2. Initial Review Procedures

2.1 Management of Protocol Submissions
2.2 Use of Study Assessment Forms
2.3 Expedited Review
2.4 Full Board Review of Submitted Protocols
2.5 Review of a Medical Device Study

Supersedes:	None
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2.1. Management of Protocol Submission

2.1.1. Purpose

To describe the initial review procedures of the Institutional Review Board (IRB) from the time that the IRB receives the protocol and related documents until the approval letter is sent by the IRB to the Principal Investigator

2.1.2. Scope

The Bicol University College of Medicine IRB accepts the following protocols for review: 1) Bicol University College of Medicine funded researches, 2) researches done in Bicol University College of Medicine, 3) researches referred from the PNHRS, PHREB, DOH, industry organizations, etc., on the condition that the host hospital/ institution where the proposal will be done accepts the review of Bicol University College of Medicine IRB and agrees to abide by the rules and regulations that the Bicol University College of Medicine IRB follows (based on PHREB and FIRBAP rules). The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept Bicol University College of Medicine IRB review.

2.1.3. Responsibility

The IRB Secretariat manages all protocol submissions to the IRB. It covers the actions to be done from the time of submission to the filing of the original protocol package in the Active Study File cabinet and the preparation of copies of the documents for distribution to the reviewers

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2.1.4. Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the initial protocol package for review and check the completeness of the documents together with the IRB Application Form signed by the PI and the protocol summary sheet	Secretariat
2	Assign a permanent code to the package	Secretariat
3	Make a duplicate of the application form and give the duplicate to the person submitting the package and attach the original copy to the protocol package to be kept in the IRB files	Secretariat
4	Log the received protocol in the IRB database	Secretariat
5	Make copies of the protocol package and prepare them for distribution to the reviewers	Secretariat
6	File the original package in a properly coded Protocol File folder and place it in the Active Study File cabinet	Secretariat

Detailed instructions

Note:

- All protocols need technical approval prior to ethical review. For Bicol University College of Medicine IRB-funded protocols, the Technical Review Committee should have addressed the technical issues apparent to the study protocol. For non- Bicol University College of Medicine IRB funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Upon submission of the initial protocol for Bicol University College of Medicine IRB review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet **(Form 2.2)**

2.1.5. Ensure that the PI has signed the Bicol University College of Medicine IRB Application Form for Protocol Review **(Form 2.1),** make a copy of the filled-in application form, keep the

original copy for the IRB files and give the duplicate to the principal investigator (PI) or his/her representative.

2.1.6. Assign a code to the package. The code will be communicated to the principal investigator in subsequent communications regarding the protocol.

2.1.7. Check the documents being submitted based on the IRB checklist.

A protocol package has to include the following:

- Review Checklist **(BUCM-IRB-2.5)**
- 8 Copies of Complete Research Protocol
- 8 Copies of Informed Consent Forms
- Accomplished Application Review Form **(BUCM-IRB-2.1)**
- Protocol Summary Sheet **(BUCM-IRB-2.2)**
- Protocol Evaluation Form **(BUCM-IRB-2.3)**
- Informed Consent Evaluation Form **(BUCM-IRB-2.4)**
- Study Tools (all data tools)
- Study drug/medical device information (Investigative brochure and relevant literatures)
- CV of PI and study team members (include proof of relevant literatures)
- Electronic copy of study protocol & **BUCM-IRB FORMS 2.1-2.5**
- Information regarding fund, sponsor, institution application
- Study/protocol budget
- Contract of MOAs, MTAs, IPO, IDE, and other relevant approval documents
- Previous IRB and approval result (if any)

2.1.8. Log the protocol in the IRB database.

2.1.9. Manage the protocol package:

For protocols requiring a full board review:

- Make sufficient copies of the protocol package for the IRB files, for each of the primary reviewers, and for each IRB member. Put the original copies in a protocol file folder.
- Put the code of the protocol on the side of the file folder.
- File the folder in the Active Study Files cabinet.

For protocols that can be subjected to expedited review,

- Make 4 copies of the protocol package for the IRB files and for each reviewer. Put the original copies in a protocol file folder.

- Put the code of the protocol on the side of the file folder.
- File the folder in the Active Study Files cabinet.

2.1.10. Prepare the copies of protocol for distribution to the reviewers. Include blank copies of the “Reviewer Assessment Form" **(Form 2.3)** and the “Informed Consent Evaluation Form" **(Form 2.4)** in the package.

2.1.11. Enter in the IRB databasethe names of the primary reviewers to whom the packages are to be delivered. Prepare a transmittal letter with the name of the reviewer, the date of actual delivery to be signed by the reviewer or a representative upon receipt.

Note:

Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to both medical and non medical or lay members, institutional and non-institutional members for review. The medical/ scientific members analyze the scientific and ethical procedures in the protocol while the lay/ non-institutional members focus their assessment on the informed consent form.

2.2. Use of Study Assessment Forms

2.2.1. Purpose

To describe the procedures related to the use of study assessment forms in ethics review

2.2.2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to Bicol University College of Medicine IRB for initial review and approval by the IRB. The IRB uses two study assessment forms. The two assessment forms are accomplished by individual reviewers. Any comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two forms.

The Study Assessment Forms are designed to standardize the review process and to facilitate reporting of recommendation

and comments given to each individual protocol and related documents.

There are two (2) Bicol University College of MedicineIRB Assessment Forms for protocol review (see Annex for samples):

a. Study Protocol Evaluation Form **(Form 2.3)**
b. Informed Consent Evaluation Form **(Form 2.4)**

2.2.3. Responsibility

It is the responsibility of the Bicol University College of MedicineIRB reviewers to individually fill-in the assessment forms after reviewing each study protocol. The Secretariat is responsible for recording and filing the **Bicol University College of Medicine** IRB's action, relevant points and deliberation about a particular protocol, including the comments for specific action. The consensus/ agreements regarding the decisions on each reviewed protocol will be reflected in the Minutes of the meeting.

2.2.4. Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Fill up the Study Assessment Forms during review of the study protocol and related documents.	Primary Reviewers
2	Submit accomplished Study Assessment Forms to the Secretariat	Primary Reviewers
3a	Include the protocol in the agenda of the meeting if it is classified under full board review	Secretariat
3b	In expedited review, communicate the comments of the reviewers to the principal investigator for revision	Secretariat
4	Prepare an Approval Letter once the protocol is approved	Secretariat
5	File copies of duly accomplished forms in the Study File folder of the particular protocol	Secretariat

Detailed instructions

2.2.5. The Bicol University College of MedicineIRBreviewer checks if the two Study Assessment Forms (Study Protocol Evaluation Formand Informed Consent Evaluation Form) are attached with each protocol package received for review.

2.2.6. The IRB primaryreviewers individually fills in both forms for each protocol.

2.2.7. The Evaluation Forms include some important items.

The Study Protocol Evaluation Form ensures assessment of the scientific and ethical aspects of the protocol that may include:

- Rationale and significance of the study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria
- Vulnerability determination
- Risk/ benefit assessment

The Informed Consent Evaluation Form checks if the following are complied with:

- Full disclosure of information, including risks
- Benefits that may be derived from the study
- Use of understandable language
- Voluntary participation
- Confidentiality
- Appropriate person to sign the consent form

2.2.8. The primary reviewer signs and submits the evaluation forms together with the reviewed protocol back to the Secretariat.

2.2.9. The Secretariat checks whether the forms are complete, compiles the checklists and submits these to the Member-Secretary and/or Chair.

2.2.10. The Member-Secretary and/or Chair reviews the compiled checklists.

2.2.11. In expedited review, if the protocol is approved, the Secretariat prepares the approval letter that is signed by the Chair and sent to the principal investigator. If there are revisions required, they are communicated to the PI who has to resubmit the revised protocol and related documents before approval is given.

2.2.12. In full board review, the Secretariat includes the protocol in the agenda of the next Bicol University College of Medicine IRB meeting for discussion and decision. An approval letter is prepared, signed by the Chair and sent to the PI once a protocol is approved. If there are revisions required, they are communicated to the PI who has to resubmit the revised protocol and related documents before approval is given.

2.2.13. A copy of the signed letter is retained in the protocol file folder.

2.3. Expedited Review

2.3.1. Purpose

To describe the procedures for the review of protocols that qualify for expedited review

2.3.2. Scope

This SOP applies to the review and approval of study protocols or amendments with minimal risk to study participants and minor revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

The following are types of protocols can be subjected to expedited review after initial submission:

a. Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
b. Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
c. Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
d. Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis
e. Proposed continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to study participants.

Criteria for Expedited Review of Resubmissions/ Amendments/ Reports

- Administrative revisions, such as correction of typing errors
- Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.

- The research activity includes only minor changes from previously approved protocol.
- Minor protocol amendments that do not change the risk/ benefit assessment
- Progress/ Final reports that do not deviate from approval given by the IRB
- SAEs from foreign sites

2.3.3. Responsibility

Expedited review is the responsibility of primary reviewers appointed to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

2.3.4. Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forward to the Chair or Member-Secretary	Secretariat
2	Determine that the protocol is for expedited review	Member-Secretary/ Chair
3	Assign reviewers for the expedited review	Member-Secretary / Chair
4	Do the expedited review and submit the decision to the Secretariat	Reviewers
5a	Communicate the decision for approval or revision to the PI	Secretariat
5b	If modifications are required, revise the protocol or related document and resubmit to the IRB	Principal Investigator
5bi	Check and review revisions	Reviewers
5bii	Prepare an Approval Letter to be signed by the Chair and sent to the PI	Secretariat
6	Report results of expedited review to full board	Secretariat

7	Keep copies of related documents in the files	Secretariat
8	Update the IRB database	Secretariat

Detailed instructions

2.3.5. The Secretariat receives thedocuments submitted for initial review. Receive the application documents submitted by investigators. Check items received using checklist as guide. Sign a copy of the application form to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

2.3.6. The Chair nominates two or more Bicol University College of Medicine IRB members (Medical member with related expertise to review the protocol and a non-medical person to review the informed consent.) The Secretariat sends the protocol and related documents to the selected primary reviewers. An independent consultant may be invited to provide expert opinion about a protocol.

2.3.7. The members carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.)

2.3.8. If consensus cannot be reached, the Chair will refer the protocol to IRB board for full review.

2.3.9. The decision is communicated to the principal investigators. If modification is required, the PI makes the necessary revisions and resubmits to the IRB.

2.3.10. The reviewers review the modifications for approval.

2.3.11. An approval letter is prepared and signed by the Chair and sent to the principal investigator.

2.3.12. Review of Resubmission, Amendments, Reports

- The Secretariat checks if the appropriate IRB forms were used and checks the completeness of documents.
- The documents are sent to the original reviewers to review.
- The reviewers review the documents and make sure that there is no change in the risk/ benefit ratio before approving the documents. Reviewers may request for clarification before recommending approval. Reviewers may refer the documents for full board in case there are issues that need resolution.
- The reviewers recommend approval if there are no issues.
- The PI is notified about approval.
- The results are summarized and reported to full board for information purposes.
- Copies of all documents are kept in the protocol files.
- The IRB database is updated.

2.4. Full Board Review of Submitted Protocols

2.4.1. Purpose

To describe the procedures when protocol submissions are classified for full board review

2.4.2. Scope

This SOP applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

2.4.3. Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms and make a recommendation for appropriate action.

The following are types of protocols that should undergo full board review after initial submission:

- Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
- Phase 4 intervention research involving drugs, biologics or device
- Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
- Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review
- Protocols that involve collection of identifiable biological specimens for research

Criteria for Full Board Review of Resubmissions/ Amendments/ Reports

- Major revisions of the protocol and informed consent after initial review
- Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
- Major amendments that change the risk/ benefit ratio

- Major protocol violations
- Progress/ Final reports that deviate from original approval given by the IRB
- Onsite SAEs or SUSARs that may require protocol amendment or reconsent of participants

The Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the **Bicol University College of Medicine**IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated. It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments and put all of this in the Study Assessment Forms before returning the reviewed protocol and assessment form to the Secretariat on the due date.

2.4.4. Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forwards to the Chair or Member-Secretary	Secretariat
2	Determine that the protocol qualifies for Full Board review	Member-Secretary/ Chair
3	Assign reviewers to review the protocol and related documents	Member-Secretary/ Chair
4	Review the protocol documents using the assessment forms and submit the decision/ recommendation to the Secretariat	Primary Reviewers
5	Include the protocol in the meeting agenda for discussion to arrive at a decision through full board	Secretariat/ Members

6	If modifications are required, revise the protocol or related document and resubmit to the IRB	Principal Investigator
7	Check and review revisions and refer to full board for decision	Primary Reviewers
8	After board approval, prepare the Approval Letter to be signed by the Chair and sent to the PI	Secretariat
9	Keep copies of all documents in the files	Secretariat
10	Update the protocol entry in the IRB database	Secretariat

Detailed Instructions

2.4.5. Receive the protocol package
- Check the completeness of the protocol package.
- Fill in the "Document Receipt Form" (Form 3.0 (A) 2011) upon receiving the package, indicate the date and affix reviewer's signature.
- Return the signed acknowledgment form back to the representative of the principal investigators

2.4.6. Determine if the protocol qualifies for full board review, select primary reviewers with appropriate qualifications (clinician/ scientist with expertise related to the protocol and a non medical person to review the consent form.) An independent consultant may be invited to provide expert opinion.
- Send the protocol files together with the assessment forms to the primary reviewers/ independent consultant.
- Note the due date for submitting the results (accomplished checklists) and the protocols back to theIRB Secretariat.

2.4.7. Review the Protocol
a. Use the Protocol Evaluation Form (**Form 2.3**) for the protocol and the Informed Consent Evaluation Form (**Form 2.4**) to review the protocol and the consent form and write relevant comments

b. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements.

- Consider whether study and training background of the principal investigator/s are related to the study.
- Look for disclosure or declaration of potential conflicts of interest.
- Non-physician principal investigators should be advised by a physician when necessary.
- Determine if the facilities and infrastructure at study sites can accommodate the study.

c. Check the "Assent Form" if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

2.4.8. The primary reviewers are advised to note the following **Review Guidelines:**

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
- In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized.
- Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coIRBive recruitment of study participants.
- The Informed Consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure for getting the Informed Consent is clear and unbiased.

- The persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
- There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact persons with address and phone numbers are included in the Informed Consent.
- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.

2.4.9. Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:

- Community consultation
- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment in benefit to local communities
- Sharing of study results with the participants/ community

2.4.10. After reviewing the protocol and the documents, the reviewer recommends a decision.

- Record the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision for resubmission, or Disapproved.
- Include comments and reasons for disapproval.
- Check the completeness and correctness of marked items in the assessment forms. Indicate the date and affix the reviewer's signature in the decision form.

2.4.11. Submit the completed forms to the Secretariat together with the protocol documents.

2.4.12. Include the protocol in the next meeting agenda.

2.4.13. Conduct a full board meeting to discuss and make a decision about the protocol and related documents.

2.4.14. For **Bicol University College of Medicine**funded proposals, a member of the TRC shall sit in the full board meeting as a consultant to explain technical issues. For non- **Bicol University College of Medicine**funded proposals, theIRB may request for comments/ approval from otherIRB -TRC to provide additional inputs as deemed necessary.

2.4.15. The members of theIRB attending the full board meeting arrive at a decision on the protocol for approval, minor revision, major revision for resubmission or disapproval.

2.4.16. If the study is approved, the **Bicol University College of Medicine**IRB determines the frequency of continuing review.

2.4.17. The Secretariat sends an Action Letter/ Approval Letter (**Form 2.5**) with a list of approved documents to the principal investigator.

2.4.18. The letter contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the principal investigator throughout the course of the study.

2.4.19. If the **Bicol University College of Medicine**IRB votes not to approve the study, the Secretariat immediately notifies the principal investigator in writing about the decision and the reason for not approving the study.

2.4.20. If the principal investigator wishes to appeal the IRB decision, he/she may do so through a written request submitted to the **Bicol University College of Medicine**IRB.

2.4.21. If the **Bicol University College of Medicine**IRB requires modifications to any of the documents, the Secretariat prepares a letter to the Principal Investigator and identifies the necessary revisions to the documents before resubmission to theIRB.

2.4.22. If the protocol is approved, the Secretariat drafts the approval letter, forwards it to the Chair to sign, then sends it to the principal investigator. There should be a file/received copy with specific date. All information regarding the date of the **Bicol University College of Medicine**IRB decision such as the date when decision was written and signed by the Chair, and date when it was delivered to the principal investigator, are entered in the IRB database.

2.4.23. All meeting deliberations and decision regarding a protocol are noted in the meeting minutes, with relevant sections filed in the specific protocol file.

2.4.24. The IRB database is updated to record the decision. Copies of the assessment forms are kept in the protocol files.

2.5. Review of a Medical Device Protocol

2.5.1. Purpose

To describe procedures in the review of medical device protocols submitted to the IRB

2.5.2. Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the **Bicol University College of Medicine**IRB.

Medical device protocols are reviewed through the same expedited or full board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the IRB. The IRB should make provisions to minimize the risks to human participants during review of the protocol and related documents.

2.5.3. Responsibility

It is the responsibility of the IRB members to review medical device protocols in accordance with international and national guidelines and regulations.

2.5.4. Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receive the submitted documents and forward to the Chair or Member-Secretary	Secretariat
2	Determine if the protocol is for Expedited or Full Board review depending on SR or Non SR determination	Member-Secretary/ Chair
3	Assign primary reviewers to review the protocol and related documents	Member-Secretary/ Chair
4	Conduct the review using the assessment forms and submit the decision/ recommendation to the Secretariat	Primary Reviewers
5a	Expedited Review: Communicate the decision from expedited reviewers for approval or revision to the PI	Secretariat
5b	Full Board Review: Include the protocol in the meeting agenda for discussion and decision by full board	Secretariat
6	If modifications are required, revise the protocol or related document and resubmit to the IRB	Principal Investigator

7	Check and review revisions	Primary Reviewers
8	Prepare an Approval Letter to be signed by the Chair and sent to the PI	Secretariat
9	Keep copies of related documents in the files	Secretariat
10	Update the protocol entry in the IRB database	Secretariat

Detailed Instructions

2.5.5. The same procedures are followed when the protocol is submitted for initial review.

When reviewing a medical device protocol, the reviewer should consider the following:

- Proposed investigational plan
- Informed consent form
- Description of the device/ Product information
- Description of study participant selection criteria
- Safety monitoring procedures
- Reports of prior investigations conducted with the device
- Principal investigator's curriculum vitae
- Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk)
- Statistical plan and analysis
- Copies of all labeling for investigational use

2.5.6. The Secretariat checks the information/communication from the principal investigator related to the Significant Risk (SR) or Non Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The protocol is assigned to expedited or full board review depending on the risk assessment.

2.5.7. Primary reviewers with appropriate expertise are assigned to review the protocol related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical

experience are assigned to review the protocol while a lay person/ non medical member reviews the consent form.

2.5.8. The same IRB assessment forms are used for review and the primary reviewers make a decision in expedited review or make a recommendation for discussion during the next full board meeting.

2.5.9. For full board review, a decision is made after discussion. If the protocols are for revision, they are sent back to the principal investigator for modification. The documents are resubmitted and reviewed through expedited channel for minor revision and sent to full board for review of major revisions.

2.5.10. Once an approval decision is reached, the approval letter is prepared, signed by the Chair and communicated to the principal investigator. The frequency of continuing review is indicated in the approval letter.

2.5.11. The relevant documents are kept in the protocol file and the IRB entry about the protocol is updated.

APPLICATION FORM FOR PROTOCOL REVIEW (FORM 2.1)

IRB Protocol Number:	

Sponsor Protocol Number:		Submission Date:	

Type of Submission:

- ☐ Initial Review
- ☐ Continuing Review
- ☐ Resubmission for re-review
- ☐ Protocol Termination
- ☐ Protocol Amendments
- ☐ Final Report

Protocol Title:	
Principal Investigator:	

Telephone number:		Fax:	

E-mail:		Preferred Contact	☐ Phone ☐ Fax ☐ Email
Institute:			
Sponsor:			

Conflict of Interest Declaration (Relationship with sponsor)

Are you a regular employee of the sponsor?	☐ Yes	☐ No
Did you do consultancy or part time work for the sponsor?	☐ Yes	☐ Yes
In the past year, did you receive P250,000 or more from the sponsor?	☐ Yes	☐ Yes
Other ties with the sponsor		

PI Signature:	

Documents submitted:

- ☐ Protocol summary
- ☐ Patient information form
- ☐ CVs
- ☐ GCP certificates

Type of Research (Clinical Trial, Genetic, Social Science)

- ☐ Informed consent form
- ☐ Advertisement
- ☐ Investigator brochure
- ☐ Protocol summary
- ☐ Case report forms (CRF)
- ☐ Research team list
- ☐ Study budget
- ☐ Revised protocol
- ☐ Revised consent form
- ☐ Amendments
- ☐ Others:

Phase 1,2,3,4: _____

Study duration _____

Received by: _____

Date: _____

PROTOCOL SUMMARY SHEET

IRB Protocol No:	Title

Principal Investigator	Sponsor

Rationale	
Objectives	
Study Design/ Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	

PROTOCOL EVALUATION FORM (FORM 2.3)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Principal Investigators:			
Department		Contact no./ Email	
Co – investigator(s):		Contact no./ Email	
Total No. of Participants:		No. of Study Sites:	
Sponsor		Contact No/ Email	
Duration of the Study:		Status:	☐ New ☐ Amended
Reviewers:			
Type of the Study	☐ Intervention ☐ Document review ☐ Social Survey	☐ Epidemiology ☐ ☐ Individual based Others, specify	☐ Observational study ☐ Genetic ☐
Review Status	☐ Full Board	☐ Expedited	

Description of the Study in brief: Mark whatever applies to the study.

☐ Randomized	☐ Drug	☐ Use of Genetic Materials
☐ Double blind	☐ Medical Device	☐ Multicenter study
☐ Single blind	☐ Vaccine	☐ Global protocol
☐ Open label	☐ Diagnostics	☐ Sponsor Initiated
☐ Observational	☐ Questionnaire	☐ Investigator Initiated

PROTOCOL DOCUMENT REVIEW

1.	Objectives of the Study ☐ clear ☐ unclear	What should be improved?	
2.	Need for Human Participants ☐ Yes ☐ No	Comment:	
3.	Methodology: ☐ clear ☐ unclear	What should be improved?	
4.	Background Information and Data ☐ sufficient ☐ insufficient	Comment:	
5.	Risks and Benefits Assessment ☐ acceptable ☐ unacceptable	Comment:	
6.	Inclusion Criteria ☐ appropriate ☐ inappropriate	Comment:	
7.	Exclusion Criteria ☐ appropriate ☐ inappropriate	Comment:	
8.	Withdrawal Criteria ☐ appropriate ☐ inappropriate	Comment:	
9.	Involvement of Vulnerable Participants ☐ Yes ☐ No	Comment:	
10.	Voluntary, Non-CoIRBive Recruitment of Participants ☐ Yes ☐ No	Comment:	
11.	Sufficient number of participants? ☐ Yes ☐ No	Comment:	
12.	Control Arms (placebo, if any)	Comment:	

☐ Yes ☐ No

13. Are the qualifications and experience of the participating investigators appropriate?
☐ Yes ☐ No
Comment:

14. Disclosure or Declaration of Potential Conflicts of Interest
☐ Yes ☐ No
Comment:

15. Facilities and infrastructure of participating sites
☐ Appropriate ☐ Inappropriate
Comment:

16. Objectives of the Study
☐ clear ☐ unclear
What should be improved?

17. Need for Human Participants
☐ Yes ☐ No
Comment:

18. Methodology:
☐ clear ☐ unclear
What should be improved?

19. Background Information and Data
☐ sufficient ☐ insufficient
Comment:

20. Risks and Benefits Assessment
☐ acceptable ☐ unacceptable
Comment:

21. Inclusion Criteria
☐ appropriate ☐ inappropriate
Comment:

22. Exclusion Criteria
☐ appropriate ☐ inappropriate
Comment:

23. Withdrawal Criteria
☐ appropriate ☐ inappropriate
Comment:

24. Involvement of Vulnerable Participants
☐ Yes ☐ No
Comment:

25. Voluntary, Non-CoIRBive Recruitment of Participants
☐ Yes ☐ No
Comment:

26. Sufficient number of participants?
☐ Yes ☐ No
Comment:

27. Control Arms (placebo, if any)
☐ Yes ☐ No
Comment:

28. Are the qualifications and experience of the participating investigators appropriate? ☐ Yes ☐ No	Comment:
29. Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
30. Facilities and infrastructure of participating sites ☐ Appropriate ☐ Inappropriate	Comment:
31. Community Consultation ☐ Yes ☐ No	Comment:
32. Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No	Comment:
33. Contribution to local capacity building ☐ Yes ☐ No	Comment:
34. Benefit to local communities ☐ Yes ☐ No	Comment:
35. Sharing of study results ☐ Yes ☐ No	Comment:
36. Are blood/tissue samples sent abroad? ☐ Yes ☐ No	Comment:

A. RECOMMENDATION

DECISION :	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Comments (Identify items for revision.)	

Reviewer's Name		Date:	

Signature :	

INFORMED CONSENT EVALUATION FORM (FORM 2.4)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Principal Investigators:			

A. INFORMED CONSENT DOCUMENT REVIEW

1. Does the Informed Consent document state that the procedures are primarily intended for research?
   ☐ Yes ☐ No
   Comment:

2. Are procedures for obtaining Informed Consent appropriate?
   ☐ Yes ☐ No
   Comment:

3. Does the Informed Consent document contain comprehensive and relevant information?
   ☐ Complete ☐ Incomplete
   Comment:

4. Is the information provided in the protocol consistent with those in the consent form?
   ☐ Consistent ☐ Inconsistent
   Comment:

5. Are study related risks mentioned in the consent form?
   ☐ Complete ☐ Incomplete
   Comment:

6. Is the language in the Informed Consent document understandable?
   ☐ Clear ☐ Unclear
   Comment:

7. Is the Informed Consent translated into the local language/dialect?
   ☐ Clear ☐ Unclear
   Comment:

8. Is there adequate protection of vulnerable participants?
   Comment:

☐ Yes ☐ No

9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?
☐ Complete ☐ Incomplete
Comment:

10. Are names and contact numbers from the research team and the IRB in the informed consent?
☐ Yes ☐ No
Comment:

11. Does the ICF mention privacy & confidentiality protection?
☐ Yes ☐ No
Comment:

12. Is there any inducement for participation?
☐ Unlikely ☐ Likely
Comment:

13. Is there provision for medical / psychosocial support?
☐ Appropriate ☐ Inappropriate
Comment:

14. Is there provision for treatment of study-related injuries
☐ Appropriate ☐ Inappropriate
Comment:

15. Is there provision for compensation?
☐ Appropriate ☐ Inappropriate
Comment:

B. Recommendation

DECISION :	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Comments (Identify items for revision.)	

Reviewer's Name		Date:	

Signature :	

Review Checklist (FORM 2.5)

STUDY PROTOCOL INFORMATION

Reference Number:	
BUCM-IRB Code:	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date: *(to be accomplished by BUCM-IRB Staff)*	<dd/mm/yyyy>
Verified Complete by: *(to be accomplished by BUCM-IRB Staff)*	<Signature over Printed Name>
Classification of Review: *(to be accomplished by BUCM-IRB)*	☐ **EXPEDITED** ☐ **FULL BOARD**
Classified by the: ☐ **BUCM-IRB CHAIR** ☐ **BUCM-IRB COORDINATOR**	<Signature over Printed Name>

Basic Documents (must submit)

- ☐ Review Checklist **[BUCM-IRB-2.5]**
- ☐ 8 Copies of Complete Research Protocol
- ☐ 8 Copies of Informed Consent Forms
- ☐ Accomplished Application Review Form **[BUCM-IRB-2.1]**
- ☐ Protocol Summary Sheet**[BUCM-IRB-2.2]**
- ☐ Protocol Evaluation Form **[BUCM-IRB-2.3]**
- ☐ Informed Consent Evaluation Form**[BUCM-IRB-2.4]**
- ☐ Study tools (all data tools)
- ☐ Study drug/medical device information (Investigative brochure and relevant literatures)
- ☐ CV of PI and study team members (include proof of relevant literatures)
- ☐ Electronic copy of study protocol &**BUCM-IRB FORMS 2.1 to 2.5**
- ☐ Information regarding fund, sponsor, institution application
- ☐ Study/protocol budget
- ☐ Contract of MOAs, MTAs, IPO, IDE and other relevant approval documents
- ☐ Previous IRB and approval result (if any)

Reviewed and verified by :

_____
IRB Secretariat

Classification :

- ☐ Expedited Review
- ☐ Full-committee Review

NOTIFICATION OF IRB DECISION (FORM 2.6)

Date _____

To: (Name of PI) _____
Contact No. _____

This is to inform you of the IRB decision related to your application for review of the following documents:

IRB Protocol No.		Sponsor Protocol No	

Type of submission
- ☐ Initial review
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Documents submitted

Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

Type of review	IRB Decision	Details of Action Required from the PI
☐ Expedited	☐ Approved	
☐ Full board	☐ Minor revisions required	
Meeting Date:	☐ Major revisions required	
_____	☐ More information required	
	☐ Others _____	

IRB Chair Person	Name	Signature	Date

APPROVAL LETTER (FORM 2.7)

Date _____

This is to certify that the following protocol and related documents have been granted approval by the **Bicol University College of Medicine**IRB for implementation

IRB Protocol No.		Sponsor Protocol No	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From (date) To	Frequency of continuing review

IRB Chair Person	Name	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments for IRB approval before implementing them
- Submit SAE and SUSAR reports to the IRB within 7 days
- Submit progress report every month
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation/ violation
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research

Received by: _____

Name _____

Signature _____ Date _____