

1. IRB Structure and Composition

- 1.1. Ethical Framework and Constitution of the IRB
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- 1.3. Selection of Independent Consultants
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- 1.5. Incentives for IRB Members and Consultants

| | |
|-----------------|---|
| 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, M.D., PhD., Dean |
| Approval Date: | July 4, 2014 |



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1.1. Ethical Framework and Constitution of the IRB

1.1.1. Purpose

To describe the composition and structure of the **Bicol University College of Medicine, Institutional Review Board (IRB)**, in compliance with national and international guidelines in ethical research

1.1.2. Specific Objectives

To describe the following IRB procedures and define the Terms of reference for the Bicol University College of Medicine, Institutional Review Board related to:

- Constitution of the IRB
- Confidentiality/Conflict of Interest Agreement with IRB members, staff and consultants
- Training of Personnel and IRB Members
- Selection of Independent Consultants
- Incentives for IRB Members and Consultants

1.1.3. Scope

The **Bicol University College of Medicine, Institutional Review Board** is an independent body created by the **Bicol University College of Medicine**, under the Dean, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in health related research and to provide public assurance of that protection. In accordance with applicable national/international regulations, the Bicol University College of Medicine IRB has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval.

The Bicol University College of Medicine, IRB reviews and monitors health researches that involve:

- Bicol University College of Medicine – BRTTH patients, done within the hospital premises by its staff and non-affiliated organizations,

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- Protocols done by Bicol University College of Medicine, full-time staff in areas outside the hospital premises, except researches undertaken by part time hospital staff done outside the hospital.

This SOP provides the Terms of Reference (TOR), that describe the framework for the constitution of the Bicol University College of Medicine, the responsibilities and activities of its officers, members, staff and consultants.

1.1.4. Responsibility

It is the responsibility of the IRB members, officers, and secretariat to understand and implement the SOPs of the Bicol University College of Medicine, Institutional Review Board.

1.1.5. Ethical basis

- a. The Bicol University College of Medicine, Institutional Review Board is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents:
 - Declaration of Helsinki (2008 and subsequent revisions)
 - CIOMS 2002 and 2009
- b. The IRB will function in accordance with national laws, regulations, and guidelines.
- c. The IRB provides its own standard operating procedures based on:
 - Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO)
 - Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)
 - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
 - National Ethical Guidelines for Health Research (2012) by the Philippine Health Research Ethics Board (PHREB)
 - Philippine Food and Drug Authority regulations and other relevant laws and regulations
- d. The IRB adheres to national and international ethical standards and recognizes that the protocols it approves may



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also be approved by national and/or local ethics committees prior to their implementation in specific localities.

- e. In evaluating protocols and ethical issues, the IRB is cognizant of the diversity of laws, cultures and practices governing health research in various countries around the world.
- f. It attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed Bicol University College of Medicine, research is being considered.
- g. The IRB will take the initiative to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research that it has approved.

1.2. Appointment of IRB Members

1.2.1. Purpose

To describe the appointment procedures of the members of the Bicol University College of Medicine, Institutional Review Board and to identify the roles and responsibilities of IRB officers and members.

1.2.2. Scope

While the Bicol University College of Medicine IRB remains under the authority of the Dean, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines. The membership SOPs cover the nomination and appointment procedures of IRB members, officers and independent consultants.

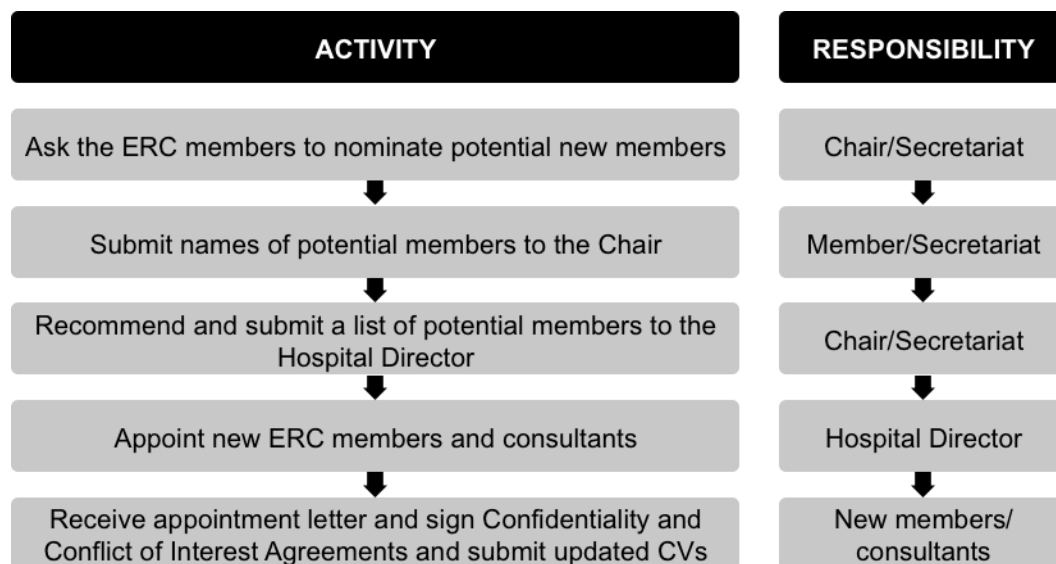
1.2.3. Responsibility

It is the responsibility of the Bicol University College of Medicine Dean to formally appoint the members and officers and consultants of the IRB after due consultation with the current members of the IRB and confirmed by the University President.

1.2.4. Process Flow/Steps

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1.2.5. Requirements for Membership/Independent Consultants

- IRB Membership
 - The Bicol University College of Medicine IRB shall be composed of at least **8** members.
 - Its membership shall be multidisciplinary and multisectoral. The IRB members should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by the Bicol University College of Medicine staff and non affiliated organizations.
 - The membership shall include persons whose primary concerns are in medical science, at least one member who is a pediatrician, at least one member who is in a non-medical/ non-scientific area, and at least one member who is non-affiliated.
 - Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the IRB should include a person who will represent the interest and concerns of the community.
 - The IRB shall aim for gender balance in its membership with equal representation of men and women members in



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order to promote gender sensitivity in its review procedures.

- The IRB shall have representatives from both the older and younger generations.
- The IRB shall invite independent consultants, whenever necessary, to provide expert opinion related to protocols under review.
- The IRB shall have an office and adequate support staff for carrying out its responsibilities.
- The IRB shall adhere to quorum requirements as defined in international and national guidelines for IRBS that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting.

1.2.6. Nomination/ Appointment

- Current IRB members shall nominate candidates for new members and independent consultants to the Chair/ Secretariat
- The Chair discusses the qualifications of the nominees and submits the list to the Hospital Director
- The Hospital Director selects from the list of nominees for IRB members and consultants and issues an appointment letter.

1.2.7. Terms of Office

- The appointing authority shall indicate in the appointment letter the IRB's functions, terms of office, scope of work, conditions of appointment, system of replacement or recall, and compensation, if any. Members are appointed for a period of *two (2) years*.
- Their appointments may be renewed by the Appointing Authority for up to *three (3) consecutive terms*.
- The IRB shall adopt some mechanism for rotation of its membership roster, to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, the development and maintenance of expertise.

Qualifications/ Appointment of Members

- 1.2.7.1. The Dean of the Bicol University College of Medicine is responsible for appointing IRB members and consultants upon the recommendation of the IRB Chair.
- 1.2.7.2. Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to volunteer their time and effort to perform their functions in the IRB.
- 1.2.7.3. Members shall have prior training in Good Clinical Practice, research methodology and research Ethics, or should be willing to undergo such training during their membership.
- 1.2.7.4. Members shall disclose in writing any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
- 1.2.7.5. Members shall submit their curriculum vitae, properly signed and dated and update them at least once every two years.
- 1.2.7.6. Members will be required to sign a confidentiality/conflict of interest agreement at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The Secretariat/ Administrative staff is likewise expected to sign a similar document.
- 1.2.7.7. The IRB shall decide on how to manage specific conflicts of interest of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions of the Confidentiality/Conflict of Interest Agreements.
- 1.2.7.8. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work.

1.2.8. Conditions of Appointment of Members

All prospective IRB members shall be willing:



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- 1.2.8.1. To make public his/her full name, profession, and affiliation as an IRB member,
- 1.2.8.2. Disclose all financial accountability, reimbursement for work and expenses, related to their work in the Bicol University College of Medicine IRB that shall record and publicly disclose its financial records upon request.
- 1.2.8.3. All IRB members and Independent Consultants shall sign the Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

1.2.9. Resignation, Disqualification, and Replacement of Members

- Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Bicol University College of Medicine Dean.
- Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- Members that have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

1.2.10. IRB Officers

The following officers through the exercise of their respective responsibilities contribute to efficient IRB operation:

| | |
|---------|--|
| Chair | <ul style="list-style-type: none"> • Presides over the IRB meetings and is accountable to the Bicol University College of Medicine Dean. • Prepares an annual report summarizing IRB activities and decision outcomes to the Bicol University College of Medicine Dean • Ensures sufficient financial and administrative support for IRB operations • Represents the IRB interests within the hospital administration • Represents the IRB to the outside world |
| Member- | <ul style="list-style-type: none"> • To be appointed by the committee chair and to |

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Secretary

be confirmed by the members.

- Supervises the IRB staff
- Decides which protocols may be expedited
- Assigns primary reviewers
- Ensures good IRB documentation
- Ensures overall IRB compliance with good clinical practice.

1.2.11. IRB Secretariat

- The Bicol University College of Medicine IRB secretariat is composed of the **Member-Secretary** and administrative support staff who are employees of the Bicol University College of Medicine and appointed by the Dean.
- The Secretariat shall have the following functions:
 - Organizing an effective and efficient tracking procedure for each proposal received
 - Preparation, maintenance and distribution of study files
 - Organizing IRB meetings regularly
 - Preparation and maintenance of meeting agenda and minutes
 - Maintaining good IRB documentation and archiving procedures
 - Communicating with the IRB members and Investigators
 - Arrangement of training for personnel and IRB members
 - Organizing the preparation, review, revision and distribution of SOPs and guidelines;
 - Providing the necessary administrative support for IRB-related activities to the Chair of the IRB
 - Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the IRB members
 - Maintaining a library of relevant resource materials and references

1.2.12. Roles and Responsibilities of IRB Members

- Participate in IRB meetings
- Review, discuss and consider research proposals submitted for evaluation



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- Assess serious adverse event reports and recommend appropriate action
- Review progress reports and monitor ongoing studies as appropriate
- Evaluate final reports
- Maintain confidentiality of the documents and deliberations during IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in health research and ethics

1.2.13. Confidentiality/Conflict of Interest Agreement

- The Secretariat provides a copy of the agreement form to each member of the Bicol University College of Medicine IRB together with the appointment letter.
- It is the responsibility of all IRB members to read, understand, accept and sign the agreement contained in the Confidentiality/ Conflict of Interest form before beginning their ethical review functions.
- If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in the Bicol University College of Medicine IRB.
- Newly appointed members obtain two copies of the Agreement Form read the text very carefully, fill in their names, sign and date the forms.
- Any member may ask questions, or ask for a clarification from the Chair or Secretariat related to the contents of the document.
- The members keep a copy for their records. The Secretariat keeps a copy of the signed Agreement in the membership files.

1.3. Selection of Independent Consultants

1.3.1. Purpose

To describe the procedures for the appointment of IRB consultants

1.3.2. Scope

This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the Bicol University College

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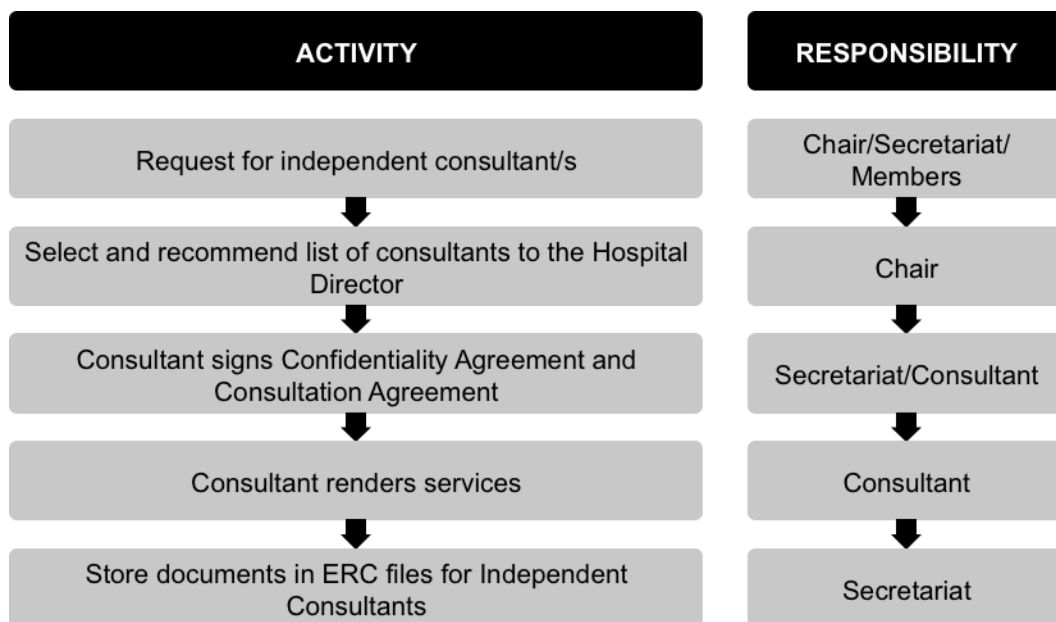
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of Medicine IRB. If the Chair of the Bicol University College of Medicine IRB determines that a study involves procedure(s) that are not within the area of competence or expertise of the IRB members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IRB.

1.3.3. Responsibility

Upon the advice or recommendation of the Secretariat or any IRB member, it is the responsibility of the IRB members to nominate and approve the name of the independent consultants to be endorsed by the Chair.

1.3.4. Process Flow/Steps





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Detailed Instructions

1.3.5. Selection of Independent Consultants

- An IRB member/secretariat nominates independent consultants to help review research where the IRB lacks expertise.
- The IRB Secretariat compiles a list of independent consultants and the IRB Chair/ Member-Secretary conducts a qualification review of the prospective consultants.
- The Chair finalizes a list based on expertise and availability criteria and submits them to the Hospital Director.
- The Hospital Director appoints independent consultants to help the IRB in protocol review.

1.3.6. Consultant signs agreements

- Contact the consultant, who will be asked to provide:
- A curriculum vitae (See appendix)
- A signed Terms of Reference
- A signed Confidentiality/Conflict of interest (See appendix)
- Keep the pertinent documents in a consultant's file.
- Prepare a roster of consultants and the areas of their expertise

1.3.7. Consultant renders services

- 1.1.1.1.** The IRB Secretariat provides study protocol documents to the concerned consultant for review, after the latter has signed the Terms of Reference and the Confidentiality/ Conflict of Interest Agreement.
- 1.1.1.2.** The consultant must complete the assessment form to be reviewed by the IRB at the time the study is reviewed.
- 1.1.1.3.** The consultant may attend the IRB meeting, present his/her assessment, and participate in the discussion but without the right to vote. The report becomes a permanent part of the study file.

1.3.8. Termination of services

- 1.3.8.1.** Consultant's services may be terminated by either the consultant or by the Bicol University College of Medicine IRB.

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1.3.8.2. Upon termination of the consultant's services, the Secretariat shall ensure that all the necessary documentation is filed with the other administrative documents.

1.3.9. Store documents in the IRB folder under Independent Consultants File in alphabetical order.

1.4. Training of IRB Members and Staff

1.4.1. Purpose

To describe Bicol University College of Medicine IRB procedures to ensure initial and continuing training of IRB members and staff

1.4.2. Scope

The Bicol University College of Medicine recognizes the importance of training and continuing professional development. This SOP describes the training requirements of Bicol University College of Medicine IRB members and staff from initial training to continuing education to maintain and update IRB competence in the review of different types of protocols.

1.4.3. Responsibility

It is the responsibility of both the Bicol University College of Medicine IRB officers, members and staff to have themselves educated and trained regularly. The Secretariat keeps track of the training needs of all members and staff and prepares a training plan.



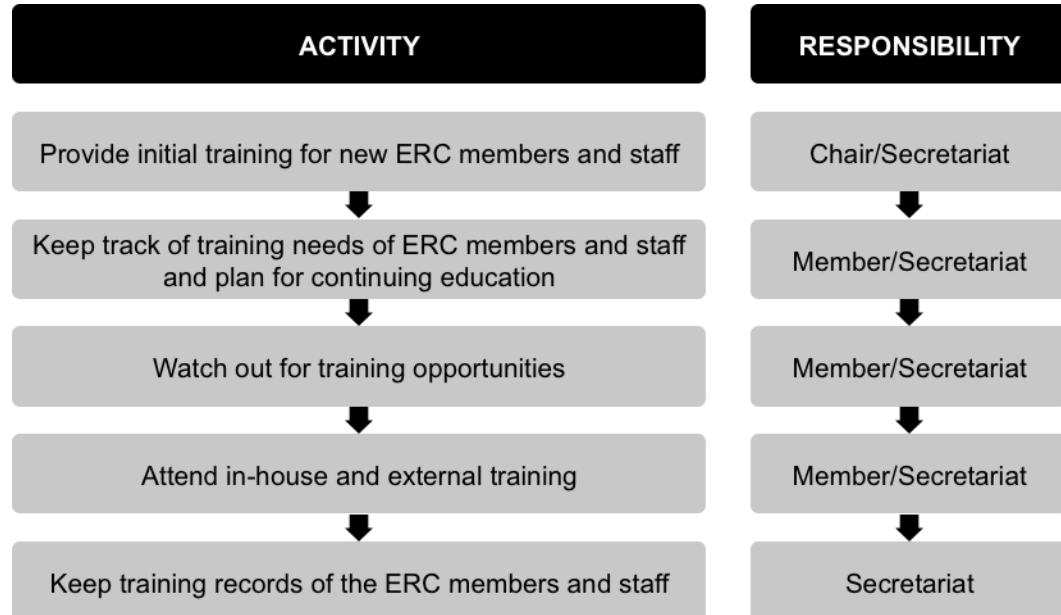
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1.4.4. Process Flow/Steps



Detailed instructions

1.4.5. Topics for training

IRB members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

1.4.6. Initial training of IRB Members

- Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in IRB standard operating procedures.
- The IRB officers shall ensure that training is provided to all new members.

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1.4.7. Continuing education of IRB members

- All members should have training in IRB SOPs. In addition, they should be provided with external training opportunities at least once a year.
- The IRB officers shall get information about training courses, workshops, conferences, etc. that are periodically announced on websites, bulletin boards and various media channels in coordination with the Secretariat.
- Plan the training activities for individual IRB members based on their training needs.
- Ensure sufficient budgetary support for training activities.
- Facilitate attendance of IRB members and staff once specific training activities are scheduled.

1.4.8. Keeping the training records

- Prepare attendance sheets of in-house training with relevant information about the topic, duration, date and venue. Ask member attendees to sign the attendance sheet and keep a copy in the membership files.
- Keep copies of training records of IRB members and staff in the membership and staff files.
- Update the CV of individual member/ staff to reflect attendance of training activities.

1.5. Incentives for the IRB Members and Consultants

1.5.1. Purpose

To describe procedures to facilitate granting of honorarium to IRB members and consultants

1.5.2. Scope

This SOP describes how IRB members and consultants may be given honorarium for their work in the Bicol University College of Medicine IRB.

1.5.3. Responsibility

It is the responsibility of the IRB officers under the leadership of the Chair to explore the possibility of providing honorarium to all IRB members.



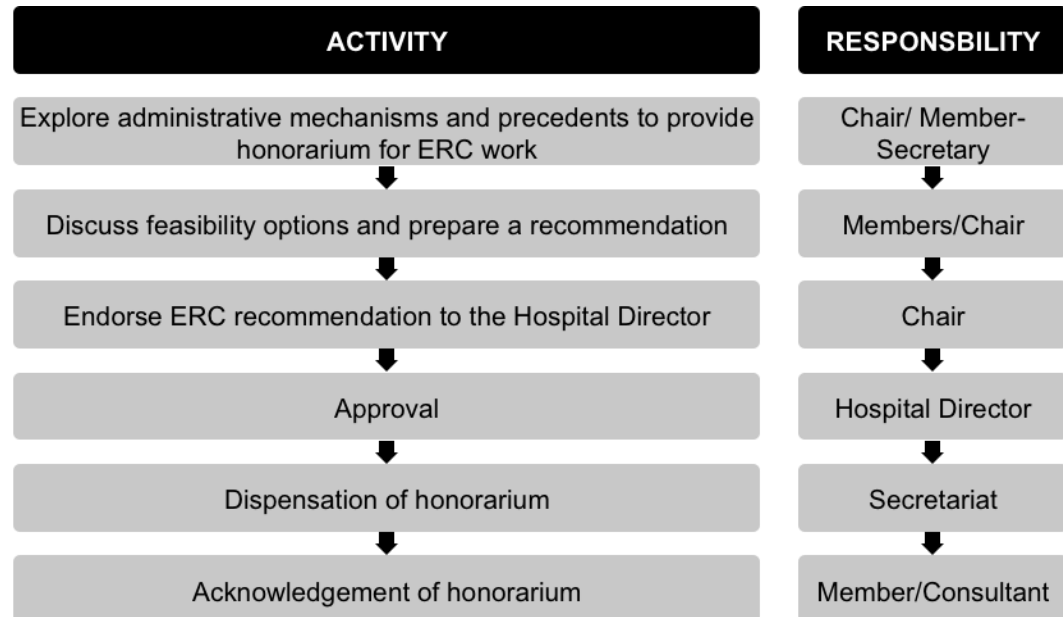
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1.5.4. Process Flow/Steps



Detailed instructions

- 1.5.5. The Chair/ Member-Secretary explores possible financial and administrative mechanisms and precedents to be able to provide honorarium for IRB work
- 1.5.6. The Chair includes the topic in the IRB meeting agenda for discussion among IRB members.
- 1.5.7. The IRB may suggest other schemes, endorse or modify the recommendation.
- 1.5.8. The Chair makes a recommendation for honorarium or its adjustment to the Hospital Director.
- 1.5.9. The Hospital Director may approve or disapprove the recommendation.
- 1.5.10. The IRB members are informed of the decision.
- 1.5.11. IRB members or consultants acknowledge in writing any honorarium that may be received from the IRB.



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LETTER OF APPOINTMENT OF IRB MEMBER (FORM 1.1)

Date

Dear _____

I have the honor to appoint you as a **Member of the** Bicol University College of Medicine IRB for a period of two years, effective _____ until _____. As a member, you will have the following roles and responsibilities:

- Participate in the IRB meetings
- Review, discuss and consider research proposals submitted for evaluation
- Assess serious adverse event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest;
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the **Bicol University College of Medicine** IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Very truly yours,



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Dean
Bicol University College of
Medicine

Conforme:

(Print name and sign)

Date

CURRICULUM VITAE (FORM 1.2)

Last name

First name

Position in
the IRB

Address

Date of 1st
Appointment

Contact No.

Educational
Background
:

Research
and Ethics
Training/s:

WORK EXPERIENCE

A. Occupation



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B. Previous work
experience

C. Present work
experience

Research-related
Experience



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CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT (Form 1.3)

Know all Men by these Presents:

In view of the appointment of (TITLE NAME INSTITUTIONAL AFFILIATION), as a member of the Bicol University College of Medicine IRB, and hereinafter referred to as the **Undersigned**, and

Whereas:

the **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the **Undersigned** as a member of the Bicol University College of Medicine IRB is based on individual merits and not as an advocate or representative of a home province/territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the Bicol University College of Medicine IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the **Undersigned** in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the Bicol University College of Medicine IRB.

Any written information provided to the **Undersigned** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

As such, the **Undersigned** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the **Undersigned** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that her performance of this agreement is consistent with Bicol University College of Medicine's policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the IRB that no member/consultant may participate in the review, comment or approval of any activity in which he/she has a



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conflict of interest except to provide information as requested by the IRB.

The **Undersigned** will immediately disclose to the Chair of the Bicol University College of Medicine IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, the member should notify the Chairperson and may not participate in the IRB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.



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Agreement on Confidentiality and Conflict of Interest

[*To the Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the Bicol University College of Medicine IRB. A copy will be given to you for your records.]

In the course of my activities as a member of the Bicol University College of Medicine IRB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

Title/Name

Date

Bicol University College of
Medicine IRB Chair

Date



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TRAINING RECORD OF AN IRB MEMBER (FORM 1.4)

| | | | |
|-----------|--|------------|--|
| Last name | | First name | |
|-----------|--|------------|--|

| BASIC COURSES | ORGANIZER | VENUE | DATE | FUNDING SOURCE |
|--|-----------|-------|------|----------------|
| 1. GCP Training | | | | |
| 2. Research Ethics | | | | |
| 3. IRB Standard Operating Procedures (SOP) | | | | |

| CONTINUING ETHICS EDUCATION : Research Ethics Workshops, Conferences, Meetings, Lectures | ORGANIZER | VENUE | DATE | FUNDING SOURCE |
|--|-----------|-------|------|----------------|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |