in the Log of Incoming Documents/Communications and creates a new final/closure report entry within the protocol details entry of the original protocol. (For updating database entries, see QSOP 30 on Maintenance of Protocol Database).

3.3. REC Admin Staff forwards the study closure/final report package to the REC Chair and Primary Reviewers.

3.4. If the submission is incomplete, make a photocopy of the accomplished Submission Checklist and give it to the principal investigator or his/her representative, together with the incomplete documents.

4. Distributing the Documents for Review to the Primary Reviewers

4.1. REC Admin Staff identifies the REC and the Primary Reviewers who did the initial review and the type of review of the initial submission – whether full-board review or expedited.

4.2. The REC Admin Staff makes sufficient copies (either for Primary Reviewers only in the case of an expedited review or for all members of the REC in the case of a full board review) of the Final Report Package.

4.3. The REC Admin Staff distributes the Final Report Package to the Primary Reviewers who did the initial review of the protocol, and also to the rest of the REC members if the Final Report review is by full board review.

4.4. As in resubmitted protocol for re-review or other post-approval reviews by expedited review procedure, the Primary Reviewers may decide to have the continuing review package reviewed by a full board review.

5. Reviewing Final Report by Full Board or Expedited Review and Communicating the Decision to the Researcher

5.1 Reviewing Final Report by Full Board or Expedited Review

5.1.1 The Primary Reviewers and the concerned REC review documents under consideration.

5.1.1.1 For Full-board Review, refer to QSOP 10 Full Board Review

5.1.1.2 For Expedited Review, refer to QSOP 09 Expedited Review

5.1.2 Upon completion of the review and discussion of the submitted Final Report, the primary reviewers and/ or the concerned REC panel shall arrive at a decision based on the completeness of the report and the Researcher's compliance with the approved protocol and ethical requirements.

5.1.3 The REC may issue any of the following decisions:

5.1.3.1 Acceptance of the Final Report

5.1.3.1.1 The Final Report is found to be complete, accurate, and compliant with the approved protocol and ethical standards. The REC shall issue a written notification of acceptance to the Researcher, and the study shall be considered ethically closed, subject to records archiving requirements.

5.1.3.2 Final Report Accepted with Required Corrections (Resubmission Required)

5.1.3.2.1 The Final Report requires minor or substantive corrections or clarifications. The REC shall issue a written notification to the Researcher specifying the required revisions and the timeline

for resubmission. The Final Report shall not be considered accepted until the required corrections have been satisfactorily addressed and reviewed

5.2 Communicating the Decision to the Researcher

5.2.1 For the communication of the decision, please refer to QSOP 26 Communication of REC Decision.

6. Filing the documents

6.1. Please refer to QSOP 27 Management of Active Files.

6.2. After getting the oversight approval of the REC Chair on the Study Closure and/or Final Study Report, the protocol files will be archived (please refer to QSOP 28 Management of Inactive Files).

7. Including the Review Decision of the Final Study Reports in the Meeting Agenda

Please refer to QSOP 12 Preparing for Meetings.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

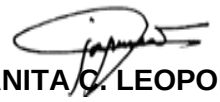
1. Log of Incoming Documents

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Revised Step 5 of the Workflow chart and its detailed instructions; and • Changed the term "noted" to "Approved" in the approval section.
1	2022 Oct 10	Lilybeth M. Matunhay and other REC members	Added provision in the Statement of Policy
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	Added Paragraphs 5.1.2 & 5.1.3 in the Detailed Instructions to include possible decisions that will be communicated to the Researcher after the discussion of the submission of the Final Report.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

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SUC President I

	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-21/01.5
	REVIEW OF EARLY STUDY TERMINATION REPORTS	Revision No.	3
		Effectivity:	02/13/2026

STATEMENT OF POLICY

1. A study may be suspended or terminated if there are serious concerns about the protection of the rights and welfare of human research participants.
2. REC has the authority to suspend or terminate approval of ethical clearance that is not being conducted in accordance with national and international and REC's requirements, or that has been associated or has the potential to be associated with unexpected serious harm to research participants in order to protect the rights, safety and welfare of the research participants and the integrity/validity of the research.
3. When the REC withdraws ethical clearance, it is responsible for promptly notifying the researcher, the Dean, Research Coordinators, research adviser, the College President, and the funding agency (if applicable).
4. REC Chair, in consultation with the majority of the members of the REC, through phone or email exchanges, may suspend or terminate ethical clearance on an urgent basis in between meetings. In this case, the suspension will be reported to the committee during its meeting.

PURPOSE

This SOP provides instructions for REC procedures related to early termination of protocol implementation.

SCOPE

This procedure describes how the REC proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), Sponsor, or Researcher, by the REC Members themselves or other authorized bodies.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Management of the early study termination report upon submission	Principal Investigator	1 day
2	Deliberating and Deciding on a Course of Action	REC Chair and Members	
3	Notifying the Researcher and Relevant Authorities of the Results of the Investigation and the REC's Decision	REC Chair and Members	1 week after the decision or REC Meeting
4	Verifying Actions Taken by Researcher	REC Chair and Members	3 days after the Researcher

			received the decision
5	Filing the Relevant Documents in the Protocol Files and in the e-Folder	REC Admin Staff	Within 1 day after the deliberation

DETAILED INSTRUCTION

1. Management of the early study termination report upon submission

1.1. An application for early study termination is submitted when a study approved by the REC is recommended for termination before its scheduled completion. This is done when the safety of the study participant is doubtful or at risk, and upon the request of the Researcher or the sponsor, owing to the existence of unresolved valid complaints.

1.2. The criteria for termination are the following:

1.2.1. Unanticipated problem associated with unexpected serious harm to research participants;

1.2.2. The research conducted poses a risk of harm to research participants; and/or

1.2.3. Serious or continuing noncompliance has taken place.

1.3. Early study termination is facilitated through the submission of the following documents relevant to the application:

1.3.1. Cover Letter

- Addressed to the REC Chair
- Statement that the study has been terminated early
- Indicated date of termination
- Brief reason(s) for early termination

1.3.2. DDOSC-REC Form 3.8 Early Study Termination Report Form

1.3.3. Participant Safety and Welfare Report

- Description of how participants were informed of the study termination
- Actions taken to ensure participant safety and well-being
- Follow-up, referrals, or monitoring provided (if applicable)
- Confirmation that no participant is left at increased risk due to termination

1.3.4. Informed Consent-related Document (if applicable)

1.4. The REC Admin Staff checks the document package submission for completeness and receives a copy of the accomplished DDOSC-REC Form 3.8 Early Study Termination Report Form from the researcher or his/her representative.

2. Deliberating and Deciding on a Course of Action

2.1. REC Chair, in consultation with the majority of the REC members through phone or email exchanges, may suspend or terminate research on an urgent basis in between meetings and when it is anticipated that meeting the quorum requirement is not likely. This is also the mode of decision-making in cases of termination of research activities started prior to the approval of the REC. But when the meeting quorum requirement is highly probable, making the decision en banc is the preferred procedure.

2.2. For possible suspension, the REC should determine the extent of the suspension in reference to the following:
- Continued participant enrollment
- Continued study treatment and/or intervention
- Use of data for analysis
- All research activities

2.3. The DDOSC-REC should consider various options and alternatives to protect the research participants. These include, but are not limited to, the following:
- additional actions to protect the rights and welfare of enrolled participants;
- continued safety follow-up of currently enrolled participants;
- continued study treatment/intervention by the same or different investigator (in the case of a multi-center study);
- withdrawal and transition of participants from research;
- notification of all current and/or former participants of the suspension or termination of research;
- continued collection and reporting of any adverse events, unanticipated problems, or outcomes to the REC;
- Additional training and education of the Researcher and research staff.

2.4. The REC should also determine which institutional officials and external agencies should be notified of the suspension or termination.

2.5. For Researcher-initiated suspensions or terminations, deliberation is not required unless the REC Chair determines that serious and/or continuing non-compliance or unexpected problems involving risks to participants or others have occurred in the research.

2.6. The REC Chair and Members have the authority to suspend the approval of the research. The sponsor, Data and Safety Monitoring Plan (DSMP), Scientific Director, and other authorized bodies can terminate the research. Even researchers can terminate their own research due to a lack of funding or resources.

3. Notifying the Researchers and Relevant Authorities of the Results of the Investigation and the REC's Decision

3.1. The REC Admin Staff prepares the Notification Letter and has it signed and dated by the REC Chair.

3.1.1. The Notification Letter should include:
- the activities to be stopped
- the reasons for the suspension or termination
- corrective actions to be taken by the Researcher
- REC action plan and established timeline for response and reporting progress to the REC
- a reminder that all study activities, such as reporting of unanticipated problems, revisions to investigator's brochures, and updated package inserts, must still be reported to the REC
- a request to immediately notify the REC with the list of names of participants who might be harmed by stopping the research procedure and an explanation of why they might be harmed.

3.1.2. The Corrective actions and stipulations necessary for the REC to reconsider the reinstatement of the research approval should be described in the letter to the PI.

3.2. The REC Chair calls the researcher to inform him of the temporary or permanent withdrawal of its approval of the research protocol in question.

3.3. The REC Admin Staff sends the Notification Letter to the researchers by e-mail within 48 hours from the time of adjournment of the REC meeting. The researcher has the right to appeal the REC's decision regarding the suspension or termination by writing to the REC Chair cc: Deans and Research Adviser.

4. Verifying Actions Taken by the Researcher

4.1. The REC Chair designates three (3) REC Members (preferably including the Primary Reviewers) to verify if the researcher has followed the recommended course of action and to submit a report not later than 1 week from the date of the notice.

4.2. The REC Admin Staff includes the follow–up report in the agenda of the next meeting of the REC review panel that approved the protocol.

5. Filing the Relevant Documents in the Protocol Files and in the e-Folder for that Particular Protocol

5.1. The REC Admin Staff keeps the original paper and e-copy of the Notification Letter, a follow-up report from the REC, and other related documents (Letter of Notice to institutional officials, sponsor, or regulatory authority if warranted) in the protocol file and the e-folder for that particular protocol. The REC Admin Staff also updates the Protocol File Index.

5.2. In the case of study termination, the REC fills up the Protocol File Index and the Archive Logbook before transferring the protocol file in question to the archive.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 3.5 Protocol Violation Deviation
2. Log of Incoming Documents/Communications

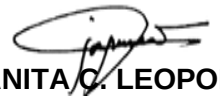
HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Revised the policy statement. • Reorganized the Scope and the Detailed Instructions; and • Change the term "noted" to "Approved" in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.

1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	Amended Paragraph 1.3, which included the list of required documents.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

1. Deviations from the approved protocol may alter the risk-benefit balance for participants, may violate the rules of beneficence, justice, and respect for persons, and/or may jeopardize the safety, rights, and welfare of participants. If the protocol violation is major, DDOSC-REC may suspend the implementation of the study, or order to stop the recruitment and enrolment of research participants until corrective measures are taken.
2. There shall be an established system by which the Researcher, Research Staff, or REC has a means of communicating information about the conduct of a research project.

PURPOSE

This SOP provides instructions for managing reports of deviations/violations from a REC-approved protocol.

SCOPE

These policies and procedures apply to all reports on protocol deviation/violation relative to research protocols approved by the REC. This set of instructions begins with receipt of the report of protocol deviation/violation and ends with the filing of relevant documents in the protocol file.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving the report on protocol deviation/violation	REC Admin Staff	1 day upon submission
2	Verifying Completeness of Protocol Package	REC Admin Staff	
3	Determining Type of Review	REC Chair	
4	Reviewing the Report, Deliberating, and Deciding on the Course of Action	DDOSC-REC Members	1 day
5	Communicating Review Decisions to the Researcher	REC Admin Staff	1 day after the review
6	Verifying Actions Taken by the Researcher	REC Admin Staff	At least 2 weeks
7	Filing the Relevant Documents in the Protocol File or in the e-Folder	REC Admin Staff	Within 1 day after review

DETAILED INSTRUCTIONS

1. Receiving the report on protocol deviation/violation

1.1. The REC Admin Staff receives the submission for protocol deviation/violation report (DDOSC-REC Form 3.5) for review from the principal investigator or representative.

1.1.1. Reports of protocol deviation/violation may come directly from the Researcher, or as a result of study site monitoring by the REC, or from related documents received by Admin Staff.

1.2. The REC Members performing monitoring of the research study at the trial site may detect protocol deviation/violation if the implementation of the research is not conducted as per the approved protocol/national and international standards.

1.3. It is the responsibility of the Principal Investigator to determine whether a protocol deviation/violation is major or minor and ensure proper reporting.

1.3.1. Major protocol violations shall be reported to the REC Office within seven (7) days of the discovery of the event, using the prescribed form.

1.3.2. Minor deviations are reported to the REC Office in the progress notes during the continuing review. If there are no protocol deviations within the protocol approval period, this must be indicated in the progress report for continuing review.

1.3.3. The only acceptable protocol deviation is when urgent action is required to eliminate an immediate danger to the research participant. But PI must submit the report as soon as possible, the reasons for the deviation, and, if called for, an appropriate protocol amendment.

2. Verifying Completeness of Protocol Package

2.1. The REC Administrative Staff reviews the protocol deviation/violation report package for completeness. The Administrative Staff ensures completeness of submitted forms and documents using the Submission Checklist.

2.2. If the protocol deviation/violation report package is complete, the Administrative Staff logs the document in the Log of Incoming Documents/Communications and creates a new final/closure report entry within the protocol details entry of the original protocol. (For updating of database entries, see QSOP 28 on Maintenance of Protocol Database.)

2.3. Administrative Staff forwards the protocol deviation/violation package to the REC Chair.

3. Determining Type of Review

3.1. The REC Chair then determines the type of review. The Chair or his/her designee, provided that they do not declare any conflict of interest, is the main person responsible for determining the type of review.

3.2. Protocol violation in a research study that involves more than minimal risk must be reviewed by Full-board Review. REC Chair informs the REC Administrative Staff to include the Protocol Violation Report in the agenda of the REC panel that approved the protocol.

3.2.1. Protocol violation in a research study that involves minimal risk may be eligible for expedited review by the Primary Reviewers who did the initial protocol review.

3.2.2. If the reported violation involves the consent process or other non-interventional activity of the study, the REC Chair assigns the review to any one of the Primary Reviewers.

4. Reviewing the Report, Deliberating, and Deciding on the Course of Action

4.1. The protocol violations' possible review decisions are as follows:

- Acknowledged – no further information or action required
- Additional information required – additional information is needed in order to properly evaluate the violation

4.1.1. Correction and/or corrective action are required (violation appears serious or continuing non-compliance may be involved) Correction and/or corrective action may include suspension of REC approval until further notice, suspend recruitment of participants until corrective actions are taken, modify the protocol, observe informed consent process, change continuing review timeline require training of PI and/or Research Staff, etc.

4.2 The assigned primary reviewer completes his/her review and defines corrective actions, if any, within seven (7) days from receipt of the Protocol Violation Report and submits their/completed Review Decision form to the Administrative Staff.

4.3 Administrative Staff emails the review decision to the REC Chair for his/her oversight review. If s/he agrees with the decision, s/he informs the Administrative Staff to prepare the Review Decision Letter to the Researcher.

4.4 If s/he does not concur with the review decision of the Primary Reviewer/s, s/he initiates e-mail/phone exchanges or a meeting with the Primary Reviewer/s to arrive at a consensus. This procedure should be completed within three (3) days from the REC Chair's receipt of the Reviewer/s' decision.

5. Communicating Review Decision to the Researcher

Refer to QSOP26 Communicating Decisions.

6. Verifying Actions Taken by the Researcher

6.1. If correction and/or corrective action is required from the Researcher, the Researcher shall be formally requested to provide the required information, clarification, or documentation within two (2) weeks from receipt of the notification. The REC Administrative Staff shall issue an automatic reminder seven (7) calendar days after the initial request if no response has been received.

6.2. In cases where no response is received after fourteen (14) calendar days, the matter shall be escalated to the REC Chair for appropriate action, which may include issuance of a final notice, temporary suspension of the study, or other measures deemed necessary to protect research participants.

6.3. Depending on the magnitude of risks to research participants, the REC, through the Chair, may request the REC–Internal Quality Audit (IQA) Team or the Primary Reviewers to conduct a study site monitoring visit to verify whether the Researcher has followed the recommended course of action. The concerned team shall submit a Study Site Monitoring Report not later than two (2) weeks from the date of the visit.

6.4. The REC Administrative Staff shall include the Researcher's follow-up report and, when applicable, the Study Site Monitoring Report in the agenda of the next scheduled REC meeting for information, deliberation, and/or appropriate action.

7. Filing the Relevant Documents in the Protocol File or in the e-Folder for that Particular Protocol

(In the case of individual-initiated studies – especially by resident physicians/ fellows/ students).

7.1. The REC Administrative Staff keeps the original paper/e-copy of the Review Decision Letter.

7.2. Completed Protocol Violation Report form and Progress Report, the Study Site Monitoring Report, Follow-up Report from the PI, and the meeting agenda and minutes in the “protocol deviation” folder of the protocol file. REC Staff updates the protocol database.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

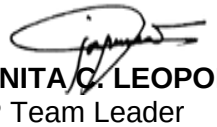
1. DDOSC-REC Form 3.5 Protocol Violation Deviation
2. Log of Incoming Documents/Communications

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Revised the policy statement; • Reorganized the Scope and the Detailed Instructions; and • Change the term "noted" to "Approved" in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 14	Juanita C. Leopoldo Kenny Jim M. Gambong	Revised Section 6 of the Detailed Instruction to include an automatic reminder after 7 days and escalation to the REC Chair after the indicated days of non-response.

APPROVAL

Prepared by:



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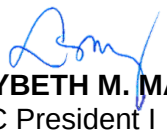
Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

The implementation of protocols approved by the REC shall be monitored to ensure the protection of the rights, safety, and welfare of research participants. Any of the following reference points shall guide the selection for site visits:

- More than minimal risk studies
- Researcher's implementing so many protocols
- Major non-compliance with international and national guidelines
- Reports of protocol violation
- Negative Events
- Protocol-related complaints
- Failure to submit the Study Closure Report or the Request for Renewal of Approval

After exercising due diligence in the notification, the absence of a formal acknowledgment or explanation from the Researcher shall not deter the planned site visit.

PURPOSE

This SOP provides instructions for monitoring the selected study sites for research protocols approved or endorsed by the REC.

SCOPE

This set of instructions applies to the conduct of regular study site visits by the REC to monitor the implementation of protocols approved or endorsed by the REC. This SOP begins with selecting the Study Site to be visited or the Protocols to be monitored, and ends with including the Study Site Visit Report in the Meeting Agenda of the Concerned REC panel.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Selecting the Study Site to be visited or the Protocols to be monitored	REC Chair	1 month before the scheduled visit
2	Selecting the Study Site Visit Team	REC Chair	
3	Preparing the Study Site Visit Plan	Designated Study Site Visit Team	
4	Notifying the Researcher/Study Site	REC Admin Staff	1 week before the scheduled visit
5	Conducting the Study Site Visit	REC Visit Team	1 day
6	Study Site Debriefing	REC Visit Team	3 hours

7	Presenting Findings to the REC	REC Visit Team	5 days after the site visit
8	Communicating the REC findings and the decision to the Researcher	REC Admin Staff	1 week after the REC visit
9	Filing of documents	REC Admin Staff	Within 1 day after the site visit
10	Including the Study Site Visit Report in the Meeting Agenda of the Concerned REC panel	REC Admin Staff	

DETAILED INSTRUCTIONS

1. Selecting the Study Site to be Visited or Protocols to be Monitored

The study site visit is randomly conducted at least once every quarter to monitor the implementation of protocols of more than minimal risk and protocols of researcher with many ongoing studies and as needed for a cause like allegation/report of major non-compliance, protocol violation, protocol-related complaints, and failure of researcher to submit Study Closure Report or Request for Renewal of Approval upon its expiration.

1.1. The REC Administrative Staff periodically reviews the review reports of Primary Reviewers on the Progress Reports and RNE Reports.

1.2. REC Administrative Staff prepares a short list of study sites to be visited for presentation to the REC Chair, who will choose the study site/s to be visited for the quarter.

1.3. A study site visit for a cause is conducted as soon as the “cause” is known. The members of the Study Site Visit Team should preferably be the Primary Reviewers or members of the REC that approved the protocol to be monitored.

2. Selecting the Study Site Visit Team

2.1. The REC Chair selects the leader and members of the Study Site Visit Team who will monitor the implementation of the selected research protocol/s.

2.2. Depending on the urgency of conducting the monitoring visit, the REC Chair may choose to designate the REC-Internal Quality Audit (IQA) Team to do the visit.

3. Preparing the Study Site Visit Plan

3.1. The designated Study Site Visit Team, in consultation with the REC Chair, is given access to the protocol file of the selected protocol/s so that they can start making appropriate notes.

3.2. The designated study site visit team may also photocopy some parts of the files (like advertisement materials, the informed consent form (ICF), and the case report form) for comparison with the documents used in the study site. Photocopied materials must be signed out and returned to the REC Admin Staff after completion of the study site visit for shredding.

4. Notifying the Researcher/Study Site

4.1. The REC Administrative Staff contacts the PI through text or email to notify him/her of the scheduled monitoring visit 2-3 days prior to the actual visit. At this time, the monitor and the research project coordinator/focal person in the study site will coordinate a time convenient to both parties, at least for the debriefing meeting.

4.2. Failure of the Researcher or the study site to formally acknowledge the site visit notification shall not deter the site visit as planned.

5. Conducting the Study Site Visit

5.1. The designated site visit team shall:

- Ensures that the Researcher and the Research Staff are adequately informed about the study;
- Verifies that the researcher and the Research Staff are performing the specified study functions in accordance with the approved protocol and any other written agreement between/among the sponsor, the researcher, and the institution, and have not delegated these functions to unauthorized individuals;
- Verifies that the researcher follows the approved protocol and all approved amendments (s), if any;
- Verifies that the researcher is enrolling only eligible participants;
- Verifies that source documents and other study records are accurate, complete, kept up-to-date, and well-maintained;
- Review the informed consent (and assent, if any) document to make sure that the site is using the currently approved version;
- Reviews randomly the participant's source files for proper informed consent documentation;
- Observes laboratory and other facilities necessary for the study at the site, if appropriate for the study;
- Debriefs the visit report/comments;
- Determines whether all RNEs are appropriately reported within the time periods required by GRP, DDOSC-REC, and the applicable regulatory authorities; and
- Fills the Site Monitoring Visit Report Form and writes comments.

6. Study Site Debriefing

6.1. The site visit team gives the researcher and Staff a summary description of the overall findings of the monitoring visit in recognition of their contribution to the research project.

7. Presenting Findings to the REC

7.1. The site visit team submits the DDOSC-REC Form 3.7 Study Site Visit Report describing the findings of the monitoring visit to the DDOSC-REC office within two (2) weeks from the date of the visit.

7.2. After the form is received, the REC Admin Staff checks for its completeness. Further queries, if any, are sent to the Researcher.

7.3. The REC Admin Staff reviews the monitoring visit findings for inclusion in the meeting agenda.

7.4. The Site Visit Team Leader or a designated member of the team presents the results of the on-site monitoring visit to the REC for deliberation.

8. Communicating REC findings and decision to the Researcher

8.1. The REC Chair conducts an oversight review of the Site Monitoring Report, including the findings and recommendations of the Study Site Visit Team.

8.2. The REC Administrative Staff formally transmits the Site Monitoring Report to the researcher within two (2) weeks after the REC meeting. The report shall include all findings and corresponding recommendations from the Study Site Visit Team and the rest of the committee.

8.3. Upon receipt of the Site Monitoring Report, the Researcher shall submit a Corrective Action Plan (CAP) addressing all findings and recommendations within two (2) weeks, unless a different timeline is specified by the REC.

8.4. If the Researcher fails to submit the required Corrective Action Plan within the prescribed period, the REC Administrative Staff shall automatically escalate the matter to the REC Chair for appropriate action.

8.5. Actions taken following escalation may include issuance of a follow-up notice, request for justification, suspension of protocol-related activities, or referral to the Full Board, as determined by the REC Chair and consistent with applicable SOPs.

8.6. All communications, submissions, and actions related to the Site Monitoring Report and Corrective Action Plan shall be properly documented and filed by the REC Secretariat.

9. Filing of documents

The REC Staff places the reports and other related documents in the concerned protocol file and updates the electronic database as appropriate.

10. Including the Study Site Visit Report in the Meeting Agenda of the Concerned REC panel

The REC Admin Staff includes the Study Site Visit Report in the concerned REC meeting agenda for the information of the entire panel.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

DDOSC-REC Form 3.7 - Study Site Visit Report

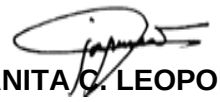
HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft

1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Changed the Title of the SOP; • Changed some responsible people in some steps and aligned them with its detailed instructions; and • Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Amended Step 8 of QSOP 23 to include the deadline for corrective plans and automatic escalation to the REC Chair if no response is received.

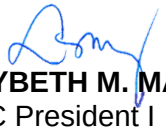
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

3. All complaints/inquiries regarding studies approved by the REC shall be reported to and acted upon promptly.
4. The REC shall ensure the protection of the rights and welfare of the human subjects participating in all research involving human-to-human data approved by the REC as its primary responsibility

PURPOSE

This SOP provides instructions for dealing with and accommodating inquiries and complaints regarding studies approved by the REC.

SCOPE

This set of instructions applies to requests or complaints related to protocols approved or favorably endorsed by REC. This starts with receiving the complaint/inquiry and ends with filing the relevant documents.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving the complaint/inquiry	Administrative Staff	1 day upon receiving the complaint/inquiry
2	Assessing the nature of inquiry/complaint	REC Chair	
3	Responding to inquiries/complaints	REC Chair	Within 15 days upon receipt
4	Preparing Report of Actions Taken	REC Chair or designated REC member	Within 1 day after assessing the inquiry
	Filing the Relevant Documents	REC Admin Staff	

DETAILED INSTRUCTIONS

1. **Receiving the inquiry/complaint**

   On certain occasions, the REC Admin Staff may receive inquiries/complaints. The Staff also logs the complaint or inquiry and refers it to the REC Chair.

2. **Assessing the nature of the inquiry/complaint**

   The REC Chair assesses the inquiries/complaints based on their urgency, their effects on the safety of research participants, and the integrity/validity of research data.

3. Responding to inquiry/complaint

3.1. **Inquiry**

The REC Chair provides the information required.

3.2. **Complaint**

3.2.1. In case the complaint requires investigation, the REC Chair may designate REC Members, preferably the Primary Reviewers of the protocol in question, to gather information and verify the complaint. The designated REC Members discuss with the REC Chair the results of the investigation.

3.2.2. The REC Chair provides feedback to the complainant, and if needed, mediates a dialogue between the complainant and the principal investigator in an attempt to resolve the matter.

3.2.3. The DDOSC-REC utilizes factual details to establish the truth and validate the complaint. Feedback should be given to the complainant within 15 days upon receipt of the complaint.

4. Preparing Report of Actions Taken and Filing the Relevant Documents

4.1. **Preparing Report of Actions Taken**

The REC Chair or designated REC Member fills up the DDOSC-REC Form 3.4 Query/Complaint Record.

4.2. **Filing the Relevant Documents**

The Admin Staff shall file other relevant documents needed and or used.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

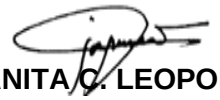
DDOSC-REC Form 3.4 Query/Complaint Record

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Changed the Statement policy, scope, and detailed instructions; and • Change the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

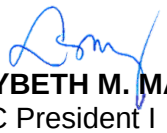
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

All Reportable Negative Events (RNE) involving risks to research participants shall be reviewed, addressed, and offered mediation by the REC under appropriate circumstances. The REC shall require the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.

PURPOSE

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

SCOPE

This SOP applies to the review of RNE reports. This SOP begins with receiving the submission of the RNE report and ends with filing the RNE report and Review Documents.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving the Submission of the RNE Report	REC Administrative Staff	1 day upon submission
2	Determining the type of review	REC Chair	
3	Designating the Reviewer to Review the RNE Report	REC Administrative Staff	
4	Reviewing the RNEs	Primary Reviewers and REC Chair	Within 1 week of their receipt of the documents
5	Communicating the decision to the Principal Investigator	REC Administrative Staff	Within 1 day after receiving the decision
6	Filing the RNE Report and Review Documents	REC Administrative Staff	Within 1 day after communicating with the Researcher

DETAILED INSTRUCTIONS

1. **Receiving the Submission of the RNE Report**
   Upon receipt of RNEs, the REC Admin Staff records the submission in the Log of Incoming Documents and informs the REC Chair. The Staff notes whether the submission is within the required timeline.

2. **Determining the type of review**
   2.1. Reportable Negative Events (RNE) are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to the

integrity of data. Examples are brewing hostilities in the research community, natural calamities, threats of harassment, etc.

2.2. The REC Chair determines whether the report is about “Reportable Negative Event”, and attribution (definitely related, possibly related, and unknown relationship), and decides whether the report requires an expedited review by the Primary Reviewer who did the initial (and subsequent review/s, if any) or full board review by the REC panel that approved the protocol.

3. Designating a Reviewer to Review the RNE Report

REC Admins Staff forwards the completed RNE Report Form to the Primary Reviewer who conducted the initial (and subsequent/post-approval reviews, if any).

4. Reviewing the RNEs

RNE Reports may be reviewed by the expedited procedure, but the Primary Reviewer may recommend Full Board Review for the said RNE Report for a reason.

4.1. The Primary Reviewers review the SAE Report and decide whether to:

- Take note and no further action
- Request a full-board meeting
- Request an amendment to the protocol
- Request further information
- Conduct a visit
- Any other action.

4.1.1. Primary Reviewer sends the results of the review and his/her recommendations to the Administrative Staff within 1 week from their receipt of the documents. If the assessment shows that immediate action is needed, the Primary Reviewer sends the review results and recommendations to the REC Chair.

4.1.2. The REC Admin Staff forwards the results in the completed DDOSC-REC Form 2.3 Protocol Evaluation Form of the review, together with a copy of the SAE Report, to the DDOSC-REC Chair for his/her oversight review.

4.2. If the RNE Report warrants a Full Board review, the Administrative Staff includes this in the meeting agenda of the DDOSC-REC that approved the protocol, provided that the submission date is at least three (3) days before the meeting date.

4.2.1. The Chair leads the discussion of the special meeting, summarizes the RNE report, and informs the REC 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 effectiveness 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 REC members deliberate on possible options, as follows:

- Recommend suspension of the study until the risk is resolved
- Withdrawal of ethical clearance
- Require an amendment to the protocol
- Submission of a plan to mitigate risk/harm
- Conduct a site visit
- Uphold original ethical clearance
- Any other action

4.2.2. REC Amin Staff collects the DDOSC-REC Form 3.6 Reportable Negative Event Report Form right after the meeting of the REC.

4.2.3. The REC Admin Staff forwards the minutes of the REC meeting, the completed Forms to the REC Chair for his/her oversight review.

5. Communicating the decision to the Principal Investigator

Refer to DDOSC-REC QSOP26 Communicating Decisions.

6. Filing the RNE Report and Review Documents

6.1. For externally funded/sponsored study, the REC Admin Staff files the original paper copy of the RNE Report and other RNE Report-related documents in the appropriate folder of the protocol file, and updates the Protocol File Index and the e-protocol database.

6.2. For an individual-initiated study, the REC Admin Staff saves the soft copy of the abovementioned documents in the e-folder for this particular protocol and updates the e-protocol database.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 3.6 Reportable Negative Event (RNE) Report Form
2. DDOSC-REC Form 4.1 Meeting Agenda Form

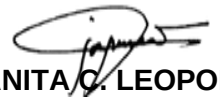
HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Realigned the Purpose, Scope, and Workflow Chart; and Change the term “noted“ to “Approved“ in the approval section.
1	2022 Oct 07	Lilybeth M. Matunhay and other REC members	Added provision on the criteria for SAEs.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Revised the whole SOP to outline the review of RNEs rather than SAEs: • Amend the Statement of Policy. • Added step 1 and its procedure; • Added paragraph 2.1; • Revised section 4;

			• Revised the DDOSC-REC Form 3.6 Reportable Negative Event Form. • Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Research involving human participants cannot be implemented until after the REC reviews and approves the research protocol, generates the letter of approval, and stamps the informed consent form (and other supplemental documents), if appropriate.

REC must ensure that its review decision is communicated to the researcher in an efficient and effective manner. The REC shall comply with the prescribed timelines for ethics review and shall not exceed 2 weeks from the review of the protocol to the communication of the decision.

PURPOSE

This SOP describes the procedure for communicating the review decision to the Principal Investigator accurately and in a timely manner.

SCOPE

This set of instructions applies to the preparation of the Notification Letter or Approval Letter to the Researcher using the REC-prescribed templates. This starts with finalizing the meeting minutes and verifying the review decision, and ends with a request for confirmation of receipt of the decision letter from the researcher and the filing of a copy of the signed and dated decision letter by the Chair in the protocol file.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Finalizing the Meeting Minutes and Verifying the Review Decision	REC Admin Staff	2 days from the meeting date
2	Preparing Decision Letter		Within 1 day after finalizing the minutes of the meeting
3	Sending Decision Letter to the Researcher		
4	Requesting Confirmation of Receipt of the Decision Letter from the Researcher		At least 2 days
5	Filing the Decision Letter in the Protocol File and updating the Protocol Database		Within 1 day after sending the decision to the Researcher

DETAILED INSTRUCTIONS

1. **Finalizing the meeting minutes and verifying the review decision**

   The REC Admin Staff prepares the draft of the meeting minutes and, within two (2) days of the meeting date, forwards it to the concerned REC Member Secretary for finalization.

2. Preparing a decision letter

2.1. The REC Administrative Staff prepares the decision letter based on the information from the final version of the provisional meeting minutes

2.2. For Notification Letter (Notification of REC Decision, Notification of Amendment Decision, Notification of Deviation Decision of SAE Report Decision, -Notification of Progress Report/Continuing Review Application Decision, Notification of Early Study Termination Decision and Notification of Study Closure/Final Report Decision) with DDOSC-REC Form 2.5 Notification Letter, REC Admin Staff copies the list of recommendations from the meeting minutes and pastes this on the letter.

2.3. REC Admin Staff requests REC Chair to sign and date the decision letter.

3. Sending decision letter to the Researcher

For submission reviewed by a full panel meeting or by expedited means, a decision letter (DDOSC-REC Form 2.5 Notification Letter and DDOSC-REC Form 2.6 Certificate of Approval) should be sent to the Researcher within a week from the date of the review meeting. For submissions reviewed by primary reviewers under an expedited procedure, the decision letter should be sent to the Researcher within a week from the date the results of the review were submitted to the REC Admin Staff.

3.1. REC Administrative Staff informs the Researcher that the decision letter is ready for pick-up.

3.2. REC Administrative Staff may scan the decision letter and email it to the Researcher as per the request of the latter.

3.3. REC Administrative Staff logs the decision letter in the Log of Outgoing Documents

4. Requesting confirmation of receipt of the decision letter from the Researcher

For researchers who requested that the decision letter be sent via email, the REC Administrative Staff shall request confirmation of receipt via email or text message. All actions taken and responses received shall be properly documented in the Log of Outgoing Documents.

In cases where confirmation of receipt is not received, the following escalation procedures shall apply:

4.1. Within three (3) working days from the initial transmission, the REC Administrative Staff shall issue a first follow-up reminder via email or text message requesting acknowledgment of receipt. This shall be recorded in the Log of Outgoing Documents.

4.2. Within five (5) working days from the initial transmission and in the absence of a response, a second follow-up shall be conducted using an alternative mode of communication (e.g., phone call or secondary email address on record). The action and outcome shall be documented.

4.3. Within seven (7) working days, if no confirmation is still received, the matter shall be elevated to the REC Chairperson, and the decision letter shall be re-sent with an indication of *"Second Official Transmission."*

4.4. After ten (10) working days with no acknowledgment despite due diligence, the decision letter shall be considered officially served, and the Log of Outgoing Documents shall be annotated as *"Presumed Received after Exhaustion of Follow-up Procedures."*

5. Filing the decision letter in the protocol file and updating the protocol database

5.1. For an investigator-initiated study, the REC Admin Staff scans the decision letter signed and dated by the Chair and saves the document file in the e-protocol file folder. After which, the REC Administrative Staff updates the e-Protocol File and the protocol database.

5.2. REC Admin Staff updates the protocol database on the same day it is performed.

5.3. REC Admin Staff updates the backup copy of the e-protocol file folders in the Google Drive on the same day it is performed.

5.4. REC Admin Staff updates back-up copy of the e-protocol file folders in the external drive on the 1st and 16th day of the month, or the following day if the day falls on a non-working day.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

1. DDOSC-REC Form 2.5 Notification Letter
2. DDOSC-REC Form 2.6 Approval Letter

HISTORY OF SOP

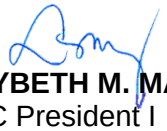
Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Revised the Policy Statement, and changed the term "noted" into "Approved" in the approval section. • Changed the term "noted" to "Approved" in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	• Added paragraphs 4.1-4.4 to provided escalation procedures if there is no confirmation in a particular duration and reflect the documentation of all follow-up attempts in the Log of Outgoing Documents. • Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Research protocol and protocol-related documents have to be filed in an organized and systematic manner for safekeeping of documents, easy inventory and retrieval, and protection of these files from breaches in privacy and confidentiality. Protocol files and related documents should be kept under lock and key.

PURPOSE

This SOP provides instructions related to the maintenance of active files in compliance with national and international guidelines and standards.

SCOPE

This SOP includes REC actions related to maintenance of active files and starts with filing protocol and other protocol-related documents in an organized manner and ends with storing properly labeled protocol file folders in file storage cabinets.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Filing protocol and other protocol-related documents in an organized manner	REC Admin Staff	Within 1 day after the decision is sent to the researcher
2	Updating of protocol file regularly as documents come or are produced		1 month
3	Storing properly labeled protocol file folders in file storage cabinets		Within 1 day of filing the documents

DETAILED INSTRUCTIONS

1. **Filing protocol and other protocol-related documents in an organized manner**
   1.1. Protocol files are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion, termination, or withdrawal from the review process. Active protocol files are either those undergoing the REC review process or REC-approved ongoing studies.

   1.2. Protocols are identified using a unique identification number described in DDOSC-REC QSOP 07 Management of Initial Submission.

1.3. The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index:
- All versions of the study protocol
- Related documents that came with the study protocol (ICF, CRF, recruitment materials, etc.)
- Principal investigator and co-investigators' CVs and valid GCP Training Certificate if required
- Reviewers' assessment forms
- Excerpt of the minutes of the meeting where the protocol was discussed
- Decision letters (notification letters or approval letter/s – initial and renewal)
- Post-Approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding reviewers' assessment and REC decision
- Participant queries/complaints
- Site Visit Reports
- Miscellaneous communication related to the protocol
- Final report

1.4. For externally funded/industry-initiated protocols:
- Place in an organized manner, following the sequence prescribed in the Protocol File Index Form, all the content of the submitted protocol package in a durable file binder – one binder per protocol.
- Stick label with the Protocol No. on the side of the file binder
- Stick label with < REC Protocol No.>, <full title of the protocol>, <name of PI>, <name of sponsor>, <Sponsor Protocol No.> on the front cover of the file binder.
- To differentiate unapproved from REC-approved protocols, stick a red round label on the side of the file binder below the label with the REC Protocol No. for unapproved protocols. Remove the round red label as soon as the protocol is approved.
- Place the filled file binder on the shelf in a vertical position and sequentially according to their REC Protocol No.
- Label the door of the file storage cabinet, indicating the REC Protocol Numbers of the protocols inside.

1.5. For investigator-initiated study:
- Create a digital folder with file name: < REC Protocol No.>_<name of PI>
- Create two (2) sub-folders with file names: 1) Before REC Approval and 2) Post REC Approval
- Arrange digital files in the e-folder according to the order in the Protocol File Index and name the file according to the following format:
    - DocumentNumber_NameofPI_ProtocolNumber_DocumentNameVersion Number_VersionDate (dd/month/yyyy)

2. Updating of protocol file regularly as documents come or are produced

2.1. For externally-funded industry-initiated protocols:
- Protocol-related paper files/documents are added to the protocol file folder on the day that they are submitted or produced (like accomplished assessment forms, excerpts of minutes, and REC review decision letters).

- Filing of additional documents should be arranged according to the sections described in the Protocol File Index and chronologically, with the most recent file/document at the top/front.
- Add file binders when needed to accommodate the increasing number of documents.
- As more file binders are used, number the protocol file binders. Place the number label above the label with Protocol No.

2.2. For investigator-initiated study:

- Scan in PDF-format protocol-related paper file/document on the day it is submitted.
- Add the document in the sub-folder (corresponding to the section in the Protocol File Index) with the file name according to the format described in Section 1.14b.ii above.
- Update the backup copy as new documents are added to the e-protocol file folder.

3. Storing properly labeled protocol file folders in file storage cabinets

3.1. For pharmaceutical-industry-initiated protocols;

- Keep all active study files in a secure file cabinet, with access limited only to REC officers and Administrative Staff. The REC Administrative Staff keeps the key to the room and the file storage cabinets.
- Each storage filing cabinet shall have a Protocol File Index – detailing the inventory of protocol files stored therein. Transfer of the
- Protocol file to the archive is logged on this sheet. Removal of the protocol file from this cabinet is logged on this sheet as well.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

None

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Changed the term “noted“ to “Approved“ in the approval section.
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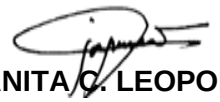
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
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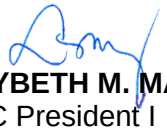
Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Archiving of research protocol, protocol-related documents, and administrative documents related to the ethical review process and other operations of the REC shall be systematized for easy inventory and retrieval, and protection from breaches of privacy and confidentiality.

PURPOSE

This SOP provides instructions for archiving terminated, inactive, and completed study protocol files and other REC administrative documents to ensure effective and efficient retrieval of information for reference and compliance with national and international guidelines and standards.

SCOPE

This SOP includes REC actions related to the archiving of terminated, inactive, and completed study protocols and other DDOSC-REC administrative documents that are for archiving. This starts with identifying completed, inactive, terminated, or withdrawn protocol files and other administrative files for archiving, and ends with reviewing and affixing appropriate labels to the files for archiving and logging in the protocol database, the Log of Outgoing Documents, and the Archiving Logbook.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Identifying completed, inactive, terminated, or withdrawn protocol files and other administrative files for archiving	REC Admin Staff	Every year
2	Reviewing and affixing appropriate labels to files for archiving and logging in protocol database, Log of Outgoing Documents, and Archiving Logbook		

DETAILED INSTRUCTIONS

1. **Identifying completed, inactive, terminated, or withdrawn protocol files and other administrative files for archiving**
   - 1.1. For Protocol Files
     - 1.1.1. Within three (3) days from the date of the REC meeting and using the approved minutes of the meeting, the REC Admin Staff identifies the protocols that are completed, terminated, inactive, or withdrawn from the review process, and updates the protocol database.
     - 1.1.2. Protocols are said to be completed when the final report of the study has been reviewed and approved by the concerned REC.

1.1.3. For industry-sponsored/externally funded studies, a protocol file is not archived until after the receipt and approval of the report from the sponsor that all study sites are closed.

1.1.4. Protocols are said to be inactive when no further communication has been received by the REC after two months from the expiry date of REC approval.

1.1.5. Protocols are categorized as terminated when a letter from the PI/Sponsor informing the REC of the early termination has been presented to the concerned REC. In the case of a study termination resulting from the withdrawal of the REC's approval for cause, the study is classified as terminated one month after the notification was sent to the PI. This is to give allowance for the appeal process, which has to be made within the month.

1.1.6. A study protocol is said to be withdrawn from the review process if the researcher fails to resubmit the protocol that is revised as per the REC's recommendations after two (2) weeks from the date of the notification letter.

1.2. For Administrative Files

1.2.1. In the first week of January of every year, the Administrative Staff performs an inventory of REC administrative files, gathers the following files that are due for archiving as per the Document Retention Schedule, and places them in an appropriate container (like an expandable envelope):

- Superseded SOP master file
- File of Meeting Agenda for the previous year
- File of Meeting Minutes for the previous year
- REC Annual Reports
- Membership File of REC Members who have resigned or whose tenure has expired
- File of accomplished Purchase Request forms
- File of payroll for honoraria of non-affiliated reviewers
- Approved Work and Financial Plan of the previous year and corresponding Annual Procurement Plan.
- Communications from external agencies pertaining to research and research ethics
- Communications from the Management and other colleges and departments pertaining to research and research ethics.

2. Reviewing and affixing appropriate labels to files for archiving and logging in protocol database, Log of Outgoing Documents, and Archiving Logbook

2.1. For Protocol Files

2.1.1. For the externally funded study where the documents in the protocol file are in paper copy, the REC ADMIN Staff should:

- Remove the contents of the entire protocol file from the storage file cabinet;
- Verify that all the documents are present in an organized manner as per the protocol file index.

2.2. For Administrative Files

2.2.1. The Administrative Staff should:

- Remove the aforementioned (in 1.2) administrative files from the storage file cabinet;
- Verify that all the documents are complete and arranged in an organized and chronological manner.

2.3. For Protocol Files:

2.3.1. REC Admin Staff assigns an archive number to the protocol file by adding the date of archiving to the original code of the study file, e.g., P001-11-2009/130104 – the first protocol accepted on 12 November 2009 was archived on 04 January 2013.

2.3.2. Correspondingly, the Administrative Staff enters the data about the study and the date of archiving in the protocol database

2.3.3. REC Admin Staff logs the protocol with its archive number and other protocol identifiers (Full Title, Name of PI, Name of Sponsor, and Sponsor Number) in the Log of Outgoing Documents (with notation in the REC Action column that the file is for transfer to the archive room), and in the Archiving Logbook.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

None

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	Enhanced the title of this SOP and its Scope; and Changed the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

The REC shall institute adequate safeguards to protect the confidentiality of documents with data and information that is personal and/or proprietary in nature. REC members and staff shall be trained to fully assume their responsibilities related to document keeping and their retrieval to ensure the maintenance of confidentiality of these documents at all times.

PURPOSE

This SOP provides instructions for managing access to confidential files to ensure the protection of the intellectual property rights of researchers and enhance the credibility and integrity of the REC.

SCOPE

This SOP includes REC actions related to managing access to confidential files. It begins with receiving and logging requests for access to confidential files and ends with returning of document to the protocol file folder.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Receiving and logging requests for access to confidential files	REC Admin Staff	1 day upon request
2	Approving requests for access and retrieval of documents	REC Chair	
3	Supervising the use of the retrieved confidential document	REC Admin Staff	
4	Returning the document to the protocol file folder	REC Admin Staff	2 days upon request

DETAILED INSTRUCTIONS

1. **Receiving and logging requests for access to confidential files**
   1.1. The DDOSC-REC considers the following as confidential:
   - Study protocols;
   - Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews);
   - Meeting Minutes;
   - Decisions, action letters/notification of REC decision, approval letters;
   - Study protocol-related communications (to/from experts, study participants, and the like).

   1.2. Access to DDOSC-REC confidential documents is subject to the following limitations:

- REC members and staff with a signed Confidentiality and Conflict of Interest Agreement Form can access confidential documents outside of regular protocol review access, upon request.
- Non-members can access specific documents by submitting a formal request. The REC Administrative Staff will provide a copy of the DDOSC-REC Form 4.3 Request to Access REC Files for signature by the borrower. The request will be accomplished by the person making the request, and signed by the REC Chair

2. Approving the request for access and retrieval of documents

2.1. Borrower must write a letter requesting access to the confidential file.

2.2. Request for access to confidential files is approved by the concerned PI and the REC Chair.

2.3. A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:

- Protocol Code Number;
- Date borrowed;
- Name of borrower;
- Signature of borrower upon retrieval;
- Signature of REC Administrative Staff upon return of document to protocol file folder;
- Document copied;
- Number of copies made;
- Number of copies received by borrower.

2.4. All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.

3. Supervising the use of retrieved confidential documents

3.1. Access to REC documents is generally for room use only under the supervision of the REC Administrative Staff.

3.2. REC Administrative Staff retrieves only the document specified in the approved request and not the entire file.

3.3. REC Administrative Staff retrieves only the document specified in the approved request and not the entire file.

3.4. Request for photocopy of the borrowed documents needs a separate approval from the Researcher and the REC Chair.

3.5. The Administrative staff photocopies only the exact number of copies requested and ensures the diligent recording of all document copies issued in the Log of Request for Photocopies of Documents. This log is filed in a separate folder labeled Log of Photocopies of Documents.

4. Returning the document to the protocol file folder

4.1. The REC Administrative Staff is responsible for returning the documents in the protocol file folder in the file storage cabinet after making sure that all documents are complete as per DDOSC-REC Form 4.4 Protocol File Index.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

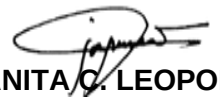
1. DDOSC-REC Form 4.3 – Request to Access REC Files
2. DDOSC-REC Form 4.4 – Protocol File Index

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 Apr 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft
1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Edited step 2 of the Workflow; and • Changed the term “noted“ into “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

	Davao de Oro State College RESEARCH ETHICS COMMITTEE	Code	DDOSC-REC QSOP-30/01.4
	MANAGEMENT OF PROTOCOL DATABASE	Revision No.	3
		Effectivity:	02/13/2026

STATEMENT OF POLICY

Information details of protocols and other documents related to the ethical review process shall be systematized for easy retrieval, reference, protection from breaches of privacy and confidentiality, and prevention of data loss.

PURPOSE

This SOP provides instructions for keeping and maintaining an electronic database of information, details of protocols, and other documents related to the ethical review process of the REC.

SCOPE

This SOP includes updating entries in the REC protocol database and performing database file backup. The updating procedure starts with identifying the submission and ends with saving of Entries in the Database. Backup starts with accessing the database account and ends with storing the external hard drive.

WORKFLOW CHART

Updating

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Identifying the submission	REC Admin Staff	1 week
2	Opening of the REC Protocol Database	REC Admin Staff	
3	Encoding of Protocol Entries	REC Admin Staff	
4	Saving of Entries in the Database	REC Admin Staff	

Backup

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Accessing the database account	REC Admin Staff	1 week
2	Backing up the database	REC Admin Staff	
3	Storing the external hard drive	REC Admin Staff	

DETAILED INSTRUCTIONS

Updating

1. **Identification of submission**

1.1. The REC Admin Staff identifies the following resubmission, amendment submission, continuing review submission, safety report submission, closure/final report submission, protocol deviation/violation submission, or site visit details for updating:
- Review date
- Decision
- Review status
- Protocol status
- Remarks
- Other protocol review-related details

2. Opening of the DDOSC-REC Protocol Database

2.1. The REC Admin Staff opens the password-protected computer account that hosts the DDOSC-REC Submissions Database.

3. Encoding of Protocol Entries

3.1. The REC Admin Staff encodes the appropriate entries in the database.

4. Saving of Entries in the Database

4.1. The REC Admin Staff saves the entries in the database, closes the database, and exits from the computer account.

Backup

1. Accessing the database account

1.1. The REC Admin Staff opens the password-protected computer account that hosts the DDOSC-REC Submissions Database.

2. Backing up of the database

2.1. The REC Admin Staff shall back up the database in an external hard drive every 16th and 30th day of the month.

3. Storing the external hard drive

3.1. The REC Admin Staff shall store the external hard drive in a cabinet that has a lock and key.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

None

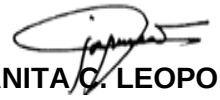
HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2018 April 18	Lilybeth M. Matunhay, Luoella A. Hugo, Rona C. Apolinario, and Rholey R. Picaza	First draft

1	2021 Aug 06	Lilybeth M. Matunhay and other REC members	• Added provisions for backing up the database; and • Changed the term “noted“ to “Approved“ in the approval section.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

The REC secretary shall record promptly and accurately in a logbook or any database all incoming and outgoing communications.

PURPOSE

This SOP aims to ensure that all incoming and outgoing communications are properly received and recorded.

SCOPE

This SOP covers REC actions related to receiving and organizing incoming and outgoing communication documents and ensuring an appropriate response to them. This SOP begins with sorting the incoming and outgoing communications (e.g., e-mails) and ends with storing or filing incoming/outgoing communications.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Sorting the incoming/outgoing communications	REC Admin Staff	Within the day of document receipt and or sent
2	Recording the incoming/outgoing communications		
3	Acting on communications		Within 1 day of filing the documents
4	Storing or filing the incoming/outgoing communications		Within the day of the receipt and/or filing of the documents

DETAILED INSTRUCTIONS

1. **Sorting the incoming/outgoing communications**
   1.1. The REC Admin Staff sorts all communications received (letters, official memoranda, or e-mails) and prepares them for recording.

   1.2. Unclaimed action letters shall be filed in the respective study protocol folders.

   1.3. In case of electronic correspondence, the REC Admin Staff prints all communications and files them in a folder.

2. **Recording the incoming/outgoing communications**

2.1. Communications related to study protocols received by the committee shall be recorded in a Communication Logbook. This Logbook is updated as each submission is received/delivered.

3. Acting on communications

3.1. All letters (decision letter, acknowledgement letter, etc.) that are sent to sponsors, investigators, and partners shall be recorded in a log book.

3.2. The REC Admin Staff ensures the receivers of the letter sign and date the logbook, indicating the letter has been duly received.

4. Storing or filing the incoming/outgoing communications

4.1. The REC Admin Staff files a copy of all communications released and received.

4.2. The REC Admin Staff writes the protocol folder content index when filing the communications.

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

None

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2021 Aug 09	Lilybeth M. Matunhay and Kenny Jim M. Gambong	First draft
1	2022 Oct 07	Lilybeth M. Matunhay and Kenny Jim M. Gambong	Specified the timeline for step no. 4.
1	2024 Jul 19	Rona C. Apolinario Kenny Jim M. Gambong	Updated the signatories in the Approval section.
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

APPROVAL

Prepared by:

JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:

LILYBETH M. MATUNHAY, PhD
SUC President I

STATEMENT OF POLICY

Administrative and protocol files that have been archived for a specific retention period shall be disposed of in accordance with the institution and the National Archive of the Philippines (NAP) guidelines.

PURPOSE

This SOP outlines the procedures for the disposal of documents in the Research Ethics Committee. The purpose of this SOP is to ensure that documents are disposed of in a secure and environmentally friendly manner, in compliance with all applicable laws and regulations.

SCOPE

This set of instructions applies to all archived, terminated, inactive, and completed protocols reviewed by the REC. This starts with identifying the archived protocol and administrative documents for disposal and ends with the disposal of the records.

WORKFLOW CHART

STEP	ACTIVITIES	RESPONSIBLE PERSON	TIMELINE
1	Identify the archived protocol and administrative documents for disposal	REC Admin Staff	Within a month after the end of the documents' retention period
2	Appraisal of records or documents	REC Admin Staff	1 week
3	Disposal of the records	REC Admin Staff	1 week

DETAILED INSTRUCTIONS

1. Identify the archived protocol and administrative documents for disposal

1.1 The REC Admin Staff shall review the records retention schedule and protocol databases to identify the records that have reached their retention period and may be disposed of.

1.2 An inventory shall be conducted with the use of the National Archive of the Philippines (NAP) Form No. 01 – Inventory and Appraisal.

2. **Appraisal of records or documents**

2.1. An appraisal is a process of determining the value of records. Records may be appraised as having archival value, historical value, or administrative value. Records with archival value should be transferred to the NAP for permanent preservation.

Records with historical value may be transferred to a historical society or other cultural institution. Records with administrative value may be disposed of, but only with the prior written approval of the NAP.

2.2. The list of records to be disposed of shall be endorsed by the REC Admins Staff to the Records Office for the appraisal of the records.

2.3. Once the records are endorsed, the office will just have to wait for the proper disposal of the listed records based on the timeline set by the National Archive of the Philippines.

3. Disposal of the records

3.1 Once the NAP has approved the request of the Records office, the list of records shall be turned over for the disposal of these records. Records may be disposed of by shredding, pulping, or incineration.

3.2

FORMS/TEMPLATES ASSOCIATED WITH THIS SOP

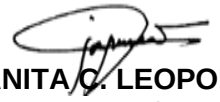
1. DDOSC-REC Form 4.6 – Archiving Log sheet
2. DDOSC-REC Protocol Database
3. National Archive of the Philippines Form No. 01 – Inventory and Appraisal

HISTORY OF SOP

Version No.	Date	Authors	Main Change
1	2023 Sep 29	Lilybeth M. Matunhay Kenny Jim M. Gambong	First draft
1	2026 Feb 13	Juanita C. Leopoldo Kenny Jim M. Gambong	Updated the signatories in the Approval section.

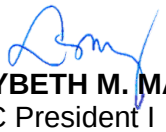
APPROVAL

Prepared by:



JUANITA C. LEOPOLDO, DBA
SOP Team Leader

Approved by:



LILYBETH M. MATUNHAY, PhD
SUC President I

REC FORMS

APPOINTMENT LETTER

Date:

TITLE, NAME, SURNAME
DESIGNATION
ADDRESS

Dear <Title, Surname>:

I am pleased to inform you that you have been nominated to be a **CHAIR/ MEMBER/ADMINISTRATIVE STAFF** of the Davao de Oro State College-Research Ethics Committee (DDOSC-REC). The primary function of the DDOSC-REC is to perform ethical review of research proposals to ensure the safety of human participants recruited by the study.

If you accept this nomination, you will be appointed for a period of _____, renewable _____, upon recommendation of the DDOSC-REC Chair and approval of the College President. The terms of reference of such appointment are as follows:

Insert Statement of Responsibilities (DDOSC-REC Form 1.1.1)

If you agree with the terms of this nomination, please signify your confirmation by signing in the space provided below, dating your signature, and returning one copy of this letter to the DDOSC-REC Admin Staff. Also, if you have any questions regarding the information outlined in this letter of appointment, you may visit the REC Office at the address and contact details indicated above for assistance.

Thank you and best regards.

Very truly yours,

JUANITA C. LEOPOLDO, DBA
DDOSC-REC Chair

NOTED (as applicable)**:**

LILYBETH M. MATUNHAY, PhD Date:
College President

CONFORM:

_____ Date:
Signature over Printed Name

STATEMENT OF DUTIES AND RESPONSIBILITIES OF A REC CHAIR

Date:

Dear _____
(Name of REC Members)

As an appointed **REC Chair** of the Davao de Oro State College REC, you will have the following roles and responsibilities:

- Sets agenda in coordination with the Member Secretary and the Administrative Staff; and presides over REC meetings;
- Conducts preliminary assessment of research protocols for review to decide on the type of review required, whether full-board or expedited;
- Designates REC member/s for expedited reviews of duly identified protocols, and ensures that the aforementioned REC members do not conflict of interest;
- Designates Ad Hoc Investigation team in cases of complaints/reports of major non-compliance by the study proponents;
- Performs oversight review of the initial review decision of the review panels, and e-mails back concurrence or comments, if any, to the REC Admin Staff;
- Serves as a review panel chair of one of the review panels;
- Ensures that all REC members receive orientation and undergo Basic Research Ethics Training immediately after their appointment, and continuing education thereafter;
- Obtains logistics and administrative support for the sustained operations of the REC;
- Submits Annual Accomplishment Report of REC to the head of the institution;
- Ensures that the REC is perceived as a fair and impartial, immune from pressure either by the institution's management, the investigators whose protocols are brought before it, or other professional and non-professional groups;
- Manages complaints from study participants, authorities, or the general public;
- Represents the REC interests within the institution's administration; and
- Represent the REC in various fora.

If you agree with the terms of this appointment, please sign in the space below and return one (1) copy to the Davao de Oro State College REC Secretariat.
Submit a duly signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

LIYBETH M. MATUNHAY, PhD
College President

Conform:

_____ _____
(Print name and sign) *Date*

STATEMENT OF DUTIES AND RESPONSIBILITIES OF A MEMBER SECRETARY

Date:

Dear _____
(Name of REC Members)

As an appointed **Member Secretary** of the Davao de Oro State College REC, you will have the following roles and responsibilities:

- Supervise the REC Administrative Staff;
- Prepares the Meeting Agenda and coordinates with the REC admin staff on dissemination of the meeting agenda to the REC members;
- Assist the REC chair in the selection of primary reviewers/independent consultants for review of the research protocol;
- Ensures secure filling, documentation, and archiving of protocol files, meeting agenda, minutes of the meeting, and other correspondence;
- Serve as the Primary Reviewer for research protocol documents within their area of expertise, and as General Reviewers for all research discussed at convened meetings of the REC;
- Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment form when they are designated as Primary Reviewers;
- Conduct expedited review on behalf of the REC of protocols assigned by the REC Chair/Member-Secretary and submit the assessment forms on time (within 7 calendar days);
- Perform post-approval review procedures of protocol-related documents within 7 calendar days;
- Update CV and training record every time an appointment is renewed;
- Conform at all times with the legal and ethical principles accepted by the REC;
- Attend basic and continuing education on Research Ethics at least once a year;
- Perform other tasks assigned by the REC Chair.

If you agree with the terms of this appointment, please sign in the space below and return one (1) copy to the Davao de Oro State College REC Secretariat.
Submit a duly signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

LIYBETH M. MATUNHAY, PhD
College President

Conformed:

_____ _____
(Print name and sign) *Date*

STATEMENT OF DUTIES AND RESPONSIBILITIES OF A SCIENTIST MEMBER

Date:

Dear _____
(Name of REC Members)

As an appointed **Scientist Member** of the Davao de Oro State College REC, you will have the following roles and responsibilities:

- Serve as the Primary Reviewer for research protocol documents within their area of expertise, and as General Reviewers for all research discussed at convened meetings of the REC;
- Review and assess research protocol and informed consent document using the Protocol and ICF Assessment form;
- Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment form when they are designated as Primary Reviewers;
- Participate in DDOSC-REC review meetings, and vote for full approval, suspend approval pending compliance with suggested revisions, or disapproval of the research protocols;
- Conduct expedited review on behalf of the REC of protocols assigned by the REC Chair/Member-Secretary and submit the assessment forms on time (within 7 calendar days);
- Perform post-approval review procedures of protocol-related documents within 7 calendar days;
- Update CV and training record every time an appointment is renewed;
- Conform at all times with the legal and ethical principles accepted by the REC;
- Attend basic and continuing education on Research Ethics at least once a year; and
- Perform other tasks assigned by the REC Chair.

If you agree with the terms of this appointment, please sign in the space below and return one (1) copy to the Davao de Oro State College REC Secretariat.
Submit a duly signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

LIYBETH M. MATUNHAY, PhD
College President

Conformed:

_____ _____
(Print name and sign) *Date*

STATEMENT OF DUTIES AND RESPONSIBILITIES OF A NON-SCIENTIST MEMBER

Date:

Dear _____
(Name of REC Members)

As an appointed **Non-scientist/Lay Member** of the Davao de Oro State College REC, you will have the following roles and responsibilities:

- Serve as the Primary Reviewer for research protocol documents within their area of expertise, and as General Reviewers for all research discussed at convened meetings of the REC;
- Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment form when they are designated as Primary Reviewers;
- Conduct expedited review on behalf of the REC of protocols assigned by the REC Chair/Member-Secretary and submit the assessment forms on time (within 7 calendar days);
- Perform post-approval review procedures of protocol-related documents within 7 calendar days;
- Update CV and training record every time an appointment is renewed;
- Conform at all times with the legal and ethical principles accepted by the REC
- Attend basic and continuing education on Research Ethics at least once a year;
- Perform other tasks assigned by the REC Chair;
- Focuses on the subject recruitment process, the informed consent process, and the informed consent document to ensure that there is no undue influence on the research subject. A non-scientist member should ask if s/he will give consent to participate if s/he or a close member of his/her family is recruited as a research subject; and
- Quorum during meetings also requires the presence of at least one non-scientist/lay member to make decisions on the proposed research. If no presence of a non-scientist member, there is no quorum.

If you agree with the terms of this appointment, please sign in the space below and return one (1) copy to the Davao de Oro State College REC Secretariat.
Submit a duly signed updated Curriculum Vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

LIYBETH M. MATUNHAY, PhD
College President

Conformed:

_____ _____
(Print name and sign) *Date*

CURRICULUM VITAE

GENERAL INFORMATION			
Name		**Date of Birth**	
Address		**Contact number**	
		Email Address	

AFFILIATION	
Name of Institution:	Name of Department:
Position:	Specialization:

HIGHEST EDUCATIONAL ATTAINMENT	
Course/Degree	
Name of Institution	
Year/s attended	

WORK EXPERIENCE	
1. Occupation	
2. Previous Work Experience	
3. Present Work Experience	
4. Research-Related Experience	

RESEARCH AND ETHICS TRAININGS		
Name of Course	*Offered by*	*Year*
1.		
2.		
3.		

Name and Signature:	*Date:*

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Known all Men by these Presents:

In view of the appointment of _____, as a member of the DDOSC-REC, and hereinafter referred to as *Undersigned*, and

WHEREAS: the Undersigned has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

The appointment of the undersigned as a member of the DDOSC-REC is based on individual merits and not as an advocate or representative of a home province/territory/community nor as the delegate of any organization or private interest;

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

The DDOSC-REC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects.

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

Conflict of Interest

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

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

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

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

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

Examples of conflict-of-interest cases may include, but are not limited to, any of the following:

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

Agreement on Confidentiality and Conflict of Interest

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

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

Whenever I have a conflict of interest, I shall immediately inform the Chair that I shall not be counted toward a quorum for voting.

I have read and accept the terms and conditions set forth in this Agreement.

_____	_____
(Title/Name)	*Date*
_____	_____
DDOSC-REC Member	*Date*

TRAINING RECORD OF REC MEMBER

Last Name: _____ First Name: _____

BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. BRE Training				
2. GRP Training				
3. REC Standard Operating Procedures (SOP)				

CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1.				
2.				
3.				
4.				
5.				

INVITATION TO INDEPENDENT CONSULTANT

_____
(Name of Independent Consultant)

_____
(Institution)

Date: _____
Dear _____

We hereby invite you to serve as an Independent Consultant for the following protocol:
(Title of Protocol) _____
(Protocol Number) _____
(Name of PI) _____
(Sponsor) _____

Please review the technical and ethical issues in the protocol based on the assessment forms that we hereby attach. Please forward your assessment/ comments to the REC Admin Staff within 7 days. Please attend the full board meeting on _____ at _____.

Thank you for the support and cooperation.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the DDOSC-REC Admin Staff. Please sign, date, and submit your latest curriculum vitae and Confidentiality and Conflict of Interest Agreement.

Very truly yours,

JUANITA C. LEOPOLDO, DBA
REC Chair

Conformed:

_____ _____
(Print name and sign) *Date*

CONFIDENTIALITY AGREEMENT FOR GUEST/OBSERVER ATTENDEES

I, _____, understand that I am allowed to attend the DDOSC-REC meeting and/or supervised access to the DDOSC-REC files as a/an_____. In the course of the meeting of the DDOSC-REC and the opening of DDOSC-REC files, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information **confidential**.

Date of DDOSC-REC Meeting : _____
DDOSC-REC Meeting Number : _____
Purpose of attendance/access : _____
_____
_____
_____
_____

_____
REC Member Secretary
Date:

_____
REC Chair
Date:

APPLICATION FOR INITIAL REVIEW

(To be filled by the researcher)

Instructions: *Please accomplish this form and ensure that you have included the documents you checked below in your submission (in Section 2 Checklist of Documents for Submission). Kindly fill in all items with a red asterisk (*).*

<table>
<tr><th colspan="5">1. GENERAL INFORMATION</th></tr>
<tr><td>*Title of the Study</td><td colspan="4">Click here to enter text.</td></tr>
<tr><td>REC Protocol Code
(to be provided by REC)</td><td>Click here to enter text.</td><td>*Study Site</td><td colspan="2">Click here to enter text.</td></tr>
<tr><td>*Name of Researcher</td><td>Click here to enter text.</td><td rowspan="3">*Contact information</td><td colspan="2">Mobile No.:
Click here to enter text.</td></tr>
<tr><td rowspan="2">*Co-Researcher/s
(if any)</td><td rowspan="2">Click here to enter text.</td><td colspan="2">E-mail:
Click here to enter text.</td></tr>
<tr><td colspan="2">Mobile No.:
Click here to enter text.</td></tr>
<tr><td>*Name of Institution
(specify the campus)</td><td colspan="4">Click here to enter text.</td></tr>
<tr><td>*Institution Address</td><td colspan="4">Click here to enter text.</td></tr>
<tr><td>*Program/Course:</td><td colspan="4">Click here to enter text.</td></tr>
<tr><td rowspan="2">*Types of Study
(mark the appropriate box)</td><td colspan="4">☐ Social or Behavioral Research
☐ Experimental Research
☐ Observational Research
☐ Others: _____</td></tr>
<tr><td>☐ Multicenter (International)</td><td>☐ Multicenter (National)</td><td colspan="2">☐ Single Site</td></tr>
<tr><td>*Source of Funding</td><td colspan="2">☐ Self-Funded</td><td colspan="2">☐ Institution Funded
☐ Others:</td></tr>
</table>

(mark the appropriate box)	☐ Government-Funded ☐ Scholarship/Research Grant	_____	
*Duration of the Study	Start Date: End Date:	*No. of Study Participants	Click here to enter text.

	YES	NO
*Are you an employee of the sponsor?	☐	☐
*Did you do consultancy or part-time work for the sponsor?	☐	☐
*Has the research undergone technical review? ***(If YES, please attach the technical review result in a separate document or fill in the Matrix for the Technical Review Results provided below)***	☐	☐

Matrix for the Technical Review Result

Comments from the Panel Members	Remarks	Signature

2. CHECKLIST OF DOCUMENTS FOR SUBMISSION

***Basic Documents (must submit):**	**Supplementary Documents** (if applicable):
☐ Application for Initial Review Form	☐ Other information or documents for participants (such as diaries, etc.)
☐ Certificate of Approval from Technical Review	☐ Memorandum of Agreement (for collaborative studies)
☐ Endorsement/Transmittal/Referral letter	☐ National Commission for Indigenous People (NCIP)
☐ Research Protocol *(Detailed Manuscript)*	☐ Clearance or permit from respective regulatory authorities (such as FDA approval for DENR local transport permit, as applicable)
☐ Summary Sheet	☐ Others: _____
☐ Informed Consent/Assent Form	
☐ Protocol Evaluation Form	
☐ Informed Consent/Assent Evaluation Form	
☐ Curriculum Vitae of PI and study team members	
☐ Study Tools *(Questionnaires)*	
☐ Proof of payment of ethics review fee (as applicable)	

*Accomplished by: _____ *Signature over printed name*	*Date Submitted:

---------- TO BE FILLED OUT BY THE REC ADMIN STAFF----------		
Completeness of Documents	☐ Complete ☐ Incomplete	(Place stamp here)
Remarks		
Date Received		
Received by		

PROTOCOL SUMMARY SHEET

(To be filled by the researcher)

Instruction: *Kindly fill in all the items with a red asterisk (*).*

REC Protocol No: _____

*TITLE:	Click here to enter text.
*Name of the Researcher/s:	Click here to enter text.
Sponsor:	Click here to enter text.
*Objectives of the Study:	Click here to enter text.
*Methodology:	Click here to enter text.
*Inclusion Criteria:	Click here to enter text.
*Exclusion Criteria:	Click here to enter text.
*Data Analysis Plan:	Click here to enter text.
*Study Outcomes:	Click here to enter text.
*Ethical Considerations:	Click here to enter text.

PROTOCOL EVALUATION FORM

Note: *Kindly fill in all the items with a red asterisk (*)*

*Title of the Study	Click here to enter text.
*Researcher	Click here to enter text.
Co-Researcher/s	Click here to enter text.
*Submission Date	

To be filled up by DDOSC-REC

REC Code:	Click here to enter text.	
Type of Review:	☐ Full Board ☐ Expedited ☐ Exempt from Review	
Reviewer:	☐ Juanita C. Leopoldo ☐ Kim F. Baloca ☐ Jeson N. Geroche	☐ Rholey R. Picaza ☐ Jerry Jake B. Hanggam
Conflict of Interest		

INSTRUCTIONS

To the Researcher: *Please indicate in the space provided below whether or not your study protocol addresses the specified assessment point. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. Further, those items with RED asterisks shall be incorporated in your Manuscript and marked as YES.*

***To the Primary Reviewer*:** *Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS". Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided*

	To be filled out by the Investigator/Researcher			
ASSESSMENT POINTS	*Indicate if the study protocol contains the specified assessment point*		*Page and paragraph where it is found*	**REVIEWER COMMENTS**
1. SCIENTIFIC DESIGN	**YES**	**N/A**		

1.1. Objectives* Review of the viability of the expected output.	☐	☐	Click here to enter text.	Click here to enter text.
1.2. Literature review* Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials.	☐	☐	Click here to enter text.	Click here to enter text.
1.3. Research design* Review of the appropriateness of design in view of objectives.	☐	☐	Click here to enter text.	Click here to enter text.
1.4. Sampling design* Review of the appropriateness of sampling methods and techniques.	☐	☐	Click here to enter text.	Click here to enter text.
1.5. Sample size* Review of the justification of the sample size	☐	☐	Click here to enter text.	Click here to enter text.
1.6. Statistical analysis plan (SAP) Review of appropriateness of statistical methods to be used and how participant data will be summarized.	☐	☐	Click here to enter text.	Click here to enter text.
1.7. Data analysis plan* Review of appropriateness of statistical and non-statistical methods of data analysis.	☐	☐	Click here to enter text.	Click here to enter text.
1.8. Inclusion criteria* Review of the precision of the criteria, both for scientific merit and safety concerns, and of equitable selection.	☐	☐	Click here to enter text.	Click here to enter text.
1.9. Exclusion criteria* Review of the criteria precision both for scientific merit and safety concerns, and of justified exclusion.	☐	☐	Click here to enter text.	Click here to enter text.
1.10. Withdrawal criteria* Review of the criteria precision both for scientific merit and safety concerns.	☐	☐	Click here to enter text.	Click here to enter text.
2. CONDUCT OF STUDY				
2.1. Specimen handling Review of specimen storage, access, disposal, and terms of use.	☐	☐	Click here to enter text.	Click here to enter text.
2.2. Researcher's qualifications* Review of CV and relevant certifications to ascertain the capability to manage study-related risks.	☐	☐	Click here to enter text.	Click here to enter text.
2.3. Suitability of site* Review of the adequacy of qualified staff and infrastructures.	☐	☐	Click here to enter text.	Click here to enter text.
2.4. Duration* Review of the length/extent of human participant involvement in the study.	☐	☐	Click here to enter text.	Click here to enter text.
3. ETHICAL CONSIDERATIONS				
3.1. Conflict of interest* Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site.	☐	☐	Click here to enter text.	Click here to enter text.
3.2. Privacy and confidentiality*	☐	☐	Click here to enter text.	Click here to enter text.

Review of measures or guarantees to protect the privacy and confidentiality of participant information as indicated by data collection methods, including data protection plans.				
3.3. Informed consent process* Review of the application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent, especially in cases of special populations like minors and those who are not legally competent to give consent, or Indigenous people who require additional clearances.	☐	☐	Click here to enter text.	Click here to enter text.
3.4. Vulnerability* Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable diseases, people who are politically powerless, or junior members of a hierarchical group. Vulnerability must always be assessed in the context of the protocol and the participants.	☐	☐	Click here to enter text.	Click here to enter text.
3.5. Recruitment* Review of the manner of recruitment, including appropriateness of identified recruiting parties.	☐	☐	Click here to enter text.	Click here to enter text.
3.6. Assent Review of the feasibility of obtaining assent vis à vis incompetence to consent; Review of the applicability of the assent age brackets in children: 0-under 7: No assent 8-under 12: Assent Form 13-under15: Simplified Assent Form 16-under18: Co-sign informed consent form with parents	☐	☐	Click here to enter text.	Click here to enter text.
3.7. Risks* Review of the level of risk and measures to mitigate these risks (including physical, psychological, social, and economic), including plans for adverse event management.	☐	☐	Click here to enter text.	Click here to enter text.
3.8. Benefits* Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to the participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant.	☐	☐	Click here to enter text.	Click here to enter text.
3.9. Incentives or compensation Review of the amount and method of compensation, financial incentives, or reimbursement of study-related expenses.	☐	☐	Click here to enter text.	Click here to enter text.
3.10. Community considerations*	☐	☐	Click here to enter text.	Click here to enter text.

Review of the impact of the research on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of the study.				
3.11. Dissemination Plan* Review of the adequacy and appropriateness of the plan for communicating research findings to relevant stakeholders, including participants, communities, institutions, and the scientific community; ensuring accuracy, accessibility, and ethical responsibility in dissemination.	☐	☐	Click here to enter text.	Click here to enter text.
3.12. Collaborative study terms of reference Review of terms of collaborative study, especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building	☐	☐	Click here to enter text.	Click here to enter text.
3.13. Other issues Review of issues not subsumed in the issues covered by items 3.1 to 3.11				Click here to enter text.
RECOMMENDED ACTION: ☐ APPROVED ☐ MINOR REVISION ☐ MAJOR REVISION ☐ DISAPPROVED				
JUSTIFICATION FOR RECOMMENDED ACTION: Click here to enter text.				

Prepared by:

Click here to enter text.

_____

Researcher *(Signature over Printed Name)*

Note by:

Click here to enter text.

_____

Research Adviser *(Signature over Printed Name)*

Reviewed by:

Click here to enter text.

_____

Reviewer *(Signature over printed name)*

INFORMED CONSENT/ASSENT EVALUATION FORM

Note: *Kindly fill in all the items with a red asterisk (*)*

REC Code	Click here to enter text.
*Study Protocol Title	Click here to enter text.
*Researcher/s	Click here to enter text.
*Submission Date	

INSTRUCTIONS

To the Researcher/s: *Please indicate in the space provided below whether or not the specified element is addressed by the Informed Consent/Assent Form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. Further, those items with RED asterisks shall be incorporated in your ICF and that be marked as YES.*

To the Primary Reviewer/s: *Please evaluate how the elements outlined below have been appropriately addressed by the Informed Consent/Assent Form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." In your comments, ensure that **vulnerability, recruitment process, and process of obtaining informed** consent are always assessed in the context of the study protocol and the participant. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in the space provided for the primary reviewer.*

	To be filled out by the Researcher			
ESSENTIAL ELEMENTS ***(as applicable to the study)***	*Indicate if the ICF has the specified element*		***Page** & **paragraph** number where the element is found*	**REVIEWER COMMENTS**
	YES	**N/A**		
1. Statement that the study involves research*	☐	☐	Click here to enter text.	Click here to enter text.
2. Statement describing the purpose of the study*	☐	☐	Click here to enter text.	Click here to enter text.
3. Study-related treatments and probability for random assignment	☐	☐	Click here to enter text.	Click here to enter text.
4. Study procedures, including all invasive (if any) procedures*	☐	☐	Click here to enter text.	Click here to enter text.
5. Responsibilities of the participant*	☐	☐	Click here to enter text.	Click here to enter text.
6. Expected duration of participation in the study*	☐	☐	Click here to enter text.	Click here to enter text.
7. Approximate number of participants in the study*	☐	☐	Click here to enter text.	Click here to enter text.
8. Study aspects that are experimental	☐	☐	Click here to enter text.	Click here to enter text.

9. Foreseeable risks to participant nursing infant; including pain, discomfort, or inconvenience associated with participation, including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure*	☐	☐	Click here to enter text.	Click here to enter text.
10. Reasonably expected benefits; or absence of direct benefit to participants, as applicable*	☐	☐	Click here to enter text.	Click here to enter text.
11. Expected benefits to the community or to society, or contributions to scientific knowledge*	☐	☐	Click here to enter text.	Click here to enter text.
12. Description of post-study access to the study product or intervention that has been proven safe and effective*	☐	☐	Click here to enter text.	Click here to enter text.
13. Alternative procedures or treatment available to the participant	☐	☐	Click here to enter text.	Click here to enter text.
14. Compensation or insurance, or treatment entitlements of the participant in case of study-related injury	☐	☐	Click here to enter text.	Click here to enter text.
15. Anticipated payment, if any, to the participant in the course of the study, whether money or other forms of material goods, and if so, the kind and amount	☐	☐	Click here to enter text.	Click here to enter text.
16. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries	☐	☐	Click here to enter text.	Click here to enter text.
17. Anticipated expenses, if any, to the participant in the course of the study	☐	☐	Click here to enter text.	Click here to enter text.
18. Statement that participation is voluntary, and that the participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled*	☐	☐	Click here to enter text.	Click here to enter text.
19. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality*	☐	☐	Click here to enter text.	Click here to enter text.
20. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the willingness of the participant to continue to participate.	☐	☐	Click here to enter text.	Click here to enter text.
21. Statement describing access of participants to the result of the study*	☐	☐	Click here to enter text.	Click here to enter text.

22. Statement describing the extent of the participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure) *	☐	☐	Click here to enter text.	Click here to enter text.
23. Foreseeable circumstances and reasons under which participation in the study may be terminated*	☐	☐	Click here to enter text.	Click here to enter text.
24. Sponsor, institutional affiliation of the investigators, and nature and sources of funds	☐	☐	Click here to enter text.	Click here to enter text.
25. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury*	☐	☐	Click here to enter text.	Click here to enter text.
26. Statement that the DDOSC-REC has approved the study, and may be reached through the following contact for information regarding the rights of study participants, including grievances and complaints: * **Name of DDOSC-REC Chair** **Address:** Purok 10, Poblacion, Compostela, Davao de Oro, Philippines 8803 **Email:** rec@ddosc.edu.ph **Mobile:** 0909-273-7108	☐	☐	Click here to enter text.	Click here to enter text.
27. Comprehensibility of language used				Click here to enter text.
28. Other comments not addressed by items 1-27				Click here to enter text.

RECOMMENDED ACTION:

☐ APPROVE
☐ MINOR MODIFICATIONS
☐ MAJOR MODIFICATIONS
☐ DISAPPROVE

JUSTIFICATION FOR RECOMMENDED ACTION

Click here to enter text.

Prepared by:

Click here to enter text.

_____

Researcher *(Signature over Printed Name)*

Note by:

Click here to enter text.

_____

Research Adviser (*Signature over Printed Name)*

Reviewed by:

Click here to enter text.

_____

Reviewer *(Signature over printed name)*

NOTIFICATION LETTER

Date:

Name of Researcher
Address

Protocol Code:
Title:

Dear **Ms./Mr._____,**

We wish to inform you that the **Davao de Oro State College – Research Ethics Committee (DDOSC-REC)** acknowledged receipt of <*Application Form/Summary Sheet/ Study Protocol/ Informed Consent Form*> dated _____
Upon review of <Application Form/ Protocol Evaluation Form/ Informed Consent Assessment Form>, the Panel action is <**DECISION>**. Recommended revisions and/or clarifications are summarized below:

PROTOCOL (Kindly refer to REC Form 2.3 for details on the number of items.)		
ITEMS FOR REVISION	**ASSESSMENT**	**RECOMMENDATIONS**
1. Scientific Design		
•	•	•
•	•	•
2. Conduct Of Study		
•	•	•
•	•	•
3. Ethical Considerations		
•	•	•
•	•	•
INFORMED CONSENT/ASSENT (Kindly refer to REC Form 2.4 for details on the number of items.)		
ITEMS FOR REVISION	**ASSESSMENT**	**RECOMMENDATIONS**
•	•	•
•	•	•

Please submit the revised documents within 15 days of receipt of this notice.

Should you have any questions or need clarification regarding the above recommendations, please contact the undersigned through the REC Secretary at rec@ddosc.edu.ph or 0909-273-7108.

The DDOSC-REC looks forward to your immediate response and action.

Very truly yours,

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

FINAL NOTICE

Date:

NAME
Researcher
Address

Dear _____,

We hope all is well!

The DDOSC-REC has already reviewed your protocol with the Protocol Code No. _____ Review dated on _____. The panel reviewer's decision is to have _____ for you to work on. Upon sending your notification letter, we have not received any revised documents of your protocol.

We wanted to send you this notice to remind you that the deadline for resubmitting the protocol is _____. Since it is approaching, we are requesting that you submit the following to comply with all the requirements needed for your REC approval:

1.

Note that if you cannot submit the revised documents by the deadline referred to above, you cannot proceed to the next stage of your research activity.

Please do not fail, as this is your last and final notice.

Thank you for your compliance with the requirements of the DDOSC-REC.

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

CERTIFICATE OF APPROVAL

DDOSC-REC Control No. _____

This is to certify that the study entitled **"**_____**"** by _____**,** a student of _____ of Davao de Oro State College, has been examined by the Davao de Oro State College-Research Ethics Committee (DDOSC-REC) as ____ and has been evaluated to have adequately complied the requirements for the study ethics protocol and is therefore, cleared for implementation using universally scientific procedures and internationally accepted ethical guidelines effective ____ until ____.

During this period, the researchers are expected to comply with the following responsibilities:

- Submit protocol amendments for DDOSC-REC approval before implementing them *(if any)*;
- Submit any Reportable Negative Events (RNEs) reports to the REC *(if any)*;
- Submit a progress report if the research needs to be extended beyond the period covered by the initial approval;
- Submit final report after completion of protocol procedures at the study site;
- Report protocol deviations/violations *(if any)*;
- Comply with all relevant international and national guidelines and regulations; and
- Abide by the principles of the National Ethical Guidelines (2022).

Given this __ day of ____ at the DDOSC-REC Office, Main Building, DDOSC Main Campus, Compostela, Davao de Oro, Philippines.

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

DDOSC-REC Control No. _____

This is to certify that the study entitled **"**_____**"** by _____**,** a student of _____ Davao de Oro State College, has been examined by the Davao de Oro State College-Research Ethics Committee (DDOSC-REC) as ____ and granted exemption and is therefore, cleared for implementation using universally scientific procedures and internationally accepted ethical guidelines.

Given this __ day of ____ at the DDOSC-REC Office, Main Building, DDOSC Main Campus, Compostela, Davao de Oro, Philippines.

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

PROTOCOL RESUBMISSION FORM

To be filled by the Researcher

REC Protocol Code: _____

Title of Study: | |

Document to be revised
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Advertisement
- ☐ Others: _____

PROTOCOL EVALUATION

1. Scientific Design

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS *(refer to the Evaluation Form DDOSC-REC Form 2.3)*	ACTION TAKEN BY THE PI *(What you did about the comments and suggestions)*

2. Conduct of the Study

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS *(refer to the Evaluation Form DDOSC-REC Form 2.3)*	ACTION TAKEN BY THE PI *(What you did about the comments and suggestions)*

3. Ethical Considerations

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS *(refer to the Evaluation Form DDOSC-REC Form 2.3)*	ACTION TAKEN BY THE PI *(What you did about the comments and suggestions)*

INFORMED/ASSENT EVALUATION

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS *(refer to the Evaluation Form DDOSC-REC Form 2.4)*	ACTION TAKEN BY THE PI *(What you did about the comments and suggestions)*

Prepared by:

_____

Researcher *(Signature over Printed Name)*
Date

Checked and verified by:

_____

Research Adviser *(Signature over Printed Name)*
Date

EXEMPT REVIEWER CHECKLIST

STUDY PROTOCOL INFORMATION

REC Code	
Study Protocol Title	
Researcher	
Study Protocol Submission Date *(to be accomplished by REC Staff)*	
Verified Complete by: *(to be accomplished by REC Staff)*	

- **EXEMPT**
  - research about public behavior (voting trends, opinion surveys, etc)
  - evaluation of public programs
  - quality control studies
  - standard educational tests and curriculum development
  - surveillance function
  - historical and cultural events
  - research involving large statistical data without identifiers
  - research not involving humans or human data
  - other studies deemed by DDOSC-REC as exempt

Classification of Review: *(to be accomplished by DDOSC-REC Staff)*	☐ **EXPEDITED** ☐ **FULL BOARD** ☐ **EXEMPT FORM REVIEW**
Decision:	☐ **APPROVED** ☐ **MINOR REVISION** ☐ **MAJOR REVISON** ☐ **DISAPPROVED**

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

ACTION PLAN
Summarized Protocol Evaluation and Informed Consent/Assent Form

REC Code :
Name of PI :
School :

Date of Receipt of the Documents :
Date Reviewed :
Type of Review :
Date of Submission of Evaluation :

DOCUMENTS SUBMITTED:
1.
2.
3.

PROTOCOL EVALUATION

1. Scientific Design

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS	ACTION TAKEN BY THE PI

2. Conduct of the Study

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS	ACTION TAKEN BY THE PI

3. Ethical Considerations

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS	ACTION TAKEN BY THE PI

INFORMED/ASSENT FORM EVALUATION

Item	Page and Paragraph	REVIEWER COMMENTS AND RECOMMENDATIONS	ACTION TAKEN BY THE PI

Noted by:

JUANITA C. LEOPOLDO, DBA
Chairperson, Research Ethics Committee

LOG SHEET OF INCOMING PROTOCOLS

YEAR: _____

DATE OF RECEIPT	**TIME OF RECEIPT**	**PROTOCOL CODE**	**TITLE**	**PROPONENT/S**	**TYPE & MODE of SUBMISSION**	**SUBMITTED BY** *(Name & Signature)*	**RECEIVED BY** *(Name & Signature)*	**ACTION**

LOG SHEET OF OUTGOING DOCUMENTS

YEAR: _____

Date	Nature of Document	Signatory	Addressee	Received by (Name and Signature)	Delivered by (Name and Signature)

PROTOCOL AMENDMENT APPLICATION FORM

GENERAL INFORMATION			
Title of the Study			
Date of Initial Approval		Date Submitted	
REC Code		Study Site	
Name of Researcher		Contact Information	Mobile no.
			Email:
Co-Researcher/s *(if any)*			Mobile No.
			Email:
Institution of Investigator/s			
Address of Institution			
Effective period of Ethics Approval	*From*	*To*	

Procedure/provisions to be amended *(Use additional sheets if necessary)*	**Original Procedure/Provision**	**Proposed Amendment/s**	**Justification**
1.			
2.			
3.			

Signature of Researcher: _____

Date: _____

Noted by:

_____

Research Adviser (Signature over printed name)

FOR REC USE

Assessment by Primary Reviewers	Type of amendments: Minor ___ Major ___ Does the amendment increase the risks to participants? Yes ___ No ___ Does the amendment increase the benefits to participants? Yes ___ No ___ Is there a favourable benefit/risk ratio? Yes ___ No ___ Comments:

Recommendations:		**Type of review:**	
	Approve		For Expedited review
	Request further information/modification		For Full board review
	Others:		

Name of Reviewer: _____

Signature: _____ Date: _____

Received by REC Secretariat: _____

REC Final Decision:		
Name of Chair:	Signature:	Date

PROGRESS REPORT FORM

To be filled up by the Researcher

REC Protocol Code | Initial Approval Date

Title of Study

Name of Investigator | Sponsor

1. Any amendment since the last review? *(Describe briefly.)*	☐ No ☐ Yes
2. Any change in participant population, recruitment, or selection criteria since the last review? *(Explain the changes.)*	☐ No ☐ Yes
3. Any change in the Informed Consent process or documentation since the last review? *(Please explain.)*	☐ No ☐ Yes
4. Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? *(Summarize)*	☐ No ☐ Yes
5. Any unexpected complication or side effect noted since the last review? *(Summarize)*	☐ No ☐ Yes
6. Were there protocol deviation/ violation reports? *(Summarize)* What corrective actions were taken?	☐ No ☐ Yes
7. Any new investigator that has been added to or removed from the research team since the last review? *(Please identify them and submit the CVs of new investigators.)*	☐ No ☐ Yes
8. Are there any new collaborating sites that have been added or deleted since the last review? (*Please identify the sites and note the addition or deletion)*	☐ No ☐ Yes

Summary of recruitment:

- ☐ Accrual ceiling set by REC
- ☐ New participants accrued since last review
- ☐ Total participants accrued since protocol began
- ☐ No. of participants who are lost to follow up
- ☐ No. of participants withdrawn from the study
- ☐ No. of participants who experienced SAEs/ SUSARs

---------- For REC USE ----------

Assessment by the Primary Reviewer:

	Yes	No	Comments
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			
Is there need to revise the ICF?			
Is there need to recon sent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			

Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI.

Recommended Action:

_____ Approve

_____ Request further information, specify

_____ Recommend further action, specify

_____ (e.g. require protocol/ ICF amendment, re-consent) to address concerns about patient safety)

Other Comments:

Primary Reviewer:	Signature:	Date:

FINAL REPORT

Kindly fill in all items with a RED asterisk.

GENERAL INFORMATION			
*Title of Study			
*REC Code		*Study Site	
*Name of Researcher		*Contact Information	Mobile No.
			Email
*Co-Researcher/s			Mobile No.
			Email
*Institution of the Researcher			
*Address of Institution			
*Effective period of Ethics Approval	*From*	*To*	

FINAL REPORT

1. *Study Aims/Objectives:

2. *Summary of recruitment:

- ☐ Accrual ceiling set by REC
- ☐ New participants accrued since the last review
- ☐ Total number of participants accrued since the protocol began
- ☐ Number of participants who are lost to follow-up
- ☐ Number of participants withdrawn from the study
- ☐ Number of participants who experienced RNE/SAEs/SUSARs

*Number of participants who completed the study: _____

3. Amendments to the original protocol, including dates of approval *(if applicable)*:

4. Summary of onsite Serious Adverse Events reported *(if any)*:

5. Summary of participants' complaints or grievances documented regarding conduct of study *(if any)*:
6. *Summary of benefits to participants:
7. Summary of indemnifications of study related injury *(if applicable):*
8. If terminated early, specify the reason for termination:
9. Progress reports submitted (with dates of approval), *if any*:
10. *Duration of the study (months):
11. *Informed Consent/Assent Form used (with version no./date).: *(Kindly attach screenshots or submit all Informed Consent Forms used during the conduct of the study. Just cover the names of the participants for privacy purposes)*
12. *Study objectives and summary of results:
*Date of Last Review:
*Signature of Researcher:
*Date:
RECEIVED BY: *(to be filled by the REC)*
REPORT SUBMISSION DATE: *(to be filled by the REC)*

For REC USE

COMMENTS OF PRIMARY REVIEWER (i.e., compliance with the terms of the approved protocol, including post-approval review requirements, and overall assessment of risks against benefits in the conduct of the study)
RECOMMENDED ACTION: ☐ APPROVE ☐ REQUEST INFORMATION: (specify) ☐ RECOMMEND FURTHER ACTION: (specify) ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE
PRIMARY REVIEWER Signature _____ Date: Name <Title, Name, Surname>

QUERY/COMPLAINT RECORD

Date received: _____ Received by _____

Request from:

- ☐ Telephone call Number _____
- ☐ Fax Number _____
- ☐ Mailed letter / Date _____
- ☐ E-mail / Date _____
- ☐ Walk-in/Date/Time _____
- ☐ Others, specify _____

Participant's Name: _____

Contact Address: _____ Phone: _____

Title of the Participating Study _____

Starting date of participation: _____

What are requested? _____

Action taken:	
Outcome:	

PROTOCOL VIOLATION/DEVIATION REPORT

REC Protocol Code: _____
Submission Date: _____

Study Title			
Researcher		Contact No.:	
Sponsor:		Contact No.:	
Reported by		Contact No.:	
Description			

FOR REC USE

Primary Reviewer Assessment

	Researcher Deviation from the Protocol _____ Major _____ Minor		Participant Non-Compliance

Recommandations :

☐Site visit needed

☐Noted (no further action needed)

☐Corrective action required

Date of Full Board meeting :

REC Decision:	
Required corrective action	

Recorded by REC Admin Staff _____

Received by Researcher _____

REPORTABLE NEGATIVE EVENT REPORT

To be filled by the Researcher

GENERAL INFORMATION			
Title of Study			
REC Protocol Code		Study Site	
Name of Researcher		Contact Information	Mobile No.
			Email
Co-Researcher/s (if any			Mobile No.
			Email
Institution of the Researcher			
Address of Institution			
Effective period of REC approval	*From*	*To*	

RNE Report	
1. Start of the Study:	2. Expected end of Study:
3. Number of enrolled participants:	4. Number of required participants:

5. Description of Negative (harms, risks) Events
   a. Involving participants

   b. Involving members of the Study Team

   c. Involving Data safety and integrity

6. Actions taken to prevent future SAEs, interventions, and Outcomes

7. Recommendations

FOR REC USE

Received by:

Name (REC Secretariat):	Signature:	Date:

Reviewer's Comments/ Recommendations

Reviewer's Name:	Signature:	Date:

Changes to the protocol recommended? ☐ No ☐ Yes
Comments:

Recommendation:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

Recommendation:

STUDY SITE VISIT REPORT

REC Protocol Number: _____
Sponsor Protocol Number: _____
Date of the Visit: _____

Study Title:

Researcher:

Mobile Number:

Sponsor:

Site:

Reason for site visit:

Persons interviewed:

Total number of expected subjects:

Total subjects enrolled:

	Yes	No	Comments
Are site facilities appropriate?			
Is the confidentiality of documents maintained (e.g., cabinets with locks and keys)?			
Are the test articles properly kept and maintained?			
Are Informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept at the site?			
Are all files related to communication with the REC available on the site?			
Does the site keep copies of all communication with the REC?			
Are copies of adverse event reports kept?			
Are Investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of the qualifications of personnel?			
Are all Case Record Forms up to date?			

Are copies of protocol deviation/violation reports kept at the site?			
Is there evidence of appropriate corrective action taken as recommended by the REC?			

Summary of findings:

Recommendations:

Duration of visit: (hours)		Starting from:		Finish:	

Names of REC Member Visitors:	

Report prepared by:		Date:	
Signature			

EARLY STUDY TERMINATION APPLICATION

REC Protocol Code:		Sponsor Protocol No.:	
Protocol Title:			
Name of the Researcher/s:			
Mobile Number:		E-Mail:	
Department:			
Sponsor:			
REC Approval Date:		Date of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	
Reason for early termination			
Summary of Results			
Accrual Data: How many have completed the study? How many are still active?			

Plans for those who are still active in the study	

CHECKLIST OF ATTACHMENTS	
☐	**Cover Letter** • *Addressed to the REC Chair* • *Statement that the study has been terminated early* • *Indicated date of termination* • *Brief reason(s) for early termination*
☐	**DDOSC-REC Form 3.8 Early Study Termination Report Form**
☐	**Participant Safety and Welfare Report** • *Description of how participants were informed of the study termination* • *Actions taken to ensure participant safety and well-being* • *Follow-up, referrals, or monitoring provided (if applicable)* • *Confirmation that no participant is left at increased risk due to termination*
☐	**Informed Consent-related Document (if applicable)**

Researcher's Signature:		Date:	

FOR REC USE

Assessment by the Primary Reviewer (any issue related to participant safety?): Recommendations: Final REC decision: Date of full board meeting:

CONTINUING REVIEW APPLICATION FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Ethical clearance or approval is typically granted for a period of one year. Continuing review is required at least once a year, commensurate with the risk assessment of the study protocol. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form 60 days prior to the expiry date. Obtain an electronic copy of this form and encode all information required in the space provided. Print the application on A4-sized paper; then date and sign this form before submission.*

REC Code:		
Study Protocol Title:		
Approval Date: <dd/mm/yyyy>		
Researcher:		
Email:	Telephone:	Mobile:
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
Email:	Telephone:	Mobile:
Application Submission Date: (*to be filled out by REC*) <dd/mm/yyyy>		

1. START DATE:
1.1. Date of research site initialization: <dd/mm/yyyy>
1.2. Explanation, if not yet initialized as of the date of this application: <reason/s>

2. ACTION REQUESTED:
2.1. ☐ Renewal: New participant accrual to continue
2.2. ☐ Renewal: Enrolled participant follow-up only
2.3. ☐ Early Termination: Study protocol discontinued ahead of study indicated duration
2.4. ☐ Other (specify):

3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?
3.1. ☐ No
3.2. ☐ Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)

4. **SUMMARY OF STUDY PROTOCOL PARTICIPANTS**:

<number>	4.1	☐ Accrual ceiling set by the Panel
<number>	4.2	☐ New participants accrued since last review/approval
<number>	4.3	☐ Total participants accrued since the study protocol began

5. ACCRUAL EXCLUSIONS
5.1. ☐ None
5.2. ☐ Male
5.3. ☐ Female
5.4. ☐ Other (specify):

6. IMPAIRED PARTICIPANTS

6.1. □ None
6.2. □ Physically
6.3. □ Cognitively
6.4. □ Both

7. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT, OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?

7.1. □ No
7.2. □ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

8. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach the latest version of the participant information sheet and informed consent form/document

8.1. □ No
8.2. □ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

9. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE PANEL'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?

9.1. □ No
9.2. □ Yes **(**Describe briefly and provide a copy of the literature cited, including the Investigator's Brochure if applicable**)**

10. HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?

10.1. □ No
10.2. □ Yes (Summarize and indicate date/s of SUSAR report submission/s **)**

11. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?

11.1. □ No
11.2. □ Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)

12. **HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL?** (Indicate registration information)

12.1 □ None
12.2 □ IND
12.3 □ IDE

FDA Registration No.
Product Name:
Sponsor:
Holder:

13. HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF THE STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL

13.1. □ No
13.2. □ Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)

14. HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?

14.1. □ No
14.2. □ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the UPMREB Review Panel)

15. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?

15.1. □ No
15.2. □ Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)

16. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?

16.1. □ No

16.2. □ Yes (Append a statement of disclosure)

17. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL?

17.1. □ NONE:

17.2. □ DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)

17.3. □ ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)

18. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis.

18.1. □ No

18.2. □ Yes **(**Describe changes and indicate date/s of Study Protocol Amendment Submission/s)

19. HAS THE STUDY SITE BEEN VISITED BY DDOSC-REC OR ANOTHER ETHICS COMMITTEE, AUDITED BY SPONSOR, OR INSPECTED BY ANY REGULATORY AGENCY?

19.1. □ No

19.2. □ Yes (Provide details regarding the visit/audit/inspection (when, where, etc), findings and recommendations, and corrective action of the site, if any)

20. PROGRESS STATUS (List the different components or activities in the approved study protocol, provide a short description, and indicate completion status, e.g., 50% complete, 75% complete)

20.1. <Component 1><Provide description as needed>

20.2. <Add components as necessary>

SIGNATURE OF PRINCIPAL INVESTIGATOR:

DATE SIGNED: <dd/mm/yyyy>

(For DDOSC-REC use only)

Comments of Primary Reviewer

RECOMMENDED ACTION:

- ☐ APPROVE
- ☐ REQUEST INFORMATION: (INDICATE INFORMATION)
- ☐ RECOMMEND FURTHER ACTION: (INDICATE ACTION)
- ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER Signature _____

Date: <dd/mm/yyyy> Name <Title, Name, Surname>

APPEAL FORM

GENERAL INFORMATION	
Protocol Code	
Research Title	
Name of Researcher	
Name of Co-Researcher/s	
Name of Institution	
Date of REC Decision Being Appealed	
Type of Decision Being Appealed	☐ Disapproval ☐ Requirement for Major Revisions ☐ Other: _____
Grounds for Appeal	☐ Procedural error in the review process ☐ Misinterpretation of study information ☐ New information or clarification not previously considered ☐ Disagreement with the ethical assessment ☐ Other: _____
Detailed Justification for the Appeal	

Supporting Documents Submitted	
☐	Revised protocol sections
☐	Point-by-point response to REC comments
☐	Additional supporting documents (specify): _____
☐	Other: _____

Appellant's Declaration:

I hereby certify that the information provided in this appeal is accurate and complete.

_____ _____

Name of Appellant (Researcher) Signature & Date

FOR REC USE ONLY

Date Appeal Received	
Received by (REC Staff)	
APPEAL REVIEW DETAILS	
Review Type	☐ Full Board ☐ Special / Ad hoc Committee
Date of Appeal Review	
Members Involved in Review	☐ ☐
Outcome of the Appeal	☐ Appeal Granted – Decision Modified ☐ Appeal Partially Granted ☐ Appeal Denied – Original Decision Sustained
Summary of REC Rationale	
FINAL ACTION	
Date Decision Communicated to Researcher:	
Mode of Communication	☐ Email ☐ Official Letter ☐ Other: _____
Prepared by (REC Staff)	
Reviewed / Approved by REC Chair (Name, Signature, Date)	

CLEARANCE CERTIFICATE

Control No. _____

This is to certify that Mr./Ms. _____**,** students of the _____ Education Department of Davao de Oro State College–_____ Campus, have already submitted and completed all requirements for the final report submissions on their study entitled "**_____".** The researchers have been **CLEARED** from all responsibilities set by the Research Ethics Committee Office of Davao de Oro State College.

This Certification is being issued for whatever purposes it may serve best.

Issued this ___ day of _____ at the DDOSC-REC Office, Main Building, Davao De Oro State College-Main Campus, Compostela, Davao de Oro, Philippines.

JUANITA C. LEOPOLDO, DBA
Chair, Research Ethics Committee

NOTICE OF MEETING

Date :

TO **:** (DDOSC-REC MEMBERS)

SUBJECT **:** (No. of Meetings) Research Ethics Committee (REC) Meeting

TIME OF MEETING **:**

VENUE OF MEETING **:**

This is to inform and remind you of our scheduled Regular Research Ethics Committee (REC) Meeting, with the above-mentioned details.

Below is the Provisional Agenda of the meeting for your reference and information:

PROVISIONAL AGENDA

ORDER OF THE CONDUCT OF THE MEETING:

- Call to Order
- Roll Call
- Declaration of Quorum
- Review and Approval of the Meeting Agenda
- Disclosure of Conflict of Interest
- Reading and Approval of the Previous Minutes of the Meeting
- Business Arising from the Previous Minutes
- Business Agenda

BUSINESS AGENDA:

1. **PROTOCOLS for FULL REVIEW**

A. NEW PROTOCOLS

A.1

Protocol Code	
Protocol Title	
Researcher/s	
Sponsor	
Primary Reviewers	

B. RESUBMITTED PROTOCOLS

B.1

Protocol Code	
Protocol Title	
Researcher/s	
Sponsor	
Primary Reviewers	

C. PROTOCOLS FOR AMENDMENTS

D. PROGRESS REPORTS

E. CONTINUING REVIEW
F. FINAL REPORTS
G. PROTOCOL DEVIATIONS
H. EARLY STUDY TERMINATION
I. SITE VISIT REPORTS
J. RNE REPORTS
K. QUERIES FOR COMPLAINTS

2. REPORTS FROM THE RESULTS OF EXPEDITED REVIEW

A. NEW PROTOCOLS

A.1

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher/s	
Primary Reviewers	
Technical Review	
Sponsor/s	
Decision	
Date of Approval	

B. RESUBMITTED PROTOCOLS

B.1

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher/s	
Primary Reviewers	
Technical Review	
Sponsor/s	
Decision	
Date of Approval	

C. PROTOCOLS FOR AMENDMENTS
D. PROGRESS REPORTS
E. CONTINUING REVIEW
F. FINAL REPORTS

F.1

Protocol Code	
Protocol Approval Date	
Date of Final Report Submission	
Protocol Title	
Researcher/s	
Primary Reviewers	
Sponsor/s	
Decision	
Date of Approval	

G. PROTOCOL DEVIATIONS
H. EARLY STUDY TERMINATION
I. SITE VISIT REPORTS
J. RNE REPORTS
K. QUERIES FOR COMPLAINTS

3. REPORTS FROM THE RESULTS OF EXEMPT FROM REVIEW

A. NEW PROTOCOLS

A.1

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher/s	
Sponsor/s	
Decision	
Date of Approval	

B. RESUBMITTED PROTOCOL
C. PROTOCOLS FOR AMENDMENT
D. PROGRESS REPORTS
E. CONTINUING REVIEW
F. FINAL REPORTS
G. PROTOCOL DEVIATIONS
H. EARLY STUDY TERMINATION
I. SITE VISIT REPORTS
J. RNE REPORTS
K. QUERIES FOR COMPLAINTS

- **OTHER MATTERS**
- **ADJOURNMENT**

Should you have other matters for inclusion, please contact the REC Admin Staff through this email address: rec@ddosc.edu.ph or the messenger: @DDOSC-REC.

Please be guided accordingly.

Sincerely,

Name and Signature
Chair, Research Ethics Committee

MEETING MINUTES

RESEARCH ETHICS COMMITTEE
(Date, Time, Venue)

ATTENDANCE

PRESENT:	ABSENT:
1)	1)
2)	2)
3)	
4)	

ORDER OF THE CONDUCT OF THE MEETING

1. CALL TO ORDER
2. ROLL CALL
3. DECLERATION OF QUORUM
4. REVIEW AND APPROVAL OF THE POVISIONAL AGENDA
5. DISCLOSURE OF CONFLICT OF INTEREST (COI)
6. READING AND APPROVAL OF THE MINUTES OF THE PREVIOUS MEETING
7. BUSINESS ARISING FROM THE PREVIOUS MINUTES
8. BUSINESS AGENDA

1. PROTOCOL FOR FULL REVIEW

A. NEW PROTOCOLS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher	
Primary reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of interest	

a. Protocol Assessment:

1. Discussion of technical issues
2. Discussion of ethical issues
3. Decision by voting (Indicate voting results)

b. ICF/IAF Assessment:

1. Discussion of issues in the Informed Consent/Assent Form:
2. Decision by voting (Indicate voting results)

c. Summary of Recommendations:

d. Decision: (Indicate voting results)

- ☐ Approval
- ☐ Minor Modification
- ☐ Major Modification
- ☐ Disapproval (reasons to be stated)

e. Duration of Approval:

B. RESUBMITTED PROTOCOLS

Protocol Code	
Protocol Approval Date	
Resubmission Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of the Amendment requested	
Recommendations	
Decision (indicate voting results)	(Approval, Major Modification, Minor Modification, Disapproval)

C. PROTOCOLS FOR MODIFICATIONS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of Researcher's response to initial review	
Recommendations	
Decision (indicate voting results)	
Approval expiration date	
Frequency of continuing review (in case of approval)	

D. PROGRESS REPORT

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Researcher	

Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Progress Report	
Recommendations	
Decision	

E. CONTINUING REVIEW

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of the Continuing Review report	
Recommendations	
Decision	

F. FINAL REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of the Final Report	
Recommendations	
Decision	

G. PROTOCOL DEVIATIONS

Protocol Code	
Protocol Approval Date	
Report Date	

Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Deviation Report	
Recommendations	
Decision	

H. EARLY STUDY TERMINATION

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Early Termination	
Recommendations	
Decision	

I. SITE VISIT REPORTS

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Researcher	
Type of Review	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Site Visit Report	
Recommendations	
Decision	(No further action, Request information, Recommend corrective action)

J. RNE REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	

Conflict of Interest:	
Assessment of SAE/SUSAR reports	
Recommendations	
Decision (indicate voting results)	(Approval, Major Modification, Minor Modification, Disapproval)

K. QUERIES FOR COMPLAINTS

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Queries for Complaints	
Recommendations	
Decision (indicate voting results)	(Approval, Major Modification, Minor Modification, Disapproval)

2. REPORTS FROM THE RESULTS OF EXPEDITED REVIEW

A. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	Approval

B. RESUBMITTED PROTOCOLS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

C. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Date of Amendment Submission	

Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

D. PROGRESS REPORTS

Protocol Code	
Protocol Approval Date	
Date of Progress Reports Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

E. CONTINUING REVIEW

Protocol Code	
Protocol Approval Date	
Date of Continuing Review Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

F. FINAL REPORT

Protocol Code	
Protocol Approval Date	
Date of Final Report Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

G. PROTOCOL DEVIATIONS

Protocol Code	
Protocol Approval Date	
Date of Protocol Deviations Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

H. EARLY STUDY TERMINATION

Protocol Code	
Protocol Approval Date	
Date of Early Study Termination Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

I. SITE VISIT REPORTS

Protocol Code	
Protocol Approval Date	
Date of Site Visit Report Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

J. RNE REPORTS

Protocol Code	
Protocol Approval Date	
Date of RNE	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	

K. QUERIES FOR COMPLAINTS

Protocol Code	
Protocol Approval Date	
Date of Queries for Complaints Submission	
Protocol Title	
Researcher	
Primary Reviewers	
Sponsor/CRO	
Decision	Approval

3. REPORTS FROM THE RESULTS OF EXEMPT FROM REVIEW

A. NEW PROTOCOLS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Researcher/s	
Sponsor/s	
Decision	
Date of Approval	

B. RESUBMITTED PROTOCOL
C. PROTOCOLS FOR AMENDMENT
D. PROGRESS REPORTS
E. CONTINUING REVIEW
F. FINAL REPORTS
G. PROTOCOL DEVIATIONS
H. EARLY STUDY TERMINATION
I. SITE VISIT REPORTS
J. RNE REPORTS
K. QUERIES FOR COMPLAINTS

9. OTHER MATTERS
10. SCHEDULE OF THE NEXT MEETING
11. ADJOURNMENT

Prepared by:

Name and Signature
REC Admin Staff/Recorder
Date:

Noted by:

Name and Signature
Member Secretary
Date:

Approved by:

Name and Signature
Chair, Research Ethics Committee
Date:

REQUEST TO ACCESS REC FILES

I, _____ as a non-member of the **Davao de Oro State College Research Ethics Committee**, understand that the documents I am given access to by the **DDOSC** Ethics Review Committee are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give, or distribute these documents to any person(s) without permission from the **DDOSC** Ethics Review Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT		Signature	
Date:		Name	<Title, Name, Surname>
Researcher		Signature	
Date:		Name	<Title, Name, Surname>
Member Secretary		Signature	
Date:		Name	<Title, Name, Surname>
REC Chair		Signature	
Date:		Name	<Title, Name, Surname>

PROTOCOL FILE INDEX

Protocol Code: _____
Title: _____
Researcher/s: _____
Reviewers: _____

FILE	Date Received
Referral Form	
Review Checklist	
Registration and Application Form for Initial Review	
Study Protocol	
Informed Consent Forms	
Investigator's Brochure	
Acknowledgment Letter to PI	
Notification to Primary Reviewers	
Study Protocol Assessment Forms	
Informed Consent Assessment Forms	
Action Letter	
Response Letter of Resubmission	
Registration and Application Form for Resubmission#1	
Resubmitted Documents	
Notification to Primary Reviewers	
Review of Resubmitted Protocol Forms	
Action Letter	
Response Letter of Resubmission	
Registration and Application Form for Resubmission#2	
Resubmitted Documents	
Notification to Primary Reviewers	
Review of Resubmitted Protocol Forms	
Action Letter	
Response Letter of Resubmission	
Registration and Application Form for Resubmission#3	
Resubmitted Documents	
Notification to Primary Reviewers	
Review of Resubmitted Protocol Forms	

Action Letter	
Response Letter of Resubmission	
Registration and Application Form for Resubmission#4	
Resubmitted Documents	
Notification to Primary Reviewers	
Review of Resubmitted Protocol Forms	
Action Letter	
Approval Letter	
Certification of Board Action	

DOCUMENT CREATION/ REQUEST FOR REVISION OF AN SOP OR GUIDELINE

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit it to the REC Chair for processing.

SOP or Guideline Code	SOP or Guideline TITLE
Reason for request (citing details of problems or deficiencies in the current document):	
Description of requested changes	
Revision Requested by: (Name and signature)	Date: (dd/mm/yyyy)

REC Members Comments:
Recommendations by REC Chair ☐ Revision requirement confirmed, forward to SOP Team ☐ Request further information (state) ☐ Forward to the content expert for opinion

Signature	
Name of REC Chair	< Name, Surname>
Date	<dd/mm/yyyy>

ARCHIVING LOG SHEET FORM

YEAR: _____

ARCHIVE CODE	TITLE	RESEARCHER/S	DATE STORED	DATE DISPOSED

ETHICS INFORMED CONSENT/ASSENT FORM

Informed Consent Form for _____
Name of the Researcher(s) _____
Institution _____

PART I: INFORMATION SHEET

INTRODUCTION

(Briefly introduce the proponent and concerned organization, emphasize that this is an invitation to participate in study/research, and that he or she can take time to reflect on whether he or she wants to participate or not. Assure the participants that he or she does not understand some of the words or concepts, that these will be explained, and that he or she can ask questions at any time.

You are invited to participate in a research study conducted by _____, at _____ because you fit the inclusion criteria for informants of our study.

Your participation is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding to discuss participation with your family or friends.

If you decide to participate, you will be asked to sign this form. You will be given a copy of this form.

PURPOSE OF THE STUDY

(Please indicate the purpose of your study. Explain the research question in ordinary, non-technical terms. Use local and simplified words rather than scientific terms and professional jargon. Consider local briefs and knowledge when deciding how best to provide the information.)

STUDY PROCEDURES

(Provide a brief introduction to the format of the research study and in which part of the study he or she will be involved, and explain the type of question that the participants are likely to be asked. If the research involves questions or discussions that may be sensitive or potentially cause embarrassment, inform the participants of this.

a. *For Focus Group Discussion – Give the location for FGD,*
b. *For interview – inform the participant about the location of the interview. Assure the participant that if he or she does not wish to answer any of the questions during the interview, the interviewer will move on to the next question.*
c. *For question survey – describe how the survey will be distributed and collected. Inform the participant that he or she may answer the questionnaire personally. Skipped the question if the participants don't want to answer the question and moved on to the next question.)*

DURATION

(Include a statement about the time commitments of the research for the participant, including both the duration of the research and follow-up if relevant.

POTENTIAL RISK AND DISCOMFORTS

You may feel discomfort during the course of the interview because of the sensitive nature of the topic being studied. You may opt not to answer questions that make you feel any psychological or emotional distress, or you can withdraw as a participant of the study if you feel that you cannot discuss the information that is asked of you. The researchers value your participation and will place your welfare as their highest priority during the course of the study.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY
(Mention only those activities that are actual benefits and not those to which they are entitled, regardless of participation)

CONFIDENTIALITY
We will keep your records for this study as far as permitted by law. Any identifiable information obtained in connection with this study will remain confidential, except if necessary to protect your rights or welfare. This certificate means that the researcher can resist the release of information about their published or discussed work in conferences, and no identifiable information will be used.

PARTICIPATION AND WITHDRAWAL
Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights, or remedies because of your participation in the research study.

RESEARCHERS'S CONTACT INFORMATION
If you have any questions or concern about the research, please feel free to contact the researcher at the _____.

RIGHTS OF RESEARCH PARTICIPANT'S CONSENT
If you have questions, concerns, or complaints about your right as a research participant or the research in general and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the _____.

PART II: CERTIFICATE OF CONSENT/ASSENT

I have read this information (or had the information read to me), I have had my questions answered, and I know that I can ask questions later if I have them.

I agree to take part in research.

_____ _____
Signature above over Printed name of the Child Date Signed

IF ILLITERATE

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

_____ _____ ☐
Signature above Printed Name of Participant Date Signed Thumb Print

To be accomplished by the Researcher Obtaining Consent:
I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____ _____
Name of Person Obtaining Consent Date Signed

Republic of the Philippines

COMPOSTELA VALLEY STATE COLLEGE

Purok 10, Poblacion, Compostela, Compostela Valley 8803
www.cvsc.edu.ph | boardsec@cvsc.edu.ph

EXCERPT FROM THE MINUTES OF THE 19TH REGULAR CVSC BOARD OF TRUSTEES MEETING HELD ON APRIL 12, 2018, 9:00AM AT THE CONFERENCE RM., 3RD FLOOR, COMMISSION ON HIGHER EDUCATION REGION XI OFFICE, BO. OBRERO, DAVAO CITY

In attendance:
Hon. Perfecto A. Alibin
Hon. Christie Jean V. Ganiera
Hon. Maria Carmen S. Zamora
Hon. Anthony C. Sales
Hon. Maria Lourdes D. Lim
Hon. Almera T. Limbo
Hon. Eupe John B. Jayectin
Dr. Raul C. Alvarez Jr.

Absent:
Hon. Francis Joseph Escudero
Hon. Almalyn N. Costelo
(on official business)

A RESOLUTION APPROVING THE CVSC RESEARCH ETHICS MANUAL SUBJECT TO THE REVIEW OF THE RESEARCH ETHICS MONITORING BOARD OF REGION XI

RESOLUTION NO. 2018-008, SERIES OF 2018

"xxx..."

RESOLVED, AS IT IS HEREBY RESOLVED, that the Compostela Valley State College (CVSC) Board of Trustees hereby approves the CVSC Research Ethics Manual subject to the review of the Research Ethics Monitoring Board of Region XI.

APPROVED UNANIMOUSLY, this 12th day of April, Two Thousand Eighteen, at CHED Region XI Office, Bo. Obrero, Davao City.

CERTIFIED TRUE AND CORRECT:

MARIA TERESITA T. BALIGA
Board Secretary-Designate

Approved:

PERFECTO A. ALIBIN, Ed.D.
Chair, CVSC Board of Trustees
Commissioner, Commission on Higher Education

CERTIFIED
PHOTOCOPY FROM
ORIGINAL FILE
MARIA TERESITA T. BALIGA
College / Board Secretary

CVSC Board of Trustees
Resolution No. 2018-08, Series of 2018

Republic of the Philippines

COMPOSTELA VALLEY STATE COLLEGE

Poblacion, Compostela, Compostela Valley, 8803, Philippines

www.cvsc.edu.ph/president.edu.ph

OFFICE OF THE COLLEGE PRESIDENT

Office Memorandum Order No. 041
Series of 2018

To :**FACULTY, STAFF AND STUDENTS**
This College

Date :MARCH 22, 2018

Subject : **ESTABLISHMENT OF THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE**

In the interest of ensuring comprehensive implementation of the policies set by the Philippine Health research Ethics Board (PHREB) and to protect the rights, safety, and welfare of human participants in researches, a Research Ethics Committee (REC) is established by the College to make an independent decision regarding the review, approval and implementation of research protocols or proposals.

Review scope of authority

The **Compostela Valley State College-Research Ethics Committee** (CVSC-REC) reviews and monitors researches involving human subjects and including researches on identifiable human materials and data that are proposed to be done within the College or proposed to be conducted by faculty, staff and students of CVSC . The committee may also review and monitor community-based researches that seek endorsement from any agency, as well as researches done in other institutions that do not have ethics review committees.

Functions of the NAME OF INSTITUTION REC

The following are the functions of the **Compostela Valley State College-Research Ethics Committee** (CVSC-REC) (based on international guidelines):

a) to determine that all proposed interventions, are acceptably safe to be undertaken in humans or to verify that another competent Research Ethics Committee has done so;

b) to determine that the proposed research is scientifically sound or to verify that another competent Research Ethics Committee has done so;

c) to ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and in practice;

d) to consider the qualifications of the investigators, including education in the principles of research practice, and the conditions of the research site with a view to ensuring the safe conduct of the trial; and

e) to keep records of decisions and to take measures to follow up on the conduct of ongoing research projects.

CERTIFIED PHOTOCOPY

LILYBETH M. MUSONG-MATUNHAY
Authorized Signature/Date

The REC shall have the following composition, responsibilities and terms of office:

- REC Chairperson
  - Serves as Review Panel Chair of one of the review panels,
  - Sets agenda and presides with the meetings,
  - Designates REC member to be the primary reviewer of a protocol where s/he has the related expertise (whether by full panel or expedited review), and ensures that aforementioned REC member does not have conflict of interest,
  - Does oversight review of the initial review decision of the review panels and emails back concurrence or comments if any, to REC technical staff,
  - Designates REC Member to act in behalf of the Chair on particular REC matters where the Chair has COI,
  - Manages complaints from study participants, authorities or the general public,
  - Ensures that all REC Members receive orientation and undergo Basic Research Ethics Training after their appointment, and continuing education thereafter, and
  - Ensures that the REC is perceived as fair and impartial, immune from pressure either by the institution's management, the investigators whose protocols are brought before it, or other professional and nonprofessional groups.
  - He/She shall be appointed for a period of three years renewable for up to several consecutive terms as determined by the head of institution

- REC Member Secretary
  - Prepares provisional meeting agenda in coordination with the REC Chair and Technical Staff,
  - Ensures that panel members completely fill out necessary forms used for the review of submissions,
  - Finalizes the meeting minutes in coordination with the REC Technical Staff, and
  - Performs internal quality audit of Review Panel's protocol files, meeting agenda and minutes;
  - He/She shall be appointed for a period of three years renewable for up to several consecutive terms as determined by the head of institution

- REC Members
  - Serve as Primary Reviewers for research protocol within their area of expertise, and as General Reviewers of all researches discussed at Full Panel meetings of the Review Panel where they belong;

CERTIFIED PHOTOCOPY
LILYBETH M. MUSONG-MATUNHAY
Authorized Signature/Date

- Review and assess research protocol and informed consent document using the Protocol and ICF Assessment forms
- Submit on time the completed Protocol and ICF Assessment Forms, and Individual Reviewer Decision form relative to the review of research protocol where they are the designated primary reviewers
- Participate in REC review meetings, and vote for full approval, suspend approval pending compliance to suggested revisions or disapproval of the research protocols
- Conduct expedited reviews on behalf of the REC when so designated by the REC Chair
- Perform post-approval review procedures relative to review of research protocol or protocol-related documents where they are the primary reviewers (whether by expedited or full panel review) such as – application for Protocol Amendment, Protocol Deviation/Violation report, Study Site Monitoring Visit for protocols of more than minimal risk, and Closure/Final Report;
- Monitor conduct of implementation of approved protocols where they are the primary reviewers
- Update CV and training record on time
- Conform at all times to the legal and ethical principles accepted by the REC
- Attend basic and continuing education on Research Ethics
- Perform other tasks requested by REC Chair;
- The REC alternate members have the same responsibilities as the regular members.
- The REC should ensure continuity of its membership such that the term of old members overlap with that of new members
- Any REC member upon completion of his/her term or upon resignation, may recommend an individual to replace him/her.

This special order shall take effect immediately and shall remain in force until revoked by the undersigned or any competent authority.

For your guidance.

CHRISTIE JEAN VILLANUEVA-GANIERA, Ed.D.
College President

cf: ODRED, VPAA, Branch Directors, HRMO, file

CERTIFIED PHOTOCOPY
LILYBETH M. MUSONG-MATUNHAY
Authorized Signature/Date

GLOSSARY

Active Principle or Ingredients – substances in a medicinal preparation that bring about the clinical effects expected; the constituents in a medicinal preparation that exert an effect pharmacologically as distinct from the fillers, wetting agents, and other excipients included in the preparation.

Adverse Events – any untoward or undesirable medical occurrence in a research participant or patient in a clinical investigation after use or administration of an investigational product (ICH-GCP). See also Adverse Drug Reaction, Serious Adverse Event, and Suspected Unexpected Serious Adverse Reaction

Alternate Members – Alternate members are individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement.

Approval – favorable or affirmative action or decision issued by a regulatory body (e.g., RECs).

Archival Research – a study involving the examination of records or documents.

Assent – authorization for one's own participation in research given by a minor or another participant who lacks the capability to give informed consent; a requirement for research, in addition to consent given by a parent or LAR; agreement by an individual not competent to give legally valid informed consent, like a child, to participate in research.

Behavioral Research – studies that apply social and behavioral theories and principles to understand the actions or reactions of persons in response to external or internal stimuli or to an intervention; in health and medicine, it includes studies on basic bio-behavioral mechanisms and social processes that are relevant to public health or disease prevention and promotion, etiology, diagnosis, treatment, and rehabilitation.

Belmont Report – statement of basic ethical principles governing research involving human participants, published by the National Commission for the Protection of Human Subjects in 1979 on the conduct of biomedical and behavioral research involving human subjects, including guidelines to ensure that research is conducted in accordance with the three identified principles: respect for persons, beneficence, and justice.

Benefits – any direct or indirect good effect, or something of positive value, from the research study, to the health or welfare to the participants. See also direct benefits, indirect benefits, and beneficence

Bias – the systematic tendency of any factors associated with the design, conduct, analysis, and evaluation of the results of a study to make the estimate of a treatment effect deviate from its true value (ICH-GCP).

Compensation – payment and/or medical care received or provided to research participants which may include reimbursement for lost earnings, travel costs, and other expenses incurred as a study participant and recompense for injury, inconvenience, and time spent; does not refer to remuneration in exchange for participating in the study. See Remuneration

Confidentiality – refers to the protection of personal information and communication related to research participants, by keeping other parties from accessing the information without their consent.

Conflict of Interest – circumstance that creates a risk that professional judgments or actions concerning a primary interest (e.g., obtaining scientifically valid results, promoting and protecting the integrity of research, safety and well-being of research participants, etc.) will be

unduly influenced by a secondary interest (e.g., personal or financial gain, career advancement, etc.) (Adapted from Lo & Fields, 2009).

Counseling – non-coercive interaction between a health professional and a research participant, or client and/or family, that is meant to clarify personal values and priorities, healthcare options, expectations, risks, benefits, and resources in order to help in decisionmaking; may be offered prior to sensitive testing (pre-test counseling) and/or after testing (post-test counseling) for comprehensive care.

Culture – way of life of groups of people that is defined by mores, shared values, traditions, and sociopolitical structures and institutions.

Debriefing – the process of giving previously undisclosed information about the research project to the participants following completion of their participation in the research.

Deception – an act characterized by dishonesty, fraud, trickery, or sham for the purpose of manipulating another person into making a decision that he or she would not have made otherwise.

De-identification – removal of elements (e.g., name, birth date, social security number, home address, telephone number, e-mail address, medical record numbers, health plan beneficiary numbers, full-face photographic images, etc.) connected with data that might aid in associating that data with an individual. See also Anonymization

Direct Benefits – Gain, advantage, or good effect derived by a research participant immediately or closely arising from the use of an experimental substance or device. See also Benefits

Disapproval – unfavorable or negative action on a request; for REC disapproval, please see The Research Ethics Review Process (page 36).

Disclosure of Data – the giving of information in connection with a proposed research undertaking, or the sharing of the results of the study, especially as they pertain to the individual's or the family's health situation.

Discontinuation – termination of participation of a research participant before the completion of all protocol procedures, initiated either by the participant (dropout) or by the researcher for safety or other reasons (withdrawal).

Effectiveness – the degree to which a diagnostic test or treatment produces a desired result in research participants.

Efficacy – an indication that the therapeutic effect of a clinical trial intervention is acceptable, that is, at least as good as the control intervention or standard of care to which it is compared; the ability of a treatment modality to produce an effect to alleviate a disease.

Eligibility Criteria – a list of criteria or conditions that describes both inclusionary and exclusionary factors to guide enrollment of participants into a study. See Inclusion Criteria and Exclusion Criteria

Ethical Clearance – also called ethical approval; a certification that a research proposal has complied with ethical requirements; an action of an REC on a research protocol that signifies approval and permission to proceed with the research. See also Approval

Ethics Review – evaluation of a research protocol by an REC to promote the safety and protection of the dignity of human participants; systematic process by which an REC evaluates a research protocol to determine if it follows ethical and scientific standards for carrying out research on human participants, and assesses protocol compliance with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted.

Focus Group Discussion (FGD) – a qualitative method of eliciting in-depth information on concepts and perceptions on selected topics or issues by having a structured or unstructured group discussion of 6-12 persons facilitated by a trained professional.

Gender – socially defined feminine or masculine roles, attitudes, and values.

Guardian – one who is legally responsible for the care and management of the person or property of an incompetent person or a minor; someone who can make important personal decisions on behalf of another person. See also Legally Authorized Representative

Human Subjects – See Research Participants

Incapacity – a person's mental status and means that signifies the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice; often used as a synonym for incompetence.

Inclusion Criteria – factors used to judge a participant's eligibility to participate in a research. See also Eligibility Criteria

Identifiable Personal Information – information on a particular person who expects that such information shall be held in privacy (e.g., culture, age, religion, and social status, as well as their life experience and educational, medical, family, relationship, or employment histories).

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

Indigenous Peoples (IP) – group of people or homogenous societies identified by self-ascription and ascription by others, who have continuously lived as organized community on communally bounded and defined territory, and who have, under claims of ownership since time immemorial, occupied, possessed and utilized such territories, sharing common bonds of language, customs, traditions and other distinctive cultural traits, or who have, through resistance to political, social and cultural inroads of colonization, nonindigenous religions and cultures, became historically differentiated from the majority of Filipinos (IPRA 1997).

Indirect Benefits – positive effects that may not immediately be derived from the participation of a research participant in a study (e.g., contributing to knowledge, sharing one's experiences to benefit others, feelings of altruism and usefulness). See also Benefits and Direct Benefits

Information in the Public Domain – data or information available and open to public observation (e.g., a list of names in the telephone directory, or events in streets and public transportation).

Informed Consent – a decision to participate in research, made by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation (adapted from CIOMS, 2009).

Informed Consent Process - a manner of obtaining agreement from a potential research participant to take part in an investigative study, or from a patient to undergo a medical intervention, including written and/or verbal means, as approved by an REC.

Informed Consent Form – written documentation of an informed consent that contains the essential information regarding a study or medical intervention and is signed by the research participant, patient, or LAR, whichever is applicable.

Investigator – a person responsible for the conduct of the clinical trial at a trial site (ICH-GCP). See Principal Investigator

Justice – the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her; principle that refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research requiring fairness in distribution of burdens and benefits. See also Ethical Principles

Legally Authorized Representative – an individual who can, in accordance with the law, provide consent on behalf of the research participant who is incapable of giving or who has diminished capacity to give informed consent. See also Guardian

Legitimate Purpose – a principle which states that the processing of information shall be compatible with a declared and specified purpose which must not be contrary to law, morals, or public policy (Data Privacy Act of 2012 IRR).

Minimal Risk – a classification of risk in research where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minors – persons who have not yet reached the age of majority, which is 18 years old in the Philippines (Act Lowering the Age of Majority from 21 to 18 or RA 6809).

Monitor – a person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for GCP for Trials of Pharmaceutical Products).

Monitoring – the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s) (ICH-GCP).

Moral Agent – a person competent of acting with reference to what is ethical or what is right and wrong; a sentient individual whose acts have an impact on others and are affected by the acts of others.

Non-disclosure of Data – the withholding of or restriction of access to information derived from research.

Participatory Research – research that involves the participation of the researcher in the activities of the research population. It could also involve research subjects in the definition of the research agenda, the conduct of research, monitoring and evaluation, and the dissemination of results.

Patent – government instrument that assigns ownership of a product or creative work that is accompanied by certain rights.

Principal Investigator – the chief or person primarily responsible for the implementation of a research project or clinical trial. See also Investigator

Privacy – the right, claim, state, ability, or condition of an individual, group, or institution to conceal, seclude, hide themselves or information about themselves and thus reveal or expose themselves selectively; a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law.

Protocol – document that describes the objective(s), design, methodology, statistical considerations, and organization of a research (ICH-GCP); the definitive document of the research or study that provides guidance for those who will conduct the research, reference for evaluators and reviewers, template for validation, substantiation for intellectual property claims, and legacy of the proponent.

Protocol Amendment – written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun.

Quality of Life – a state or condition wherein an individual is able to live as a normal person wants to live his or her life.

Remuneration – payment for participation in research. See also Compensation

Research – an activity that aims to develop or contribute to knowledge that can be generalized (including theories, principles, relationships), or any accumulation of information using scientific methods, observation, inference, and analysis.

Research Participants – the primary subjects of a study; individuals who participate in a clinical trial, either as recipients of the investigational product(s) or intervention, or as controls (ICH-GCP).

Respect for Persons – an ethical principle that emphasizes the protection of the autonomy of all people, treating them with courtesy and respect, and allowing for informed consent.

Respondent – a person or a group of persons answering or replying to research questions or providing the data that is collected during the research. See also Research Participants.

Risk – the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. See also Minimal Risk

Risk Factors – variables or conditions that increase the risk or chances of disease or infection; determinants of disease development. See also Risk

Scientist Member – a REC member who has education, training, or extensive experience in the sciences.

Serious Adverse Event (SAE) – or serious adverse drug reaction, is an adverse event that results to death, life life-threatening incident, or causes immediate risk of death from the event; results to in a research participant or prolongation of hospitalization, causes significant disability, incapacity, and congenital anomaly, or another episode which is considered a significant hazard to the participant.

Side Effect – undesired effect of a treatment which is either immediate or long-term.

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

Technical Review – the process of examining, assessing, or evaluating a research protocol by technical experts, seasoned researchers, statisticians, and other relevant specialists or authorities, to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the researcher(s).

Termination of the Research – ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.

Transparency – principle which states that the data subject must be aware of the nature, purpose, and extent of the processing of his or her personal data, including the risks and safeguards involved, the identity of personal information controller, his or her rights as a data subject, and how these can be exercised; and that any information and communication relating to the processing of personal data should be easy to access and understand, using clear and plain language (Data Privacy Act 2012).

Undue Influence – an inappropriate power, pressure, or control or domination, which may be mental, moral, or physical, that deprives a person of freedom of judgment, choice, and thus, substitutes another's choice or desire in place of their own.

Voluntary – free of coercion, duress, or undue inducement; used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity (IRB Guidebook, US Department of Health and Human Services).

Vulnerability – the state of being relatively or absolutely incapable of deciding for oneself whether or not to participate in a study, for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others.

Vulnerable Persons or Groups – individuals or groups that require special protection because of certain characteristics or situations that render them relatively or absolutely incapable of deciding for themselves whether or not to participate in a study.

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