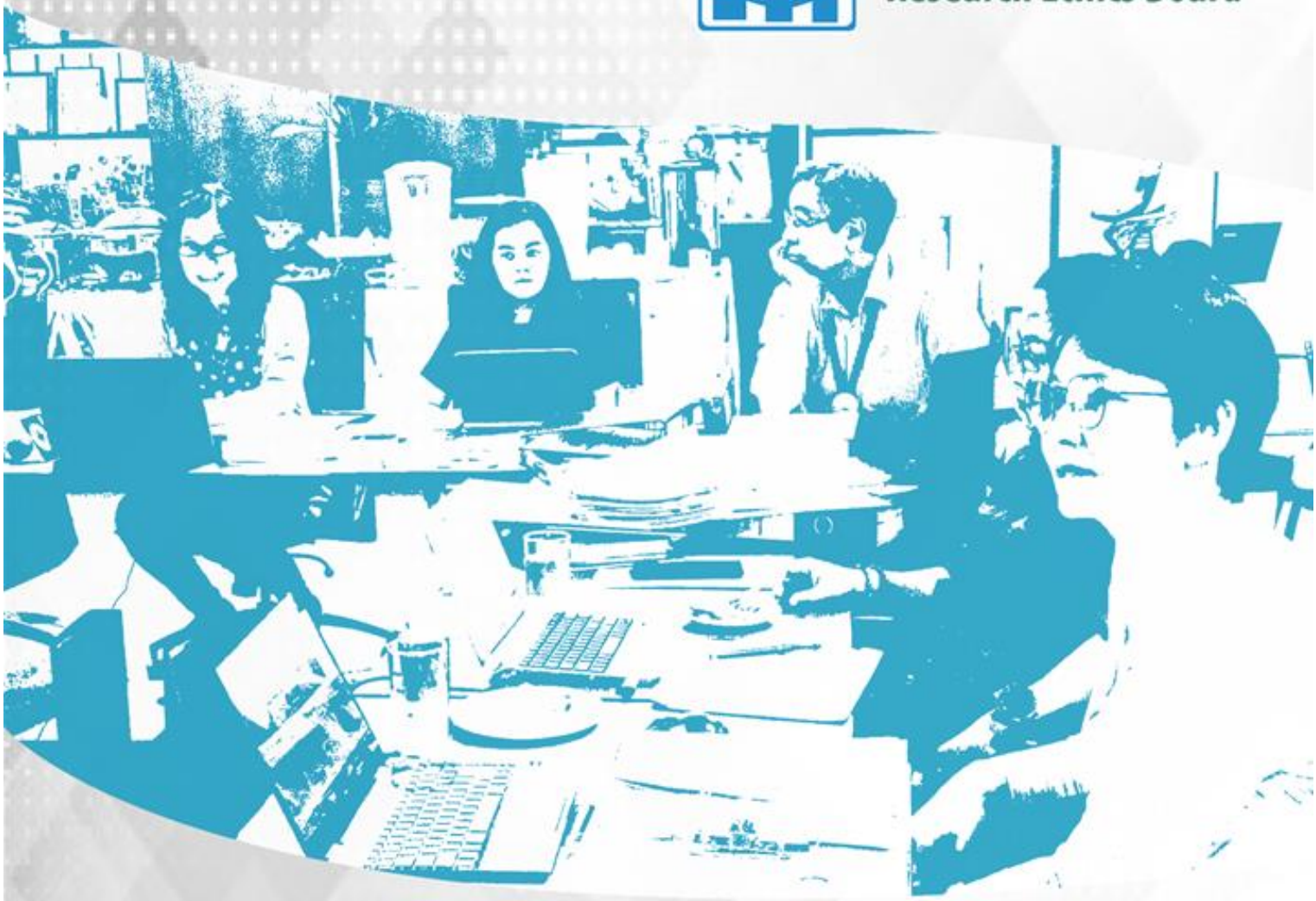
Philippine Health
Research Ethics Board



2020 PHREB STANDARD OPERATING PROCEDURES

MESSAGE

JAIME C. MONTOYA, MD, MSc, PhD, CESO II
Executive Director, Philippine Council for Health Research and Development
Department of Science and Technology (DOST-PCHRD)

Launch of 2020 PHREB SOP Workbook
23 June 2020

It is a great pleasure to congratulate the Philippine Health Research Ethics Board (PHREB) on the launch of Workbook for Developing Standard Operating Procedures (SOP).

The rights, safety, and welfare of research participants should always be the most important consideration in the conduct of health and health-related research. And as part of the health research community, we are mandated to make sure that these principles are carried out in all our efforts.

The establishment of PHREB has been instrumental in providing effective and integrated support for all aspects of ethics review for research involving human participants. The SOP workbook is a testament of PHREB's commitment to the universal principles for the protection of human participants in research.

The SOP workbook will guide Research Ethics Committees (RECs) to ensure consistency, transparency, and quality in ethical review. It contains step-by-step description of the different procedures and easy to follow instructions designed specifically for RECs.

I commend the dedicated efforts of PHREB and its committee members whose shared vision of human research participants' protection led to the development of this SOP workbook. I hope RECs in the country will use this in planning, developing, and improving their own SOPs.

I am certain that PHREB will continue to be relentless in addressing emerging ethical issues and in safeguarding the rights, safety, dignity and well-being of research participants. We, in DOST-PCHRD, are pleased to be part of this another milestone of PHREB.

Thank you and Mabuhay!

Jaime C. Montoya, MD, MSc, PhD, CESO II
Executive Director
Philippine Council for Health Research and Development
Department of Science and Technology

FOREWORD

The system of accrediting research ethics committees (RECs) is a very important component of our national effort to ensure the protection of human research participants in the country. We have invested a lot of resources so that the process of accreditation can be done professionally and expediently. Dr. Marita V. T. Reyes, former PHREB Chair, invested much of her own time and energy in preparing the first PHREB SOP Workbook that came out in 2015.

The 2020 PHREB SOP Workbook, is a fruit of Dr. Reyes' continuing investment in the professionalization of research ethics committees. It provides guidance for institutions establishing research ethics committees and applying for PHREB accreditation.
Using the workbook, RECs can expect to gain from Dr. Reyes' insights drawn from her accumulated experience in ensuring that there is consistency, transparency, and quality assurance in the ethics review of health and health-related research proposals. The second edition of the workbook is meant to assist RECs not only in preparing but also in revising their current standard operating procedures. It provides samples of forms and templates that may be adopted by the research ethics committees.

The entire research ethics review community will be indebted to Dr. Reyes for her voluntary contribution in producing the 2020 SOP Workbook and to all the kind-hearted people who gave their relevant and helpful comments in improving the workbook.

Leonardo D. De Castro, PhD
Chair, PHREB

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INTRODUCTION

Standard Operating Procedures (SOPs) are the step-by-step description of the different procedures done to accomplish the objective of an activity. SOPs guide Research Ethics Committees (RECs) in ensuring consistency, transparency, and quality in ethical review. They consist of simple and easy to follow instructions. SOPs are supposed to answer the question, "How does the REC do this particular activity efficiently and consistently?"

This Workbook is intended for RECs who are planning to develop their SOPs and for those who would like to revise and improve theirs. This edition follows the first edition that came out in 2015. It differs from the first edition in how the SOPs are organized and numbered, the strict observance of the principle that SOPs are from the perspective of the REC, the inclusion of new SOPs like Management of Resubmissions, Management of an Application for Continuing Review, and Management of Appeals. As before, the workbook was developed from the materials used by the Philippine Health Research Ethics Board (PHREB) in its conduct of SOP seminar-workshops since 2016 and is a work in progress.

THE SOP MANUAL

The Workbook begins with an outline of the SOP manual.

The SOP Manual contains an **OVERVIEW** that presents the environment where the REC operates. Here, the rationale for establishing an REC should be well stated. This rationale should be related to the Vision-Mission of the Institution. An organogram that shows the governance structure of the institution, the location of the REC and how it relates with the other units should be included. It is also suggested that institutional policies related to human protection and research ethics review be mentioned including the structure, composition, and mandate of the REC. The international and national ethics research guidelines and regulations that inform the review and decisions of the REC are cited. It will also be informative if the history of the research ethics committee, how it was established, when, the former Chairs and their accomplishments are included.

In RECs with limited activities, a straightforward listing of SOPs may suffice and be simpler to use. The order of listing may vary depending on how RECs sequence their activities. Below is a list of SOPs recommended for RECs.

SOP 01 – Selection and Appointment of REC Members
SOP 02 – Designation of REC Officers
SOP 03 – Appointment of Independent Consultants
SOP 04 – Expedited Review
SOP 05 – Full Review
SOP 06 – Management of Initial Submissions

SOP 07 – Management of Resubmissions
SOP 08 – Review of Progress Report
SOP 09 – Review of Amendments
SOP 10 – Management of Protocol Deviation and Violations Report
SOP 11A– Review of RNE Reports
SOP 11B - Review of SAE and SUSAR Reports
SOP 12 – Management of an Application for Continuing Review
SOP 13 – Review of the Final Report
SOP 14 – Review of Early Termination Reports
SOP 15 – Management of Appeals
SOP 16 – Conduct of Site Visits
SOP 17 – Preparing for a Meeting
SOP 18 – Preparing the Meeting Agenda
SOP 19 – Conduct Meetings
SOP 20 – Preparation of the Minutes of Meeting
SOP 21 – Communicating REC Decisions
SOP 22 – Management of Incoming/Outgoing Communications
SOP 23 – Management of Active Files (Administrative and Study Files)
SOP 24 – Archiving
SOP 25 – Management of Access to Confidential Files
SOP 26 – Management of Queries/Complaints
SOP 27 – Writing and Revising SOPs

Each SOP is developed using a recommended template consisting of the header and 10 sections. Many sections are accomplished by answering questions meant to guide the REC. Some questions have sample answers. These sample answers maybe adopted by the REC in a manner reflective of the specific context and actual practice of the committee. ***Italicized*** entries indicate examples. These examples may not apply to all institutions and the REC can customize these to fit its specific context.

The **Header** consists of the name and logo of the Institution, name of the REC, title of the SOP (i.e. Activity), the SOP Number, Version Number, Date of Approval, and Effective Date. The header codifies the SOP through the assignment of the SOP number and version number. The version number is the latest edition of the SOP. The suggested format is as follows:

<table>
<tr><td rowspan="4">Logo and name of Institution</td><td colspan="2">Name of the REC (e.g. Research Ethics Committee,Ethics Review Committee, Institutional Ethics Review Committee, Institutional Review Board)</td></tr>
<tr><td rowspan="3">SOP No. ___
SOP TITLE</td><td>Version No:</td></tr>
<tr><td>Date of Approval:</td></tr>
<tr><td>Effectivity Date:</td></tr>
</table>

Section 1. The **Policy Statement** consists of institutional or committee policies upon which the activity and procedures are based. This section may also include specific provisions from international and national guidelines pertinent to the activity.

Section 2. The **Objective** refers to the purpose of the activity (e.g. for SOP **Preparing for a Meeting**, the objective may be stated as "Preparing for a meeting aims to ensure that all meeting documents and necessary logistics are available during the meeting.").

Section 3. The **Scope** is based on the Workflow (Section 5) and includes the initial and final steps involved in the activity.

Section 4. The **Workflow** section is a diagram or a matrix briefly showing the different steps involved in the activity and the responsible persons. It may be illustrated as a flowchart using standard symbols like circles (denoting the start and end steps), rectangles (denoting the specific steps), and diamonds (for decision points). The person/s doing the action in each step is identified. Usually, verb-nouns like "receipt of", "submission of", "conduct of ", "distribution of", "filing of", "approval of" are used.

Section 5. Detailed Description of Procedures describes the performance of each step in the Workflow. The person/s responsible and the forms to be used are mentioned and cited. The active forms of verbs are used. It is important to ensure that the number of steps in the Workflow (Section 4) is the same number of steps described in Section 5.

Section 6. The **Glossary** is a list of terms, including acronyms and abbreviations used in the SOP that need to be defined or explained. (Note: the glossaries of the different SOPs may be put together in one list and included as an annex or appendix of the whole SOP Manual).

Section 7. The **Forms** section lists the specific forms (and corresponding codes) used in the activity (e.g. application form, checklist, review guide, communication templates).

Section 8. The **History** section is a tabulation of the version dates and number, authors, and the enumeration of major changes that the SOP has undergone. For example, the history section of **SOP Designation of REC Officers** may be represented as follows:

Version Number	Date	Authors	Change/s
1	2012 June 12	ABC	Initial version
2	2014 December 10	DEF	Added the determination of type of review as a responsibility of the member secretary
3	2018 December 5	GHI	Included a co-chair as an officer.

Section 9. The **References** section is a list of guidelines, other institutional SOPs, manuals used in the development of the SOP.

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 01** **Selection and Appointment of REC Members**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The Policy Statement should cite international, national and institutional policies with regards to selection of committee members. Which policy shall be used by the appointing authority in constituting the REC? How will the members be selected, e.g. through a nomination process or by direct appointment? Will there be regular and alternate members?

Compliance with the provisions of the WHO Operational Guidelines/CIOMS Guidelines and the National Ethical Guidelines on the composition of ethics review committees need to be mentioned.

Example: *The selection of REC members shall be through a nomination process that ensures representation of different disciplines (scientists and non-scientists, medical and non-medical members), sectors (male and female, older and younger age groups) and member/s who are not affiliated with the institution. Members shall be classified as regular or alternate members. The regular members shall serve for a period of 3 years but may be renewed for a number of terms. The alternate members shall serve on a yearly basis and shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.*

2. Objective of the Activity

The objective of the activity specifies the intended outcomes of the steps involved in the selection and appointment of REC members. For example, *"Selection and Appointment of REC Members aims to ensure that the composition of the REC complies with the international, national and institutional guidelines and that appropriate expertise is taken into consideration."*

3. Scope

Some institutions have different kinds of review committees, such as the Institutional Animal Care and Use Committee (IACUC) and the biosafety committee. Therefore, it is important to clarify that the SOP is applicable only to the Research Ethics Committee.

For example: "*This SOP applies specifically to the selection of members of the REC. This SOP begins with the call for nominations and ends with the filing of appointment documents and CVs of REC members in the membership file."*

4. Workflow

What are the different steps involved in the process of selection and appointment of the REC members? Who is the actor in each of these steps?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Call for nominations	*Chair*
Step 2: Receipt of nominations	*Staff*
Step 3: Shortlisting of nominees	*Chair*
Step 4: Receipt of Appointment of new members	*Chair*
Step 5: Forwarding of Appointment papers to the new members	*Staff*
Step 6: Signing of conforme, conflict of interest disclosure and confidentiality agreement	*New Member/s*
Step 7: Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files (SOP#__))	*Staff*

5. Description of Procedures

Based on the workflow (see above) describe each step.

Step 1 - Call for nominations: *The Chair informs the Research Authority regarding the need for new member/s. The call for nominations should be based on qualifications and requirements stated in the international, national and institutional policies. It shall require accomplishment of a nomination form (Form ##) and submission of other documents, e.g. CV (Form ##) and acceptance of nomination (Form ##). The call of nominations is coursed through the head of the institution and sent to the heads of units or other entities that the authorities deemed to be concerned.*

Step 2 - Receipt of nominations: "*The nominators submit the nomination form (Form ##) and other required documents including CVs and acceptance of nomination to the REC Office. The Staff checks the completeness of the nominations, e.g. CVs of the nominees, Ethics training record, endorsement of the unit/department, etc.*"

Step 3 - Shortlisting of nominees: How will the nominees be shortlisted? Who will do this? Example. "*The REC Chair prepares a shortlist of the nominees for both regular and alternate members based on requirements and qualifications.*"

Step 4 - Receipt of Appointment papers of new members: Who is the appointing authority? What should be included in the appointment document (e.g. terms of reference) (*Form ##*)? *The staff receives the appointment papers from the University President and informs the Chair accordingly. The appointment papers specify the conditions of the appointment including the roles and responsibilities.*

Step 5 - Forwarding of Appointment papers to the new members: *The Chair signs the appointment papers as noted and dated and then instructs the staff to forward the documents to the concerned new member.*

Step 6- Signing the conforme, and the conflict of interest disclosure and confidentiality agreement: *The new REC member/s sign the confidentiality and conflict of interest disclosure agreements (Form ##).*

Step 7 - Filing of appointment documents and CVs and signed Agreements in the membership file: See SOP Management of Active Files.

6. Glossary

What terms/abbreviations used in this SOP need to be defined for better for effective implementation? *Examples:*

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

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

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

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? The forms should be numbered and labelled. Examples:

Form ##: Nomination Form
Form ##:CV Template
Form ##: Acceptance of Nomination

Form ##: Appointment Letter Template
Form ##: Confidentiality and COI Disclosure Agreements

8. History of SOP

Indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Change in the appointing authority*
3	*2018 June 03*	*GHI*	*Added responsibilities of members in the Terms of Reference*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

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

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 02** **Designation of REC Officers**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The policy statement shall indicate who are the officers of the Research Ethics Committee, e.g. Chairperson, Vice-Chair, Member-Secretary, their qualifications and how they are chosen. For example, *"The ethics review committee shall have a chair, vice-chair, and member-secretary who shall be selected among the members who have been with the committee for, at least, one year, by election in a special meeting initially presided by an outgoing officer."* The requirement of membership for, at least, one year may not be necessary. It is just used here as an example.

Institutional policies regarding selection of committee officers need to be mentioned for compliance. For example, it may be a requirement that committee officers are full-time personnel.

In many instances, the Chair is pre-selected by the appointing authority and the task of the REC is just to select other officers (i.e. Vice. Chair, Member Secretary, or even a Treasurer).

2. Objective of the Activity

The objective of the activity specifies the intended outcomes of the procedures involved in designation of REC officers What are the intended outcomes of the procedures involved in designation of REC officers? For example, *"This activity aims to ensure that the REC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice."*

3. Scope

Common across all institutions to have a Chair and Secretary, but may not have a Vice Chair. A statement must indicate the types officers covered by the SOP. For example: *"The scope of this SOP includes the selection of Chair, Vice-Chair and Committee Secretary. It starts with the call for a special meeting to elect the concerned officers and ends with the filing of appointment documents of the officers."*

4. Workflow

The procedure involved in the selection of REC officers varies in different institutions. Some by direct appointment of the authorities. Others elect the officers during a special committee meeting. In the latter case, the workflow will be as follows:

ACTIVITY	*RESPONSIBILITY*
Step 1: Call for a special meeting (SOP on Preparing for a Meeting (SOP #__)	*Incumbent REC Chair*
Step 2: Nomination of specific official	*REC Members*
Step 3: Election of specific official	*REC Members*
Step 4: Endorsement	*REC Chair*
Step 5: Receipt of Appointment of new officers	*REC Staff*
Step 6. Signing of Conforme	*New Officers*
Step 7: Filing of appointment documents (SOP on Managing Active Files (SOP #__))	*REC Staff*

5. Description of Procedures (Note that the following steps are described based on the above workflow)

Step 1 - Call for a special meeting: see SOP on Preparing for a Meeting (SOP #__) *The REC Staff upon instruction of the incumbent Chair sends a Notice of Meeting (Form ##) to all members of the REC. Copy furnished the Head of the Research Division of the Institution stating the purpose of the meeting to be the election of (an) officer/s.*

Step 2 - Nominations:
The incumbent Chair presides over the nomination process for the next Chair. In case, the incumbent Chair may be nominated for another term, a REC member may be asked to preside over the process. In turn, the newly elected Chair leads the nomination process for the Vice-Chair and Committee Secretary who must also have been members of the REC for at least one year.

Step 3 - Election:
Election of officers shall be by secret ballot and is based on the majority rule. A tie shall be settled by a "toss-coin" or alternative process.

Step 4 - Endorsement: *The list of elected officers is submitted to the appointing institutional authority,*

Step 5 - Receipt of the Appointment of new officers: *The REC Office receives the appointment papers of the elected officers that contain the role and responsibilities of the specific officers and the corresponding term of office.*

Step 6 - Signing of Conforme: *The REC staff notifies the officers of their appointments and the need to sign the conforme. The concerned officers forthwith report to the REC office to sign the conforme documents.*

Step 8 - Filing of appointment documents: *The REC Staff files the appointment papers accordingly (see SOP for Management of Active Files (SOP 21).*

6. Glossary

What terms/abbreviations used in this SOP need to be defined for an effective implementation of this SOP? The terms must be defined accordingly. *Examples:*

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

Secret Ballot – is a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

Majority rule- is a policy based on the principle that the decision made by the greater number should be carried/accepted.

Term of office – the specified length of time that a person serves in a particular designation /role.

Appointing authority- the institutional official that has the power to designate or appoint individuals to specific offices or roles.

Conforme- acceptance of or agreement to an assignment or designation.

7. Forms

Form ##: Notice of meeting

8. History of SOP

Indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP #__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Changed the election process*
3	*2018 June 03*	*GHI*	*Added a Vice Chair as an officer*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 03** **Appointment of Independent Consultants**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The REC shall secure the services of affiliated or non-affiliated consultants when their expertise is needed to make an effective review of a protocol. Their role is not to review but rather to clarify technical aspects of the protocol (e.g. an engineer may be needed to explain the mechanics of a new medical device that is being proposed for a study).

A sample policy could be, *"The REC shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/she need not be affiliated with the institution."*

2. Objective of the Activity

The objective of the activity specifies the intended outcomes of the procedures involved in appointment of independent consultants. For example, *"This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the REC."*

3. Scope

The work of research ethics committees is supported by independent consultants. The scope begins with the identification of studies that require an independent consultant and ends with the inclusion of the name of the Independent Consultant in the pool of consultants. For example, if a study requires expertise outside those that are represented in the current membership, an independent will be invited to review the study. Sample statement: *This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the REC. This SOP begins with the identification of the study that requires an independent consultant and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.*

4. Workflow

What are the different steps involved in the process of selection and designation of independent consultants? For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Identification of the study that requires an independent consultant	*Primary Reviewer, Member-Secretary, or Chair*

Step 2: Identification of the independent consultant	*Primary Reviewer, Member-Secretary, or Chair*
Step 3: Invitation to the independent consultant	*Chair*
Step 4: Receipt of the Appointment of independent consultant	*REC Staff*
Step 5: Receipt of the Signed conflict of interest disclosure and confidentiality agreement	*REC Staff*
Step 6: Inclusion in the pool of independent consultants	*REC Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Identification of the study that requires an independent consultant: *Either the Primary Reviewer, Member-Secretary, or Chair identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of the REC.*

Step 2 - Identification of the independent consultant: *The Chair refers to the roster of specialists in the institution or in other institutions for the necessary expertise and selects the appropriate expert. S/he instructs the REC staff to prepare the letter of invitation.*

Step 3 - Invitation of the independent consultant: *The REC Staff prepares a letter of invitation (Form ##) containing the Terms of Reference for signature of the Chair and sends this to the identified expert. The letter of invitation contains a section for acceptance of the invitation.*

Step 4 - Appointment of independent consultant: *Upon receipt of the acceptance of the invitation, the REC Staff prepares a letter of appointment (Form ##) for signature of the Chair and sends the appointment to the independent consultant together with the COI disclosure and confidentiality Agreement.*

Step 5 - Receipt of the signed conflict of disclosure and confidentiality agreement: *The staff receives the signed Confidentiality and Conflict of Interest Disclosure agreement and files this in the appropriate folder.*

Step 6 - Inclusion in the pool of independent consultants: *The REC Staff enters the name of the new independent consultants in the appropriate database containing name, expertise, institution and date of appointment.*

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples which must be defined accordingly:

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

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

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

7. Forms

Form ##: Invitation Letter
Form ##: Letter of Appointment
Form ##: Confidentiality and Conflict of Interest Disclosure Agreement Form

8. History of SOP

Indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Added of criteria for selection of Independent Consultants*
3	*2018 June 03*	*GHI*	*Changed terms of reference*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

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

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 04** **Expedited Review**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The policy statement should provide guidance on the type of research that will require expedited review by the REC and how long it should take. Sample policy statement, *"An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. The results of the initial review shall be released to principal investigator within four weeks after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting."*

2. Objective of the Activity

The objective of the activity is the intended outcome of expedited review. For example, *"Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants."*

3. Scope

RECs may exempt submitted protocols from review or decide to conduct an expedited or full review. This SOP is about the conduct of expedited review. What are the limits of applicability of this SOP? For example, *"This SOP applies to initial review of protocols and post-approval submissions which do not entail more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise. This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting."*

4. Workflow

What are the different steps involved in the conduct of an expedited review? Who are responsible in each of these steps? For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of Reviewers or Independent Consultant/s (SOP#___ Appointment of Independent Consultants)	*Chair*
Step 2: Notification of Reviewers or Independent Consultant/s	*Staff*

Step 3: Provision of study documents and evaluation forms (Form ___) to reviewers	*Staff*
Step 4: Accomplishment and submission of evaluation forms	*Reviewers*
Step 5: Finalization of review results	*Chair*
Step 6: Communication of review results to the researcher (SOP# _____Communicating REC Decisions)	*Chair and Staff*
Step 7: Filing of documents in the protocol file (SOP # ____Management of Active Files)	*Staff*
Step 8: Inclusion of the Review in the Agenda of the next meeting (SOP# ___ Preparing the Meeting Agenda)	*Chair and Staff*

5. Description of Procedures

Step 1 - Assignment of Reviewers or Independent Consultant/s: What expertise is necessary for an adequate review of the study protocol? Is the expertise present among the REC members? Is it necessary to designate an independent consultant (see SOP on Appointment of Independent Consultants (SOP#__))?

Step 2 – Notification of Reviewers or Independent Consultant/s: How soon should the reviewers be notified? Prompt notification provides an opportunity to assess conflict of interest, availability, and suitability of reviewers. Usually, the response from the assigned reviewers should be received within two days after notice.

Step 3 - Provision of documents and evaluation form to reviewers: Who provides the documents and forms to the reviewers? *The REC Staff gathers the pertinent documents (for example, for initial submissions: the complete submission package; for post approval submissions: the pertinent information from the retrieved protocol and the report itself).* How will these be sent (e.g. by email, courier, or post)?

Step 4 -Accomplishment and Submission of Evaluation forms: Are the reviewers trained in completing the assessment forms in a most comprehensive and informative manner? What is the timeline given to the reviewers? How will the reviewers submit the completed forms?

Step 5 - Consolidation and Finalization of the review results: Who will consolidate the review results? How will the review results be finalized? Usually, it is the Chair that consolidates and finalizes the review results. What procedures will be used in order to harmonize differing opinions? If the 2 reviewers considerably differ in opinion about the study, the Chair may have the final say.

Step 6 - Communication of review results to the researcher: See SOP on Communicating REC Decisions (SOP#__)

Step 7 - Filing of documents in the protocol file: See SOP on Managing Active Files (SOP#__)

Step 8 - Inclusion of the Review in the Agenda of the next REC regular meeting: See SOP on Preparing the Meeting Agenda (SOP#__)

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

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

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Protocol Evaluation Worksheet

Form ## Informed Consent Evaluation Worksheet

Form ## Decision letter template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Included list of types of studies that may fall under expedited review*
3	*2018 June 03*	*GHI*	*Revised the evaluation form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 05** **Full Review**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The policy statement shall indicate which protocols undergo full review. For example: "*"A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants.* Does the committee use the primary reviewer system? Will the researcher/proponent be invited to the meeting? Will there be provisions for the presence of resource persons or independent consultants? What is the maximum period for a full review to be accomplished after submission of a complete set of documents? For example, "*Only protocols submitted for, at least, 2 weeks before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within six weeks after submission of required documents.*

2. Objective of the Activity

The objective of the activity specifies the intended outcome of the activity. For example, *"A full review aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials."*

3. Scope

RECs may exempt submitted protocols from review or decide to conduct an expedited or full review. This SOP is about the conduct of full review. For example, *"This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents."*

4. Workflow

What are the different steps involved in the conduct of a full review? Who are responsible in each of these steps? For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#__))	*Chair*

Step 2: Notification of primary reviewers or Independent Consultants	*Staff*
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	*Staff*
Step 4: Provision of protocol and protocol-related documents to the rest of the committee members	*Staff*
Step 5: Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP#__))	*Primary Reviewers*
Step 6: Discussion of technical and ethical issues	*Committee members*
Step 7: Summary of issues and resolutions	*Chair*
Step 8: Committee action	*Committee members and Chair*
Step 9: Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (SOP#__))	*Staff*
Step 10: Communication of Committee Action to the researcher (SOP Communicating REC Decisions (SOP#__))	*Chair and Staff*
Step 11: Filing of protocol-related documents and Updating of the Protocol Database	*Staff*

5. Description of Procedures

Step 1 - Assignment of primary reviewers or Independent Consultants. How are the primary reviewers assigned? Who does this? What criteria will be used? What expertise is necessary for an adequate review of the study protocol? Is the expertise present in the REC membership? Is it necessary to designate an independent consultant (see SOP on Appointment of Independent Consultants (SOP#__)? Sample statements, *The Chair assigns members who have the necessary expertise as primary reviewers (designates an independent consultant in case such expertise is not present among the members) including a non-scientist member to review the Informed Consent Process and Form.*

Step 2 - Notification of primary reviewers and/or Independent Consultants: How will the primary reviewers and/or independent consultants be notified about their assignment? Who will do this? Sample statement: *The Staff notifies the assigned primary reviewers and/or independent consultants about their assignment by email with a request that they confirm their acceptance and availability within 3 days*

Step 3 - Provision of protocol and protocol-related documents and assessment forms to primary reviewers/independent consultants: Will all the committee members be provided with the full protocol and the assessment forms? Sample statement: *Upon receipt of*

confirmation/acceptance, the staff *prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery to the primary reviewers and/or independent consultants.*

Step 4 - Provision of protocol and protocol-related documents to the rest of the committee members: What documents will be provided to the rest of the REC members? Sample statement: *The 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, Form ## Application Form) three (3) days before the committee meeting, at the latest.*

Step 5 - Presentation of review findings and recommendations during a committee meeting: Do the primary reviewers need to be present during the meeting? Will the presentations be guided by the assessment form? For example, *The primary reviewers submit their findings and recommendations (Form ## Protocol evaluation worksheet and Form ## ICF evaluation worksheet) to the chair 3 days before the meeting and present these during the actual meeting. If a primary reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.*

Step 6 - Discussion of technical and ethical issues: How does the chair manage the discussion? Which technical and ethical issues should be highlighted during the meeting? Will the independent consultant and/or the proponent be present for clarificatory interview/s? Example: *The chair leads the discussion of the technical and ethical issues using the protocol assessment check list (Form ##) and the Informed Consent Assessment checklist (Form ##) and the assessment of the primary reviewers as guides for an orderly exchange of ideas.*

Step 7 - Summary of issues and resolutions: How are issues summarized in order to guide the decision making process? For example, *"The Chair summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved."*

Step 8 - Committee action: What are the possible actions for a specific submission *(e.g. approval, minor modifications, major modifications, disapproval)?* How will the final decisions be settled? RECs often decide by voting and the majority decision is adopted. Other RECs do it by consensus such that as long as there is a strong objection, the deliberation continues the strong objector is convinced.

Step 9 - Documentation of committee deliberation and action: How will the committee deliberation be documented? See SOP on Preparing the Meeting Minutes (SOP#__).

Step 10 - Communication of Committee Action to the researcher: See SOP on Communicating REC Decisions (SOP#__)

Step 11 - Filing of protocol-related documents and Updating of the Protocol Database: See SOP on Managing Active Files (SOP#__)

6. Glossary

What terms/abbreviations used in this SOP need to be defined for better for effective implementation? Examples:

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

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

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

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

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

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

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

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

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

Protocol-related Documents- consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,

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

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

Consensus – a collective agreement.

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Protocol Evaluation Worksheet

Form ## Informed Consent Evaluation Worksheet

Form ## Decision letter template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised assessment form*
3	*2018 June 03*	*GHI*	*Changed timeline for full review*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 06** **Management of Initial Submissions**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The REC receives applications for ethical review through several modes (e.g. hand-carried by the researcher, via messenger or email). Shall the REC limit submissions to a particular mode? What documents shall be required in an application for ethics review? How will these be recorded and identified? Management of Initial Submissions includes the determination of whether or not it is exempted from review and the type of review it shall undergo. An example of a policy statement can be *"The REC shall require the submission of a set of pertinent documents for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be "exempted from review".*

2. Objective of the Activity

The objective of the activity specifies the intended outcomes of managing initial submissions. For example, *"Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review."*

3. Scope

The scope of this SOP must be consistent with the mandate given to the REC that is described in the Overview section. Shall the REC review only study protocols submitted by the faculty? How about those from students and administrative staff? How about study protocols from faculty of other institutions that will be implemented in the site? How about studies in other institutions that do not have their own RECs? Procedure-wise, it includes the first and last steps in the Workflow. For example, "*The REC shall accept for initial review only study protocol submitted by the faculty, staff, and students of the institution. This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database."*

4. Workflow

What are the different steps involved in the process of management of initial submissions?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Receipt of study documents for initial review and determination of completeness of submission .	*Staff*
Step 2: Entry into the logbook	*Staff*
Step 3: Coding	*Staff and Member Secretary*
Step 4: Determination of type of Action/ Type of Review *a. Exemption from Review* *b. Expedited Review (SOP on Expedited Review (SOP#__))* *c. Full Review (SOP on Full Review (SOP#__))*	*Chair*
Step 5: Preparation of a protocol folder	*Staff*
Step 6: Entry into the database	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt of study documents for initial review and determination of completeness of submission: Who receives documents? Will there be forms (checklists) to determine completeness of the package? What will be done if the package is incomplete? Example, *The REC office is open from 8:00 AM to 5:00 PM during which the Staff accepts study documents. The Staff checks completeness of the documents based on the checklist (Form ##). If incomplete, the Staff informs the proponent of the missing documents.*

Step 2 - Entry into logbook: The REC logbook is an official document of having received particular documents on a specific date and time. It includes information on (1) title of the study, (2) name of proponent, (3) date of submission, (4) name of receiver and (5) Action. It is also good to include the name and signature of the individual who actually submitted the documents in case s/he is not the proponent.

Step 3 - Coding: The usual code includes information on the year of submission and series number, For example*, If the documents are determined to be complete, the staff with the supervision of the member secretary assigns a protocol code such that if , for example, Mr. Juan De la Cruz submitted a protocol on HIV in 2015 and it was the 5th study protocol received for the year, then the code for the documents will be 2015-05. This code is the ID number of the protocol and cannot be assigned to any other protocol. When referring to the protocol in communications or presentations, the code is lengthened to include the proponent and topic as follows, 2015-05 - DelaCruz-HIV, to become more informative.*

Step 4 - Determination of type of Review/Action: The Chair conducts a preliminary review of the protocol to determine whether it is Exempted from Review or for review as Expedited or Full.

If the Chair decides that the protocol is exempted from review, s/he directs the REC staff to follow the procedure to communicate the decision to the researcher (SOP #___ Communicating REC Decisions).

If the Chair determines that the protocol should undergo either Full or Expedited review, then the REC staff proceeds to follow either SOP # ___Expedited Review or SOP # ____ Full Review.

Step 5 - Preparation of a Protocol Folder: The staff files the protocol documents in a protocol folder and labels it accordingly. (SOP #_____ Managing Active Files)

Step 6 - Entry into the database: In the latter case, there will be a need for subsequent entries in a database as described in SOP # ____ Managing Active Files.

6. Glossary

What terms/abbreviations used in this SOP needs to be defined? Examples:

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

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

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

Amendment – a change in /revision of the protocol made after its approval.

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

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done.

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

Exemption from Review – a decision made by the REC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1.

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

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

7. Forms: What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Application Form

Logbook

8. History of SOP

Indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Added requirements in the checklist*
3	*2018 June 03*	*GHI*	*Added information in the coding system*

9. References

What references were used in the preparation of this SOP (e.g. other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 07** **Management of Resubmissions**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The policy statement guides the REC in the management of resubmissions including the determination of the level of review and the required timeline. Example of a policy statement can be "*The REC shall require a resubmission of a protocol that requires either minor or major modification/s not later than 4 weeks after receipt of the Decision Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review.*"

2. Objective of the Activity

The objective of the activity specifies the intended outcome of managing resubmissions. For example, "*Management of resubmission ensures that the researcher addressed the required modifications before approval of the protocol.*"

3. Scope

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

4. Workflow

What are the different steps involved in the management of resubmissions? Who are the responsible persons?

For example:

ACTIVITY	*RESPONSIBLE PERSONS*
Step 1: Receipt and Entry in the Logbook	*Staff*
Step 2: Coding of Resubmitted Protocol Documents	*Staff*
Step 3: Evaluation by the Chair or Notification of Reviewers and Reviewers	*Chair and Staff*
Step 4: Review of the Resubmission *a. Expedited Review (SOP#___ Expedited Review)* *b. Full Review (SOP#___ Full Review)*	*Assigned Reviewers*
Step 5: Communication of Decision	*Staff*

Step 6: Filing of Documents in the Protocol File and Update of the database	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt and Entry in the Logbook: As in the SOP on Initial Submissions (SOP 06), who receives the resubmission documents? What procedures are done to record the receipt of documents? For Example, *The Staff receives study document, checks the nature of the document and ensures that the submission is properly logged.*

Step 2 - Coding of Resubmitted Protocol Documents: *The staff stamps/indicates the code assigned to the protocol when it was initially submitted and the date of receipt on all the documents.*

Step 3 - Notification of the Chair and Reviewers: *The staff retrieves the Decision Letter (Form#_____) that pertains to the original protocol and informs the Chair about the resubmission and about the nature of the modifications required from the researcher. Given the necessary information, the Chair either evaluates the resubmitted protocol at his/her level or directs the staff to inform the reviewers concerned and to forward to them the necessary documents.*

Step 4 - Review of the Resubmission: *The assigned reviewers conduct review of the resubmitted protocol by referring to the resubmission form noting the different recommendations made by the REC and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit the report to the Chair for inclusion in the next regular meeting.*

Step 5 - Communication of Decision: *For Resubmissions approved at the level of the Chair: the Chair dictates his/her decision to staff for preparation of the draft letter, finalization and sending to the researcher. For the resubmissions that underwent Full Review, refer to SOP # _____ Communicating Committee Decisions.*

Step 6 - Filing of Documents in the Protocol Folder and update of the database: *The staff gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter,) and enters the relevant information on resubmission in the appropriate protocol database.*

6.Glossary

What terms/abbreviations used in this SOP needs to be defined? Examples:

Initial Submission – refers to the first (initial) package of study documents forwarded to the REC for review.

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

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

Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC so that review can be conducted

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

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done.

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

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

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

***7.Forms**: What forms/templates/tools are used in the implementation of this SOP? Examples:*

Form ## Decision Letter

Form ## Resubmission Form

Form ## Approval Letter

8.History of SOP

Indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2018 July 15*	*ABC*	

9.References

What references did you use in the preparation of this SOP (e.g. other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 08** **Review of Progress Report**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

What policy does the REC have regarding submission of progress reports? For example, "*The REC shall require the submission of progress reports at a frequency based on the level of risk of the study. This requirement shall be explicitly stated in the Approval Letter.*

2. Objective of the Activity

The objective of the study specifies the intended outcomes of reviewing progress reports. For example, *"This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted."*

3. Scope

The scope of the SOP defines the limits of the review procedures with regard to progress report. For example, *"This SOP applies to the management and review of progress submitted by the proponent while the study is on-going or has ended. This SOP begins with the receipt and entry to logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file."*

4. Workflow

What are the different steps involved in the process of review of progress report? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and entry into logbook of the progress report (SOP on Management of Active Files (SOP#__))	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair and Primary Reviewers	*Staff*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP#__)) or full review (SOP on Full Review (SOP#__))	*Chair and Primary Reviewers*
Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP#__))	*Chair*
Step 6: Filing of Progress report and decision letter and update of the protocol database. SOP on Management of Active Files (SOP#__))	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt and entry to logbook: Does the REC have specific forms for progress report submission? How will these be recorded? Example, *The Staff receives the progress report written in the Progress Report Form ## and enters the date and pertinent information in the logbook of incoming documents (See SOP 21: Management of Active files).*

Step 2 - Retrieval of pertinent protocol file: Which pertinent document will be retrieved (e.g. approved protocol)? Example, *The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.*

Step 3 - Notification of Chair and Primary Reviewers: How (by SMS, email etc.) and when will the Chair and the Primary Reviewers be notified about the submission? Example, *Within two days after receipt of the progress report, the Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.*

Step 4 - Determination of type of review: expedited or full review: Usually, the Primary Reviewer recommends the type of review to the Chair and the Chair will determine the final type of review. Example, *The Chair and the Primary Reviewers, together, decide the type of review and proceed accordingly. For Expedited review, see SOP 4: and for Full review, see SOP 5.*

Step 5 - Communication of committee decision: The REC communicates the committee action, see SOP 19: Communicating REC Decisions. For progress reports, the committee action may be "approved" or "additional information required" or "specific action/s required from the researcher". *Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional information or specific action/s.*

Step 6 – Filing of Progress Report and committee decision and update of the database: For example, *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.*

6. Glossary

What terms/abbreviations used in this SOP for review of progress report? Examples:

Progress Report – description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form ##. The frequency of submissioin (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.

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

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

Full Review – is the ethical evaluation of a research proposal and other protocol-related

documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done.

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Progress Report Form
Form ## Decision letter template

Logbook

Database

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	
2	*2013 May 01*	*DEF*	*Change of timeline for submission of progress reports*
3	*2018 June 03*	*GHI*	*Change of entries in the progress report form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 09** **Review of Amendments**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

What policy does the REC have regarding submission of amendments? For example, "*The REC shall require the submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.*

2. Objective of the Activity

The objective of the study specifies the intended amendments outcomes of reviewing amendments. For example, *"This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants."*

3. Scope

The scope of the SOP defines the limits of the review procedures with regard to amendments. For example, *"This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is on-going. This SOP begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file."*

4. Workflow

What are the different steps involved in the process of review of progress report? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and entry into logbook of the submission of amendments (SOP # on Management of Active Files).	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair and Primary Reviewer	*Staff*
Step 4: Determination of type of review: expedited (SOP# on Expedited Review) or full review (SOP# on Full Review)	*Chair and Primary Reviewer*
Step 5: Communication of committee action (SOP# on Communication REC Decisions)	*Chair*

Step 6: Filing of Amendments and decision letter and update of the protocol database. SOP# on Management of Active Files)	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt and entry to logbook: Does the REC have specific forms for submission of amendments? How will these be recorded? Example, *The Staff receives Application for Review of Amendments Form ## and enters the date and pertinent information in the logbook of incoming documents (See SOP 21: Management of Active files).*

Step 2 - Retrieval of pertinent protocol file: Which pertinent document will be retrieved (e.g. approved protocol)? Example, *The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers.*

Step 3 - Notification of Chair and Primary Reviewer: How (by SMS, email etc.) and when will the Chair and the Primary Reviewer be notified about the submission? Example, *Within two days after receipt of the Application for Review of Amendments, the Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers.*

Step 4 - Determination of type of review: expedited or full review: Usually, the Primary Reviewer recommends the type of review to the Chair and the Chair will determine the final type of review. Example, *The Chair and the Primary Reviewer, together, decide the type of review and proceed accordingly. For Expedited review, see SOP 4: and for Full review, see SOP 5.*

Step 5 - Communication of committee decision: The REC communicates the committee action, see SOP 19: Communicating REC Decisions. For amendments, the committee action may be any of the following "approved", "additional justification/information required", "reconsent required" or disapproved. *Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional justification/information or specific action/s e.g. reconsent required or disapproved.*

Step 6 – Filing of Amendment documents and committee decision and update of the database: For example, *The Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.*

6. Glossary

What terms/abbreviations used in this SOP for review of progress report? Examples:

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

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

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

Full Review – is the ethical evaluation of a research proposal and other protocol-related

documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Amendment Form
Form ## Decision letter template
Logbook
Database

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	
2	*2013 May 01*	*DEF*	*Inclusion of the updating of the protocol database as a final step.*
3	*2018 June 03*	*GHI*	*Inclusion. of "additional justification/information required" as a possible REC action*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 10** **Management of Protocol Deviation and Violation Report**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Protocol deviations and violations impact safety and welfare of the research participants and integrity of data. In sponsored clinical trials, the ICH-GCP guidelines shall be followed in reporting protocol deviations and violations which are usually done by clinical monitors and auditors. However, in researcher-initiated studies, what should be the policy of the REC in reporting protocol deviations or violations? For example, *"Researchers shall report protocol deviations and violations in the conduct of approved researches within a week from the detection of the protocol violation/deviation. Major protocol violations undergo full review."*

2. Objective of the Activity

What are the intended outcomes of review of protocol deviations and violations? For example, *"Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained."*

3. Scope

The scope of this SOP includes the procedures done to effectively address the issue of protocol deviation/violation. For example, *"This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents* and update of the *database."*

4. Workflow

What are the different steps involved in the review of report of protocol violations and deviations? Who are responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of report of protocol violations and deviations in the logbook.	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*

Step 3: Notification of Chair and primary reviewers.	*Staff*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP#__)), full review (SOP on Full Review (SOP#__))	*Chair*
Step 5: Inclusion of report in the agenda of the next REC regular meeting (SOP on Preparing the Meeting Agenda (SOP#__); SOP on Conduct of Meeting (SOP#__))	*Staff and Chair*
Step 6: Communication of decision to the Principal Investigator/researcher (SOP on Communicating REC Decisions (SOP#__))	*Staff and Chair*
Step 7: Filing of all related documents and update of the protocol database (SOP on Managing Active Files (SOP#__))	*Staff*

5. Description of Procedures

What are the detailed steps involved in review? What documents and forms are needed in the review process?

Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database: Does REC require a specific report form? What information about the submission will be entered in the log? Example, *The Staff receives the report on protocol deviation or violation in the appropriate report form (Form ##) and records this in the logbook for incoming documents.*

Step 2 - Retrieval of pertinent protocol file. Which pertinent information about corresponding protocol will be retrieved (e.g. identity of primary reviewers and all other earlier reports). Example, *The Staff retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair in the selection/ designation of reviewers.*

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

Step 4 - Determination of type of review: expedited or full review: Who will determine whether the violation or deviation is minor or major? How will this be done? For example, *The Chair and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. See SOP##: Expedited Review and SOP ##: Full Review.*

Step 5 - Inclusion of report in the agenda of the next REC regular meeting. See SOP on Preparing the Meeting Agenda and SOP on Conduct of Meetings. Example, *The Chair includes the report on protocol deviation and violation in the Agenda of the next meeting if it is for Full review or the decision report if Expedited review.*

Step 6 - Communication of Decision to the Principal Investigator/researcher: See SOP on Communicating REC Decisions. What are the possible actions of REC on reports of protocol

violations and deviations? For example, *The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) Requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance.*

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

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

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

Researcher- is the individual primarily responsible for the conceptualization, planning and implementation of a study.

Sponsored Clinical Trials – are clinical studies on investigational drugs.

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

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

Regular Meeting – a periodically scheduled assembly of the REC.

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Protocol Deviation/Violation Report Form
Form ## Decision Letter Template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Change in the definition of major protocol deviation/violation*
3	*2018 June 03*	*GHI*	*Change in the definition of minor protocol deviation*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

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

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 11A** **Review of Reportable Negative Events Reports**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Reportable Negative events are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported to the REC as essential to the continuing concern for a favorable balance of risks and benefits from the study. An example of a policy statement is as follows:*" 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.*

2. Objective of the Activity

The objective of the activity specifies the intended outcomes of reviewing the reports on negative events. For example, *"Review of RNE reports aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated."*

3. Scope

Review of Reportable Negative Events is an important responsibility of RECs in non-drug-therapeutic studies e.g., social science studies. For example, *"This SOP applies to the review of RNE reports. This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database."*

4. Workflow

What are the different steps involved in the process of review of RNE reports? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of submission of RNE report in the logbook.	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair	*Staff*

Step 4: Call for a Special Meeting	*Chair*
Step 5: Deliberation on the RNE	*REC members*
Step 6: Communication of REC action to the researcher (SOP ##on Communication of REC Decisions) and to the Institutional authority	*Chair*
Step 7: Filing of all related documents (SOP ## Management of Active Files) and Update of the protocol database	*Staff*

5. Description of Procedures

Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database: Does REC require a specific RNE report form? Was the form properly accomplished? Was the date of submission within the required timeline? What information about the submission will be entered in the log? For example, *The Staff receives the accomplished RNE report form (Form ##) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.*

Step 2 - Retrieval of pertinent protocol file: Which pertinent information about corresponding protocol will be retrieved (e.g. identity of primary reviewers)? For example, *The Staff retrieves the approved protocol file and checks the identity of the primary reviewers.*

Step 3 - Notification of Chair: How and when will the Chair or designated officer be notified about the submission? For example, *The Staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.*

Step 4 - Call for a Special Meeting. *The staff prepares for a special meeting (SOP ##). The researcher and other members of the study team may be invited for a clarificatory meeting.*

Step 5 - Conduct of the Special Meeting. *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 clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on 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 risk is resolved.*
- *withdrawal of ethical clearance*
- *submission of a plan to mitigate risk/harm*
- *require an amendment to the protocol*
- *uphold original ethical clearance*

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

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

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.

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

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

Clarificatory Meeting/ Interview – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## RNE Report

Form## Notice of Meeting

Form ## REC Decision Letter

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Constitution of a SAE Subcommittee*
3	*2018 June 03*	*GHI*	*Revision of SAE/SUSAR Report Form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 11B** **Review of SAEs and SUSARs**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) are important issues in sponsored clinical trials. Reporting SAEs and SUSARs is the responsibility of the sponsor who collects such reports from all its study sites. This report is sent to the individual principal investigators for submission to their institutional REC. Review of these reports is an important function of Level 3 RECs. There is need to consult international and national guidelines and local regulations for specific details such as timelines for safety reports. What may be applicable in this SOP would be the ICH-GCP Guideline E2A which the Philippine FDA has adopted.

What is the policy of the REC regarding the submission of reports of SAEs and SUSARs? For example, "*The REC shall require the submission of reports of SAEs and SUSARs within 4 weeks after the event has come to the attention of the researcher.*" Does the REC have a separate subcommittee or point person to analyze SAEs and SUSARs? If so, then a related policy should be stated in this section. For example, *"The evaluation of the SAEs and SUSARs shall be conducted by the Subcommittee on SAEs and SUSARs whose recommendation shall be submitted to the REC for final action.*

2. Objective of the Activity

The objective of the activity specifies the intended outcome of reviewing SAEs and SUSARs. For example, *"Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated."*

3. Scope

For example, *"This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database."*

4. Workflow

What are the different steps involved in the process of review of SAE and SUSAR reports? Who will be responsible in each of these steps?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook.	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair	*Staff*
Step 4: Submission of report to the SAE Subcommittee	*Staff*
Step 5: Inclusion of report of Subcommittee in the agenda of the next regular REC meeting	*Staff and Chair*
Step 6: Communication of REC action to the Principal Investigator/researcher (SOP on Communication of REC Decisions (SOP#__))	*Staff and Chair*
Step 7: Filing of all related documents (SOP ## Management of Active Files) and Update of the protocol database	*Staff*

5.Description of Procedures

Step 1 - Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database: Does REC require a specific SAEs and SUSARs report form? Was the form properly accomplished? Was the date of submission within the required timeline? What information about the submission will be entered in the log? For example, *The Staff receives the accomplished SAE/SUSARs report forms (Form ##) and enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.*

Step 2 - Retrieval of pertinent protocol file: Which pertinent information about corresponding protocol will be retrieved (e.g. identity of primary reviewers and earlier reports on SAEs and SUSARs)? For example, *The Staff retrieves the identity of the primary reviewers (if there is no SAE/SUSAR subcommittee) and a tabulation of earlier SAE/SUSAR reports.*

Step 3 - Notification of Chair: How (by SMS, e-mail, memo, etc.) and when will the Chair or designated officer be notified about the submission? For example, *The Staff notifies and sends the report and the retrieved documents to the Chair.*

Step 4 - Submission of report to SAE Subcommittee or point person: How and when will the SAE Subcommittee or point person be informed about the submission? Are there forms to be used? How much time is allotted to the subcommittee to act on the report? Will the Subcommittee or point person use an REC form? *The Chair forwards the report and pertinent documents to the primary reviewers (or to the SAE/SUSAR Subcommittee) for action which should not be later than 3 days prior to the next committee meeting.*

Step 5 - Inclusion of report of SAE Subcommittee or point person in REC meeting agenda: What are the possible actions of REC on SAE and SUSAR report? For example, *The suggested action/decision of either the primary reviewer or the SAE/SUSAR Subcommittee is included in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda). for ratification or*

discussion and final decision. Possible actions include: notation with no further action required, further information or action required or suspension of recruitment.

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

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

6.Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

whether or not it is related to the study intervention.

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

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

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

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

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

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

7.Forms

What forms/templates/tools are or used in the implementation of this SOP? Example:

Form ## SAE/SUSAR Report

Form ## Evaluation of SAE/SUSAR Reports

Form ## REC Decision Letter

8.History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Constitution of a SAE Subcommittee*
3	*2018 June 03*	*GHI*	*Revision of SAE/SUSAR Report Form*

9.References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)?

Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 12** **Management of An Application for Continuing Review**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

A sample policy could be: *"The REC shall require the submission of an application for Continuing Review at least 4 weeks before the expiration of the ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols that underwent Expedited review shall undergo Expedited review in its application for Continuing review."*

2. Objective of the Activity

The objective specifies the intended outcomes in the management of an application for continuing review. For example, *"This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study."*

3. Scope

The scope defines the management of an application for Continuing Review in preparation for expiration of the initial ethical clearance. For example, *"This SOP applies to the management of an application for Continuing review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the entry to logbook and protocol database."*

4. Workflow

What are the different steps involved in the management of an application for Continuing review? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of the application for Continuing Review and entry to logbook(SOP ## Management of Active Files)	*Staff*
Step 2: Retrieval of pertinent protocol files	*Staff*
Step 3: Notification of Chair and Primary Reviewers	*Staff*
Step 4: Determination of type of review: expedited (SOP ## Expedited Review) or full review (SOP ## Full Review)	*Chair and Primary Reviewers*

Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP#__))	*Chair*
Step 6: Filing of documents in the appropriate protocol folder and Update of the Protocol Database	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt of the application for continuing review and entry to logbook: Does the REC have specific form for an application for continuing review? Was the form adequately accomplished? Example, *The Staff receives, logs and enters in the protocol database the information included in the application for Continuing review (Form ##: Application for Continuing Review).*

Step 2 - Retrieval of pertinent protocol file: Which pertinent documents will be retrieved (e.g. approved protocol and Informed Consent Form versions, related past submissions)? Example, *The Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.*

Step 3 - Notification of Chair and Primary Reviewers: How (by SMS, email etc.) and when will the Chair and the Primary Reviewers be notified about the submission? Example. *The Staff notifies the Chair and the Primary Reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.*

Step 4 - Determination of type of review: expedited or full review: For example, *The Chair shall determine the type of review based on the policy that protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review (see SOP 4: Expedited Review and SOP5: Full Review).*

Step 5 - Communication of committee action: For example, *The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form ##). Possible decisions include the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.*

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

6. Glossary

What are the terms/abbreviations used in this SOP for review of progress, final, and early termination reports and protocol amendments that need to be defined? Examples:

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

Progress Report – A description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form ##. The frequency of submissioin (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.

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

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

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

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

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

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

RNE – an occurrence in the study site that indicates risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

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

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

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

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done.

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ##: Continuing Review Application Form
Logbook
Database
Form ##: Decision letter template

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	
2	*2013 May 01*	*DEF*	*Change of timeline for submission of application for continuing review*
3	*2015 June 03*	*ABC* *DEF*	*Change of entries in the application form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples are:

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

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 13** **Review of Final Report**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Submission and review of final reports signal the completion of the study and its acceptance by the research ethics committee. This is an important step in the timeline of the study, on which will depend other researcher/institutional/funding agency decisions regarding the study, e.g., student/trainee graduation, publication/ release of final funding tranche. The Final Report Form is useful in checking the consistency of study implementation with the approved protocol and the knowledge gained from the endeavor. What is the policy of the REC regarding submission of final reports? For example, "*The REC shall require the submission of the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.*"

2. Objective of the Activity

The objective specifies the intended outcomes of the review of final reports. For example, *"This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study."*

3. Scope

The SOP on management of Review of Final reports defines the steps taken in the process guided by the policy statement. For example, *"This SOP applies to the management and review of final reports submitted by proponents at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database."*

4. Workflow

What are the different steps involved in the process of review of the final report? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of final report and entry into logbook (SOP on Management of Active Files (SOP#__))	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair and Primary Reviewer	*Staff*

Step 4: Full review (SOP ## on Full Review)	*Chair, Primary Reviewer, Committee Members*
Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP#__)	*Chair*
Step 6: Filing of the Final Report and related documents and update of the protocol files.	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

Step 1 - Receipt and entry of final report into logbook : Does the REC have specific form for final report (Form ##)? Example, *The Staff receives and enters the date of receipt of the final report into the logbook.*

Step 2 - Retrieval of pertinent protocol file: Which pertinent documents will be retrieved (e.g. approved protocol and Informed Consent Form versions, related past submissions)? For example: *"The staff retrieves the corresponding protocol file as reference in the review of the Final Report."*

Step 3 - Notification of Chair and Primary Reviewer: For example: *"The staff notifies the Chair and the primary reviewers of the receipt of the Final Report and awaits further instructions."*

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

Step 5 - Communication of committee action (SOP ## Communicating REC Decisions): It is suggested that the REC consider the following decisions in the review of a final report: acceptance of the Final Report or to require resubmission with corrections.

Step 6 - Filing of the Final Report and related documents and update of the protocol database:

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

6. Glossary

What are the terms/abbreviations used in this SOP for review of progress, final, and early termination reports and protocol amendments that need to be defined? Examples:

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

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

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

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

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

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

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

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

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Final Report Form
Decision Letter

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	
2	*2013 May 01*	*DEF*	*Change of timeline for submission of final reports*
3	*2018 June 03*	*GHI*	*Revision of the Final Report Form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 14** **Review of Early Termination Reports**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Early termination may be a decision of the researcher/investigator or the sponsor for reasons that make the continuation of the research untenable, e.g. poor recruitment, high number of SUSARs, lack of funding. In some occasions the REC may recommend early termination of the study when, based on its assessment, the participants and/or the study team may be at high risk of harm that cannot be mitigated. The REC policy regarding early termination of the research maybe, for example, *"When a decision for early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review"*

2. Objective of the Activity

The objective specifies the intended outcome/s of reviewing early termination reports. For example, *"Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have already been recruited and that there is adherence to the principle of fairness for all concerned."*

3. Scope

This SOP describes the steps involved in the review of early termination reports. For example, *"This SOP applies to the review of early termination reports. This SOP begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database."*

4. Workflow

What are the different steps involved in the review of early termination reports? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of the early termination report and entry into the logbook (SOP## Management of Active Files)	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair and Primary Reviewers	*Staff*

Step 4: Full review (SOP on Full Review (SOP#__))	*Primary Reviewers and Members*
Step 5: Communication of committee action (SOP## Communicating REC Decisions) and update of the protocol database (SOP ## Management of Active Files)	*Chair, Staff*

5. Description of Procedures

Each of the identified steps in the workflow should be described in detail.

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

Step 2 - Retrieval of pertinent protocol file: Which pertinent documents will be retrieved (e.g. approved protocol and Informed Consent Form versions, related past submissions)? *The REC Staff retrieves the protocol folder and summarizes the documents that have been submitted.*

Step 3 - Notification of Chair and Primary Reviewers: How (by SMS, email etc.) and when will the Chair and the Primary Reviewers be notified about the submission? *The REC staff informs the Chair and the primary reviewers by email about the report and the summary of documents that have been submitted. S/he waits for further instructions.*

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

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

6. Glossary

What are the terms/abbreviations used in this SOP for review of progress, final, and early termination reports and protocol amendments that need to be defined? Examples:

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

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

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

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

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Early Termination Report Form

Form ## Decision Letter Template

Logbook

Database

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	
2	*2013 May 01*	*DEF*	*Policy to conduct Full Review for all early termination reports.*
3	*2018 June 03*	*GHI*	*Development of an Early Termination Report Form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 15** **Management of Appeals**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

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

2. Objective of the Activity

The objective specifies the intended outcome/s of management of appeals. For example: *Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.*

3. Scope

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

4. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of an appeal	*Staff*
Step 2: Retrieval of pertinent protocol file	*Staff*
Step 3: Notification of Chair and Primary Reviewer/s	*Staff*
Step 4: Inclusion in Agenda of the next regular meeting	*Chair and Primary Reviewer*
Step 5: Discussion of and deliberation on the appeal	*Chair and REC Members*
Step 6: Communication of committee action (SOP## Communicating REC Decisions)	*Chair*

Step 7: Filing of documents and updating of the protocol database	*Staff*

5. Description of Procedures

Each of the identified steps in the workflow shall be described in detail.

Step 1 - Receipt of an Appeal: *The staff receives the letter of appeal and enters the pertinent information into the logbook.*

Step 2: Retrieval of pertinent protocol file: *The staff retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.*

Step 3: Notification of Chair and Primary reviewers: *The staff notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.*

Step 4. Inclusion in the Agenda of the next regular meeting: *The Chair instructs the staff to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.*

Step 5: Discussion of and Deliberation on the Appeal: *The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.*

Step 6: Communication of Committee Action: *Based on the deliberations, the Chair summarizes the decision points and instructs the REC staff to prepare the draft decision letter (Form ## Decision Letter Template) for his/her finalization and forwarding to the researcher. (SOP ## Communicating REC Decisions):*

Step 7: Filing of Documents and Update of Protocol Database: *The staff files all the documents into the appropriate folder and updates the protocol database accordingly.*

6. Glossary

Appeal – a request of a researcher/ investigator for a reconsideration of the REC recommendation.

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

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

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

7. Forms

Form ## Decision Letter Template

8. History

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2018 July 15*	*ABC*	*New SOP*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 16** **Conduct of Site Visits**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Site visits are important REC action that can be done in the performance of their oversight and monitoring responsibilities. Relative to this action, the REC shall establish criteria that shall help determine whether a site should be visited. Examples of such criteria are - high risk studies, significant deviation reports and participant complaints. Thus, the policy statement could be as follows: *"The ERC shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports from the and (e) multiple studies conducted by a researcher."*

2. Objective of the Activity

The objective specifies the intended outcomes of the procedures involved in site visits. For example, *"Site visits are mechanisms with which the REC monitors compliance with approved protocols, ICF process and continuing protection and promotion of participant's dignity, rights and well-being."*

3. Scope

This SOP covers criteria for site visits, notification, conduct of the visit, documentation, presentation of results to the REC, and communication of REC action to the researcher for example, *"This SOP includes the steps in conducting visits to study sites for reasons set by the REC. It begins with the selection of the site to be visited and ends with filing of Site-Visit Reports in the protocol folder and updating of the protocol database*

4. Workflow

What are the different steps involved in the process of site visits? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Selection of site to visit	*ERC Members*
Step 2: Notification of researcher	*ERC Staff*
Step 3: Creation of Site Visit Team	*Chair*

Step 4: Conduct of site visit	*Site Visit Team (members)*
Step 5: Draft of report and presentation of report during meeting and discussion for recommendations	*Site Visit Team (members)*
Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator	*Chair/ Staff*
Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database	*Staff*

5. Description of Procedures

Step 1 - Selection of site to visit: How does the REC decide of which research site to visit? Examples of criteria are high risk studies, consistent non-submission or failure to submit after-approval submission requirements, reports of major protocol noncompliance, significant number of serious adverse events, reports of complaints from study participants. If the ERC has a Serious Adverse Event Committee or Subcommittee, does this committee have a role in selecting sites? How does the ERC arrive at a decision to do a site visit (e.g. during a committee meeting)?

Step 2 - Notification of researcher: How much lead time is given to the investigator or researcher before the visit (e.g. two weeks before the scheduled visit)? How is the investigator informed (e.g. through a letter)? What information is provided (e.g. visit details, documents to prepare)?

Step 3 - Creation of Site Visit Team: Who creates the Site Visit team? What is the composition? How do the members of the team prepare to do their task? What documents do they need to be familiar with (e.g. Site Visit Report Form)? What documents do they need to review ahead of time?

Step 4 - Conduct of Site Visit: How is the Site Visit Report Form used? What are the points of observation on the documents in the study site? Will there be a debriefing with the researcher and research staff at the end of the site visit?

Typically, important points to cover during the site visit include:

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

Step 5 - Draft of report and presentation of report during meeting and discussion for recommendations: How does the team complete the Site Visit Report Form? What is the timeline for this process, including cut off dates for inclusion in the agenda of the next meeting? How is this process documented? Who among the team members will make the presentation during the REC meeting? How does the committee make a determination of action?

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

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

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

Site Visit -is an action of the REC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

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

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

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Site Visit Report Form

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Added criteria for site visit*
3	*2018 June 03*	*GHI*	*Revised Site Visit Report Form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 17** **Preparing for a Meeting**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Meetings are one of the major activities of the research ethics committee. They are venues for deliberations and decision-making regarding ethical evaluation of study proposals and are opportunities for RECs to be informed, and to be updated regarding its operations and relevant administrative matters. It is important that the REC have regular meetings. How often does the REC meet? Does it hold special meetings? For example, *"The REC shall have a regular schedule of meetings every 2nd Friday of the month. All meetings shall be held within the premises of the institution. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity."*

2. Objective of the Activity

The objective specifies the intended outcomes in preparing for a meeting. For example, *"Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings."*

3. Scope

What is covered by this SOP? For example, *"This SOP covers all activities prior to the conduct of an REC meeting. This SOP begins with the preparation of the agenda and ends with the notification of REC Members and confirmation of attendance."*

4. Workflow

What are the different steps involved in the process of preparing for a meeting? Who are responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Preparation of the agenda (SOP## Preparing the Meeting Agenda)	*REC Staff and Member Secretary*
Step 2: Coordination with the physical plant division	*REC Staff*
Step 3: Assembly of materials and documents needed for the meeting	*REC Staff*
Step 4: Preparation of presentation and recording equipment, food arrangements for the meeting	*REC Staff*

Step 5: Notification of REC Members and confirmation of attendance	*Member Secretary and REC Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the meeting?

Step 1 - Preparation of the agenda: What are the usual items included in the agenda of a meeting? How are they identified? (See SOP ## Preparing the Meeting Agenda)

Step 2 - Coordination with the physical plant division: How does the REC ensure that the venue for the meeting will be available on the scheduled date? Does the REC have a conference room of its own? For example: *The REC staff notifies the Physical Plant Division (or its equivalent) regarding the upcoming meeting of the REC (date, time, appropriate conference room) one week before the schedule.*

Step 3 - Assembly of materials and documents needed for the meeting: What documents should be prepared and be made available during the meeting? Typically, these includes the meeting agenda, minutes of the previous meeting, relevant protocol folders, memorandums, administrative documents, etc. How many copies should be provided? For example: '*The staff gathers the documents and materials for the meeting based on the provisional agenda, e.g. copies of the provisional agenda, provisional minutes of the previous meeting, protocols and related documents submitted, at least 2 weeks before the meeting, post-approval reports, expedited review reports, administrative memos, etc.'*

Step 4 - Preparation of presentation and recording equipment, food arrangements for the meeting: What equipment is needed for the meeting? Will the time and duration of the meeting require provision for meals or food? Will there be a need for the presence of support staff? If the members receive honorarium for meetings, how will payments be ensured? For example: *The staff ensures that the following are prepared and available for the meeting: laptop (2), projector, and screen, microphones (3), adequate food and drinks/water depending on the expected duration of the meeting, respective honoraria of committee members.*

Step 5 - Notification of REC Members and confirmation of attendance: When and how will the REC members be notified? What information should be included in the notice of meeting? How will the attendance be confirmed? How soon? How will a lack of quorum be managed? When and how will the alternate members be invited? For example: *The member secretary supervises the staff in the preparation of the Notice of Meeting (Form ##) that includes the provisional agenda. The staff sends the notice of meeting to the members of the committee, at least, one week before the schedule and follows-up the confirmation of attendance to ensure quorum. In case, quorum cannot be met, the staff informs the Chair and the member secretary so that alternate members may be called in.*

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

Quorum – presence of the majority of the REC members including the non-affiliated and the non-scientist members.

Support Staff – institutional personnel assigned by administration to assist in the operations of the REC.

Regular Meeting - a periodically scheduled assembly of the REC

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

Administrative Documents – documents that pertain to the operations of the REC and are not directly related to a study or protocol.

Honorarium- monetary payment for specific professional services.

Physical Plant Division – unit within the institution that is in charge of the maintenance and use of physical facilities.

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Notice of Meeting

Form ## Attendance Confirmation Form

Form ## Agenda Template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised notice of meeting form*
3	*2018 June 03*	*GHI*	*Inclusion of preparation of honoraria of members*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 18** **Preparing the Meeting Agenda**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The meeting agenda is the guide in the conduct of a meeting. It ensures order and completeness of topics for discussion. It is recommended that the agenda template includes the following: date, time, and venue of the meeting; titles of protocols for full review; titles of protocols that underwent expedited review, after approval reports, administrative issuances and operations. An example of a policy statement would be, *"The meeting agenda shall be based on the submissions received, at the latest, two (2) weeks before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting."*

2. Objective/s of the Activity

What are the intended outcomes of the procedures involved in the preparation of meeting agenda? For example, *"The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings."*

3. Scope

The SOP covers procedures that are needed to generate the Meeting Agenda. For example, *"This SOP describes how the REC determines what items are to be included in the agenda of regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda."*

4. Workflow

What are the different steps involved? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Preparation of the draft meeting agenda	*Staff and Member Secretary*
Step 2: Preparation of the provisional meeting agenda	*Chair*
Step 3: Distribution of the provisional meeting agenda (SOP ## Preparing for a Meeting)	*REC Staff*
Step 4: Approval of the provisional meeting agenda	*REC Members*

Step 5: Filing of the final meeting agenda (SOP ## on Management of Active Files)	*REC Staff*

5. Detailed Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

Step 1 - Preparation of the draft meeting agenda: Does the REC use a meeting agenda template or form? How and when is the template completed? What information should the REC Staff use to accomplish this form (e.g. new protocols for full review, expedited review reports, post-approval reports, administrative issuances, etc.)? What kind of supervision is needed by the REC Staff to complete this task? For Example: *The staff under the supervision of the Member Secretary prepares the draft agenda two (2) weeks before the scheduled meeting, using the Meeting Agenda Template (Form ##_____). The agenda includes the following:*

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

Step 2 - Preparation of the provisional meeting agenda: Who approves the draft meeting agenda? How long is this process and how is it initiated and concluded? It is important to cite specific timelines to properly guide REC staff. *The Chair reviews the draft agenda (within 2 days) as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting.*

Step 3 - Distribution of the provisional meeting agenda: What is the method of distribution of the provisional meeting agenda to members? It is important to cite specific timelines to properly guide REC Staff. Note that this step is related to the SOP on Preparing for a Meeting. *The provisional agenda is included in the Notice of Meeting (SOP ## Preparing for a Meeting).*

Step 4 - Approval of the provisional meeting agenda: When is the provisional meeting agenda approved and finalized? *The REC members approves the provisional agenda during the meeting.* (SOP ## Conduct of Meeting).

Step 5 - Filing of the final meeting agenda: It is recommended that the REC maintain a central file of all final meeting agenda by year to facilitate retrieval. *The staff files the final (approved)*

meeting agenda in a special folder that contains all meeting agenda in a chronological order. See SOP ## Managing Active Files).

6. Glossary

What terms/abbreviations used in this SOP need to be defined for better compliance? Examples:

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

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

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

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

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

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

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

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

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

Administrative Issuance – official communications or announcements from institutional authorities.

7. Forms:

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Meeting Agenda Template

Form ## Notice of Meeting

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the

first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Included the Invocation in the Meeting Agenda Template*
3	*2018 June 03*	*GHI*	*Removed the Invocation in the Meeting Agenda Template*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 19** **Conduct of Meetings**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The policy statement should include the rule on quorum, presiding officer, conflict of interest, and adherence to the agenda. For example, *"Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review."*

2. Objective/s of the Activity

The objective specifies the intended outcomes of conducting meetings. For example, *"Meetings are conducted to provide an opportunity for the REC to arrive at collegial decisions regarding study protocols and REC operations and to be informed of pertinent administrative matters."*

3. Scope

The SOP on the Conduct of Meeting covers activities required for an effective and efficient conduct of a meeting. For example, *"This SOP describes the manner by which the REC conducts all its meetings. It covers REC actions and activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials."*

4. Workflow

What are the different steps involved in the conduct of meeting? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Distribution of meeting materials	*REC Staff*
Step 2: Declaration of quorum (formal start)	*Member Secretary or Chair*
Step 3: Approval of the provisional agenda	*REC Members*

Step 4: Declaration of conflict of interest (COI)	*REC Members (who have COI)*
Step 5: Approval of minutes of the previous meeting	*REC Members*
Step 6: Discussion of "Business arising from the minutes"	*REC Members*
Step 7: Review of protocols and protocol-related submissions (SOP on Full Review (SOP#__))	*REC Chair and Members*
Step 8: Report of results of expedited review (SOP on Expedited Review (SOP#__))	*Designated Reviewers*
Step 9: Discussion of operations-related matters	*REC Chair and Members*
Step 10: Adjournment	*Chair*
Step 11: Collection, storage, and disposal of meeting materials	*Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

Step 1 - Distribution of meeting materials: What documents need to be made available during the meeting? These documents should have been prepared ahead in accordance with SOP on Preparing for a Meeting. How many copies are needed? Who are responsible for preparation? It is recommended that these documents be available already before the start of the meeting.

Step 2 – Declaration of quorum: What is the policy regarding quorum? Who is in charge of declaring quorum? How is quorum manifested to signal the formal start of the meeting?

Step 3 - Approval of the provisional agenda: How is the provisional agenda approved? Usually the Chair invites the members to examine the provisional agenda and to propose addition or deletion of items.

Step 4 - Declaration of Conflict of Interest: How does the REC define conflict of interest in a meeting? How does the committee manage a disclosure of conflict of interest? For example, some RECs prefer to declare COI early in the meeting so that the Chair will note it and implement the policy on conflict of interest management (e.g. conflicted member stepping out of the room or non-participation in the decision making process).

Step 5 - Approval of minutes of previous meeting: How is the review of the minutes of the previous meeting done? Who leads in this review? How are questions or objections about the minutes managed? How are corrections managed? How is approval declared?

Step 6 - Discussion of "Business arising from the minutes": Who reports on "business arising from the minutes"? How are issues on "business arising from the minutes" resolved?

Step 7 - Review of protocols and protocol-related submissions: Does the REC require researchers/principal investigators to make a presentation? Are they invited for a clarificatory interview? If so, how is this managed or facilitated in the discussion? What is the role of the independent consultant during the meeting?

What is the sequence of review? It is recommended that the discussion is structured in the following order: technical issues, ethical issues, and informed consent process/form issues. The primary reviewers should be guided by the assessment form in their presentations. See SOP ## Full Review.

How does the REC arrive at a decision (e.g. voting, consensus)? For REC's that require voting, how is the voting done (e.g. by secret ballot or raising hands)?

Step 8 - Report of results of expedited review: Who presents the results of expedited review to the members? What do members do with the information? In practice, expedited review results are for the information of the REC members, only, as well as for the documentation of the review results.

Step 9 - Discussion of operations-related matters: What are the usual items that fall under operations-related matters? Which of these items will need to be deliberated upon and approved by the members? Which are for information only?

Step 10 - Adjournment: What policies cover adjournment of the meeting? How is adjournment declared? For example, "Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared." Sometimes, meetings are adjourned based on a strict timeframe, whether or not all items in the agenda have been discussed.

Step 11 - Collection, storage, and disposal of meeting materials: How does the REC staff sort the documents distributed during the meeting? Are they returned to the shelves? Are extra copies disposed of? What is the manner of disposal? How does the REC staff keep track of meeting documents? See SOPs on Managing Active Files (SOP#__) and SOP ## Preparation of Agenda

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

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

Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.

Voting – act of formally manifesting a choice in a meeting.

Ballot – voting (indicating the choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.

Consensus – the process of arriving at a decision without voting but by generating the over all sentiment of a group such that deliberations continue until no more strong objection is registered.

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

Meeting Minutes - – the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Attendance Sheet
Form ## Secret Ballot Form
Form ## Protocol Assessment Form
Form ## ICF Assessment Form
Form ## REC Decision Form

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Included the independent consultant in the meeting attendance*
3	*2018 June 03*	*GHI*	*Included an adjournment policy*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 20** **Preparation of the Minutes of Meetings**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The minutes are the official documentation of the proceedings of an REC meeting. They represent the evidence for transparency and integrity of the decision-making process. They are guided by the approved agenda. A sample policy statement may be as follows, *"The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols."*

2. Objective of the Activity

The objective specifies the intended outcomes of the procedures involved in preparing the meeting minutes. For example, *"The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an REC meeting."*

3. Scope

This SOP on Preparation of Minutes of Meetings covers procedures to document the proceedings of the meeting especially pertaining to the deliberations in the full review of protocols. For example, *"This SOP includes REC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes."* Does the REC have special requirements for this type of document? Most RECs typically use a template for meeting minutes

4. Workflow

What are the different steps involved in the process of preparing the minutes of the meeting? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Entry of preliminary information on the minutes template	*REC Staff*
Step 2: Preparation of the draft minutes	*REC Staff and Member Secretary*
Step 3: Notation of the draft minutes	*Chair*

Step 4: Approval of the minutes in the next REC meeting	*Chair and Members*
Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP#__))	*REC Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

Step 1- Entry of preliminary information on the minute's template: Does the REC use a minute's template? Does the REC have a system to organize this document ahead of the meeting date such as filling it out with preliminary or relevant information ahead of the meeting (e.g. protocol-related information, other matters)? Who supervises the REC Staff in fulfilling this task?

Step 2 - Preparation of the draft minutes: How does the REC prepare the draft minutes? During the meeting, the REC Staff is tasked with documentation of proceedings in accordance with the agenda. How does the REC Staff document all board opinions and actions (e.g. take down notes, project the template on screen and do real-time note-taking) in all specific sections of the agenda? How does the REC ensure that the REC staff documents the discussion as the agenda is developed and discussed, with respective reasons for protocol-related actions? What information is mandatory to be included from the discussion (e.g. comments and recommendations on the scientific issues, ethical issues, and informed consent form issues)? Note that opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members? How much time is needed for this task? Who has oversight on the fulfilment of this task by the REC Staff?

Step 3 - Notation of the draft minutes: How will the draft minutes be completed? How soon should the draft minutes be prepared for notation of the Chair? What does the REC Staff do after completing the draft of the minutes? To whom does the REC Staff submit the draft (e.g. Member Secretary or Chair)? In how many days after the meeting should the REC complete, correct, and finalize the draft? In general, the following items are included in the minutes of the meeting:

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

Step 4 - Approval of the minutes in the next REC meeting: How is the approval of the provisional minutes signified? For example, approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.

Step 5 - Storage of the approved minutes: What type of storage system does the REC have for the final minutes of meeting? What kind of documentation is necessary to complete this task? It is recommended that the REC maintain a central file of all meeting minutes by year to facilitate retrieval. See SOP on Managing Active Files (SOP#__).

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

Draft Meeting Minutes – Proceedings of the meeting prepared by the Secretariat under the supervision of the Member-Secretry.

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Minutes Template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised the procedure in preparing the draft minutes from audio recording to real-time note taking*

3	*2018 June 03*	*GHI*	*Revised the timeline in approving meeting minutes*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 21** **Communicating REC Decisions**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The REC must be clear, informative and timely in communicating its decisions. An example of a policy, in this regard, may be as follows, *"The REC shall communicate its decisions to the researcher within ___ (reasonable timeframe not later than six weeks) after the receipt of complete set of submission documents. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the REC and signed by the chair."*

2. Objective of the Activity

The objective specifies the intended outcome of managing the communication of REC decisions. For example, "*The management of communicating REC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REC."*

3. Scope

The scope of the SOP on communicating REC decisions covers procedures and special requirements for notification of researchers/investigators of decisions or actions of the REC. Usually the REC uses either a Notification Form or an Approval Form to summarize required modifications in the protocol or to its approval respectively. For example, *"This SOP covers REC actions related to the communicating REC decisions (e.g. actions to applications submitted to the REC). This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file."*

4. Workflow

What are the different steps involved in communicating REC decisions? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Finalization of recommendations of the committee (in case of full review) (SOP ## Full Review)) or Finalization of recommendations of reviewers (in case of expedited review) (SOP ## Expedited Review)	*Chair*
Step 2: Transfer of information from meeting minutes or reports to REC decision forms or templates	*REC Staff, Member Secretary*

Step 3: Approval of the REC decision document	*Chair*
Step 4: Transmittal of REC decision to researcher	*REC Staff*
Step 5: Filing of the decision document in the protocol file (SOP ## Managing Active Files) and Update of Protocol Database	*REC Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

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

Step 2 - Transfer of information from meeting minutes to REC decision forms or templates: Upon approval of the draft minutes, or finalization of the reviewers' recommendations, how does the REC relay the information to the researchers? Does the REC have an Approval Letter or Notification Letter to send to the researcher, as the case may be? Who drafts the document? Who oversees this process? How long should this process take?

Step 3 - Approval of the REC decision document: Who reviews and approves the decision documents? How is this approval signified? How long does this process take?

Step 4 - Transmittal of REC decision to researcher: How do researchers get the results of the review (e.g. email or hand-delivered or pick up at the REC office)? How long does this process take? Who oversees this process?

Step 5 - Filing of the decision document in the protocol file and Update of the Protocol Database: It is recommended that the REC maintains all protocol related decisions or actions in the protocol folder to facilitate retrieval. The action should also be noted in the protocol database. What type of storage system does the REC have for protocols? What kind of documentation is necessary to complete this task (e.g. protocol index, database)? See SOP on Managing Active Files (SOP#__).

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Decision Form/Letter
Form ## Approval Form/Letter

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised template of notification*
3	*2018 June 03*	*GHI*	*Use of the protocol database*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 22** **Management of Incoming and Outgoing Communications**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Incoming and outgoing communications need to be recorded for monitoring and tracking purposes as evidence of quality service and efficient operations of the REC. The policy may be stated as, *"All communications shall be recorded accurately and appropriately in a physical log book and electronic database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly."*

2. Objective/s of the Activity

The objectives specify the intended outcomes of the procedures involved in managing REC incoming and outgoing communications? For example, *"The management of REC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system."*

3. Scope

The SOP on Management of Incoming and Outgoing Communications covers procedures involved in receiving, processing and filing communications. For example, *"This SOP covers REC actions related to organizing incoming and outgoing documents and ensuring an appropriate REC response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications."* Does the REC have special requirements for this type of document? Most RECs use a scheme to systematically sort and store documents.

4. Workflow

What are the different steps involved in managing REC incoming and outgoing communications? Who are the persons responsible in each of these steps? For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Sorting of incoming/outgoing communications	*REC Staff*
Step 2: Recording of incoming/outgoing communications	*REC Staff*
Step 3: Acting on incoming communications	*Chair or Member Secretary*
Step 4: Filing of incoming/outgoing communications and Updating of respective Databases	*REC Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

Step 1 - Sorting of incoming/outgoing communications: What kind of communications is received by the REC (e.g. letters, official memoranda, or emails)? Does the REC differentiate procedures depending on source (e.g. researchers, sponsors, regulators)? What procedures are in place to organize these communications so that they are addressed in a relevant and timely manner (e.g. separating protocol-related from process-related communication)? Who is responsible for this action? Who oversees this process?

Step 2 - Recording of incoming/outgoing communications: How does the REC record the incoming/outgoing communications? Does the REC have a recording system that documents the date received, source (person who sent communication), subject, person who received communication, action taken (with details of who received it from the REC), such as logbook or log of submissions? Who is responsible for this action? Who oversees this process?

Step 3 - Acting on communications: Who is responsible for initiating response on incoming communications? Who finalizes these responses? Who is the usual signatory for outgoing communications?

Step 4 - Storing or filing of incoming/outgoing communication: What storage system does the REC have for incoming/outgoing communications? What is the practice of the REC related to filing of communications (e.g. protocol-related communications are filed in the study protocol file while non-protocol-related documents are filed in the appropriate administrative file)? Does the REC use an indexing system for file of communications, and if so, how does it work? Who is responsible for this action? Who oversees this process?

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

Administrative Documents - documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.

Protocol-related File/ Documents - consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions Indexing System.

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Logbook for Incoming Communications
Logbook for Outgoing Communications
Form ## Index of Protocol File

8. History of the SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Included "Topic" as entry on Logbook for Outgoing Communications*
3	*2018 June 03*	*GHI*	*Included Member Secretary as alternate signatory for outgoing communications*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

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

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 23** **Management of Active Files**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

The REC needs to classify its protocol files into active or inactive. Considerations include proper labelling and manner of storage. An example of a policy may be as follows, *"Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP#__)"*

2. Objective/s of the Activity

The objective specifies the intended outcomes of managing active files. For example, *"The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality."*

3. Scope

The SOP on Management of Active Files covers storage of files and access procedures. For example, "*This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the REC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file."*

4. Workflow

What are the different steps involved in the process of managing active files? Who are the persons responsible in each of these steps?

ACTIVITY	***RESPONSIBILITY***
Step 1: Classification and coding of Active Files	*Member Secretary and Staff*
Step 2.: Preparation of the Protocol Folder	*Staff*
Step 3: Periodic updating of the Protocol File	*Member Secretary and Staff*

5. Description of Procedure

Step 1. Classification and coding of active files: *The staff under the supervision of the member secretary classifies active files as follows:*

- *Initial Submission*
- *Resubmission*

- *Progress Report*

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

The staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial member that indicate the sequence order of receipt. For example, a protocol received in 2019 as the 10th submission in that year will be coded as 2019-010.

Step 2. Preparation of the Protocol Folder: *The staff files all documents pertaining to a study in a vertical folder that is labelled on the front cover and along the spine with: Protocol Code- Study Title - Proponent's Family Name - Sponsor or Funding Agency. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.*

Step 3. Periodic Updating of the Protocol File: *The staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:*

- *Protocol (Original and Revised) versions*
- *Informed consent (Original and Revised) versions*
- *Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports*
- *Assessment Forms for each of the submitted and reviewed reports which should be signed and dated*
- *Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda*
- *Decision and Approval Letters*
- *Communications*

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

6. Glossary

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

Resubmission- the revised study proposalth at is forwarded to the REC in response to the recommendations given during the initial review.

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

Amendments- a change in or revision of the protocol made after it has been approved.

Protocol Deviation- non-compliance with the approved protocol that does not increase risk

nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data.Example: missed visit, non-submission of a food diary on time.

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

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

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

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

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

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

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

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

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

7. Forms:

Form ## *Protocol Index*

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised Coding System*
3	*2018 June 03*	*GHI*	*Revised List of documents to be included in the protocol File*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 24** **Archiving**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Protocols for archiving include those (a) with approved/ accepted Final Reports, (b) with approved Early Termination reports and (c) whose proponent/researcher/investigator has not submitted a response to the REC recommendation after 3 months (or as specified by the REC). What institutional policies or standards exist which are relevant to archiving research files (e.g. ISO coding system, database management)? Will these apply to REC documents? How? What is the policy on retrieval of archived files?

The prescriptions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines need to be followed, including security of file storage and access, document control, and document tracking.

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

2. Objective/s of the Activity

The objective/s specify the intended outcomes of archiving terminated, inactive, and completed protocols? For example, *"Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines."*

3. Scope

The SOP on archiving covers procedures in identifying documents to be archived, securing their storage, and providing access when necessary. For example, *"This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database."*

4. Workflow

What are the different steps involved in the process of archiving of terminated, inactive, and completed files? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Acceptance of Final or Early Termination Reports (SOP## on Review of Final Reports, SOP ## Review of Early Termination Reports, and Identification of a Protocol as Inactive.	*REC Members, Chair*
Step 2: Updating of corresponding protocol folder	*REC Staff*
Step 3: Transfer of the protocol folder in the archives and Update of the Protocol Database	*REC Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

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

Step 2 - Updating of the corresponding active file: *The staff files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.*

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

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Example:

Form ## Borrower's Log

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Changed timeline for keeping inactive files*
3	*2018 June 03*	*GHI*	*Added policy on access to inactive files*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 25** **Management of Access to Confidential Files**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

It is the responsibility of the REC to keep particular documents in its custody confidential. This is to protect the intellectual property rights of research proponents and to protect REC members from unnecessary scrutiny and pressure from non-authorized individuals. In the Philippines, personally identifiable documents entered into a database system are subject to protections under the Data Privacy Act of 2012, emphasizing the need to lay down policies authorizing access to such documents. Confidential files include study protocol-related documents (e.g. protocols, case report forms, informed consent documents, scientific documents, expert opinions or reviews), meeting minutes, decisions, action letters/notification of committee decision, approval letters, and study protocol-related communications. Generally, institutions have in-house policies or standards to promote confidentiality of institutional files. RECs must make an effort to be familiar with these policies and procedures so that these can be adopted by the REC. For example: who determines confidentiality of documents? Who can have access to these files (e.g. REC members, institutional authorities, regulatory agencies, sponsors)? Does the REC have a policy regarding the use of confidential files for training purposes? Who will be responsible for anonymization? The prescriptions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines need to be followed for security, storage, and access of files.

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

2. Objectives of the Activity

The objectives specify the intended outcomes of the procedures involved in managing requests for access to confidential files. For example, *"Management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the REC."*

3. Scope

The scope of this SOP includes all the procedures necessary to control access to confidential files. For example, *"This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.*

4. Workflow

What are the different steps involved in maintaining the confidentiality of study files? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Receipt and logging of request for access to confidential files	*Staff*
Step 2: Approval of requests for access and retrieval of documents	*Member Secretary or Chair*
Step 3: Supervision of use of retrieved document	*Staff*
Step 4: Return of document to the files	*Staff*

5. Description of Procedures

What are the detailed steps involved in the SOP and documents and forms that must be included in the review process?

Step 1 - Receipt and logging of request for access to confidential files: For example: *The staff receives the request (Form ##) to access specific files and refers this to the Chair or Member Secretary.*

Step 2 - Approval of requests for access and retrieval of documents: What are the requirements for approval of requests for access to confidential files (e.g. authority of the requesting individual, reason for the request, and signing of confidentiality agreement)? *The Chair or Member Secretary considers the indicated reason for the request and when found satisfactory approves it. The staff asks the individual requesting to sign the confidentiality agreement and proceeds to retrieve the pertinent document.*

Step 3 - Supervision of use of retrieved document: How will the REC supervise the use of the retrieved documents? *The staff asks the user to sign the logbook, enforces the restriction to room-use of documents and limits photocopying to concerned researchers/principal investigators.*

Step 4 - Return of document to the files: Who is responsible in ensuring that the document is returned to the proper file? The staff returns the retrieved files to the protocol file.

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REC and the researcher.

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

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

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

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

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

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

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

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Request Form
Form ## Log of Requests
Form ## Log of Access

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Revised policy on photocopying*
3	*2018 June 03*	*GHI*	*Added "reason for access" in the request form*

9. References

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 26** **Management of Queries and Complaints**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

Queries and complaints may come from various stakeholders but the responsibility of the REC is highest for those coming from research participants and their families. Nevertheless, all queries and complaints must be addressed as promptly, diligently, and appropriately as possible. An example of a policy statement would be, *"Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the REC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion."*

2. Objective/s of the Activity

The objectives specify the intended outcomes in managing queries and complaints. For example, *"Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the REC and to ensure that the rights and well-being of participants are attended to.*

3. Scope

The scope of this SOP includes all the procedures for receiving and appropriately responding to queries and complaints. For example, *"This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the REC. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the REC meeting."*

4. Workflow

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing REC Incoming and Outgoing Communications)	*REC Staff*

Step 2: Referral of query or complaint to competent authority. *2.1 Referral of protocol-related query to primary reviewers.* *2.2. Referral of all complaints to the REC Chair*	*REC Staff*
Step 3: Formulation of response *3.1. Protocol-related queries* *3.2. Minimal-risk complaints* *3.3. More than minimal risk complaints : en-banc committee*	 *Primary Reviewers* *Primary Reviewers* *Chair and REC members*
Step 4: Communication of response (SOP on Communicating REC Decisions (SOP#__))	*REC Staff*
Step 5: Logging of the response (SOP on Managing REC Incoming and Outgoing Communications (SOP#__)) and inclusion in the agenda of the REC meeting (SOP on Preparing the Meeting Agenda (SOP#__))	*REC Staff*

6. Description of Procedures

Based on the workflow (see above) describe each step. For example:

Step 1 - Receipt, logging, and acknowledgement of queries and complaints: Does the REC have a logbook dedicated to queries and complaints? What information is included in the logbook? For example, date, time, name of concerned party, specific study, nature of query or complaint.

Step 2 - Referral of query or complaint to competent authority: Does the REC have an algorithm that guides the staff on who can respond to general/usual queries and complaints?
2.1. The staff refers queries related to specific protocols approved by the REC to the primary reviewers.
2.2. On the other hand, the staff refers all complaints to the REC chair who determines the level of risk effected by the issue.

> *2.2.1. Minimal risk complaints are referred to the primary reviewers of the concerned protocol.*
> *2.2.2. Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The staff notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.*

Step 3 - Formulation of response: Does the REC have a special form for documenting responses to queries and complaints?
3.1. For queries, the primary reviewers accomplish the Form ## Query Reply.

3.2. For minimal risk complaints, the primary reviewers accomplish Form ## Complaints Resolution.

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

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

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

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

- request for explanation/justification from researcher

- accept request/demand of participant

- suspension of further recruitment

- amendment of protocol and re-consent of participants

- others

Step 4 - Communication of response: Is there a special form for communicating the response to queries and complaints? Who prepares this? Who signs? See SOP on Communicating REC Decisions (SOP#__).

Step 5 – Logging of the response and inclusion in the agenda of the REC meeting: How will the response be documented? See SOPs on Managing REC Incoming/Outgoing Communications (SOP#__) and Preparing the Meeting Agenda (SOP#__).

5. Glossary

What terms/abbreviations used in this SOP need to be defined for better for effective implementation? Examples:

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

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

Regular Meeting– a periodically scheduled assembly of the REC.

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

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

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

Site Visiting Team– members/staff of the REC (2-4 members) assigned by the REC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

6. Forms:What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Query/Complaint Form

Form ##Query/Complaint Response Form

7. **History of SOP**: Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	***Date***	***Authors***	***Main Change***
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Designated competent authority*
3	*2018 June 03*	*ABC* *DEF*	*Revised the Query/Complaint Response Form*

8. **References**

What references did you use in the preparation of this SOP (e.g. guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations)? Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Name and Logo of Institution	Name of the REC *e.g. Research Ethics Committee,* *Ethics Review Committee,* *Institutional Ethics Review Committee,* *Institutional Review Board*
Version No:	**SOP No. 27** **Writing and Revising SOPs**
Date of Approval:	
Date of Effectivity :	

1. Policy Statement

SOPs ensure efficiency, transparency, and consistency of REC operations. The SOP manual needs to be periodically reviewed to determine the need for revision or new SOPs in order to respond to emerging operational issues of the REC. A policy statement could be stated as, "*The REC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.*"

2. Objective of the Activity

The objective specifies the intended outcome of writing and revising SOPs. For example, *"Writing and revising SOPs ensures continuing quality assurance of REC functions."*

3. Scope

This SOP on Writing and Revising SOPs covers the procedures the REC has put in place in order to be able to develop new and relevant SOPs and to revise and update old SOPs. For example, *"This SOP applies to all REC activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination."*

4. Workflow

What are the different steps involved in the process of writing, reviewing, approving and disseminating SOPs of the REC? Who are the persons responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Proposal and approval for revision or writing of a new SOP	*Any REC Member or Staff*
Step 2: Designation of the SOP Team	*Chair*
Step 3: Drafting of the revision or new SOP	*SOP Team*
Step 4: Review and finalization of SOP	*REC Members*
Step 5. Submission of finalized SOP to the institutional authority	*Chair*

Step 6: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	*REC Staff*

5. Description of Procedures

What are the detailed steps involved in the writing, reviewing, approving of SOPs and documents and forms that must be included in this process?

Step 1 - Proposal for a revision of an SOP or a new SOP and its approval: Who can propose? What is the procedure for initiation of a request for new SOPs and amendments to existing ones? What process for approval is used (e.g. in a regular meeting, special meeting, or referendum)?

Step 2 - Designation of the SOP Team: How will the members of the SOP Team be selected? Who will select?

Step 3 - Drafting of the revision or new SOP: Does the REC use an SOP template? This would greatly harmonize the writing of SOPs. *In designing this template, the following contents are recommended:*

(a) *Title, which is descriptive of contents*

(b) *Policy statement*

(c) *Objective/s of the activity, which defines the purpose and intended outcome*

(d) *Scope, which defines the extent of coverage of the SOP and its limitations*

(e) *Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.*

(f) *Detailed instructions, which elaborates the steps listed in workflow*

(g) *Glossary – acronyms and terms which need to be defined*

(h) *Forms, documents to be accomplished by different parties as required by the SOP,*

(i) *Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes*

(j) *References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies*

How does the REC code SOPs? For example, **SOP XX/YY** where XX can refer to the SOP number, YY the Version of the SOP (starting from 01),

Step 4 - Review and approval of SOP: What happens to the draft version once ready? Is it submitted by a specific person to a committee/person/office? Does the review require an REC meeting? Or an assembly of specific people designated to do this task? Does the review require deliberation, collection of comments, or voting? What are the details involved (e.g. determination

of favorable action, deferment, documentation of action)? Is there a timeline? Is it possible to have unfavorable outcomes in these procedures? If so, how will they be managed? These issues should be presented in steps, and the outcome should be a form of functional approval by the REC of the draft SOP.

When will the new or revised SOP be effective? Who approves the final version (e.g. signature and date of signing by head of institute on)? This procedure should end with a formal approval, indicated by an action (such as a signature).

Step 5 – Submission of the SOP to the institutional authority

Step 6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination: How will the SOP be made available? Hard copy? E-copy? Is there a timeline from approval to dissemination (e.g. within thirty (30) days of approval by the head of institution for hard copies and immediately for e-copies)? Who is the custodian of the official approved copy? Is there a procedure for reproducing the approved SOP? In case of amended or revised SOP, how is the old version retired or superseded and stored separately from the new version? This step should end with filing of approved SOP.

6. Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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

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

Format- general style or layout of the document

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

7. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples:

Form ## Request for Creation/Revision of an SOP

Form ##SOP Template

8. History of SOP

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#__)).

Version No.	*Date*	*Authors*	*Main Change*
1	*2010 July 15*	*ABC*	*First draft*
2	*2013 May 01*	*DEF*	*Added criteria for proposing a new SOP*

3	*2015 June 03*	*ABC* *DEF*	*Revised the layout/format of SOP Template*

9. References

What references did you use in the preparation of this SOP: guidelines, other institutional SOPs, institutional policies, institutional documents, local regulations?

Examples:

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

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

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

Glossary

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

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

Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.

Administrative Documents/File – documents that pertain to the operations of the REC and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.

Administrative Issuance – official communications or announcements from institutional authorities

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

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

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

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

Anonymization – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.
Appeal – a request of a researcher/ investigator for a reconsideration of REC recommendation.

Appointing authority - the institutional official that has the power to designate or appoint individuals to specific offices or roles.

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

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

Ballot – voting (indicating a choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.

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

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

Clarificatory Interview/meeting – is a face-to-face consultation between the REC and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period as a significant step in quality control.

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

Clinical Trial – a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers in order to discover or verify the effects of and/or identify and adverse reactions to investigational products with the object of ascertaining their efficacy and safety.

Coding- a unique number assigned to a document. A protocol code indicates the year and order of receipt. The SOP code indicates its serial position among the other SOPs and its version number.

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

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

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

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

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

Conforme- an indication of acceptance of or agreement to an assignment or designation

Consensus – a collective agreement.

- *the process of arriving at a decision without voting but by generating the over all sentiment of a group such that deliberations continue until no more strong objections are registered.*

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

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

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

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

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

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

Draft Meeting Minutes – Proceedings of the meeting prepared by the Secretariat.

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

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

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

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

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

Expedited Review Reports – is an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review presented during a regular REC meeting for information of the REC members and for record purposes.

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

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

Final Reports/ Close Out Reports – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of

all participants. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Format- general style or layout of the document

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

Honorarium- monetary payment for a specific professional service.

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

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

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

Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC for assessment that can be expedited or full review

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

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

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

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signture of the Receiving Person and Action done.

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

Majority rule- is a policy based on the principle that the decision made by the greater number should be carried/accepted.

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

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

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

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

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

Non-affiliated Member/s – are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution since they do not receive regular salary or stipend from the institution.

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

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

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

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

Physical Plant Division – unit within the institution that is in charge of the maintenance and use of physical facilities.

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

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

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

Progress Report – A systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form ##. The frequency of submissioin (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.

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

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

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

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

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

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

Protocol-related Documents- consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form ,Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions.

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

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

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

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

Quorum – the minimum number (i.e., majority of the members) and type of members of the REC that are required to be present in any meeting for the proceedings to be

considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.

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

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

Regular Meeting – a periodically scheduled assembly of the REC.

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

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

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

Researcher- is the individual primarily responsible for the conceptualization, planning and implementation of a study.

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

Resubmissions- the revised study proposals that are forwarded to the REC in response to the recommendations given during the initial review.

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

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

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

Secret Ballot – is a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

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

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

- *Death*

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

whether or not it is related to the study intervention .

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

Site Visiting Team – members/staff of the REC (2-4 members) assigned by the REC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.

Special meeting – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.

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

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

Standard Operating Procedures - are the step-by-step description of the different procedures done to accomplish the objective of an activity.

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

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

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the REC and the researcher.

Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.

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

SAE Subcommittee – a group of experts designated to analyze SAE/SUSAR reports and make the necessary recommendations to the REC. The experts may or may not be members of the REC.

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

Term of office – the specified length of time that a person serves in a particular designation /role.

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

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

SAMPLE FORMS

GROUP A

Name and logo of institution	**RESEARCH ETHICS COMMITTEE**		
	CURICULUM VITAE FORM	REC Form No.	
		Version No.	
		Date of Effectivity	

1. General Information			
Name		Date of birth:	
Address:		Contact number: Email address:	
Affiliation:	Name of Department:	Name of Institution:	
Position:		Specialty:	
Highest Educational Attainment :	Name of Institution:	Course/Degree:	Year/s attended:
Research Related Trainings including Research Ethics:	Name of Course: 1.	Offered by: 1.	Year: 1.

Name and signature: Date:

Name and logo of institutioin	**RESEARCH ETHICS COMMITTEE**		
	NOMINATION FORM	REC Form No.	
		Version No.	
		Date of Effectivity	

1. General Information			
Name of Nominee			
Affiliation:	Name of Department:	Name o Institution:	
Position:			
Highest Educational Attainment :	Name of Institution:	Year/s attended:	Course/Degree:
Research Related Trainings including Research Ethics:	Name of Course: 1.	Offered by:	Year:

Acceptance of Nomination: Signature of Nominee Date:
Name and signature of Nominator: Date: Position: Institution:

Received by: _____
Date: _____

GROUP B

APPOINTMENT OF MEMBER TEMPLATE

Name and logo of Institution

Date

NAME
Department and Position
Institutional Affiliation

Subject: Appointment as _____

Dear ***Name:***

You are hereby appointed as _____ of the Research Ethics Committee (REC) effective (from) to (to). As member/ independent consultant, your responsibilities are as follows:

(As member)

1. Attend REC meetings consistently.
2. Participate in the ethical review of research proposals and other related reports. The non-scientific member shall give special attention to the Informed Consent Form and process to ensure that these are comprehensible by ordinary persons and are considerate of community values.
3. Participate in the after-review activities, e.g., continuing review, site visits, etc.
4. Declare any conflict of interest (COI) in the review of research proposals.
5. Maintain confidentiality of the documents and deliberations of the REC meetings.
6. Attend continuing ethics education and other related activities.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the member / Independent Consultant of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____
Name and signature of Appointee

APPOINTMENT OF REC OFFICER TEMPLATE

Name and logo of Institution

Date

NAME
Department and Position
Institutional Affiliation

Subject: Appointment as Chair/Vice Chair/Member Secretary_____

Dear ***Name:***

You are hereby appointed as Chair/Vice Chair/Member Secretary of the Research Ethics Committee (REC) effective (from) to (to). As Chair/Vice Chair/Member Secretary, your responsibilities are as follows:

(As Chair)
Over and above duties as a Member, the Chair shall have the following responsibilitie:

1. Represent the REC in internal and external meetings and conferences.
2. Preside over REC Meeting.
3. Oversee review of protocols.
4. Assign Primary Reviewers of protocols based on expertise and experience.
5. Supervise development and revisions of SOPs.
6. Prepare and submit annual budget of the REC.
7. Prepare and submit annual report of the REC to the office of the Institutional Authority and to PHREB.
8. Ensure initial and continuing research ethics trainings of members and staff.

(As Vice Chair)
Over and above duties as a Member, the Vice Chair shall have the following responsibilities:

1. Perform duties of Chair in his/her absence.
2. Perform tasks assigned by Chair Participate in the review of research proposals and other related reports when requested.

(As Secretary)
Over and above duties as a Member, the Member Secretary shall have the following responsibilities:

1. Supervise the administrative Staff in the daily operations of the REC.
    a. Receipt of protocol documents
    b. Preparation of protocol files and folders
    c. Preparation of draft of communications
    d. Preparation of draft Agenda and Minutes
    e. Updating of records
2. Assist the Chair in assigning Primary Reviewers.
3. Assist the Chair in the preparation of the Agenda, Annual Report, and budget.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the Chair/Vice Chair/Member Secretary of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____
Name and signature of Appointee

APPOINTMENT OF INDENDENT CONSULTANT TEMPLATE

Name and logo of Institution

Date

NAME
Department and Position
Institutional Affiliation

Subject: Appointment as Independent Consultant

Dear ***Name:***

You are hereby appointed as Independent Consultant of the Research Ethics Committee (REC) effective (from) to (to). As member/ independent consultant, your responsibilities are as follows:

1. Attend REC meeting when requested.
2. Participate in the review of research proposals and other related reports when requested.
3. Declare any conflict of interest (COI) in the review of research proposals.
4. Maintain confidentiality of the documents and deliberations of the REC meetings.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the member / Independent Consultant of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____
Name and signature of Appointee

GROUP C

DECISION LETTER TEMPLATE

Name and Logo of the Institution

(Date)

(NAME OF PROPONENT)
(Designation)
(Institution)
(Address)

RE: (Title of project/study)

REC code:

Subject: (Nature of action requested, e.g. ethical clearance extension, acceptance of report, etc.)

Dear ***(Name of proponent)***:

This is to acknowledge receipt of your request and the following supporting documents dated_____.

- _
- _
- _
- _
- _

The above documents underwent full/expedited review which generated the following:

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any)

Very truly yours,

(Signature)
(Name)
Chair

ETHICAL CLEARANCE TEMPLATE

Name and logo of the Instittion

(Date)

(NAME OF PROPONENT/RESEARCHER)
(Designation)
(Institution)
(Address)

RE: (Title of project/study)
REC code:

Subject: Ethical Clearance

Dear ***(Name of proponent)***

(Acknowledgment of request (date of letter) and submitted documents with version numbers and dates)

- _
- _
- _
- _
- _

(Information on type of review and date of meeting, if full review)

(Validity of ethical clearance)

(Provisions for post-approval submissions)

Very truly yours,

(Signature)
(Name)
Chair

CERTIFICATE OF EXEMPTION FROM REVIEW TEMPLATE

Name and Logo of the Institution

(Date)

(NAME OF PROPONENT)
(Designation)
(Institution)
(Address)

RE: (Title of project/study)
EC code:

Subject: Certificate of Exemption from Review

Dear ***(Title and Family name of proponent)***

This is to acknowledge submission of the following documents (include version numbers and dates)

- _
- _
- _
- _
- _

After a preliminary review of the above documents, the Research Ethics Committee deemed it appropriate that the above proposal be EXEMPTED FROM REVIEW.

This means that the study may be implemented without undergoing an expedited or full review. Neither will the proponents be required to submit further documents to the committee as long as there is no amendment nor alteration in the protocol that will change the nature of the study nor the level of risk involved.

Very truly yours,

(Signature)
(Name)
Chair

GROUP D

Logo and name of insstitution	**Ethics Committee**		
	Confidentiality Agreement (For Members, Observers or Guests of the National Ethics Committee)	EC Form No.	
		Version No.	
		Date of Effectivity	

I sign this document as _____ of the Ethics Committee for Human Research and voluntarily agree not to disclose or reproduce any confidential information and/or research protocols under consideration during the course of my activities with the Committee, or anytime afterwards.

Confidentiality covers information or materials prepared by the investigators, and/or sponsors for the ethics committee review either in written or verbal forms. This information includes technical and scientific data, financial and personal information concerning wages, remunerations, salaries and benefits. I agree to return the related data or document to the office of EC after the completion of the activity.

In case I have to disclose the confidential information by court order, I will so inform the committee within two days after notification.

Signature _____

Name _____

Institutional Affiliation _____

Address_____

Noted

_____

EC Chair

Date _____

Logo and name of institution	ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	DISCLOSURE OF CONFLICT OF INTEREST **AGREEMENT** (For Members and Consultants of the Research Ethics Committee)	REC Form No.	
		Version No.	
		Date of Effectivity	

In general, *Conflict of Interest* occurs when there is conflict (actual, potential or perceived) between an individual's duties and his/her personal or private interest. *Conflict of Interest* impairs one's abilities to exercise objectivity in the performance of official duties.

The Members (including the Chair) of the National Ethics Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of research protocols and other related documents.

The following can be used as a guide to determining whether he/she has *Conflict of Interest*.

INSTRUCTIONS TO NEC MEMBERS OR CONSULTANTS

Before affixing your signature below, please consider each of the following statements in relation to: 1) all your past and current official positions; and 2) all your immediate family members, especially spouse and children. Then, check (√) your answer in the 'yes' or the 'no' column.

STATEMENTS	YES	NO
• I/My family have owned stocks and shares in the proponent organization(s).		
• I/My family have received a salary, an honorarium, a compensation, concessions and gifts from the proponent organization(s).		
• I/My family have served as an officer, director, advisor, trustee, consultant or an active participant in the activities of the proponent organization(s).		
• I/My family/my other organizations have had research work experience with the principal investigator(s).		
• I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.		
• I/My family have regular social activities, such as parties, home visits and sports events, with the principal investigator(s).		
• I/my family/my other organizations have an interest in or an ownership issue against the proposed topic.		

As a member/consultant of the National Ethics Committee I shall disclose any conflict of interest that I may have in connection with the review of specific research protocols and related documents.

I shall do this before or during any deliberations so that I may not participate in the decision regarding the said protocol.

_____ _____

SIGNATURE OVER PRINTED NAME DATE

_____

INSTITUTIONAL AFFILIATION

_____

ADDRESS

GROUP E

Name and logo of Institution	RESEARCH ETHICS COMMITTEE		
	PROTOCOL REVIEWER WORKSHEET	REC Form No.	
		Version No.	
		Date of Effectivity	

Title of Study					
REC Code		Type of Review			
Project Leader		Institution			
Reviewer		Date Received	Primary reviewer	☐ Yes	☐No

Guide questions for reviewing the proposal / protocol			
Does the study have social value? Comment: (e.g. scientific value, relevance to national /community needs)	☐ Unable to Assess	☐ Yes	☐ No
Is the study background adequate? Comment:	☐ Unable to Assess	☐ Yes	☐ No
Are the research questions supported by the Review of Literature? Comment:	☐ Unable to Assess	☐ Yes	☐ No
Are the study objectives Specific, Measurable, Attainable, Realistic, Time-bound? Comment:	☐ Unable to Assess	☐ Yes	☐ No
Is the research design appropriate? • Is the population identified and defined?	☐ Unable to Assess	☐ Yes	☐ No
• Is the selection of study participants described?	☐ Unable to Assess	☐ Yes	☐ No
• Is the sample size justified?	☐ Unable to Assess	☐ Yes	☐ No
• Is the plan for data analysis described? Are there dummy tables? Comment:	☐ Unable to Assess	☐ Yes	☐ No
Does the research need to be carried out with human participants? Comment:	☐ Unable to Assess	☐ Yes	☐ No
Does the study have a vulnerability issue? Comment:	☐ Unable to Assess	☐ Yes	☐ No

Are appropriate mechanisms/interventions in place to address the vulnerability issue/s? ☐ Unable to Assess ☐ Yes ☐ No Comment:
Are there risks/ probable harms to the human participants in the study? ☐ Unable to Assess ☐Yes ☐ No Comment:
Are there measures to mitigate the risks? ☐ Unable to Assess ☐ Yes ☐ No Comment:
Is the informed consent procedure / form ade ☐ Unable to Assess ☐ Yes ☐ No and culturally appropriate? Comment:
Is/are the investigator/s adequately trained and do ☐ Unable to assess ☐ Yes ☐ No they have sufficient experience to undertake the study? Comment:
Is there a disclosure of conflict of interest? ☐ Unable to assess ☐ Yes ☐ No Comment:
Are the research facilities adequate? ☐ Unable to assess ☐ Yes ☐ No Comment:
Are there any other concerns in the study?

Recommendation: ☐ **Approved**
☐ **Minor revision/s required**

_____

_____

☐ **Major revision/s required**

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Review Date**

Logo and name of institution	RESEARCH ETHICS COMMITTEE		
	INFORMED CONSENT CHECKLIST	REC Form No.	
		Version No.	
		Date of Effectivity	

Title of Study					
REC Code		Type of Review			
Proponent		Institution			
Reviewer		Primary reviewer	☐ Yes		☐ No

Guide questions for reviewing the informed consent process and form

Is it necessary to seek the informed consent of the participants? ☐ Yes ☐ No If NO, please explain.	☐ Unable to Assess	☐
If YES, are the participants provided with sufficient information regarding:		
• Purpose of the study?	☐ Yes	☐No
• Expected duration of participation?	☐ Yes	☐No
• Procedures to be carried out?	☐Yes	☐No
• Discomforts and inconveniences?	☐ Yes	☐ No
• Risks (including possible discrimination)?	☐ Yes	☐ No
• Random assignment to the trial treatments?	☐ Not applicable	☐ Yes ☐ No
• Benefits to the participants?	☐ Yes	☐ No
• Alternative treatments/ procedures?	☐ Not applicable	☐ Yes ☐ No
• Compensation and/or medical treatments in case of injury?	☐ Yes	☐ No
• Who to contact for pertinent questions and / or for assistance in a research- related injury?	☐ Yes	☐ No
• Refusal to participate or discontinuance at any time will involve penalty or loss of benefits to which the subject is entitled?	☐ Yes	☐ No
• Extent of confidentiality?	☐ Yes	☐ No
Is the informed consent written or presented in simple language that participants can understand?		☐ Yes ☐ No
Does the protocol include an adequate process for ensuring that consent is voluntary?		☐ Yes ☐ No

Do you have any other concerns?

Recommendation: ☐ **Approved**
☐ **Minor revisions required**

_____

_____

_____

☐ **Major revisions required**

_____

_____

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____

_____

_____ _____

Name and Signature of Reviewer **Review Date**

Logo and name of institution	**ETHICS COMMITTEE**		
	PROTOCOL REVIEWER WORKSHEET (FOR STEM CELL RESEARCH)	REC Form No.	
		Version No.	
		Date of Effectivity	

Title of the Study			
NEC Code		Type of Review	
Proponent			
Institution		Has an ERC/IRB? ____yes ____no	
Sponsor			
Funding Agency			
Name of Reviewer		Primary Reviewer	____yes ____no

GUIDE QUESTIONS

Is there comprehensive literature review and information?

that describes the development of the stem cell therapy

in this study? _____ yes _____ no

Comment:

Nature of Stem Cell Use: ____ Clinical Trial ___ Phase 1 ____ Phase 2 ____ Phase 3

____ Experimental Therapy

____ Established Therapy for new indications/formulation

Source of Stem Cells: ____ Human (adult) ____ autologous ____ allogeneic

____ Human (embryonic)

____ cellular reprogramming

____ Animal (pls. identify_____)

____ Plant (pls. identify _____)

____ Others (pls. describe _____)

Will the stem cells be directly transplanted to the human recipient? _____yes _____no

If YES, where? _____ outside the Philippines, pls specify _____

_____ locally, pls. specify _____

If NOT, will the stem cells be

stored? ____yes ____no _____not indicated

processed? ____yes ____no _____not indicated

cultured? ____yes ____no _____not indicated

expanded? ____yes ____no _____not indicated

or genetically modified? ____yes ____no _____not indicated

Is the laboratory GMP/GLP certified? _____ yes _____ no ____not indicated

Is the hospital accredited by the DOH Bureau of Health

Facilities and Services (DOH-BHSF) for stem cell use? _____ yes _____ no ____not indicated

Will animal serum/feeder cells be used? _____ yes _____ no ____not indicated

Are release criteria described/indicated? _____ yes _____ no ____not indicated

Which stem cell markers will be used? _____

Comment:

What is the route of administration/transplantation?

_____ intravenous

_____ intrathecal

_____ subdermal

_____ intramuscular

_____ direct to the target organ , _____

Are indicators of clinical efficacy described?

Are there homing indicators? _____ yes _____ no

Are there functional indicators? _____ yes _____ no

Are there persistence indicators? _____ yes _____ no

Comment:

Does the study design address the study objectives? _____ yes _____ no

Comment:

Is the selection of patients fair and equitable? _____ yes _____ no

Comment

Do the participants/ subjects belong to vulnerable groups? _____ yes _____ no

Is vulnerability addressed? _____ yes _____ no

Comment:

Are the benefits adequately described? _____ yes _____ no

Comment:

Will surrogate markers for good outcomes be used? _____ yes _____ no ____ not indicated

What are these?

Are the risks identified? _____ yes _____ no

Comment:

Do the benefits outweigh the risks? _____ yes _____ no

Comment:

Is the process for obtaining informed consent described?

in the protocol? _____ yes _____ no

Who will obtain the informed consent? _____ attending physician _____ project leader

_____ principal investigator _____ nurse

_____ others, pls. identify _____

Will standard health care be provided? _____ yes _____ no ____ not indicated

Comment:

Are financial arrangements reasonable and fair? _____ yes _____ no ____ not indicated

Comment:

Is there a potential conflict of interest? _____ yes _____ no Comment:
Is the training and practice of the researcher/principal/ investigator adequate and appropriate to ensure safe and competent conduct of the study and care of the participants? _____ yes _____ no Comment:
Is there a commitment to publish study results? _____ yes _____ no _____ not indicated Comment:

Recommendation: ☐ **Approved**
☐ **Minor revisions required**

_____

_____

☐ **Major revisions required**

_____

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Review Date**

Logo and name of institution	**RESEARCH ETHICS COMMITTEE**		
	INFORMED CONSENT CHECKLIST (FOR STEM CELL RESEARCH)	REC Form No.	
		Version No.	
		Date of Effectivity	

Title of the Study			
REC Code		Type of Review	
Proponent			
Name of Reviewer		Primary Reviewer	____yes ____no

GUIDE QUESTIONS

Is there a separate document for patient information and informed consent?

_____ yes _____ no

Comment:

Is the participant/patient provided with sufficient information

with regard to each of the following items?

- Purpose of the study _____ yes _____ no
- Unproven and experimental aspects of cell-based intervention _____ yes _____ no
- Clarification of therapeutic misconception _____ yes _____ no
- Expected duration of participation _____ yes _____ no
- Permanency of stem cell therapy _____ yes _____ no
- Discomforts and inconveniences _____ yes _____ no
- Alternative care _____ yes _____ no
- Risks (nature and likelihood) _____ yes _____ no
- Benefits (nature and likelihood) _____ yes _____ no
- Confidentiality / Protection of Privacy _____ yes _____ no
- Voluntary withdrawal _____ yes _____ no
- Financial arrangements _____ yes _____ no
- Compensation _____ yes _____ no
- Provision of standard of care _____ yes _____ no
- Contact information of person/s in-charge _____ yes _____ no

Comments:

Recommendation: ☐ **Approved**
☐ **Minor revisions required**

_____

_____

_____

☐ **Major revisions required**

_____

_____

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____

_____

_____ _____

Name and Signature of Reviewer **Review Date**

GROUP F

Name and logo of Institution	**RESEARCH ETHICS COMMITTEE**		
	APPLICATION FOR ETHICS REVIEW OF A NEW PROTOCOL	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked ~~below~~ (in Section 3. Checklist of Documents~~)~~.

1. General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
*Type of Study	☐ Clinical Trial (Sponsored) ☐ Clinical Trials (Researcher-initiated) ☐ Health Operations Research (Health Programs and Policies) ☐ Social / Behavioral Research ☐ Public Health / Epidemiologic Research ☐ Others _____	☐ Biomedical research (Retrospective, Prospective and diagnostic studies) ☐ Stem Cell Research ☐ Genetic Research ☐ Others _____	
	☐ Multicenter (International) ☐ Multicenter (National) ☐ Single Site		
*Source of Funding	☐ Self-funded ☐Government-Funded ☐ Scholarship/Research Grant	☐ Sponsored by a Pharmaceutical Company Specify: _____ ☐ Institution-Funded ☐ Others _____	
*Duration of the study	Start date: End date:	No. of study participants	

*Has the Research undergone Technical Review?	☐ Yes (please attach technical review results) ☐ No
*Has the Research been submitted to another REC?	☐ Yes ☐ No

2. Brief Description of the study

3. Checklist of Documents

Basic requirements:

☐ Letter request for review
☐ Endorsement/Referral Letter
☐ Full proposal / study protocol
☐ Technical Review Approval
☐ Curriculum Vitae of Researcher/s
☐ Informed Consent Form
☐ English version ☐ Filipino version
☐ Others _____
☐Assent Form (if applicable)
☐ English version ☐ Filipino version
☐ Others: _____

Supplementary Documents:

☐ Questionnaire (if applicable)
☐ Data Collection Forms (if applicable)
☐ Product Brochure (if applicable)
☐ Philippine FDA Marketing Authorization or Import License (if applicable)
☐ Permit/s for special populations (please specify)
_____
_____
☐ Others (please specify)
_____
_____

Accomplish

_____
Signature

Date submitted

---------- To be filled by the REC Secretariat ----------

Completeness of Document	☐ **Complete** ☐ **Incomplete**	(place stamp here)
Remarks		
Date Received		
Received by		

Logo and name of institution	**RESEARCH ETHICS COMMITTEE**		
	RESUBMISSION FORM	REC Form No.	
		Version No.	
		Date of Effectivity	

General Information			
*Title of Study			
Version number/date			
*REC Code (To be provided by NEC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			

REC Recommendations	Response of Researcher	Section and page number of revisions

Signature of Researcher: _____

Date: _____

Logo and name of institution	ETHICS COMMITTEE		
	APPLICATION FOR ETHICS REVIEW OF AMENDMENTS	EC Form No.	
		Version No.	
		Date of Effectivity	

General Information			
*Title of Study			
Version number/date of the EC approved protocol			
*EC Code (To be provided by EC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			
Effective period of ethical clearance	From	To	

Procedure/provisions to be amended (Use additional sheets if necessary)	Original Procedure/Provision	Proposed Amendment/s	Justification

Signature of Researcher: _____

Date: _____

Logo and name of instution	RESEARCH ETHICS COMMITTEE		
	APPLICATION FOR ETHICS REVIEW OF PROGRESS REPORTS	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked below (in Section 3. Checklist of Documents).

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Progress Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Number of participants who withdrew			
6. Deviations from the approved protocol		7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio	
8. Issues/problems encountered			

Name and logo of institution	**RESEARCH ETHICS COMMITTEE**		
	PROTOCOL VIOLATION/DEVIATION REPORT	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			

Progress Report	
1. Start of study	2. Expected end of study
3. Number of enrolled participants	4. Number of required participants
5. Number of participants who withdrew	
6. Deviations from the approved protocol	7. Explanation for deviation/violation
8. Impact of deviation/violation on participants' risks/harms and integrity of data	9. Actions taken to prevent future deviation/violation

Name and logo of institution	**RESEARCH ETHICS COMMITTEE**		
	REPORTABLE NEGATIVE EVENT REPORT	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			

RNE Report	
1. Start of 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 RNEs, interventions and Outcomes
7. Recommendations	

Logo and name of institution	**RESEARCH ETHICS COMMITTEE**		
	APPLICATION FOR CONTINUING REVIEW	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Progress Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Number of participants who withdrew			
6. Deviations from the approved protocol		7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio	
8. Issues/problems encountered			
9. Justification for application for Continuing Review			

Logo and name of institution	RESEARCH ETHICS COMMITTEE		
	SITE VISIT REPORT	REC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Site Visit Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Reasons for Site Visit		6. Person/s present during visit	
7. Findings		8. Recommendations	

Site Visit Team

1. -
2. -
3. -

Report submitted by:

_____

Name and signature

Date:

Name and logo of institution	ETHICS COMMITTEE		
	EARLY TERMINATION REPORT	NEC Form No.	
		Version No.	
		Date of Effectivity	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Recommended by:	(e.g. Sponsor, Funding Agency, Data Safety Monitoring Board, Researcher/Proponent)		
Early Termination Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Reason/s for termination		6. Support mechanisms/Interventions for Enrolled Participants	
7. Post-Termination Actions			

_____

Name and signature of Proponent
Date:

Received by:
Date:

Logo and name of institution	**RESEARCH ETHICS COMMITTEE**		
	FINAL REPORT FORM	REC Form No.	
		Version No.	
		Date of Effectivity	

General Information			
*Title of Study			
Version number/date of the EC approved protocol			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			
Effective period of ethical clearance	From:	To:	

Final Report	
1. Start of study	2. End of study
3. Number of enrolled participants	4. Number of required participants
5. Number of participants who withdrew	
6. Deviations from the approved protocol	7. Issues/problems encountered
8. Summary of findings:	
9. Conclusions:	
10. Actions for dissemination of study results:	

Signature of Researcher: _____
Date: _____

GROUP G

Name and logo of institutioin	RESEARCH ETHICS COMMITTEE		
	NOTICE OF MEETING	REC Form No.	
		Version No.	1
		Effectivity Date	

Date of Notice:
Date of Meeting:
Venue:
Time:

Items for Discussion:

1. Full Review of New Proposals (Initial)
   1.1. REC Code - Title
   1.2. REC Code - Title
2. Report on Expedited Review of Proposals
   2.1. REC Code - Title
   2.2. REC Code - Title
3. Updates on Full Review of Proposals (Resubmission)
   3.1. REC Code - Title
   3.2. REC Code - Title
4. Updates on Expedited Review of Proposals (Resubmissions)
   4.1. REC Code - Title
   4.2. REC Code - Title
5. Updates on Approved, Ongoing Researches
   5.1. REC Code - Title
   5.2. REC Code - Title
6. Other Matters

Name and logo of institution	**RESEARCH ETHICS COMMITTEE**		
	PROVISIONAL AGENDA	REC Form No.	
		Version No.	
		Date of Effectivity	

Venue:	
Date:	Time:

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising
7. New Business
8. Full Review of New Proposals (Initial)
   8.1. REC Code - Title
   8.2. REC Code - Title
9. Report on Expedited Review of Proposals
   9.1. REC Code - Title
   9.2. REC Code - Title
10. Updates on Full Review of Proposals (Resubmission)
    10.1. REC Code - Title
    10.2. REC Code - Title
11. Updates on Expedited Review of Proposals (Resubmissions)
    11.1. REC Code - Title
    11.2. REC Code - Title
12. Updates on Approved, Ongoing Researches
    12.1. REC Code - Title
    12.2. REC Code - Title
13. Other Matters
14. Adjournment

Logo and name of institution	RESEARCH ETHICS COMMITTEE		
	MINUTES OF THE MEETING	REC Form No.	
		Version No.	
		Date of Effectivity	

Type of Meeting:
Date:
Time:
Venue:

Attendance:
Present

Name	Office

Also Present

Name	Office

Absent

Name	Office

1. **Call to Order**
2. **Declaration of Quorum**
3. **Disclosure of Conflict of Interest**
4. **Approval of the Provisional Agenda**
5. **Review and Approval of the Minutes of the Previous Meeting (Date)**
6. **Business arising from the minutes of the meeting**
7. **Full Review of Proposals (Initial)**

7.1.

NEC Code:	
Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments: **Scientific Soundness:** **Ethical Considerations** **-Social Value** **-Vulnerability issue** **-Measures to protect vulnerability population** **-Risk/benefit ratio** **-Measures to mitigate risks** **-Confidentiality and privacy** **-Informed Consent process, form and content**	
Recommendations:	
Decision:	
Decision letter date	

8. Report on Expedited Review of Proposals (Initial)

8.1.

NEC Code:	
Title:	
Researcher/s:	
Reviewers:	
Submission Date	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

9. Updates on Full Review of Proposals (Resubmissions)

9.1.

NEC Code:	
Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

10. Updates on Expedited Review of Proposals (Resubmissions)

10.1.

NEC Code:	

Title:	
Researcher/s:	
Submission date	
Reviewers:	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

11. Updates on Approved, Ongoing Researches

11.1.

NEC Code:	
Title:	
Researcher/s:	
Submission date	
Approval letter sent	
Amendment/Report submission date	
Lead Reviewers	
Discussion/Comments/Recommendations:	
Decision:	
Decision letter date	

12. Other Matters

13. Adjournment

Prepared by:

Date:

Noted : (Chair)

Date:

GROUP H

Logo and name of institution	RESEARCH ETHICS COMMITTEE		
	LOGBOOK OF OUTGOING COMMUNICATIONS	REC Form No.	
		Version No.	
		Date of Effectivity	

YEAR: _____

Date	Nature of document (Decision letter, Approval letter, Invitation, Notice of Meeting, etc.)	Signatory	Addressee	Received by (Name and Signature of Recipient)	Delivered by (Name and Signature)
1.					
2.					

Name and logo of Institution	**RESEARCH ETHICS COMMITTEE**		
	LOGBOOK OF PROTOCOL SUBMISSIONS	REC Form No.	
		Version No.	
		Date of Effectivity	

YEAR: _____

Date of Submission	Code Number	Title	Proponent	Submitted by (Name and Signature)	Received by (Name and Signature)	Action
1.						
2.						

Logo and name of institution	**RESEARCH ETHICS COMMITTEE**		
	PROTOCOL FOLDER INDEX	REC Form No.	
		Version No.	
		Date of Effectivity	

Date of Filing	Nature of document (Initial Submission of Protocol and related documents version number, Excerpts of Minutes, Protocol and ICF Assessment, Decision letter, Approval letter, Post-Approval submissions, Communications from Researchers, Final Report, etc.)	Name and signature of Filer	Date Document Withdrawn	Name and Signature of Staff Member-in-charge
1.				
2.				

Please visit our website
ethics.healthresearch.ph