3. Post Approval Procedures

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3.6. Site Visits
3.7. Review of Early Protocol Termination

Supersedes:	None
Authored by:	DOH SOP Team
Effective Date:	July 4, 2014
Approved by:	Jesson V. Butcon, RN, PhD, Chair of the Board
Approved by:	Ruben Caragay, MD, PhD, Dean
Approval Date:	

3. Purpose

To describe the review procedures of the Bicol University College of Medicine IRB related to events reported to the IRB and PI submissions required by IRB during the conduct of the study. The period covered begins after approval has been granted by the IRB until the completion of the study at the IRB approved site.

3.1. Review of Serious Adverse Events

3.1.1. Purpose

To describe the IRB review procedures for serious adverse events

3.1.2. Scope

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the Bicol University College of Medicine IRB to comply with ICH GCP. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study.
ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

- results in death,
- is life threatening,
- requires hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability or incapacity, or
- results in a congenital anomaly or birth defect.

A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

3.1.3. Responsibilities

- The primary responsibility of the Bicol University College of Medicine IRB is to conduct an appropriate review of SAE and SUSAR reports to ensure oversight over the safety of participants enrolled in the study.
- The IRB should also make sure that researchers are made aware of its policies and procedures concerning SAE reporting.
- The Bicol University College of Medicine IRB sets up the necessary mechanisms to receive SAE and SUSAR reports

from investigators and sponsors of researches that it has approved.

- The primary responsibility of the Bicol University College of Medicine IRB is to receive and review SAE and SUSAR reports from its own site and to take the necessary action to ensure the safety of participants in the study.
- In multicenter studies, the IRB also receives SAE and SUSAR reports from other sites within and outside the country. It is the responsibility of the Bicol University College of Medicine IRB to be updated about safety issues related to studies that it has approved.
- The Bicol University College of Medicine IRB has the authority to suspend or terminate approval of research at its site when the safety of participants is no longer assured. When Bicol University College of Medicine IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator, the sponsor, the institution and relevant regulatory authorities.

3.1.4. **Process Flow/Steps**

ACTIVITY	RESPONSIBILITY
Report SAE and SUSAR	Investigators, sponsors
Receive SAE and SUSAR reports	Secretariat
Refer SAE Reports to appropriate ERC Members	Secretariat
Review SAE and SUSAR reports and make a recommendation	Chair, Members & Secretariat
Summarize and report to full board for appropriate action	Chair, Members & Secretariat
Inform Investigator, sponsor & other officials about ERC decision, whenever it is necessary	Secretariat

Detailed Instructions

3.1.5. The IRB should inform investigators that they are required to report SAEs and SUSARs to the IRB for all studies approved by the IRB. They should use **Form 3.1** to report SAEs.

3.1.6. The Bicol University College of Medicine IRB Secretariat shall be responsible for receiving and distributing the SAE and SUSAR reports within 5 working days to primary reviewers/ designated IRB members for review. They should classify the SAE/ SUSAR reports according to their origin or sites where they happened: foreign site, local site, onsite.

3.1.7. Classification of SAE/ SUSAR according to site **–** The IRB reviewers should adopt appropriate response depending on the site where the SAE/ SUSAR happened.

- For multicenter, international studies, note the trend of occurrence of SAE/ SUSAR in study sites in foreign counties and other local sites.
- For multicenter, national studies, note the nature (related or expected) of the SAE/ SUSAR
- For SAEs that occur onsite, the Bicol University College of Medicine IRB should analyze the investigator/ sponsor assessment (related, unexpected) and may need to recommend some form of action to the investigator to ensure the safety of participants. The designated IRB members should inform the Chair about their recommendation for appropriate IRB action.

3.1.8. Criteria for the review
To review SAE reports, designated IRB members should use the same form (**Form 3.1**) filled up by the principal investigator and fill up Section 2 that recommends appropriate action to be done by the IRB. The review procedures are as follows:

- Assessment of the SAE is unlikely or unrelated to the study drug or article: The report is forwarded to the Chair for review and determination if the report should be reviewed at the convened meeting by full Board.
- Assessment of the SAE is definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full Board.
- Assessment of the SAE is unexpected/ unanticipated and definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full Board.

3.1.9. SAE and SUSAR are discussed and reviewed during Bicol University College of Medicine IRB meetings for appropriate action.
Review and discuss:

a. After reviewing the report and the recommendation by designated IRB members, the Chair presides over the board

discussion of the SAEs and similar adverse experiences or advisories.

b. If appropriate to the discussions, the Chair or another Board member may call for a consensus on whether to:

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

3.1.10. Inform the investigator and the sponsor, when necessary about the IRB decision and keep a record in the IRB files.

- If any of the above actions are taken, the Bicol University College of Medicine IRB secretariat notifies the investigator of the action taken.
- If the Bicol University College of Medicine IRB takes no action, a notation is made in the minutes and the study is allowed to continue.
- The Bicol University College of Medicine IRB secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the Bicol University College of Medicine IRB decision.
- Get the Chair to approve, sign and date the letter.
- Send the letter and record the delivery date.

SERIOUS ADVERSE EVENT REPORT FORM (FORM 3.1)

Whenever there is any SAE event in any research approved by the **Bicol University College of Medicine** IRB, it has to be reported by the principal investigator (PI) to the IRB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:

Study Title: | Protocol No.:

Name of the study medicine/device:

Report Date:
☐ Initial ☐ Follow-up
Onset Date:

Sponsor:

Date of first use:

Title of the Report

Date of the report

Subject's initial/number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:

Laboratory findings:

SAE:

Treatment:
Outcome: ☐ Resolved ☐ On-going

Seriousness:
☐ Death ☐ Life Threatening
☐ Hospitalization: ____

Relation to
☐ Drug ☐ Device ☐ Study
☐ Not related

☐ Initial ☐ Prolonged

☐ Disability/Incapacity
☐ Congenital Anomaly

☐ Others

☐ Possibly

☐ Probably
☐ Definitely related

☐ Unknown

Note: PI should attach standard SAE report form to this IRB form.

SECTION 2 (to be filled up by the designated IRB representative)
Document receipt by the IRB

Name (IRB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

IRB Final Action:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action is needed.
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting _____

Name of Member- Secretary:	Signature	Date

3.2. Review of Amendments

3.2.1. Purpose

To describe the IRB review procedures for amendments of the protocol and related documents

3.2.2. Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval by the Bicol University IRB. Any amendment of the study related documents may not be implemented until reviewed and approved by the IRB.

3.2.3. Responsibilities

It is the responsibility of the IRB Secretariat to manage protocol amendment package submitted by the PI.

It is the responsibility of the original primary reviewers to review the amendments and recommend appropriate action.

It is the responsibility of the IRB Chair to determine whether the amendment goes to expedited or full board review. The IRB approves the final decision for amendments submitted by the PI to the IRB.

3.2.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Submit Application for Amendment	Investigator
Receive and manage Amendment Package	Secretariat
Refer Amendment Documents to original primary reviewers	Secretariat
Review amendments and make a recommendation	Member Primary Reviewers
Review recommendations and determine if amendment should be referred to full board	Chair
Discuss at full board, if necessary	Members
Inform Investigator about ERC decision	Secretariat
Keep a copy of all amendment related documents in the protocol file	Secretariat

Detailed Instructions

3.2.5. The IRB should properly inform investigators to submit an amendment application whenever there is any change regarding the composition of the study team, the study site and the protocol related documents for approvals previously granted by the IRB.

3.2.6. The IRB Secretariat checks the completeness of the amendment package submitted by the Investigator. **Use Form 2.1 and Form 3.2.**

3.2.7. The IRB Secretariat refers the amendment package to the original primary reviewers.

3.2.8. The original primary reviewers check the amended documents and compare them with the previously IRB approved documents in the protocol files. They check if the amendments would alter the risk/ benefit ratio of the study to make appropriate recommendations using **Form 3.2.** Amendments that may potentially alter the risk/ benefit ratio of a study are referred to full board for discussion.

3.2.9. Protocol amendment which increase risk to study participants may include, but is not limited to the following:

- a change in study design
- additional treatments or the deletion of treatments
- any change in the inclusion/exclusion criteria
- change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
- significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
- significant decrease or increase in dosage amount

3.2.10. If only minor changes are involved in the amendment, the reviewers recommendation become the basis for the final decision of the IRB and a letter granting approval is prepared by the IRB Secretariat.

3.2.11. If major changes are involved in the amendment (alters the risk/ benefit ratio of the study), the amendment is referred to full board after review by the primary reviewers. The members discuss the issues related to the amendments to arrive at a decision.

3.2.12. The Secretariat prepares a communication letter to inform the investigators about the board decision. The Secretariat forwards the letter to the investigators for proper action.

3.2.13. The Secretariat keeps a copy of all amendment related documents in the protocol files.

PROTOCOL AMENDMENT REVIEW (FORM 3.2)

IRB Protocol No.	Sponsor Protocol No	Date of submission

Date of approval

Title	

Principal Investigator	Sponsor	Contact Number

List of Amendments	Reasons
1.	
2.	
3.	

Comments of Primary Reviewers	

IRB Decision	Name of Chair	Date

Signature

3.3. Review of Progress and Final Reports

3.3.1. Purpose

To describe the IRB review procedures for progress and final reports

3.3.2. Scope

This SOP provides instructions for the review of progress reports that are required by the Bicol University College of Medicine IRB to be submitted by the PI to monitor the safety of participants enrolled in a study. The annual progress report becomes the basis for continuing review of protocols whose approval needs to be renewed every year. This SOP also aims to provide instructions for the review of final reports that are submitted by the PI after completion of subject enrollment and all follow up procedures.

This SOP applies to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

This SOP describes the follow up of progress and final reports by the IRB Secretariat and the review of such reports submitted by the PI by designated members of the IRB in compliance with ICH-GCP requirements.

3.3.3. Responsibility

It is the responsibility of the Bicol University College of Medicine IRB Secretariat to remind investigators to submit the progress and final reports before due date, to forward the reports to the primary reviewers for review comments, to communicate with the investigators if there is need for further information or action and to submit to full board a list of progress and final reports for approval.

It is the responsibility of the primary reviewers to review the reports to check completeness of information and ensure that the data are in accordance with the protocols and other related documents approved by the IRB.

3.3.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Remind PIs to submit progress or final report one month before due date	Secretariat
Submit progress or final report on or before due date	Investigators
Check completeness of information in the report and forward to the primary reviewers for assessment/comments	Secretariat
Review the progress or final report if it is in accordance with the approved protocol and related documents	Primary Reviewers
Recommend approval or require more information or other action from the PI	Primary Reviewers
Report approval/ other recommendations to full board	Secretariat
Discuss at full board and make a decision	Members, Secretariat
Communicate ERC decision to PI	Secretariat

Detailed Instructions

3.3.5. Submission and management of Final Reports

- The Secretariat checks the database and tracks due dates of progress or final reports of Study Protocols approved by the Bicol University College of Medicine IRB.
- The Secretariat prepares and sends reminder letter/notice addressed to the PI one month before the due date of the report.
- The Secretariat reviews the completeness of submitted report based on the items in **Progress Report Form 3.3** and **Final Report Form 3.4** and forwards the report to the primary reviewers.

3.3.6. Review of Progress/ Final Reports

- The primary reviewers conduct continuing review of progress/ final report if they are in accordance with the protocol and related documents approved by the IRB.
- The primary reviewers refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of amendments.
- The primary reviewers recommend approval of the progress/ final report if there is no deviation or violation of IRB approvals.
- If there is any deviation or violation of approvals given by the IRB, the primary reviewers recommend that appropriate action be taken by the PI (e.g. amendment of the protocol or consent form, etc. for progress reports; explanation of deviation or violation for final reports, etc.)

- Approval or other recommendations by the primary reviewers of progress/ final report is reported to the board meeting by the Secretariat.
- Approval of the annual progress report is necessary to renew the initial approval of the protocol and allow the investigator to continue the conduct of research. Approval of the final report enables the IRB Secretariat to close the protocol files.
- Related issues or recommendations related to progress/ final reports are included in the agenda for discussion during the board meeting in order to arrive at a decision for appropriate action.
- The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.

3.3.7. Communicating Bicol University College of Medicine IRB decisions for Progress Reports

- The IRB Secretariat notifies the investigator of IRB decision.
- The IRB accepts the annual progress report and notifies the investigator about the renewal of approval of the protocol and related documents to enable the PI to continue the conduct of the research.
- The IRB accepts the Final Report and considers the study as completed.
- The IRB Secretariat keeps a copy in the protocol files of the progress/final report signed by the Primary Reviewers and the Chair or Member-Secretary.
- The IRB Secretariat marks the folder of the completed protocol and archives the entire study protocol.

PROGRESS REPORT (FORM 3.3)

IRB Protocol No.		Approval Date	
Protocol Title			
Investigator.		Sponsor	

ACTION REQUESTED:

- ☐ Renew - New participant accrual to continue
- ☐ Renew - Enrolled participant follow up only
- ☐ Terminate - Protocol discontinued

Any amendment since the last review? (Describe briefly.)	☐ No	☐ Yes
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes.)	☐ No	☐ Yes
Any change in the Informed Consent process or documentation since the last review? (Please explain.)	☐ No	☐ Yes
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.)	☐ No	☐ Yes
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.)	☐ No	☐ Yes
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)	☐ No	☐ Yes

Any new investigator that has been added to or removed from ☐ No ☐ Yes

Primary Reviewers:	Signature:	Date:

Summary of protocol participants:

- ☐ Accrual ceiling set by IRB
- ☐ New participants accrued since last review
- ☐ Total participants accrued since protocol began

Total participants accrued since protocol began

ACCRUAL EXCLUSIONS

- ☐ None
- ☐ Male
- ☐ Female
- ☐ Others (Specify) _____

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. ☐ No ☐ Yes

Impaired Participants

- ☐ None
- ☐ Physically
- ☐ Cognitively
- ☐ Both

To be filled up by IRB

Date received:		Received by:	
		Printed name:	
		Signature:	

Recommendations

- ☐ Approve
- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting: _____

Changes to the protocol recommended Comments:	☐ No	☐ Yes

Changes to the informed consent form recommended? Comments:	☐ No	☐ Yes

IRB Final Decision:	

Certified by:

Name of Member-Secretary:	Signature:	Date

FINAL REPORT (FORM 3.4)

IRB Protocol No.		Approval Date	
Protocol Title			
Principal Investigator.			
Phone number:		E-mail address :	
Sponsor's Name			
Address:			
Phone number:		E-mail address :	
Study site(s):			
Total Number of study participants :		No. of Study Arms	
Number of participants who received the test articles:			
Study materials:			
Treatment form:			
Study dose(s):			
Duration of the study			
Objectives:			
Results: *(Use extra blank paper, if more space is required.)*			
Signature of P.I.			

3.4. Review of Protocol Violation/Protocol Deviation

3.4.1. Purpose

To describe the IRB review procedures for protocol violation/ deviation

3.4.2. Scope

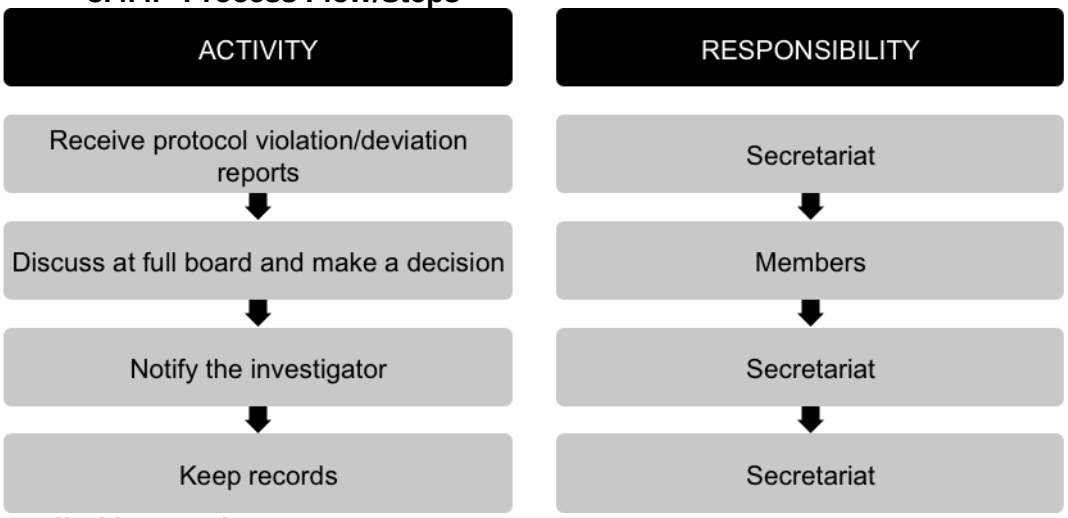
This SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violations:

- It includes investigators who fail to comply with the procedures in the approved protocol or to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the IRB's requests.
- It also covers action taken by the IRB related to protocol violation/ deviation reports submitted by the PI related to any event at the site that is not in compliance with the protocol documents previously approved by the IRB.

3.4.3. Responsibility

It is the responsibility of the IRB Secretariat to receive protocol violation/ deviation reports submitted to the IRB.
It is the responsibility or the board members or designated members to take action related to protocol violation/ deviation.

3.4.4. Process Flow/Steps



Detailed instructions

3.4.5. The Secretariat or any IRB member may receive protocol violation/ deviation reports from investigators and other parties related to any event in the site that is not in compliance with the previously IRB approved protocol and related documents. The

Secretariat gets full information about the event and puts the report in the next full board meeting agenda.

3.4.6. Whenever protocol deviation / non-compliance / violation has been observed:

- Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the Bicol University College of Medicine IRB meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the Bicol University College of Medicine IRB's request for information/action.
- The Bicol University College of Medicine IRB may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

3.4.7. Basis of committee/board action/decision:

- Prior approval may be withdrawn for the following reasons
- SAE directly or indirectly attributed to the research
- Breach of previously approved conduct of the research
- Major changes, deviations or amendments to the approved protocol without another approval by the IRB
- Revisions in the informed consent form

3.4.8. Notification of the Bicol University College of Medicine IRB's decision

- The IRB Secretariat members records the Bicol University College of Medicine IRB decision.
- Draft and type a notification letter.
- Get the Chair to sign and date the letter.
- Make four copies of the notification letter.
- Send the original copy of the notification to the investigator.
- Send a copy of the notification to the relevant national authorities and institutes.
- Send the third copy to the sponsor or the sponsor's representative of the study

3.4.9. Keep records and follow up

- Keep the last copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Follow up the action after a reasonable time.

DEVIATION / NON-COMPLIANCE / VIOLATION REPORT (FORM 3.5)

IRB Protocol No.	Sponsor Protocol No.	Date of Submission

Study Title:			
Investigator		Contact No.:	
Sponsor:		Contact No.:	
Reported by		Contact No.:	

☐ PI Deviation from protocol ☐ Participant Non-Compliance

☐ Major ☐ Minor

Description:	
IRB Decision:	
Actions taken:	

Reported by:	Noted by (Secretariat)
Date:	Date:

3.5. Responding to Participant's Requests/Queries

3.5.1. Purpose

To describe the IRB procedures related to participant requests and queries

3.5.2. Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the Bicol University College of Medicine IRB.

3.5.3. Responsibility

A designated member of the secretariat is responsible for receiving participant queries and requests related to their participation, refers relevant issues to the IRB Chair or members for the IRB to take appropriate action. The Secretariat keeps records of all action taken by the IRB.

3.5.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Receive the request or query	Secretariat
Assess nature of the request and refer to appropriate person	Secretariat and Chair
Take action and refer to full board if necessary	Chair, Members
Communicate decision to person who made the query	Secretariat
File the documents	Secretariat

Detailed Instructions

3.5.5. Receive the request or query.

- The Bicol University College of Medicine IRB secretariat receives the inquiry or requests from research participants/patients or the community through various forms of communication (email, telephone call, letter, etc.)
- Reply to the request or query, if it is within the authority of the Secretariat or refer to the Chair or IRB member for appropriate action.
- Record the request and information in the request record form **(Form 3.6)** and keep a copy in the files.

3.5.6. Take action

A designated IRB member takes appropriate action.

- Investigate the fact.
- Record information and any action or follow-up taken in the **Form 3.6**
- Sign and date the form and forward to the Secretariat for filing.
- Report to the Bicol University College of Medicine IRB about the action taken and the outcomes.

3.5.7. File the request document

- Keep the record form in the “response” file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled shelf.

REQUEST/ QUERY RECORD (FORM 3.6)

Date received:		Received by	

Request from :	☐ Telephone call Number	_____
	☐ Fax Number	_____
	☐ Mailed letter / Date	_____
	☐ E-mail / Date	_____
	☐ Walk-in/Date/Time	_____
	☐ Others, specify	_____

Participant's Name:			
Contact Address:		Phone:	
Title of the Participating Study			
Starting date of participation :			
What are requested?			
Action taken:			
Outcome:			

3.6. Site Visits

3.6.1. Purpose

To describe the IRB procedures related to the conduct of site visits

3.6.2. Scope

This SOP applies to any visit made in any study site, on behalf of the Bicol University College of Medicine IRB, to check compliance with GCP and IRB approved protocol and related documents.

3.6.3. Responsibility

It is the responsibility of the Bicol University College of Medicine IRB to perform or designate some members or qualified representatives to perform on its behalf on-site visit of the research projects it has approved.

The Bicol University College of Medicine IRB members or Secretariat in consultation with the Chair may initiate an on-site evaluation of a study site for cause or for a routine audit.

3.6.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Select study sites and inform the PI about the planned visit	Members and Secretariat
Check approval given by the ERC from the protocol files and collect relevant information about the study site	Members and/or ERC representative
Check the onsite documents and compare with documents in the protocol files; interview PI and/or research staff	Members and/or ERC representative
Write a report and make a recommendation	Members and/or ERC representative
Present the findings to the Full Board which adopts an appropriate action	Members
Communicate board decision to the PI	Secretariat
PI implements board recommendation and reports action to the board	PI
File copies of documents	Secretariat

Detailed Instructions

3.6.5. Selection of study sites

- Review periodically the database files of the submitted/approved study protocols.
- Select study sites needed to be monitored based on the following criteria:
  - New study sites or new PIs
  - Reports of remarkable serious adverse events
  - Big number of studies carried out at the study site
  - Frequent protocol submission for Bicol University College of Medicine IRB review
  - Non-compliance or suspicious conduct
  - Frequently fail to submit final reports
  - Frequent protocol violations

3.6.6. Before the visit

The Bicol University College of Medicine IRB representatives will

- Contact the site to notify them that they will be visiting them. Coordinate a time for the site evaluation visit.
- Make the appropriate travel arrangements.
- Review the Bicol University College of Medicine IRB files for the study and site
- Make appropriate notes, or
- Copy some parts of the files for comparison with the site files.

3.6.7. During the visit

a. Use the Site visit checklist **(Form 3.7)**
b. The Bicol University College of Medicine IRB representatives will
   - Review the informed consent document to make sure that the site is using the most recent version,
   - Review randomly the subject files to ensure that subjects are signing the correct informed consent,
   - Check if the files are orderly and confidentiality is maintained
   - Debrief the PI about site visit findings and comments.
   - Get immediate feedback.

3.6.8. After the visit

The Bicol University College of Medicine IRB representative will:

- Write a report/comment (**use Form 3.5**) within 1 week describing the findings during the audit
- Forward a copy of the site visit to the Secretariat for inclusion in the next board meeting.
- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.

3.6.9. Present the site findings to the Full Board.
- Present the site visit report to the Full Board.
- Board makes a decision about appropriate action.

3.6.10. Secretariat communicates the board decision to the PI for appropriate action.

3.6.11. PI follows board recommendation and reports to the IRB.

3.6.12. Secretariat reports PI's action to the board.

3.6.13. Secretariat keeps a copy of the files.

SITE VISIT REPORT (FORM 3.7)

IRB Protocol No.		Date of the Visit:	
Study Title:			
Principal Investigators:		Phone:	
Department:		Address:	
Sponsor		Address:	
Total number of expected subjects:		Total subjects enrolled:	

Are site facilities appropriate? ☐ Yes ☐ No — Comment:

Are Informed Consents Recent? ☐ Yes ☐ No — Comment:

Any adverse events found? ☐ Yes ☐ No — Comment:

Any protocol non-compliance/violation? ☐ Yes ☐ No — Comment:

Are all Case Record Forms up to date? ☐ Yes ☐ No — Comment:

Are storage of data and investigating products locked? ☐ Yes ☐ No — Comment:

How well are participants protected? ☐ Good ☐ Fair ☐ Not good — Comment:

Any outstanding tasks or results of visit? ☐ Yes ☐ No — Give details:

Duration of visit: (hours)		Starting from:		Finish:	
Name of IRB member/representatives and companion:					

Completed by:		Date:	

3.7. Early Protocol Termination

3.7.1. Purpose

To describe the IRB procedures related to early termination of protocol implementation

3.7.2. Scope

This procedure describes how the IRB proceeds and manages the premature or early termination of a protocol when subject enrollment are discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IRB itself or other authorized bodies

3.7.3. Responsibility

It is the responsibility of the IRB to act on any early protocol termination application. It is also the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full board for appropriate action.

The Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to full board.

3.7.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Receive the application or recommendation for early termination	Members and Secretariat
Check approval given by the ERC from the protocol files and collect relevant information	Primary reviewers/ Designated ERC Member
Review the termination package or termination issues and make recommendations	Primary reviewers/Designated ERC Member
Discuss at full board for appropriate decision	Members
Communicate board decision to the PI	Secretariat
File copies of documents	Secretariat

Detailed Instructions

3.7.5. Receive application or recommendation for early study termination.

- Receive recommendation and comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.
- Inform the principal investigator to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principal investigator.
- Check the completeness of the contents of the package to include the Study Termination **(Form 3.8)**
- The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.

3.7.6. Check approval given by the IRB from the protocol files and collect relevant information.

3.7.7. Review the termination package or termination issues and make recommendation. The primary reviewers review the safety data. It is important for the termination package to contain a plan to follow up the participants who are still active in the study.

3.7.8. Discuss at full board for appropriate decision.

3.7.9. Communicate the IRB decision.

3.7.10. Keep the files.

STUDY TERMINATION (FORM 3.8)

IRB Protocol No:		Sponsor Protocol No.	
Protocol Title:			
Principal Investigator:			
Phone :		E-Mail:.	
Department:			
Sponsor:			
IRB Approval Date:		Date Of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	
Summary of Results			
Accrual Data:			
P.I. Signature:		Date:	