Philippine Health Research Ethics Board
Workbook on Standard Operating Procedures
"The SOP Workbook"

INTRODUCTION

Standard Operating Procedures (SOPs) are the step-by-step description of the different procedures done to accomplish the objectives of an activity. They guide Ethics Review Committees (ERCs) in ensuring consistency, transparency, and quality assurance in ethical review. They should be simple and easy to follow instructions. Operationally, the question is "How does the ERC do this particular activity efficiently?"

This Workbook is intended for ERCs who are planning to develop their SOPs. It was developed from the materials used by the Philippine Health Research Ethics Board (PHREB) in its conduct of SOP seminar-workshops.

The Workbook begins with an outline of the SOP manual. The different SOPs are presented in a template format which is suggested for easy reference. ***Italicized*** entries indicate examples illustrating the specific SOP section. These examples may not apply to all institutions and the ERC can customize these to its specific context.

THE SOP MANUAL

The SOP Manual should have an **OVERVIEW** that presents the environment where the ERC operates. Here, the rationale for establishing an ethics review committee should be well stated. This rationale should be related to the Vision-Mission of the Institution. An organizational chart that shows the governance structure of the institution should be included, showing the location of the ERC and how it relates with the other units. 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 ERC. The international and national ethics research guidelines and regulations that inform the review and decisions of the ERC should be cited.

SOPs may be organized into ten major activities. Some activities may have several related SOPs. This system of organizing SOPs need not be used by all ERCs. For example, in ERCs with limited activities, a straightforward listing of SOPs may suffice and be simpler to use.

SOP 1 – ERC Structure and Composition
1.1 Selection and Appointment of Members
1.2 Designation of Officers
1.3 Appointment of Independent Consultants

SOP 2 – Management of Initial Submissions and Resubmissions

SOP 3 – Management of Post Approval Submissions
3.1 Review of Progress, Final, and Early Termination Reports, and Protocol Amendments
3.2 Review of SAE and SUSAR Reports
3.3 Review of Protocol Deviations and Violations

SOP 4 –Review Procedures
4.1 Expedited Review
4.2 Full Review

SOP 5 – Meeting Procedures
5.1 Preparing for a Meeting
5.2 Preparing the Meeting Agenda
5.3 Conduct of Regular and Special Meetings

SOP 6 – Documentation of ERC Actions
6.1 Managing the Meeting Minutes
6.2 Communicating ERC Decisions

SOP 7 – Management and Archiving of Files
7.1 Managing ERC Incoming/Outgoing Communications
7.2 Managing Active Files (Administrative and Study Files)
7.3 Archiving of Terminated, Inactive, and Completed Files
7.4 Managing Access to Confidential Files

SOP 8 – Site Visits

SOP 9 – Management of Queries/Complaints

SOP 10 – Writing and Revising SOPs

THE PHREB SOP TEMPLATE

Each SOP is developed using a recommended template. The template consists of 10 sections with a header. Each section includes several questions which are meant to guide the ERC in crafting the content of the section. These questions refer to the what, why, where, who, and how of the activity being described. Some of these questions have sample answers. However, **the ERC should endeavour to answer these questions on their own in order to reflect the specific context and actual practice of the committee**.

The sections of each SOP are as follows:

> The Header consists of the name and logo of the Institution, 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 SOP number and version number. The version number and pertinent dates are changed whenever the SOP is revised. The suggested format is as follows:

<table>
<tr><td rowspan="4">Name and Logo of Institution</td><td>Name of the ERC</td><td>SOP No:</td><td>_____</td></tr>
<tr><td rowspan="3">SOP TITLE</td><td>Version No:</td><td>_____</td></tr>
<tr><td>Approval Date:</td><td>_____</td></tr>
<tr><td>Effective Date:</td><td>_____</td></tr>
</table>

Section 1. The **Policy Statement** section consists of statement/s 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** section is a statement that explains the purpose of the activity (e.g. for the SOP on Preparing for a Meeting, the objective may be stated as "The preparation for meetings aims to ensure that all meeting requirements are met such as logistics, documents, agenda").

Section 3. The **Scope** section identifies the limits of applicability of the SOP.

Section 4. The **Responsibilities** section identifies the person/s and/or office/s in charge of implementing the SOP and their corresponding roles and responsibilities. It is good to draft the workflow (see section 5) first before accomplishing this section in order to ensure that all the responsibilities are properly accounted for.

Section 5. The **Workflow** section is a diagram representing the different steps involved in the activity. It may also 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.

Section 6. The section on **Detailed Description of Procedures** describes the manner and timeline in each step. The person/s responsible and the forms to be used are also included. In filling out this section, it is important to be guided by the workflow. For example, if there are five steps in the workflow, then there should be five steps described in this section.

Section 7. The **Glossary** section includes terms that need to be defined, acronyms, and abbreviations that need to be explained. The list of terms in the different SOPs is not comprehensive, the ERC may need to expand this as neccessary. (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 8. The **Forms** section lists the specific forms used in the activity (e.g. application form, checklist, review guide, communication templates).

Section 9. The **History** section is a tabulation of the version dates and number, authors, and description of major changes that the SOP has undergone. For example, the versions of an SOP on Designation of Officers may be represented as follows:

Version No.	**Date**	**Authors**	**Main Change**
01	2010 July 15	ABC	
02	2013 May 01	DEF	Added functions of the member-secretary
03	2015 June 03	ABC DEF	Included a co-chair and corresponding responsibilities

Section 10. 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 ERC	SOP No:	1.1
	1.1 Selection and Appointment of Members	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What institutional policies would apply to the selection of committee members in general? Does the ERC need other policies or more specific policies? Which policy will be used by the committee or appointing authority? This should be well stated. How will the members be classified? Will there be regular and alternate members?

The provisions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines on the composition of independent ethics review committees need to be mentioned as being complied with.

Example: *The selection of ERC members shall ensure the representation of different disciplines (scientists and non-scientists), gender, and age. There shall be a non-affiliated member (i.e. a member who is not affiliated with the institution). Members shall be classified as regular or alternate members.*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the selection and appointment of ERC members? For example, *"This activity aims to ensure that the selection of members complies with the international and national guidelines and that appropriate expertise is taken into consideration."*

3. Scope

What are the limits of applicability of this SOP? Some institutions have different kinds of review committees, such as animal ethics committee, biosafety committee, and therefore it is important to clarify if the SOP is applicable only to the Institutional Research Ethics Review Committee.

For example: *This SOP shall apply specifically to the selection of members of the ERC.*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of selection and appointment of the ERC members? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

Name and Logo of Institution	Name of the ERC	SOP No:	1.1
	1.1 Selection and Appointment of Members	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

What are the different steps involved in the process of selection and appointment of the ERC members? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Call for nominations	*Head of Research Division of the Institution*
Step 2: Submission of nominations	*Heads of Institutional Units*
Step 3: Shortlisting of nominees	*Research Division of the Institution*
Step 4: Invitation to and confirmation of interest of the nominees	*Chair*
Step 5: Appointment of new members	*Head of Research Division of the Institution*
Step 6: Signing of conflict of interest disclosure and confidentiality agreement	*New ERC Members*
Step 7: Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files (SOP#__))	*ERC Staff*

6. Description of Procedures

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

Step 1 - Call for nominations: What qualifications should the nominees have? Who can nominate?

Step 2 - Submission of nominations: What documents are required to support the nomination?

Step 3 - Shortlisting of nominees: How will the nominees be shortlisted? Who will do this?

Step 4 - Invitation to and confirmation of interest of the nominees: Who will issue the invitation? What will be the content of the invitation letter? What information (e.g. duties and responsibilities of members, terms of office, etc.) should be included in the letter of invitation? How will the nominee confirm interest?

Step 5 - Appointment of new members: What are the steps involved in endorsing the final appointment of new members? What are the contents of the appointment document (e.g. terms of reference)? What is the difference between the terms of reference of regular members and alternate members?

Step 6 - Signing of conflict of interest disclosure and confidentiality agreement: The ERC members shall sign the forms on conflict of interest disclosure and confidentiality agreement.

Step 7 - Filing of appointment documents and CVs in the membership file: See SOP on Managing Active Files (SOP#__).

7. Glossary

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

Non-affiliated Member
Scientists
Non-Scientists
Regular Members
Alternate Members

8. Forms

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

Nomination Form
CV Template
Invitation Letter
Appointment Letter

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Changed the appointing authority*
03	*2015 June 03*	*ABC* *DEF*	*Added responsibilities of members in the terms of reference*

10. 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 2002

CIOMS International Ethical Guidelines for Epidemiological Studies 2009

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

National Ethical Guidelines for Health Research 2011

Name and Logo of Institution	Name of the ERC	SOP No:	1.2
	1.2 Designation of Officers	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

Who shall be the officers of the Ethics Review Committee? Chairperson? Vice-Chair? Member-Secretary? For example, *"The ethics review committee shall have a chair, vice-chair, and member-secretary who shall be selected among the members by the appointing authority."*

What institutional policies exist in connection with selection of committee officers, in general? Will these same policies apply to the selection of the officers of the ERC? If so, then state them here. If not, what policy needs to be applied here? It may be a requirement that committee officers must be full-time employees.

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

2. Objective of the Activity

What are the intended outcomes of the procedures involved in designation of ERC officers? For example, *"This activity aims to ensure that the designation of ERC officers conforms with institutional practice."*

3. Scope

To which specific committee does this SOP apply? Some institutions have different kinds of review committees, such as animal ethics committee, biosafety committee, and therefore it is important to clarify if the SOP is applicable only to the institutional Research Ethics Review Committee.

For example: *"This SOP for the selection of officers is specific for the ethics review committee of the institution."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of designation of ERC officers? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

Designation of ERC officers can be done either by direct appointment of the authorities or maybe elected through a special committee meeting. In the latter case, what shall be the different steps? For example, a committee meeting may be called by the current ERC Chair, where the members are expected to nominate and vote either by secret-balloting or viva-voce. This will be followed by an endorsement from the ERC Chair to the appointing authority to finalize the appointment. In this case, the workflow will be as follows:

ACTIVITY	***RESPONSIBILITY***
Step 1: Call for meeting (*SOP on Preparing for a Meeting (SOP #__))*	*Chair*
Step 2: Nominations	*ERC Members*
Step 3: Election	*ERC Members*
Step 4: Endorsement	*Chair*
Step 5: Appointment of new officers	*Head of Research Division of the Institution*
Step 6: Filing of appointment documents (SOP on Managing Active Files (SOP #__))	*ERC Staff*

6. Description of Procedures

Step 1 - Call for meeting: see SOP on Preparing for a Meeting (SOP #__)

Step 2 - Nominations: What qualifications are required of nominees? How many nominees per position?

Step 3 - Election: How will the election be conducted? Will it be by secret balloting or *viva voce*? Will there be room for declining? Will the ERC Chair vote?

Step 4 - Endorsement: What will be the contents of the endorsement letter? Is there an ERC form for endorsement?

Step 5 - Appointment of new officers: What are the contents of the appointment letter? When is the effective date of appointment? What are the terms of office?

Step 6 - Filing of appointment documents: see SOP for Managing Active Files (SOP #__)

7. Glossary

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

Tenure
Fixed Terms
Secret Ballot Voting
Viva Voce Voting

8. Forms

Does the ERC or institution have prescribed forms that are used in the designation of ERC officers? Sometimes – institutions require submission of CVs in a particular format, then – if this format is a "form" then it should be mentioned in this section. Examples:

Nomination Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Changed the election process*
03	*2015 June 03*	*ABC* *DEF*	*Added other officers*

10. 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:

Philippine Health Research Ethics Board Workbook on Standard Operating Procedures "The SOP Workbook"

Name and Logo of Institution	Name of the ERC	SOP No:	1.3
	1.3 Appointment of Independent Consultants	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What policy does the ERC have with regard to the selection and designation of independent consultants? Should they be affiliated or non-affiliated with the institution? Under what circumstances should the ERC invite an independent consultant? Will there be an established roster of consultants? How will it be ensured that they are "independent"? In many ERCs, the list of consultants is developed when the ERC is set up, and this list is expanded as the need arises. Others invite consultants on an *ad hoc* basis.

The ERC 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 ERC 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

What are 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 ERC."*

3. Scope

To which specific activity will this SOP apply? For example, this SOP will probably not apply to the invitation of resource persons during a training seminar or to consultants in a referral system. Therefore, "*This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the ERC."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of appointment of independent consultants? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

Name and Logo of Institution	Name of the ERC	SOP No:	1.3
	1.3 Appointment of Independent Consultants	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

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 of the independent consultant	*Chair*
Step 4: Acceptance of invitation	*Independent Consultant*
Step 5: Appointment of independent consultant	*Head of Research Division of the Institution*
Step 6: Signing of conflict of interest disclosure and confidentiality agreement	*Independent Consultant*
Step 7: Inclusion in the pool of independent consultants	*ERC Staff*
Step 8: Filing of appointment documents (see SOP Managing Active Files (SOP#__))	*ERC Staff*

6. 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: Is the expertise needed for the study present among the ERC members? The criteria to be used in justifying the need for independent consultants should be stated.

Step 2 - Identification of the independent consultant: How will the independent consultant be identified? Who can recommend the appropriate consultant? Who approves?

Step 3 - Invitation of the independent consultant: What will be the contents of the invitation letter? Who will be the signatories of the invitation letter?

Step 4 - Acceptance of invitation: How will the independent consultant accept? Is there a form attached to the letter?

Step 5 - Appointment of independent consultant: What are the contents of the appointment letter? When is the effective date of appointment? What are the terms of reference?

Step 6 - Signing of conflict of disclosure and confidentiality agreement: The Independent Consultant shall sign the forms on conflict of disclosure and confidentiality agreement.

Step 7 - Inclusion in the pool of independent consultants: Is there an existing pool of independent consultants? Is this in a form of a list or a database?

Step 8 - Filing of appointment documents: see SOP for Managing Active Files (SOP#__)

7. Glossary

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

Independent Consultant
Technical Review

8. Forms

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

Invitation Letter
Protocol Evaluation Guide
Confidentiality Agreement Form
Conflict of Interest Disclosure Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Added of criteria for selection of Independent Consultants*
03	*2015 June 03*	*ABC* *DEF*	*Changed terms of reference*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	2
	2 Management of Initial Submissions and Resubmissions	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement[1]

The ERC will usually receive various documents through different ways (e.g. hand-carried by the researcher, submission by messenger or by email). Will the ERC limit submissions to a particular way? What different documents are expected? How will these be recorded and identified?[2] How does the ERC process resubmissions (see Glossary)? What is the guideline of the ERC regarding resubmissions?
For example, the policy statement could be "*The ERC requires a set of documents listed in a checklist for initial submission and only complete submissions shall be accepted.*"

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the management of initial submissions and resubmissions? For example, *"This activity aims to ensure that study documents which are submitted by proponents for initial review are properly received, identified, and recorded."*

3. Scope

The scope of this SOP identifies the different submissions that the ERC accepts. Should the ERC review only those 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 your site? How about studies in other institutions that do not have their own ERCs? The scope of this SOP must be consistent with the mandate given to the ERC that is described in the Overview section.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of management of initial submissions and resubmissions? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

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[1] The ERC should be aware that some submissions may neither need an expedited nor a full review. This means that the submission does not fall within the mandate for review of the ERC. An obvious example would be researches that are limited to the use of laboratory animals. Other examples are evaluations of various educational strategies or health operational researches, particularly, if these studies are not primarily intended to generate new knowledge, and are very narrow in scope. Nevertheless, these submissions should be clearly evaluated before they are declared "exempted from review" and the proponent should be so informed. This decision will mean that the proponent will no longer be required to submit further reports or documents for review of the ERC.

5. 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 or resubmission	*ERC Staff*
Step 2: Coding	*ERC Staff*
Step 3: Entry into logbook/database	*ERC Staff*
Step 4: Determination of type of Review/ Action *a. Expedited Review (SOP on Expedited Review (SOP#__))* *b. Full Review (SOP on Full Review (SOP#__))* *c. Exemption from Review (SOP on Communicating ERC Decisions (SOP#__))*	*Chair*

6. 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 or resubmission: Where will these documents be received? Who receives documents? Will there be forms (checklists) to use in order to determine completeness of the package? What will be done if the package is incomplete?

Step 2 - Coding: How will study protocols be coded? The usual code includes information on the year of submission, serial number, surname of proponent, and study topic. For example, *if 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-DelaCruz-HIV.* Coding must take into consideration reporting and institutional databases.

Step 3 - Entry into logbook/database: The ERC may have a simple logbook or an electronic database. It is important that this logbook/database include information on (1) study code, (2) title of the study, (3) name of proponent, (4) date of submission and resubmission, (5) name of receiver. These items are initial entries. There will be a need for subsequent entries and these should be described in SOP on Managing Active Files (SOP#__)).

Step 4 - Determination of type of Review/Action: The ERC usually conducts expedited or full review. However, occasionally, there are requests for review that may not be within the

mandate of the ERC and in this case the decision will be "Exempted from Review". In your ERC, who determines the type of review? After the determination of the type of review, the ERC should follow the SOP of either Full or Expedited Review except for the submission that is "Exempted from Review." In the latter case, the appropriate communication to the researcher should be sent (SOP on Communicating ERC Decisions (SOP#__)).

7. Glossary

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

Initial Submissions
Resubmissions
Study Documents
Initial Review
Coding
Logbook
Database
Expedited Review
Full Review
Exempt from Review

8. Forms

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

Application Form
Submission Checklist
Acknowledgment Template

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Added requirements in the checklist*
03	*2015 June 03*	*ABC* *DEF*	*Added information in the coding system*

10. References

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

National Ethical Guidelines for Health Research 2011

Institutional Research Office Manual

SOP Training-Workshop Handout (date)

Name and Logo of Institution	Name of the ERC	SOP No:	3.1
	3.1 Review of Progress, Final, and Early Termination Reports and Protocol Amendments	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What is the policy of the ERC regarding submission of progress and final reports? For example, "*The ERC shall require the submission of progress reports at a frequency based on the level of risk of the study. Submission of a final report shall be within a month after completion of the research.*"

What is the policy of the ERC regarding early termination of the research? For example, *"Early termination of the research should ensure adequate protection and welfare of subjects that had been recruited."*

What is the policy of the ERC regarding submission of amendments to previously approved protocols? For example, "*The ERC shall require the submission of an application for an amendment to an approved protocol and/or other related documents (e.g. Informed Consent Form) prior to the implementation of these changes.*"

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the process of review of progress, final, and early termination reports and protocol amendments? 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 types of post-approval submissions that shall be reviewed by the ERC. For example, *"This SOP applies to the management and review of progress, final or early termination reports, and protocol amendments submitted by the proponent while the study is on-going or has ended."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of review of progress, final, and early termination reports and protocol amendments? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

Name and Logo of Institution	Name of the ERC	SOP No:	3.1
	3.1 Review of Progress, Final, and Early Termination Reports and Protocol Amendments	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

What are the different steps involved in the process of review of progress, final, and early termination reports and protocol amendments? Who will be responsible in each of these steps?

For example:

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and entry to logbook or database of the progress, final, or early termination reports, or amendment application for review (SOP on Management of Active Files (SOP#__))	*ERC Staff*
Step 2: Retrieval of pertinent protocol file	*ERC Staff*
Step 3: Notification of Chair and Primary Reviewer	*ERC 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 Reviewer*
Step 5: Communication of committee action (SOP on Communication ERC Decisions (SOP#__))	*ERC Chair*

6. Description of Procedures

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

Step 1 - Receipt and entry to logbook or database of the progress, final, or early termination reports, or amendment application for review: Does the ERC have specific forms for each type of post-approval submission? Was the form adequately accomplished? What kind of logging system is used by the ERC (e.g. Excel file, specific database software, or manual logbook)? Will there be a unique suffix appended to the original code in order to refer to this submission? For example, "A1" for the 1st amendment, "FR" for final report, "ET" for early termination, "PR1" for the 1st progress report.

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)?

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?

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 based on the SOP for either Expedited or Full Review.

Step 5 - Communication of committee action: It is suggested that the ERC consider the following decisions: For review of progress reports, the committee action may be 'approved' or to require additional information or specific action/s from the proponent. For final report, the decision of the committee will be to accept or to require resubmission with corrections. For amendments, the decision of the committee will be approval and/or revision of protocol or protocol related documents. For early termination, the committee will accept or request for additional information or action.

7. Glossary

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

Post-approval Submission
Progress Report
Final Report
Early Termination
Protocol Amendment
Primary Reviewer
Expedited Review
Full Review
Informed Consent Form
Logbook
Database
Specific Database Software

8. Forms

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

Progress Report Form
Final Report Form
Amendment Form
Early Termination Report Form

9. 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***
01	*2010 July 15*	*ABC*	
02	*2013 May 01*	*DEF*	*Change of timeline for submission of final reports*
03	*2015 June 03*	*ABC* *DEF*	*Change of entries in the progress report form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	3.2
	3.2 Review of SAE and SUSAR Reports	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement[1]

Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) are important issues in sponsored clinical trials. 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[2] that the Philippine FDA has adopted.

What is the policy of the ERC regarding the submission of reports of SAEs and SUSARs? For example, "*The ERC shall require the submission of reports of SAEs and SUSARs within ___ (indicate period of time that the ERC will be able to reasonably deliberate on the matter) after the event has come to the attention of the researcher."* Does the ERC 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 ERC for final action"*

[1] Severe Adverse Events (SAEs) and Suspected, Unexpected Serious Adverse Reactions (SUSARs) need to be defined and differentiated by the ERC especially as they relate to clinical and non-clinical studies that are under review. SAEs are events that may occur in both clinical and non-clinical studies while SUSARs are incidental to the use of drugs.
In particular, in sponsored clinical trials, the SAEs and SUSARs are collected by the Sponsor and reports are provided to the Principal Investigator, who in turn is required to submit the same to the institutional ERC in compliance with GCP standards. Thus, in sponsored clinical trials the ERC is able to obtain comprehensive information on SAEs and SUSARs in all the sites and will focus on reports from its local site/s. In researcher initiated clinical trials, the above reporting mechanism is not a practice and it is up to the ERC to set up such a mechanism.

[2] **(1)** Fatal or Life-Threatening Unexpected Adverse Drug Reactions (ADRs) Certain ADRs may be sufficiently alarming so as to require very rapid notification to regulators in countries where the medicinal product or indication, formulation, or population for the medicinal product are still not approved for marketing, because such reports may lead to consideration of suspension of, or other limitations to, a clinical investigations program. Fatal or life-threatening, unexpected ADRs occurring in clinical investigations qualify for very rapid reporting. Regulatory agencies should be notified (e.g. by telephone, facsimile transmission, or in writing) as soon as possible but no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar medicinal products. **(2)** All Other Serious, Unexpected ADRs Serious, unexpected reactions (ADRs) that are not fatal or life-threatening must be filed as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the process of review of SAEs and SUSARs Reports? For example, *"This activity of reviewing aims to ensure that the safety and welfare of human participants in the study are safeguarded and that information on SAEs and SUSARs are properly documented."*

3. Scope

The scope of the SOP should define the submission to which the SOP applies. For example, *"This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process review of SAE and SUSAR reports? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For example, *"The ERC staff receives and documents the SAE and SUSAR reports, retrieves the pertinent protocol file, notifies the Chair, and forwards the report to the SAE Subcommittee. The Chair notes the submission and ensures that the report of the SAE Subcommittee is included in the agenda of the next ERC meeting."*

5. 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/database	*ERC Staff*
Step 2: Retrieval of pertinent protocol file	*ERC Staff*
Step 3: Notification of Chair	*ERC Staff*
Step 4: Submission of report to the SAE Subcommittee/Point Person	*ERC Staff*
Step 5: Inclusion of report of Subcommittee in the agenda of the next regular ERC meeting	*ERC Staff and Chair*
Step 6: Communication of ERC recommendation to the Principal Investigator/researcher (SOP on Communication of	*ERC Staff and Chair*

ERC Decisions (SOP#__))	
Step 7: Filing of all related documents (SOP on Management of Active Files (SOP#__))	*ERC Staff*

6. Description of Procedures

Step 1 - Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database: Does ERC require a specific SAEs and SUSARs report form? Was the form properly accomplished? Was the date of submission within the required timeline? Is this submission recorded in an Excel file, database, or manual logbook? What information about the submission will be entered in the log? Will there be a unique suffix appended to the original code in order to refer to this submission on SAEs and SUSARs?

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)?

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?

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 ERC form?

Step 5 - Inclusion of report of SAE Subcommittee or point person in ERC meeting agenda: What are the possible actions of ERC on SAE and SUSAR report? Suggested possible actions include: "accepted with no further action" or "requires further information or action". See SOP on Preparing the Meeting Agenda.

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

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

7. Glossary

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

SAE
SUSAR
SAE Subcommittee
Point Person

Principal Investigator
Sponsor
Researcher
Researcher Initiated Clinical Trials
Sponsored Clinical Trials

8. Forms

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

SAE Report Form
SUSAR Report Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Assignment of a point person*
03	*2015 June 03*	*ABC* *DEF*	*Changed SAE Report Form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	3.3
	3.3 Review of Protocol Deviations and Violations	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement[1]

Protocol deviations and violations have implications on the safety and welfare of the research participants and on the integrity of data. What is the policy of the ERC in reporting protocol deviations or violations? For example, *"Researchers shall report protocol deviations and violations in the conduct of approved researches within a week of the event. Major protocol deviations and violations shall undergo a full review."*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the process of review of protocol deviations and violations? For example, *"This activity of reviewing protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility of data is maintained."*

3. Scope

This section on scope defines the submissions that need to be reviewed by the ERC after approval. For example, *"This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of review of protocol deviations and violations? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For example, *"The Principal Investigator/researcher reports major protocol violations and deviations at the time specified in approval letter. The ERC Staff receives and documents the report, retrieves the pertinent protocol file and notifies the Chair. The Chair determines the type of review and ensures inclusion of the report in the agenda of the next ERC meeting. The concerned reviewers evaluate the report of protocol violations/deviations. The members of ERC finalize the decision regarding the report."*

[1] In sponsored clinical trials, protocol deviations and violations are documented by clinical auditors and monitors in a particular site. The principal investigator is required to submit a copy of the report to ERC. Thus the ERC receives such reports periodically and recommends appropriate action. In researcher initiated clinical studies, reporting of protocol deviations and violations must be established as a matter of policy.

5. 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/database	*ERC Staff*
Step 2: Retrieval of pertinent protocol file	*ERC Staff*
Step 3: Notification of Chair	*ERC Staff*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP#__)), full review (SOP on Full Review (SOP#__))	*ERC Chair*
Step 5: Inclusion of report in the agenda of the next ERC regular meeting (SOP on Preparing the Meeting Agenda (SOP#__); SOP on Conduct of Meeting (SOP#__))	*ERC Staff and Chair*
Step 6: Communication of decision to the Principal Investigator/researcher (SOP on Communicating ERC Decisions (SOP#__))	*ERC Staff and Chair*
Step 7: Filing of all related documents (SOP on Managing Active Files (SOP#__))	*ERC Staff*

6. 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 ERC require a specific report form? Was the form properly accomplished? Is this submission recorded in an Excel file, database or manual logbook? What information about the submission will be entered in the log? Will there be a unique suffix appended to the original code in order to refer to this submission on protocol violations and deviations?

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.

Step 3 - Notification of Chair. How (by SMS, email, memo, etc.) and when will the Chair or designated officer be notified about the submission?

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?

Step 5 - Inclusion of report in the agenda of the next ERC regular meeting. See SOP on Preparing the Meeting Agenda and SOP on Conduct of Meetings.

Step 6 - Communication of Decision to the Principal Investigator/researcher: See SOP on Communicating ERC Decisions. What are the possible actions of ERC on reports of protocol violations and deviations? Suggested possible decisions include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) clarificatory interview with Principal Investigator/researcher, (4) site visit, (5) suspension of recruitment, and (6) suspension of the study.

Step 7 - Filing of all related documents. See SOP on Managing Active Files (SOP#__).

7. Glossary

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

Minor Protocol Deviation
Major Protocol Deviation
Minor Protocol Violations
Major Protocol Violations
Principal Investigator
Researcher
Regular Meeting
Protocol File
Full Review
Expedited Review
Site Visit
Clarificatory Interview

8. Forms

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

Protocol Deviation Report Form
Protocol Violation Report Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Change in the definition of major protocol deviation*
03	*2015 June 03*	*ABC* *DEF*	*Change in the definition of minor protocol violation*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	4.1
	4.1 Expedited Review	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

When is expedited review conducted? What is the expected duration of an expedited review? For example, *"An expedited review shall be conducted for study protocols that do not entail more than minimal risk to the study participants and when the study participants do not belong to a vulnerable group. The results of the initial review shall be released to principal investigator within four weeks after the submission of all the required documents."* The titles and proponents of protocols that have been reviewed through the expedited process are included in the agenda, but not deliberated upon, at the next regular board meeting.

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the process of expedited review? For example, *"Review of studies that do not entail more than minimal risk to study participants and those involving participants not belonging to a vulnerable group aims to demonstrate due diligence and high standards in the system of protection of human participants."*

3. Scope

What are the limits of applicability of this SOP? For example, *"This SOP applies to initial and post-approval submissions on protocols which have been classified as not involving more than minimal risk to study participants and whose participants do not belong to vulnerable groups."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the conduct of expedited review? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

What are the different steps involved in the conduct of an expedited review? Who are responsible in each of these steps? Note that this SOP follows the SOPs on either Management of Initial Submissions or Management of Post-Approval Submissions.

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Assignment of Reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#__))	*Chair*
Step 2: Notification of Reviewers or Independent Consultant/s	*ERC Staff*
Step 3: Provision of study documents and evaluation form (Form ___) to reviewers	*ERC Staff*
Step 4: Accomplishment and submission of evaluation forms	*Reviewers*
Step 5: Finalization of review results	*ERC Chair*
Step 6: Communication of review results to the researcher (SOP on Communicating ERC Decisions (SOP#__))	*ERC Staff and Chair*
Step 7: Filing of documents in the protocol file (SOP on Management of Active Files (SOP#__))	*ERC Members and Chair*
Step 8: Inclusion of the Review in the Agenda of the next meeting (SOP on Preparing the Meeting Agenda (SOP#__))	*ERC Staff and Chair*

6. 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 in the ERC membership? 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? Notifying the reviewers as a step gives the reviewers the opportunity to assess conflict of interest, availability, and suitability. 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: Usually, the ERC 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? What procedures will be used in order to harmonize differing opinions?

Step 6 - Communication of review results to the researcher: See SOP on Communicating ERC 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 ERC regular meeting: See SOP on Preparing the Meeting Agenda (SOP#__)

7. Glossary

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

Expedited Review
Vulnerable Group
Minimal Risk
More than Minimal Risk
Reviewer
Independent Consultant

8. Forms

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

Evaluation Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Included list of types of studies that may fall under expedited review*

03	*2015 June 03*	*ABC* *DEF*	*Revised the evaluation form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	4.2
	4.2 Full Review	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What criteria should be used in deciding whether a research protocol should undergo a full review? Does the committee use the primary reviewer system? What is the maximum period for a full review to be accomplished after submission of a complete set of documents? 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. Such a protocol shall be deliberated and decided upon during a regular meeting, preferably within six weeks after submission of required documents. Full review shall be conducted through a primary reviewer system."*

A primary reviewer is an expert on the subject of the protocol. His main responsibility is to review the protocol thoroughly, present a summary of the protocol as well as educate the board on its technical aspects before a deliberation and decision by the board are made.

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the conduct of full? 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

What are the limits of applicability of this SOP? For example, *"This SOP applies to initial, revisions. and post-approval submissions on protocols which have been classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the conduct of full review? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

What are the different steps involved in the conduct of a full review? Who are responsible in each of these steps? Note that this SOP follows the SOPs on either Management of Initial Submissions or Management of Post-Approval Submissions.

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	*ERC Staff*
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	*ERC Staff*
Step 4: Provision of protocol and protocol-related documents to the rest of the committee members	*ERC Staff*
Step 5: Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP#__))	*ERC Chair*
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#__))	*ERC Staff*
Step 10: Communication of Committee Action to the researcher (SOP Communicating ERC Decisions (SOP#__))	*Chair and ERC Staff*
Step 11: Filing of protocol-related documents	*ERC Staff*

6. 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 ERC membership? Is it necessary to designate an independent consultant (see SOP on Appointment of Independent Consultants (SOP#__)?

Step 2 - Notification of primary reviewers or Independent Consultants: Which documents will be provided to the primary reviewers? How?

Step 3 - Provision of protocol and protocol -related documents and assessment forms to reviewers: Will all the committee members be provided with the full protocol and the assessment forms? Will the researcher/proponent be invited to the meeting? Will there be provisions for the presence of resource persons?

Step 4 - Provision of protocol and protocol-related documents to the rest of the committee members: Will the review be conducted if the primary reviewers cannot make it to the meeting?

Step 5 - Presentation of review findings and recommendations during a committee meeting: Do the primary reviewers need to be present during the meeting? Will both reviewers present? Will the presentations be guided by the assessment form? Are the recommendations comprehensive and organized for better appreciation of the members?

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?

Step 7 - Summary of issues and resolutions: How are issues summarized in order to guide the decision making process?

Step 8 - Committee action: What are the possible actions for a specific submission (e.g. approval, minor modifications, major modifications, disapproval)?

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 ERC Decisions (SOP#__)

Step 11 - Filing of protocol-related documents: See SOP on Managing Active Files (SOP#__)

7. Glossary

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

Full Review
Vulnerability
Minimal Risk
More than Minimal Risk
Independent Consultant
Primary Reviewers
Major Modification
Minor Modification
Protocol-related Documents

8. Forms

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

Assessment Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Revised assessment form*
03	*2015 June 03*	*ABC* *DEF*	*Changed timeline for full review*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	5.1
	5.1 Preparing for a Meeting	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

Does the ERC conduct both special and regular meetings? For what reasons? For example, *"The ERC shall conduct regular meetings once a month on the 2nd Friday of each month. All meetings shall be held within the premises of the institution and shall be coordinated with physical plan division. Special meetings shall be held to resolve issues that require immediate attention."*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in the preparation of meetings? For example, *"The preparation 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 ERC meeting."* Most ERCs typically use one set of procedures for regular and special ERC meetings, but the ERC can decide to have separate procedures for special meetings.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of preparing for a meeting? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. 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 on Preparing the Meeting Agenda (SOP#__))	*ERC Staff and Member Secretary*
Step 2: Coordination with the physical plant division	*ERC Staff*
Step 3: Assembly of materials and documents needed for the meeting	*ERC Staff*
Step 4: Preparation of logistics for the meeting	*ERC Staff*
Step 5: Notification of ERC Members and confirmation of attendance	*ERC Staff*

6. Description of Procedures

Name and Logo of Institution	Name of the ERC	SOP No:	5.1
	5.1 Preparing for a Meeting	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

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 on Preparing the Meeting Agenda (SOP#__))

Step 2 - Coordination with the physical plant division: How does the ERC ensure that the venue for the meeting will be available on the scheduled date? Does the ERC have a conference room of its own?

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 can include meeting agenda, minutes of the previous meeting[1], protocol folders, memorandums, administrative documents, etc. How many copies should be provided? Who is responsible for these?

Step 4 - Preparation of logistics 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? Who and how many? If the members receive honorarium for meetings, how will payments be ensured?

Step 5 - Notification of ERC Members and confirmation of attendance: When and how will the ERC 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?

[1] In some ERCs, the inclusion of the minutes of the previous meeting in the assembly of documents for distribution is really necessary because of the length of the minutes for deliberation.

7. Glossary

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

Quorum
Support Staff
Logistics
Special Meeting
Regular Meeting
Administrative Documents
Honorarium
Physical Plan Division
Meeting Agenda
Alternate Members

8. Forms

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

Notice of Meeting
Attendance Confirmation Form
Agenda Template

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Revised notice of meeting form*
03	*2015 June 03*	*ABC* *DEF*	*Identified new venue for meetings*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	5.2
	5.2 Preparing the Meeting Agenda	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

The meeting agenda is an important guide in the conduct of meeting. It ensures order and completeness of 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. An example of a policy statement would be, *"The meeting agenda shall be based on the submissions received within ___ (specified cut-off time) of the scheduled regular meeting. It shall follow the established template for meeting agenda."*

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

What is covered by this SOP? For example, *"This SOP describes how the ERC determines what items are included in the agenda of the regular and special meetings."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of preparing the meeting agenda? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. 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	*ERC Staff and Member Secretary*
Step 2: Preparation of the provisional meeting agenda	*Chair*
Step 3: Distribution of the provisional meeting agenda (SOP on Preparing for a Meeting (SOP#__))	*ERC Staff*
Step 4: Approval of the provisional meeting agenda	*ERC Members*
Step 5: Filing of the final meeting agenda (SOP on	*ERC Staff*

Management of Active Files (SOP#__))	

6. 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 ERC use a specific meeting agenda template or form? How and when is the template completed? What information should the ERC 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 ERC Staff to complete this task?

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 ERC staff.

Step 3 - Distribution of the provisional meeting agenda: What is the method of distribution of the provisional meeting agenda to members? How long is this process and how is it initiated and concluded? It is important to cite specific timelines to properly guide ERC Staff. Note that this step is related to the SOP on Preparing for a Meeting.

Step 4 - Approval of the provisional meeting agenda: When is the provisional meeting agenda approved and finalized? Note that this approval usually takes place during the meeting. See SOP on Conduct of Meeting (SOP#__).

Step 5 - Filing of the final meeting agenda: What type of storage system does the ERC have for the approved agenda after it has been distributed? Is there a specific file for meeting agenda? How is this organized? It is recommended that the ERC maintain a central file of all final meeting agenda by year to facilitate retrieval. What kind of documentation is necessary to complete this task? See SOP on Managing Active Files (SOP#__).

7. Glossary

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

Draft Meeting Agenda
Provisional Meeting Agenda
Final Meeting Agenda
New Protocols for Full Review

Expedited Review Reports
Post-approval Reports
Administrative Issuances

8. Forms

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

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Included the Invocation in the Meeting Agenda Template*
03	*2015 June 03*	*ABC* *DEF*	*Removed the Invocation in the Meeting Agenda Template*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	5.3
	5.3 Conduct of Meetings	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

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

What are the intended outcomes of the procedures involved in the conduct of meetings? For example, *"Meetings are conducted to provide an opportunity for the ERC to arrive at collegial decisions regarding study protocols and ERC operations."*

3. Scope

What is covered by this SOP? For example, *"This SOP describes the manner by which the ERC conducts all its meetings. It covers ERC actions and activities from the time quorum is confirmed to the time the meeting is adjourned."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the conduct of the meetings? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. 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	*ERC Staff*
Step 2: Determination of quorum (formal start)	*Member Secretary or Chair*
Step 3: Approval of the provisional agenda	*ERC Members*
Step 4: Declaration of conflict of interest (COI)	*ERC Members (who have COI)*
Step 5: Approval of minutes of the previous meeting	*ERC Members*
Step 6: Discussion of "business arising from the minutes"	*ERC Members*
Step 7: Review of protocols and protocol-related submissions	*ERC Chair and Members*

(SOP on Full Review (SOP#__))	
Step 8: Report of results of expedited review (SOP on Expedited Review (SOP#__))	*Designated Reviewers*
Step 9: Discussion of operations-related matters	*ERC Chair and Members*
Step 10: Adjournment	*Chair*
Step 11: Collection, storage, and disposal of meeting materials	*ERC Staff*

6. 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 - Determination 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 ERC define conflict of interest in a meeting? How does the committee manage a disclosure of conflict of interest? For example, some ethics committees 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[1]: Does the ERC 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 as follows: 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 on Full Review.

How does the ERC arrive at a decision (e.g. voting, consensus)? For ERC's that require voting, how is the voting done (e.g. balloting 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 ERC 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 ERC 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 ERC staff keep track of meeting documents? See SOPs on Managing Active Files (SOP#__)

7. Glossary

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

[1] This step is related with the process of Full Review of initial protocol submissions and after-approval submissions. Thus, the ERC should refer to the SOP on Full Review.

Quorum
Conflict of Interest
Adjournment
Voting
Balloting
Consensus
Collegial Decisions
ERC Operations
Study Protocols
Business Arising from the Minutes
Operations-related Matters
Clarificatory Interview

8. Forms

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

Attendance Sheet
Secret Ballot Form
ERC Decision Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Included the independent consultant in the meeting attendance*
03	*2015 June 03*	*ABC* *DEF*	*Included an adjournment policy*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	6.1
	6.1 Preparing the Meeting Minutes	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

The minutes are an important documentation of the proceedings of an ERC meeting. They provide evidence of 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

What are 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 ERC meeting."*

3. Scope

What is covered by this SOP? For example, *"This SOP covers ERC actions related to the documentation of a full board meeting, the final output of which is the minutes of the meeting."* Does the ERC have special requirements for this type of document? Most ERCs typically use template for meeting minutes one set of procedures for regular and special ERC meetings, but the ERC can decide to have separate procedures for special meetings.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in preparing meeting minutes? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. 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	*ERC Staff*
Step 2: Preparation of the draft minutes	*ERC Staff and Member Secretary*
Step 3: Notation of the draft minutes	*Chair*
Step 4: Approval of the minutes in the next ERC meeting	*Chair and Members*

Step 5: Storage of the approved minutes (SOP on Managing Active Files (SOP#__))	*ERC Staff*

6. 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 minutes template: Does the ERC use a minutes template? Does the ERC 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 ERC Staff in fulfilling this task?

Step 2 - Preparation of the draft minutes: How does the ERC prepare the draft minutes?[1] During the meeting, the ERC Staff is tasked with documentation of proceedings in accordance with the agenda. How does the ERC 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 ERC ensure that the ERC 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 need for this task? Who has oversight on the fulfilment of this task by the ERC 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 ERC Staff do after completing the draft of the minutes? To whom does the ERC Staff submit the draft (e.g. Member Secretary or Chair)? In how many days after the meeting should the ERC 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)
- Independent consultants, primary investigators, guests, and observers attendance (if any)

[1] ERCs have different ways of preparing the draft minutes. Many ERCs tape the proceedings and use it as reference in preparing the draft minutes. Others record the proceedings on real-time by projecting the template and entering the elements of the discussion as the meeting progresses.

- Time when the meeting was called to order
- Presiding officer
- Conflict of Interest (COI) declaration
- Items discussed, issues raised, and resolutions
- ERC 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 ERC meeting: How is the approval of the 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 ERC have for the approved minutes? What kind of documentation is necessary to complete this task? It is recommended that the ERC maintain a central file of all meeting minutes by year to facilitate retrieval. See SOP on Managing Active Files (SOP#__).

7. Glossary

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

Meeting Agenda
Meeting Minutes
Draft Minutes
Approved Minutes
Real-time Recording
Conflict of Interest

8. Forms

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

Minutes Template

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Revised the procedure in preparing the draft minutes from audio recording to real-time note taking*
03	*2015 June 03*	*ABC* *DEF*	*Revised the timeline in approving meeting minutes*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	6.2
	6.2 Communicating ERC Decisions	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

The ERC must be prompt, clear, and informative in communicating its decisions. An example of a policy, in this regard, may be as follows, *"The ERC 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 ERC and signed by the chair."*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in preparing the meeting minutes? For example, "*The management of communicating ERC decisions ensures that all stakeholders are appropriately informed of the results of deliberations of the ERC."*

3. Scope

What is covered by this SOP? Does the ERC have special requirements for this type of document? For example, *"This SOP covers ERC actions related to the communicating ERC decisions (e.g. actions to applications submitted to the ERC)."* Most ERCs typically use a form for various ERC actions.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the communicating ERC decisions? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC Members, who collectively decide about committee actions during meetings, the ERC Staff, which handles all administrative processes, and the Chair, who usually approves and signs documents.

5. Workflow

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

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Approval of the minutes of the meeting (in case of full review) (SOP on Preparing the Meeting Minutes (SOP#__)) or Finalization of recommendations of reviewers (in case of expedited review) (SOP on Expedited Review (SOP#__))	*Chair*
Step 2: Transfer of information from minutes or reports to ERC decision forms or templates	*ERC Staff, Member Secretary*
Step 3: Approval of the ERC decision document	*Chair*
Step 4: Dispatch of ERC decision document to researcher	*ERC Staff*
Step 5: Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP#__))	*ERC Staff*

6. 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 - Approval of the minutes of the meeting (in case of full review) or finalization of recommendations of reviewers (in case of expedited review): See SOP on Preparing the Meeting Minutes (SOP#__) or for Finalization of Reviewers' Recommendations, see SOP on Expedited Review (SOP#__).

Step 2 - Transfer of information from minutes to ERC decision forms or templates: Upon approval of the minutes, or finalization of the reviewers' recommendations, how does the ERC relay the information to the researchers? Does the ERC 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 ERC decision document: Who reviews and approves the decision documents? How is this approval signified? How long does this process take?

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

Step 5 - Storage of the decision document in the protocol file: It is recommended that the ERC maintains all protocol related decisions or actions in the protocol folder to facilitate retrieval. What type of storage system does the ERC have for protocols? What kind of

documentation is necessary to complete this task (e.g. physical indexing, database)? See SOP on Managing Active Files (SOP#__).

7. Glossary

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

Expedited Review
Full Review
Physical Indexing
Database
Active Files

8. Forms

What forms/templates/tools are used in the implementation of this SOP? Examples: *Approval Form/Letter* or *Decision Form/Letter*

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Revised template of notification*
03	*2015 June 03*	*ABC* *DEF*	*Changed from physical indexing to database*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	7.1
	7.1 Managing ERC Incoming and Outgoing Communications	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

Incoming and outgoing communications need to be recorded for monitoring and tracking purposes as evidence of the quality services and efficient operations of the ERC. The policy may be stated as, *"Incoming and outgoing communications shall be recorded promptly and accurately in an electronic logbook or database."*

2. Objective/s of the Activity

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

3. Scope

What is covered by this SOP? For example, *"This SOP covers ERC actions related to organizing incoming and outgoing documents and ensuring an appropriate ERC response."* Does the ERC have special requirements for this type of document? Most ERCs use a scheme to systematically sort and store documents.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in managing ERC incoming and outgoing communications? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC Staff, which handles all administrative processing, the Member Secretary who supervises the ERC Staff, and the Chair, who usually approves the outgoing documents.

5. Workflow

What are the different steps involved in managing ERC 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	*ERC Staff*
Step 2: Recording of incoming/outgoing communications	*ERC Staff*
Step 3: Acting on communications	*Chair or Member Secretary*
Step 4: Storing or filing of incoming/outgoing communications	*ERC Staff*

6. 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 ERC (e.g. letters, official memoranda, or emails)? Does the ERC 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 ERC record the incoming/outgoing communications? Does the ERC 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 ERC), 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 ERC have for incoming/outgoing communications? What is the practice of the ERC related to filing of communications (e.g. if protocol-related, it is filed in the study protocol file and if not protocol-related, it is filed in an administrative file)? Does the ERC 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?

7. Glossary

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

Incoming Communications
Outgoing Communications
Administrative File
Protocol-related File
Indexing System

8. Forms

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

Logbook for Incoming Communications
Logbook for Outgoing Communications

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Included "Topic" as entry on Logbook for Outgoing Communications*
03	*2015 June 03*	*ABC* *DEF*	*Included Member Secretary as alternate signatory for outgoing communications*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	7.2
	7.2 Managing Active Files	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

The ERC needs to classify its protocol files into active or inactive. Considerations may include 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

What are the intended outcomes of the procedures involved in managing active files? For example, *"The management of active files ensures accessibility, easy retrieval of current files, and protection of their confidentiality."*

3. Scope

What is covered by this SOP? Does the ERC have special requirements for this type of file? For example, "*This SOP covers ERC actions related to protocols accepted for review, undergoing review, or has been approved by the ERC."* Most ERCs limit access to these files which are treated separately from study files that are considered inactive.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in managing active files? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC members, who collectively decide on procedures, the ERC Staff, which handles all administrative processes, the Member Secretary who oversees the management of files, and the Chair, who usually approves document movements.

5. Workflow

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

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Classification and coding of active files	*Member Secretary and ERC Staff*
Step 2: Entry in the active file logbook/database	*ERC Staff*
Step 3: Organization of the physical folder	*ERC Staff*
Step 4: Maintenance of file	*ERC Staff*

6. 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 - Classification and coding of active files: How does the ERC label the protocols it reviews sequentially (e.g. alphanumeric, numeric)? Who is responsible for this task? Who oversees its implementation?

Step 2 - Entry in the active file logbook/database: What kinds of logbook/database does the ERC have? For examples, logbooks/databases for study submissions, ERC membership, independent consultants, researchers/Principal Investigators, protocols under review. What fields of information captured in the logbook/database (e.g. Protocol code, Protocol title, PI and details, Submission date, Type of Review, Review date, reviewers, review decision, ERC meeting date, approval date, timeline for progress reports)? What type of database is being used (e.g. MS Excel, MS Access)? Who manages the logbook/database?

Step 3 - Organization of the physical folder: How is the file organized? What kind of folder is used? How does the ERC label the folder (e.g. sticker label)? Is there an index or table of contents? What are the contents (e.g. all version of protocol, all ERC decisions, CVs of study team, all post approval submissions and respective decisions)? Who is responsible for this task? Who oversees the accuracy of this procedure?

Step 4 – Maintenance of file: Where are the protocol files kept? Is the storage facility properly labelled as well with respective contents? What is the frequency of updating the contents of file (e.g. once a week)? Who can retrieve protocol files?

7. Glossary

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

Active Study Files

Inactive Study Files
Database
Index of File Contents
Physical Folder

8. Forms

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

Index of File Contents
Protocol Access Form
Logbooks/Databases for Study Submissions
Logbooks/Databases for ERC Membership
Logbooks/Databases for Independent Consultants
Logbooks/Databases for Researchers/Principal Investigators
Logbooks/Databases for Protocols under Review

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Added new policy on access of active files*
03	*2015 June 03*	*ABC* *DEF*	*Revised duration of keeping active files*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	7.3
	7.3 Archiving of Terminated, Inactive, and Completed Files	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What institutional policies or standards exist which are relevant to management of inactive research files (e.g. ISO coding system, database management)? Will these apply to ERC documents? How? 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. What is the policy on retrieval of archived files? How long are inactive files maintained?

2. Objective of the Activity

What are the intended outcomes of the procedures involved in archiving of terminated, inactive, and completed files? For example, *"Archiving terminated, inactive, and completed files ensures efficient and effective retrieval of information for reference and compliance with national and international guidelines."*

3. Scope

What is covered by this SOP? For example, *"This SOP includes ERC actions related to storage and retrieval of protocols that are classified as inactive either by termination or completion."* Does the ERC have special requirements for these types of files? Most ERCs limit access to these files which are treated separately from study files that are considered active.

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in archiving of terminated, inactive, and completed files? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC Members, who collectively decide on procedures, the ERC Staff, which handles all administrative processing, the Member Secretary who oversees the management of files, and the Chair, who usually approves document movements.

5. 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 Progress, Final, and Early Termination Reports, Protocol Amendments (SOP#__))	*ERC Members, Chair, Member Secretary*
Step 2: Retrieval and updating of corresponding active file	*ERC Staff*
Step 3: Reclassification of the file as inactive file	*ERC Staff*

6. 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: How is the approval or acceptance of the final or early termination report documented? See SOP on Review of Progress, Final, and Early Termination Reports, Protocol Amendments (SOP#__).

Step 2 - Retrieval and updating of corresponding active file: How will the documents on the completion and early termination of studies be incorporated in the corresponding active file?

Step 3 - Reclassification of the file as inactive file: What is the procedure for archiving? How does the ERC account for the contents of entire file? Is a verification process required? Are the inactive study files removed from the active section of the filing cabinet and transferred to area designated as inactive? Or are the files marked instead of removed? What does the ERC do with unnecessary copies? How are they disposed of?

7. Glossary

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

Inactive Study File
Active Study File
Archiving

8. Forms

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

Borrower's Log

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Changed timeline for keeping inactive files*
03	*2015 June 03*	*ABC* *DEF*	*Added policy on access to inactive files*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	7.4
	7.4 Managing Access to Confidential Files	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

What institutional policies or standards exist that are relevant to document control (e.g. ISO, approval, archiving, reproductions) in order to promote confidentiality of institutional files? Will these apply to ERC documents? How? Which ERC documents are classified as confidential? Examples are Study protocols, Study protocol-related documents (e.g. case report forms, informed consent documents, scientific documents, expert opinions or reviews), meeting minutes, decisions, action letters/notification of committee decision, approval letters, study protocol-related communications. Does this include correspondences with experts, auditors, and other pertinent individuals and offices? Who determines confidentiality of documents? Is access restricted to members? Or is access extended to persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors)? When do you photocopy documents? Does the ERC 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.

2. Objective of the Activity

What are the intended outcomes of the procedures involved in managing requests for access to confidential files? For example, *"Management of requests for access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the ERC."*

3. Scope

What is covered by this SOP? For example, *"This SOP comprises ERC actions on requests for access to confidential files including document handling and distribution."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in managing requests for access to confidential files? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC members, who collectively decide on procedures, the ERC Staff, which handles all administrative processing, the Member

Secretary who oversees the management of files, and the Chair, who usually approves document movements.

5. 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	*ERC Members, Chair, Member Secretary*
Step 2: Approval of requests for access and retrieval of documents	*ERC Staff and Member Secretary*
Step 3: Supervision of use of retrieved document	*ERC Staff*
Step 4: Return of document to the files	*ERC Staff*
Step 5: Logging of access	*ERC Staff*

6. 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: Who can request for access to confidential files? Usually, the ERC Members and Staff are the only authorized persons who can access confidential files. However, occasionally, regulatory and accrediting authorities (e.g. FDA, PHREB, FERCAP) and researchers/principal investigators may request access to confidential files.

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)? When can files be accessed (e.g. upon request)? Are non-members allowed access to specific documents? How is access facilitated? An example is through a formal request and completion/signing of confidentiality agreement for non-members signed by the chair. How does the ERC make files available for regulatory authorities (e.g. FDA, PHREB, FERCAP)? How does the ERC document the requests to access, especially if there is also a request to reproduce the file? Who approves the requests?

Step 3 - Supervision of use of retrieved document: How will the ERC supervise the use of the retrieved documents? Signing of confidentiality agreements, anonymization of documents, and restriction to room-use of documents are examples of supervisory mechanisms. Photocopying may be limited 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?

Step 5 - Logging of access: What information is recorded by the ERC when confidential files are accessed? Who is responsible for recording?

7. Glossary

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

Confidentiality
Document Copy
Study Protocol-related Communications
Meeting Minutes
Regulatory Authorities
Conflict of Interest
Anonymization
FDA
FERCAP
PHREB
Room-use Restriction

8. Forms

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

Request Form
Log of Requests
Log of Access

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Revised policy on photocopying*
03	*2015 June 03*	*ABC* *DEF*	*Added entries in the request form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	8
	8 Site Visits	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

Site visits are important activities in the oversight and monitoring responsibilities of ERCs. The ERC should establish the criteria and other characteristics of a study that would qualify a site for an ERC visit. High risk studies, studies with significant deviation reports and participant complaints are examples of criteria that may require a site visit. An example of a policy statement would be, *"The ERC shall designate a site visit team to conduct visits of selected sites of approved protocols that fall within the established criteria."*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in site visits? For example, *"Site visits are mechanisms to enable the ERC to monitor compliance of the conduct of study with approved protocols. It may also be an opportunity to determine the reasons for increases in reported risks."*

3. Scope

What is covered by this SOP? For example, *"This SOP includes the processes in conducting visits to study sites for reasons set by the ERC."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in site visits? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

For this SOP, the typical personnel involved are: the ERC Members, who collectively decide on procedures and compose the Site Visit Team, the ERC Staff, which handles all administrative processing to organize the visit, the Member Secretary who oversees the management of files, and the Chair, who forms the Site Visit Team.

5. 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)*

6. 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 - Selection of site to visit: Does the ERC mandate site visit for all sites or for specific sites using a set of criteria? Examples of criteria are high risk studies, frequent non-submission or failure to submit continuing review 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? Does this require a formal document (e.g. notice of creation of team)? 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? How does the team end the visit? Is there a debriefing with the site? Typically important points to cover include:

- Study protocol
- Informed consent documents and verify if the site is using the most recently approved version

- Post-approval documents and verify if these have been approved
- Security, privacy, and confidentiality of the documents at the study site
- Facilities in the study site
- Overall 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 (e.g. consensus)? To whom is the report submitted? 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 ERC meeting? How does the committee make a determination of action?

7. Glossary

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

Site Visit
Serious Adverse Events
Serious Adverse Events Committee
Protocol Deviations
High Risk Studies
Significant Deviation Reports

8. Forms

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

Site Visit Report Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Added criteria for site visit*
03	*2015 June 03*	*ABC* *DEF*	*Revised Site Visit Report Form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	9
	9 Managing Queries and Complaints	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

Queries and complaints may come from various stakeholders but the responsibility of the ERC is highest for those coming from research participants. 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."*

2. Objective/s of the Activity

What are the intended outcomes of the procedures involved in managing queries and complaints? For example, *"Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the ERC, among research participants."*

3. Scope

What are the limits of applicability of this SOP? For example, *"This SOP is limited to queries and complaints research participants, or their families, in studies that have been issued an ethical approval by the ERC."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in the process of managing queries and complaints? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

5. Workflow

What are the different steps involved in the managing queries and complaints? Who will be responsible in each of these steps?

For example:

ACTIVITY	*RESPONSIBILITY*
Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing ERC Incoming and Outgoing Communications)	*ERC Staff*
Step 2: Referral of query or complaint to competent authority	*ERC Staff*
Step 3: Formulation of response	*Chair and/or ERC Members*
Step 4: Communication of response (SOP on Communicating ERC Decisions (SOP#__))	*ERC Staff*
Step 5: Logging of the response (SOP on Managing ERC Incoming and Outgoing Communications (SOP#__)) and inclusion in the agenda of the ERC meeting (SOP on Preparing the Meeting Agenda (SOP#__))	*ERC 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 ERC 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 ERC have a designated competent authority who can respond to general/usual queries and complaints? Are there specific days when this person is available?

Step 3 - Formulation of response: Does the ERC have a special form for documenting responses to queries and complaints? Has the ERC established a mechanism for systematically addressing queries and complaints? For example, is there a "Quick Response Team" for emergent cases? Is there room for calling a special meeting? Can it just be included in the agenda of the next regular meeting? What criteria will be used to apply the aforementioned mechanisms?

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 ERC Decisions (SOP#__).

Step 5 – Logging of the response and inclusion in the agenda of the ERC meeting: How will the response be documented? See SOPs on Managing ERC Incoming/Outgoing Communications (SOP#__) and Preparing the Meeting Agenda (SOP#__).

7. Glossary

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

Query
Complaint
Regular Meeting
Special Meeting
"Quick Response Team"
Competent Authority

8. Forms

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

Query/Complaint Form
Query/Complaint Response Form

9. 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***
01	*2010 July 15*	*ABC*	*First draft*
02	*2013 May 01*	*DEF*	*Designated competent authority*
03	*2015 June 03*	*ABC* *DEF*	*Revised the Query/Complaint Response Form*

10. References

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

Name and Logo of Institution	Name of the ERC	SOP No:	10
	10 Writing and Revising SOPs	Version No:	01
		Approval Date:	MM/DD/YY
		Effective Date:	MM/DD/YY

1. Policy Statement

SOPs ensure efficiency, transparency, and consistency of ERC operations. The SOP manual needs to be periodically reviewed to determine the need for new SOPs or revision in order to respond to emerging operational issues of the ERC. A policy statement could be stated as, "*The ERC shall designate a team to regularly (state the schedule) review its set of SOPs to determine its continuing relevance and effectiveness to its operations."*

2. Objective of the Activity

What are the intended outcomes of the procedures involved in site visits? For example, *"Writing and revising SOPs establishes quality assurance of ERC functions."*

3. Scope

What is covered by this SOP? For example, *"This SOP applies to all ERC activities involved in the development of its SOPs and their revisions as published and distributed by the institution."*

4. Responsibilities

Who are the persons and which offices play significant roles and responsibilities in writing and revising SOPs? Check the workflow (see section below) and summarize the responsibilities attributed to the different individuals involved.

Typically, the ERC Staff is responsible for administrative processing, storage, and distribution.

5. Workflow

What are the different steps involved in the process of writing, reviewing, approving and disseminating SOPs of the ERC? 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 ERC 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 approval of SOP	*ERC Members*
Step 5: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	*ERC Staff*

6. 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: What justification is needed to warrant revision or writing of a new SOP? 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 ERC use an SOP template? This would greatly harmonize the writing of SOPs. In devising this template, the following contents are recommended:

- Number and version, which follows the SOP on coding of SOPs, and Guidelines
- Title, which is descriptive of contents
- Policy statement
- Objective/s of the activity, which defines the purpose and intended outcome
- Scope, which defines the extent of coverage of the SOP and its limitations
- Responsibilities, which delineates tasking and accountabilities for SOP implementation
- Workflow when necessary, which provides a graphic representation of the essential steps to implement the SOP
- Detailed instructions, which elaborates the steps outline in workflow

- Glossary
- Forms, which are documents to be filled out or accomplished by different parties as required by the SOP, with a list of forms
- Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies
- Appendices attachments including glossary and list of abbreviations

How does the ERC code SOPs?[1] For example, **SOP XX/YY-W,** where XX can refer to the SOP number, YY the Version of the SOP (starting from 01), W minor changes in the SOP (starting from 0).

How should the page look like? What should be the minimum components arranged or laid out in the page of the SOP. These can include:

- Institutional seal or logo
- Name of institution
- SOP code
- SOP/ title
- Effective date
- Page number
- SOP content and a footer indicating file name, directory and path included, of the corresponding electronic document, if the file can be accessed through a website or Uniform Resource Locator (URL), or a server

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 ERC 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 ERC of the draft SOP.

What is the effective date of the SOP and how is this defined (e.g. by functional approval)? What happens to the draft version reviewed by respective parties or the ERC itself? What is

[1] For ERCs who are following the ISO format or coding, feel free to adopt the ISO coding system.

the indication of final approval (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 – 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.

7. Glossary

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

Standard Operating Procedures
Coding
Format
Functional Approval
Effective Date
ISO
ISO Coding
SOP Manual

8. Forms

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

Request for Creation/Revision of an SOP
SOP Template

9. 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***
01	*2010 July 15*	*ABC*	*First draft*

02	*2013 May 01*	*DEF*	*Added criteria for proposing a new SOP*
03	*2015 June 03*	*ABC* *DEF*	*Revised the layout/format of SOP Template*

10. References

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