4. Documentation and Archiving

4.1. Preparation of Meeting Agenda
4.2. Preparation of Meeting Minutes
4.3. Preparation of Communication Records
4.4. Management of Active Study Files
4.5. Archiving of Terminated, Inactive, or Completed Studies
4.6. Maintenance of Confidentiality of Study Files and IRB Documents

Supersedes:	Previous SOPs of the IRB
Authored by:	BUCM-IRB
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:	July 4, 2014

4.1. Preparation and Distribution of Meeting Agenda

4.1.1. Purpose

To describe procedures for the preparation and distribution of the IRB meeting agenda

4.1.2. Scope

This SOP provides instructions related to the preparation of the IRB meeting agenda and its distribution to inform IRB members and other interested individuals about the items for discussion during a full board meeting.

4.1.3. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the IRB within a given period to include them in the next full board meeting agenda for discussion or information of the EC members.

4.1.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Collect all documents submitted to the ERC within a given period to prepare the full board meeting agenda	Secretariat
Have agenda approved by the Chair	Secretariat, Chair
Distribute notice of meeting and agenda to ERC members and interested parties	Secretariat
Communicate with the members to check if they can attend the meeting to ensure quorum	Secretariat
File the notice of meeting and agenda	Secretariat

Detailed Instructions

4.1.5. Collect all documents submitted to the IRB within a given period and put them in the full board meeting agenda for discussion or information of the IRB members.

4.1.6. The standard notice of meeting or agenda contains the ff:

- Date of preparation
- Date, time and venue of meeting
- Agenda items
  - New protocols for initial review of full board
  - Resubmission
  - Amendments
  - Progress reports
  - Final reports
  - SAE reports
  - Protocol violation/ deviation, participant queries, etc.
  - Reports (expedited meeting results, site visit, etc.)
  - Other matters

4.1.7. Recommendations on protocols requiring clarifications from the Principal Investigator during an IRB full board meeting are made by Bicol University College of Medicine IRB primary reviewers, who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the IRB meeting is communicated to them.

4.1.8. The Secretariat informs and consults the Chair about the agenda items.

4.1.9. The Secretariat arranges the venue and other logistics for the meeting at least one week before the scheduled meeting prior to preparation of the notice of meeting.

4.1.10. The Secretariat makes copies of the notice of meeting containing the approved agenda to the Bicol University College of Medicine IRB members, at least one week before the meeting.

4.1.11. The Secretariat communicates with the IRB members to confirm their attendance and ensure quorum during the next board meeting.

4.1.12. The Secretariat files a copy of the agenda in the Agenda and Minutes folder.

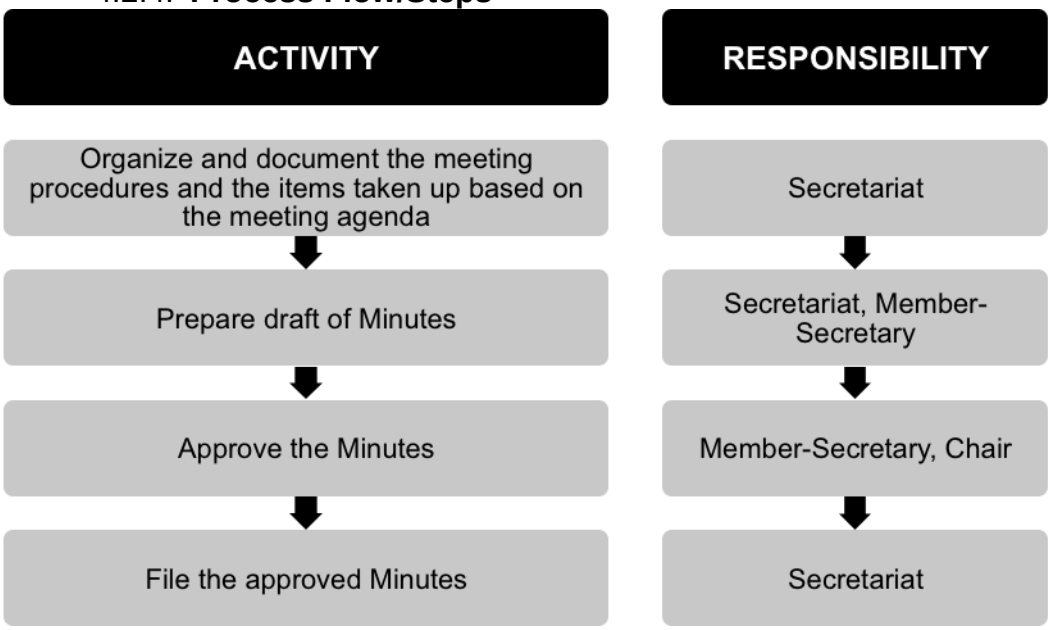
4.2. Preparation of Meeting Minutes

4.2.1. **Purpose**
To describe procedures for the preparation and approval of the minutes of the IRB full board meeting

4.2.2. **Scope**
This SOP provides instructions related to the preparation of the IRB full board meeting minutes and its approval by the IRB members.

4.2.3. **Responsibility**
It is the responsibility of IRB Secretariat, under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the IRB meeting agenda.

4.2.4. **Process Flow/Steps**



Detailed Instructions

4.2.5. The Secretariat uses **Form 4.2** as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.

4.2.6. The Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.

4.2.7. The Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections:

- Date and venue of meeting
- Member attendance (members present and absent) to determine quorum
- Guests and observer attendance
- Time when the meeting was called to order
- Presiding officer
- Conflict of interest declaration by IRB members
- Discussion of items based on the Meeting Agenda
- Decisions and recommendations arrived at during the meeting
- Name and signature of person who prepared the Minutes
- Name and signature of the Chair with the date of approval

4.2.8. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.

4.2.9. The Secretariat submits a complete draft of the minutes to the Member- Secretary within **one week** after the meeting for corrections, and submits the corrected draft to the Chair for approval.

4.2.10. The Secretariat uses the information in the minutes to communicate full board IRB decisions to the respective Principal Investigators.

4.2.11. The minutes of the IRB full board meeting, once they are finalized, are sent to the members for comments or correction. The minutes are formally approved during the next full board meeting.

4.2.12. The Secretariat files the signed minutes in the Minutes of the Meeting folder of the IRB.

4.3. Preparation of Communication Records

4.3.1. Purpose

To describe the preparation of IRB communication records and the filing of such records

4.3.2. Scope

This SOP provides instructions related to the preparation of IRB communication to various parties and the management of such files.

4.3.3. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to document all communication made by the IRB secretariat to different parties that deal with the IRB.

4.3.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Organize all communications received and issued by the ERC	Secretariat Staff
Record the details of the communication	Secretariat Staff
File communication documents	Secretariat Staff

Detailed Instructions

4.3.5. IRB communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all IRB communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries.

4.3.6. The IRB Secretariat organizes a log of communications which also functions as a log of submissions if the communication comes with a submission. This log should have at least the following elements:

- Date of communication/submission
- Name of IRB party contacted
- Study information, i.e., sponsor, protocol number, principal investigator, etc.
- Content of communication or submission
- Notation of any follow-up necessary
- Type of submission (if communication refers to a submission)
- Contact information (address, telephone number, and e-mail) of sending party
- Name and signature of individual who received the communication and completed the record

4.3.7. A copy of the communication/submission is filed in the:

- Protocol file folder
- IRB Communications folder

- Others, as appropriate

4.4. Management of Active Study Files. Documents and Records

4.4.1. Purpose

To describe the IRB procedures related to the management of active study files, documents and records

4.4.2. Scope

This SOP provides instructions related to the management of active study files originating from protocol submissions and includes all documents that reflect all actions taken by the IRB before completion of the study. It also provides instructions for other the maintenance and storage of other IRB documents and records.

4.4.3. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to manage all protocol submissions and all documents that reflect all IRB actions and organize them into orderly files that are kept at the IRB office. The Secretariat also manages the maintenance and storage of all relevant IRB documents and records.

4.4.4. **Process Flow/Steps**

ACTIVITY	RESPONSIBILITY
Design a standard coding system for all protocols submitted to the ERC for review	ERC
File all submitted documents in a protocol folder and chronologically organize the contents of the active study files according to time of receipt	Secretariat
Update the active protocol files regularly and ensure that all actions are also recorded in the database	Secretariat
Keep the active protocol files in the office	Secretariat

Detailed Instructions

4.4.5. Protocol files of Bicol University College of Medicine IRB-approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. It is necessary to use a unique identifier or code to refer to this file for efficient file management.

4.4.6. Code active study files as follows: Bicol University College of Medicine IRB- yyyy (year) –number (chronological number based on order of receipt). For example, if Protocol entitled “First Clinical Drug Trial on Pediatric Patients” is the first protocol received in 2012, the code Bicol University College of Medicine **IRB 2012-01** is the code that should be used to identify this protocol.

4.4.7. File protocol documents in sturdy file folders, using one folder per study protocol title. The folders are kept in secured well-identified locked cabinets.

4.4.8. File folders are labeled using the code of the study file.

4.4.9. Study file information is entered into the IRB database using its unique code.

4.4.10. The study file folder contains the following documents and should have an index:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents
- Reviewers' assessment forms
- Amendment reports
- Continuing review applications
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Approval letters
- Notifications of IRB Decision
- Miscellaneous communication
- Final report

4.4.11. The active files, records and documents should be properly maintained and updated

4.4.12. Keep all active study files in a secure file cabinet, with access limited only to IRB Secretariat who will be entrusted to keep the lock and key.

4.4.13. Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status. The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:

- Protocol Code
- Protocol title
- Department
- PI and details
- Submission date
- Full board or Expedited Review date
- Reviewers
- Review decision
- Board meeting date

- Approval date
- Date for progress report

4.4.14. The Secretariat updates the study file folder and the database every week.

4.4.15. Actives files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.

4.5. Archiving of Terminated, Inactive, or Completed Studies

4.5.1. Purpose

To describe IRB procedures related to archiving of terminated, inactive and completed studies

4.5.2. Scope

This SOP provides instructions to the Secretariat related to requirements for archiving complete3d documents after the final report or other relevant documents have been received.

4.5.3. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Member- Secretary, to archive in an orderly manner all protocol files that have been terminated, completed or are no longer active. They are kept together in a designated place in the hospital where confidentiality and security of the documents can be maintained.

4.5.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Approve final report or early study termination report	Reviewers, Members
Archive studies with approved final report or early study termination report	Secretariat
Retrieve protocol documents when needed	Secretariat, Members, and others
Record protocol documents retrieval	

Detailed Instructions

4.5.5. Archived study files refer to protocols that that are completed/inactive/terminated (or withdrawn). They are retained for at least three years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors.

4.5.6. Upon approval of the Final Report or Early Study Termination, the protocol is reclassified as inactive and the Secretariat initiates archiving procedure.

4.5.7. The Secretariat reviews the contents of the protocol file and transfers it from the active study filing area to the designated archive room.

4.5.8. An archive number is assigned to the protocol by adding the ***/(***year of archiving) as a suffix to the original protocol code. For example if the Final Report of Protocol Bicol University College of Medicine **IRB 2010-002** is approved in 2012, the archiving code is Bicol University College of Medicine **IRB 2010-002/2012.**

4.5.9. The archiving data should be entered accordingly in the protocol database.

4.5.10. Archived protocols can be retrieved within the three-year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.

4.6. Maintenance of Confidentiality of Study Files and IRB Documents

4.6.1. **Purpose**
To describe IRB procedures related to maintaining the confidentiality of the study files and other IRB documents

4.6.2. **Scope**
This SOP provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

4.6.3. **Responsibility**
It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to ensure that confidentiality is maintained in the management of all study files and records.

4.6.4. **Process Flow/Steps**

ACTIVITY	RESPONSIBILITY
Classify which ERC documents are confidential	Members/ Secretariat
Restrict access to confidential documents	Secretariat
Record copies made of confidential documents	Secretariat
File log of copies	Secretariat

Detailed Instructions

4.6.5. Properly handle original documents and copies of these documents during the day-to-day operation of the IRB to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the IRB.

4.6.6. Study files submitted to the Bicol University College of Medicine IRB and related documents are considered confidential, such as:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- Bicol University College of Medicine IRB documents (Meeting minutes, advice, and decisions)
- Correspondence (experts, auditors, study participants, etc.)

4.6.7. Access to Bicol University College of Medicine IRB confidential documents is subject to the following limitations:

4.6.8. Bicol University College of Medicine IRB members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* (Form 1.3) can access confidential

documents outside of regular protocol review access, upon request.

4.6.9. Non-members can access specific documents by submitting a formal request. The Secretariat will provide a copy of the *Confidentiality Agreement Form for Non-members Requesting for Copies of Bicol University College of Medicine IRB Documents* (Form 4.3) to be accomplished by the person making the request, and signed by the Chair.

4.6.10. Regulatory authorities have full access to Bicol University College of Medicine IRB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

4.6.11. The Secretariat records the retrieval of Bicol University College of Medicine IRB documents.

4.6.12. The Secretariat makes a record every time a document of the Bicol University College of Medicine IRB is accessed as described above.

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

- Study file code
- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval
- Signature of Bicol University College of Medicine IRB Secretariat upon return of document to file box
- Document copied
- Number of copies made
- Number of copies received

4.6.14. Access to Bicol University College of Medicine IRB documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.

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

4.6.16. The Secretariat makes only the exact number of copies requested.

4.6.17. The recipient signs for the copies requested in the Bicol University College of Medicine IRB upon receipt of the copies.

FORMAT FOR THE AGENDA OF THE MEETING (FORM 4.1)

Bicol University College of Medicine Ethics Review Committee
Address
Telephone
(Date)

NOTICE OF MEETING

To : Bicol University College of Medicine Ethics Review Committee Members:
(NAME OF IRB MEMBER 1)
(NAME OF IRB MEMBER 2)
(NAME OF IRB MEMBER 3)
(NAME OF IRB MEMBER 4)
(NAME OF IRB MEMBER 5)
(NAME OF IRB MEMBER 6)
(NAME OF IRB MEMBER 7)
(NAME OF IRB MEMBER 8)
(NAME OF IRB MEMBER 9)

DATE OF MEETING:
TIME OF MEETING:
VENUE OF MEETING:

AGENDA:

1. PROTOCOL REVIEW
   - 1.1. New Protocols
   - 1.2. Protocols for Modifications
   - 1.3. Protocol for Clarificatory Interview
   - 1.4. Protocol Amendments
   - 1.5. Continuing Review
   - 1.6. Final Reports
   - 1.7. Protocol Deviations
   - 1.8. Early Study Termination
   - 1.9. Site Visit Reports
   - 1.10. SAE/AE Reports
   - 1.11. Queries or Complaints

2. OTHER MATTERS

Prepared by

(Name of IRB Member-Secretary)
Chair, Ethics Review Committee

MINUTES OF THE MEETING (FORM 4.2)

Bicol University College of Medicine Ethics Review Committee
Minutes of the Meeting
(Date), (Venue), (Time)

1. ATTENDANCE
   PRESENT: ABSENT:

2. CALL TO ORDER
3. DETERMINATION OF QUORUM
4. DISCLOSURE OF CONFLICT OF INTEREST (COI)
5. READING AND APPROVAL OF THE MINUTES LAST MEETING
6. BUSINESS ARISING FROM THE MINUTES
7. PROTOCOL REVIEW
   7.1. New Protocols

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Primary reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of interest	

Assessment of ethical issues	Conflict of Interest: Privacy and confidentiality including data protection plan Vulnerability Risks Benefits Informed consent process and recruitment: Informed Consent Form (ICF) (including translation)

Documentation of collaborative study TOR

Recommendations
Decision
Approval expiration date
Frequency of continuing review (in case of approval)

1.1. PROTOCOLS FOR MODIFICATIONS

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of PI response to initial review	
Recommendations	
Decision	
Approval expiration date	
Frequency of continuing review (in case of approval)	
Protocol Code	

1.2. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	

Conflict of Interest:	
Assessment of amendment requested	
Recommendations	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

1.3. CONTINUING REVIEW

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of progress reported	
Recommendations	
Decision	

1.4. FINAL REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of final report	
Recommendations	
Decision	

1.5. PROTOCOL DEVIATIONS

Protocol Code	
Protocol Approval Date	
Report Date	

Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Deviation Report	
Recommendations	
Decision	

1.6. EARLY STUDY TERMINATION

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of risks from early termination	
Recommendations	
Decision	

1.7. SITE VISIT REPORTS

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	

Assessment of Site Visit Report	
Recommendations	
Decision	(Uphold original approval with no further action, Request information, Recommend further action)

1.8. SAE/AE REPORTS

Protocol Code	
Protocol Approval Date	
Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of SAEs reported	
SAE I	
Submission Date	
Date of SAE	
Date of randomization	
Age	
Sex	
Country	
Nature of AE	
Co-morbidities	
Status	
Recommendations	
Decision	

1.9. QUERIES OR COMPLAINTS

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	

Quorum status	
Conflict of Interest:	
Assessment of query or complaint	
Recommendations	
Decision	

APPENDICES

REPORT OF RESULTS OF EXPEDITED REVIEW

1. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

2. PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

3. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	
Date of Amendment Submission	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

4. OTHER MATTERS

5. ADJOURNMENT

Prepared by:	Approved by:
Signature over Name Bicol University College of Medicine IRB SECRETARIAT Date:	Signature over Name Bicol University College of Medicine IRB Chair Date:

CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING TO ACCESS Bicol University College of Medicine IRB DOCUMENTS (FORM 4.3)

I, (Name, Surname) as a non-member of the **Bicol University College of Medicine** Ethics Review Committee, understand that the documents I am given access to by the **Bicol University College of Medicine** Ethics Review Committee are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the **Bicol University College of Medicine** Ethics Review Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>
IRB MEMBER-SECRETARY	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>