



Department of Health  
Jose R. Reyes Memorial Medical Center  
Rizal Avenue, Sta. Cruz, Manila



## INSTITUTIONAL REVIEW BOARD

Version No.: ~~33~~ **34**

Effective Date:  
~~06 January 20~~

# 1. IRB STRUCTURE & COMPOSITION

- 1.1. Ethical Framework and Constitution of the IRB
- 1.2. Appointment of IRB Members
- 1.3. Selection of Independent **Consultant Reviewers**
- 1.4. Training of IRB Members and Staff
- 1.5. Incentives for IRB Members and **Consultant Reviewers**

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Authored by:	JRRMMC IRB SOP Team Headed by: <b>DR. IDA MARIE T. LIMMICHELLE Y. OTAYCO</b>
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Approved by:	<b>DR. ZHARLAH G. FLORES</b> Chair of the Board
Approved by:	<b>DR. EMMANUEL F. MONTAÑA, JR., FACS, MHA, FPCS</b> Hospital Director
Approval Date:	<del>14 June 2021</del> <b>January 6, 2020</b>

## 1.1. Ethical Framework and Constitution of the IRB

### 1.1.1. Purpose

To describe the composition and structure of the Jose R. Reyes Memorial Medical Center **Institutional Review Board** ~~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 Jose R. Reyes Memorial Medical Center **Institutional Review Board** ~~Institutional Review Board~~ **(IRB)** related to:

1.1.2.1. Constitution of the IRB

1.1.2.2. Confidentiality/Conflict of Interest Agreement with IRB members, staff, and ~~consultantreviewers~~

1.1.2.3. Training of Personnel and IRB Members

1.1.2.4. Selection of Independent ~~ConsultantReviewers~~

1.1.2.5. Incentives for IRB Members and ~~ConsultantReviewers~~

### 1.1.3. Scope

The Jose R. Reyes Memorial Medical Center **Institutional Review Board** ~~Institutional Review Board~~ **IRB** is an independent body created by the Jose R. Reyes Memorial Medical Center under the Hospital Director, 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. ~~Following the In accordance with a~~ applicable national/international regulations, the Jose R. Reyes Memorial Medical Center **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 Jose R. Reyes Memorial Medical Center **IRB** reviews and monitors health researches that involve:

1.1.3.1. Jose R. Reyes Memorial Medical Center patients, done within the hospital premises by its staff and non-affiliated organizations;

1.1.3.2. Protocols ~~were~~ done by Jose R. Reyes Memorial Medical Center full-time or part-time staff in areas outside the hospital premises.

This SOP provides the Terms of Reference (TOR) that describe the framework for the constitution of the Jose R. Reyes Memorial Medical Center **IRB**, the responsibilities and activities of its officers, members, staff, and ~~consultantreviewers~~.

### 1.1.4. Responsibility

It is the responsibility of the IRB members, officers, and secretariat to understand and implement the SOPs of the Jose R. Reyes Memorial Medical Center **IRB**.

### ~~1.1.10~~ 1.1.5. Ethical basis

1.1.5.1. The Jose R. Reyes Memorial Medical Center **IRB** is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents:

~~1.1.10.1.~~

~~1.1.10.1.2.1.1.5.1.1.~~ Declaration of Helsinki (~~2008-2013~~ and subsequent revisions) and **WMA Declaration of WMA Declaration of** Helsinki-Ethical Principles for Medical Research Involving Human Subjects 2018

~~1.1.10.1.3.1.1.5.1.2.~~ International Ethical Guidelines for Health-related Research Involving Human (CIOMS) 2016

~~1.1.10.2.1.1.5.2.~~ The IRB will function in accordance with national laws, regulations, and guidelines.

~~1.1.10.3.1.1.5.3.~~ The IRB provides its ~~own~~ standard operating procedures based on:

~~1.1.10.3.1.1.1.5.3.1.~~ Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO)

~~1.1.10.3.2.1.1.5.3.2.~~ Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)

~~1.1.10.3.3.1.1.5.3.3.~~ International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) **E6-R2 2017**

~~1.1.10.3.4.1.1.5.3.4.~~ National Ethical Guidelines for Health Research (2017) by the Philippine Health Research Ethics Board (PHREB)

~~1.1.10.3.5.1.1.5.3.5.~~ Philippine Food and Drug Authority regulations and other relevant laws and regulations

**1.1.5.3.6.** DOH AO 2019-049 as a guideline for joint review

~~1.1.10.3.6.1.1.5.3.7.~~ **SIDCER Survey and PHREB Accreditation SOPs 2020**

~~1.1.10.4.1.1.5.4.~~ The IRB adheres to national and international ethical standards and recognizes that the protocols it approves may also be approved by national and/or local ethics committees ~~prior to before~~ their implementation in specific localities.

~~1.1.10.5.1.1.5.5.~~ 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.

~~1.1.10.6.1.1.5.6.~~ 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 Jose R. Reyes Memorial Medical Center research is being considered.

~~1.1.10.7.1.1.5.7.~~ 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 Jose R. Reyes Memorial Medical Center **IRB** and to identify the roles and responsibilities of IRB officers and members.

### 1.2.4.1.2.2. Scope

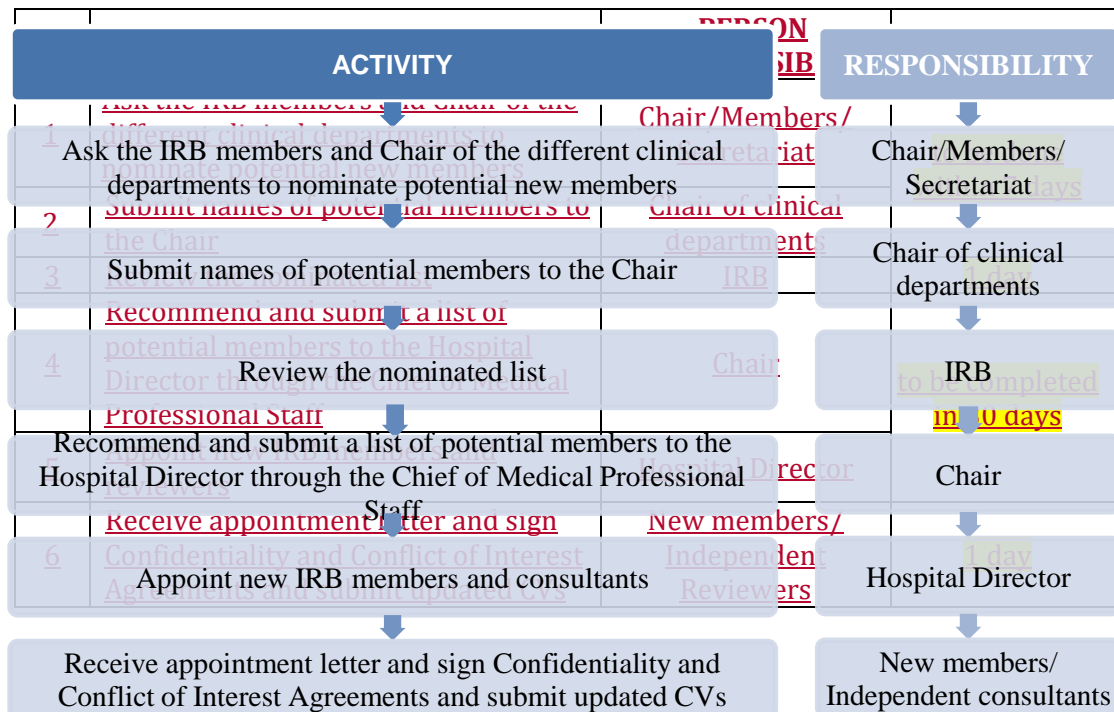
While the Jose R. Reyes Memorial Medical Center **IRB** remains under the authority of the Hospital Director, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines. The membership SOPs cover the nomination and appointment procedures of IRB members, officers, and independent consultant reviewers. (see Appendix 1, Organizational Chart)

### 1.2.5.1.2.3. Responsibility

It is the responsibility of the Jose R. Reyes Memorial Medical Center Director to formally appoint the members and officers and consultant reviewers of the IRB after due consultation with the current members of the IRB.

### 1.2.6. Process Flow/Steps

#### 1.2.4.



### 1.2.1.1.2.5. Requirements for Regular Membership/Independent Consultant Reviewers

#### 1.2.1.1.2.5.1. IRB Regular Membership

The Jose R. Reyes Memorial Medical Center IRB shall be composed of at least eight 8 members.

1.2.1.1.1.2.5.1.1. Its membership shall be multidisciplinary and multi-sectoral. The IRB members should have diverse backgrounds and experiences to foster a comprehensive and efficient review of research activities commonly conducted by the Jose R. Reyes Memorial Medical Center staff and non-affiliated organizations.

1.2.1.1.2.1.2.5.1.2. 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. In the absence of a pediatrician member, an independent reviewer with expertise in Pediatrics will be asked to review protocols involving pediatric subjects as the need arises.

~~1.2.1.1.5.~~1.2.5.1.3. 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.

~~1.2.1.1.6.~~1.2.5.1.4. The IRB shall aim for gender balance in its membership with equal representation of men and women members ~~in order~~ to promote gender sensitivity in its review procedures.

~~1.2.1.1.7.~~1.2.5.1.5. The IRB shall have representatives from both the older and younger generations.

~~1.2.1.1.8.~~1.2.5.1.6. The IRB shall invite independent ~~consultant reviewers~~, whenever necessary, to provide expert opinions related to protocols under review.

~~1.2.1.1.9.~~1.2.5.1.7. The IRB shall have an office and adequate support staff for carrying out its responsibilities.

~~1.2.1.1.10.~~1.2.5.1.8. 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.

### ~~1.2.3.1.2.6.~~ **Detailed Instructions**

#### ~~1.2.3.1.1.2.6.1.~~ **Nomination/Appointment**

~~1.2.3.1.1.1.~~1.2.6.1.1. Current IRB members shall nominate candidates for new members and independent ~~consultant reviewers~~ to the Chair/Secretariat.

~~1.2.3.1.2.~~1.2.6.1.2. The Chair of the different clinical departments will be asked to submit their recommended IRB Member.

~~1.2.3.1.3.~~1.2.6.1.3. The Chair together with the IRB members discusses the qualifications of the nominees.

~~1.2.3.1.4.~~1.2.6.1.4. The Chair submits the final list of nominees to the Hospital Director through the Chief, Medical Professional Staff.

~~1.2.3.1.5.~~1.2.6.1.5. The Hospital Director issues an appointment letter.

~~1.2.3.1.6.~~1.2.6.1.6. The newly appointed members and independent ~~consultant reviewers~~ shall sign the Confidentiality and Conflict of Interest Agreements and submit an updated Curriculum Vitae.

## 1.2.4.1.2.7. Terms of Office

1.2.4.1.1.2.7.1. The appointing authority shall indicate in the appointment letter the IRB's functions, terms of office, the scope of work, conditions of appointment, a system of replacement or recall, and compensation, if any. Members are appointed by the Medical Director yearly. This is renewable for several consecutive terms depending on their performance.

1.2.4.2.1.2.7.2. 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.

1.2.4.3.1.2.7.3. If any member would resign, the committee will meet and nominate a new member to replace him/her.

## 1.2.5.1.2.8. Qualifications/Appointment of Members

1.2.5.1.1.2.8.1. The Director of the Jose R. Reyes Memorial Medical Center is responsible for appointing IRB members and consultant reviewers upon the recommendation of the IRB Chair.

1.2.5.2.1.2.8.2. 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.

1.2.5.3.1.2.8.3. 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.

1.2.5.4.1.2.8.4. Members shall disclose in writing any financial, professional, or personal interest or involvement in a project or proposal under consideration, which is in conflicts with their function as a reviewer.

1.2.5.5.1.2.8.5. Members shall submit their curriculum vitae, properly signed and dated, and update them yearly.

1.2.5.6.1.2.8.6. 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.

1.2.5.7.1.2.8.7. 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.

1.2.5.8.1.2.8.8. 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.

**1.2.6.1.2.9. Conditions of Appointment of Members**

All prospective IRB members shall be willing:

**1.2.6.1.1.2.9.1.** To make public his/her full name, profession, and affiliation as an IRB member.

**1.2.6.2.1.2.9.2.** Disclose all financial accountability, reimbursement for work and expenses, related to their work in the Jose R. Reyes Memorial Medical Center IRB that shall record and publicly disclose its financial records upon request.

**1.2.6.3.1.2.9.3.** All IRB members and Independent ~~Consultant~~ Reviewers shall sign the Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

**1.2.7.1.2.10. Resignation, Disqualification, and Replacement of Members**

**1.2.7.1.1.2.10.1.** Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Hospital Director.

**1.2.7.2.1.2.10.2.** Members may be separated from the committee by disqualification for valid reasons as determined by the majority vote of the committee members.

**1.2.7.3.1.2.10.3.** Members that have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.

**1.2.7.4.1.2.10.4.** The terms of the replacement shall be limited to the remaining term of the member that he/she has replaced.

**1.2.10.1.2.11. Roles and Responsibilities of IRB**

**1.2.10.1.1.2.11.1. IRB Officers**

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

<b>Chair</b>	<ul style="list-style-type: none"> <li>• Presides over the IRB meetings and is accountable to the Hospital Director.</li> <li>• Prepares an annual report summarizing IRB activities and decision outcomes to the Hospital Director.</li> <li>• Ensures sufficient financial and administrative support for IRB operations</li> <li>• Assigns primary reviewers</li> <li>• <del>Decides which protocols may be expedited</del></li> <li>• Represents the IRB interests within the hospital administration</li> <li>• Represents the IRB to the outside world <u>or as who may be assigned by the Chair.-</u></li> </ul>
<b>Vice-Chair</b>	<ul style="list-style-type: none"> <li>• Presides over meetings in the absence of the Chair</li> </ul>

- Performs other duties as designated by the Chair
- Decides which protocols may be expedited
- In charge of final review of SAE's and SUSAR's.
- Monitors submission of Final Reports of Resident Physicians, and Final
- Report of Resident Physicians.

## Member-Secretary

- Decides which protocols may be expedited
- Supervises the IRB staff and management of the office.
- Ensures good IRB documentation
- Ensures overall IRB compliance with good clinical practice
- Supervision of the staff in the management of the office
- Audit of protocol and SAE/SUSARs database.
- Monitors post-approval reports and continuing review reports.
- 

## 1.2.10.2.1.2.11.2. IRB Secretariat

The Jose R. Reyes Memorial Medical Center IRB secretariat is composed of the **Member-Secretary** and administrative support staff who are employees of the Jose R. Reyes Memorial Medical Center and appointed by the Hospital Director.

The Secretariat shall have the following functions:

- 1.2.10.2.1.2.11.2.1. Organizing an effective and efficient tracking procedure for each proposal received.
- 1.2.10.2.2.1.2.11.2.2. Preparation, maintenance, and distribution of study files.
- 1.2.10.2.3.1.2.11.2.3. Organizing IRB meetings regularly.
- 1.2.10.2.4.1.2.11.2.4. Preparation and maintenance of meeting agenda and minutes.
- 1.2.10.2.5.1.2.11.2.5. Maintaining good IRB documentation and archiving procedures.
- 1.2.10.2.6.1.2.11.2.6. Communicating with the IRB members and Investigators.
- 1.2.10.2.7.1.2.11.2.7. Arrangement of training for personnel and IRB members.
- 1.2.10.2.8.1.2.11.2.8. Organizing the preparation, review, revision, and distribution of SOPs and guidelines.
- 1.2.10.2.9.1.2.11.2.9. Providing the necessary administrative support for IRB-related activities to the Chair of the IRB.
- 1.2.10.2.10.1.2.11.2.10. Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the IRB members.
- 1.2.10.2.11.1.2.11.2.11. Maintaining a library of relevant resource materials and references.

## 1.2.10.3.1.2.11.3. IRB Members

- 1.2.10.3.1.1.2.11.3.1. Participate in IRB meetings
- 1.2.10.3.2.1.2.11.3.2. Review, discuss and consider research proposals submitted for evaluation
- 1.2.10.3.3.1.2.11.3.3. Assess serious adverse event reports and recommend appropriate action

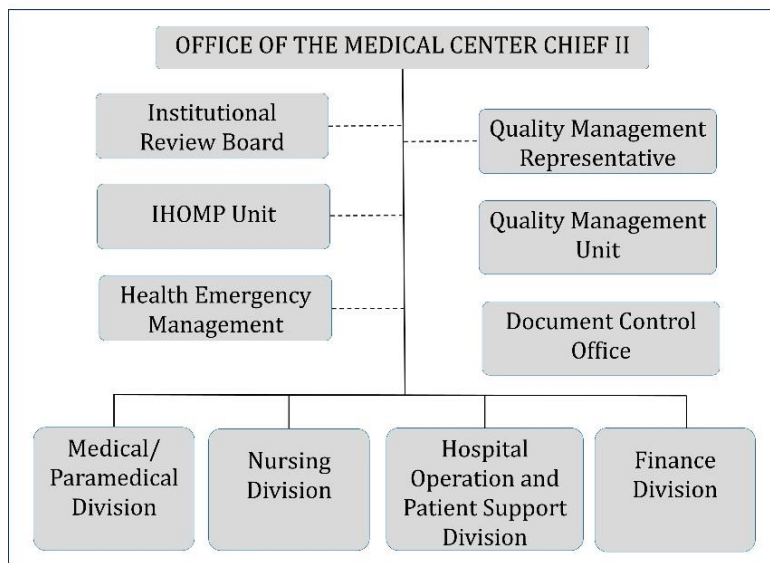


- ~~1.2.10.3.4~~~~1.2.11.3.4.~~ Review progress reports and monitor ongoing studies as appropriate
- ~~1.2.10.3.5~~~~1.2.11.3.5.~~ Evaluate final reports
- ~~1.2.10.3.6~~~~1.2.11.3.6.~~ Maintain confidentiality of the documents and deliberations during IRB meetings
- ~~1.2.10.3.7~~~~1.2.11.3.7.~~ Declare any conflict of interest
- ~~1.2.10.3.8~~~~1.2.11.3.8.~~ Participate in continuing education activities in health research and ethics

**1.2.10.4.1.2.11.4. The Organizational Chart of the IRB**



**ORGANIZATION CHART**

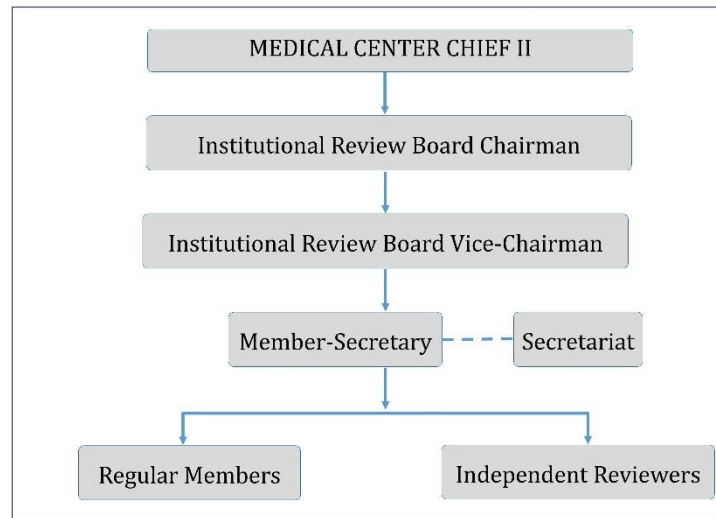


Approved:

**EMMANUEL F. MONTANA, JR., M.D., MHA**  
 Medical Center Chief II  
 Jose R. Reyes Memorial Medical Center



## ORGANIZATION CHART



Approved:

  
EMMANUEL F. MONTANA, JR., MD, MHA  
Medical Center Chief II  
Jose R. Reyes Memorial Medical Center

### 1.2.11.1.2.12. -Confidentiality/Conflict of Interest Agreement

1.2.11.1.2.12.1. The Secretariat provides a copy of the agreement form (Form 1.3) to each member of the Jose R. Reyes Memorial Medical Center IRB together with the appointment letter.

1.2.11.2.1.2.12.2. 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.

1.2.11.3.1.2.12.3. If a member refuses to sign such an agreement, this may be a ground for his/her disqualification to serve in the Jose R. Reyes Memorial Medical Center IRB.

1.2.11.4.1.2.12.4. Newly appointed members obtain two copies of the Agreement Form read the text very carefully, fill in their names, sign and date the forms.

1.2.11.5.1.2.12.5. Any member may ask questions, or ask for a clarification from the Chair or Secretariat related to the contents of the document.

1.2.11.6.1.2.12.6. 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 Reviewers Consultants

#### 1.3.1. Purpose

To describe the procedures for the appointment of IRB independent reviewerconsultants.

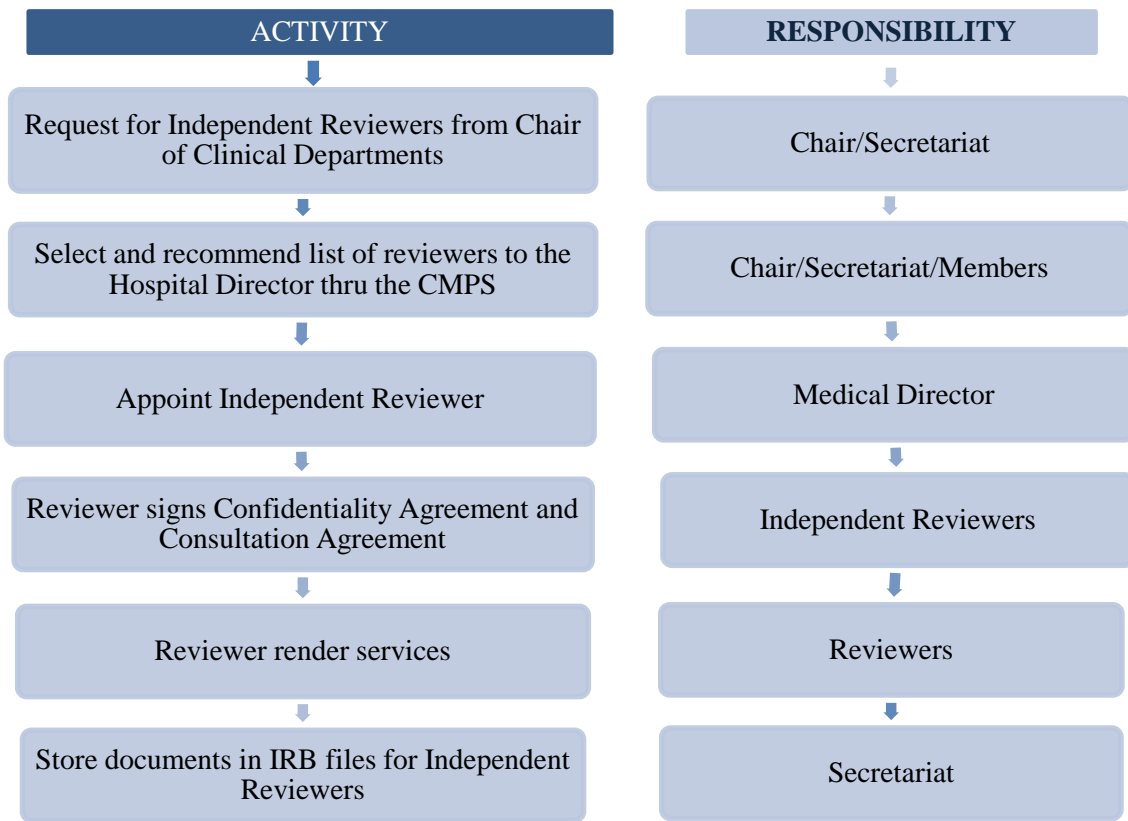
#### 1.3.2. Scope

This SOP describes the procedures for engaging the services of a professional/expert as a reviewerconsultant to the Jose R. Reyes Memorial Medical Center IRB. If the IRB Chair 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 together with the recommendation from the Chair of different clinical departments, it is the responsibility of the IRB members to nominate and approve the name of the independent consultants reviewers to be endorsed by the Chair.

### 1.3.4. Process Flow/Steps



### 1.3.4.

<u>No.</u>	<u>ACTIVITY</u>	<u>PERSON RESPONSIBLE</u>	<u>TIMELINE</u>
<u>1</u>	<u>Request for Independent Reviewer from Research Coordinators</u>	<u>Chair/Secretariat</u>	<u>2 weeks</u>
<u>2</u>	<u>Consultant signs Confidentiality Agreement and Consultation Agreement</u>	<u>Independent Reviewers</u>	
<u>3</u>	<u>Recommend list of consultants to the Hospital Director thru the CMPS</u>	<u>Chair/Members / Secretariat</u>	<u>2 days upon completion of the list</u>
<u>4</u>	<u>Appoint Independent Reviewer</u>	<u>Hospital Director</u>	<u>Within 7 days</u>
<u>5</u>	<u>Consultant render services</u>	<u>Independent Reviewer</u>	<u>As per the assigned review of protocols/ Monthly meeting</u>
<u>6</u>	<u>Store documents in IRB files for Independent Consultants</u>	<u>Secretariat</u>	<u>1 day</u>

### 1.3.5. Detailed Instructions:

#### 1.3.5.1. Selection of Independent Consultant Reviewers

- 1.3.5.1.1. The IRB Chair sends a letter to the Research Coordinators Chair of clinical departments ~~for as an their recommended~~ independent reviewer.
- 1.3.5.1.2. An IRB member/secretariat may nominate independent consultant reviewers to help review research where the IRB lacks expertise.
- 1.3.5.1.3. The IRB Secretariat compiles a list of independent consultant reviewers and the IRB Chair/ Member-Secretary conducts a qualification review of the prospective consultant reviewers.
- 1.3.5.1.4. The Chair finalizes a list based on expertise and availability criteria and submits them to the Hospital Director through the Chief of Medical Professional Staff, for approval.
- 1.3.5.1.5. The Hospital Director appoints independent consultant reviewers to help the IRB in protocol review.

#### 1.3.5.5-1.3.5.2. Consultant Reviewer signs agreements

—— Contact the consultant reviewer, who will be asked to provide:

- 1.3.5.1.1. Curriculum vitae (See appendix)
- 1.3.5.1.2. A signed Terms of Reference
- 1.3.5.1.3. A signed Confidentiality/Conflict of interest (See appendix)
- 1.3.5.1.4. Keep the pertinent documents in a consultant reviewer's file.
- 1.3.5.1.5. Prepare a roster of consultant reviewers and the areas of their expertise.

#### 1.3.5.4-1.3.5.3. Consultant Reviewer renders services

1.3.5.4.1-1.3.5.3.1. The IRB Secretariat provides study protocol documents to the concerned consultant reviewer for review, (with a minimum of 5 days) after the latter has signed the Terms of Reference and the Confidentiality/Conflict of Interest Agreement.

1.3.5.4.2-1.3.5.3.2. The consultant reviewer must complete the assessment form to be reviewed by the IRB at the time the study is reviewed.

1.3.5.4.3-1.3.5.3.3. The consultant reviewer 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.

#### 1.3.5.6-1.3.5.4. Termination of services

~~1.3.5.6.1.1.3.5.4.1.~~ 1.3.5.4.1. ~~ConsultantReviewer~~'s services may be terminated by either the ~~consultantreviewer~~ or by the Jose R. Reyes Memorial Medical Center IRB which should be made in writing.

~~1.3.5.6.2.1.3.5.4.2.~~ 1.3.5.4.2. Upon termination of the ~~consultantreviewer~~'s services, the Secretariat shall ensure that all the necessary documentation is filed with the other administrative documents.

**1.3.5.5.** Store documents in the IRB folder under the Independent ~~ConsultantReviewers~~ File in alphabetical order.

## 1.4. Training of IRB Members and Staff

### 1.4.1. Purpose

To describe Jose R. Reyes Memorial Medical Center IRB procedures to ensure initial and continuing training of IRB members and staff

### 1.4.2. Scope

The Jose R. Reyes Memorial Medical Center recognizes the importance of training and continuing professional development. This SOP describes the training requirements of Jose R. Reyes Memorial Medical Center 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 the Jose R. Reyes Memorial Medical Center IRB officers, members, and staff to have themselves educated and trained regularly.

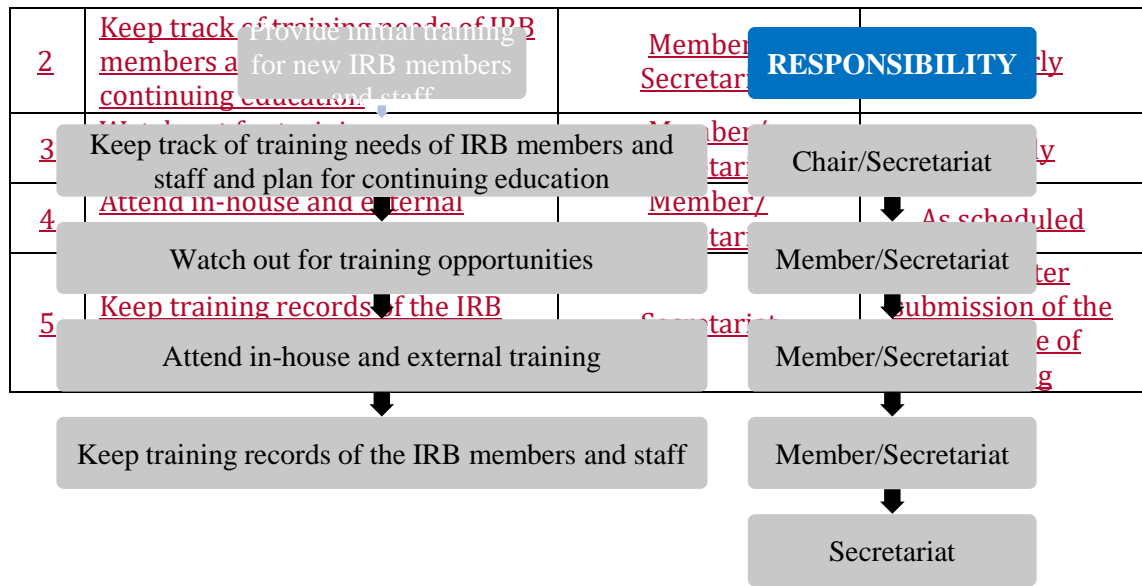
It is the responsibility of the Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent ~~ConsultantReviewers~~, and staff.

The Secretariat keeps track of the training needs of all members, Independent ~~ConsultantReviewer~~s, and staff ~~in accordance with~~ following the training plan.

## Process Flow/Steps

### 1.4.4.

<u>No.</u>	<u>ACTIVITY</u>	<u>PERSON RESPONSIBLE</u>	<u>TIMELINE</u>
<u>1</u>	<u>Provide initial training for new IRB members and staff</u>	<u>Chair/Secretariat</u>	<u>per schedule (ref. UPM-NIH)</u>



## 1.4.24.1.4.5. Detailed Instructions:

### 1.4.5.1.2.1.4.5.1. Topics for training

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

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

### 1.4.5.7.1.4.5.2. Initial training of IRB Members

~~1.4.5.7.1~~~~1.4.5.2.1~~. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in IRB standard operating procedures.

~~1.4.5.7.2~~~~1.4.5.2.2~~. The IRB officers shall ensure that training is provided to all new members.

### ~~1.4.5.8~~~~1.4.5.3~~. Continuing education of IRB members

~~1.4.5.8.1~~~~1.4.5.3.1~~. All members should have training in IRB SOPs. In addition, they should be willing to undergo continuing training during their membership.

~~1.4.5.8.2~~~~1.4.5.3.2~~. 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.

~~1.4.5.8.3~~~~1.4.5.3.3~~. Plan the training activities for individual IRB members based on their training needs.

~~1.4.5.8.4~~~~1.4.5.3.4~~. Ensure sufficient budgetary support for training activities.

~~1.4.5.8.5~~~~1.4.5.3.5~~. Facilitate attendance of IRB members and staff once specific training activities are scheduled.

### ~~1.4.5.9~~~~1.4.5.4~~. Keeping the training records

~~1.4.5.9.1~~~~1.4.5.4.1~~. 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.

~~1.4.5.9.2~~~~1.4.5.4.2~~. Keep copies of training records of IRB members and staff in the membership and staff files.

~~1.4.5.9.3~~~~1.4.5.4.3~~. Update the CV of individual members/staff to reflect attendance of training activities.

## 1.5. Incentives for the IRB Members and Consultant Reviewers

### 1.5.1. Purpose

To describe procedures to facilitate granting of honorarium to IRB members and consultant reviewers.

### 1.5.2. Scope

This SOP describes how IRB members and consultant reviewers may be given an honorarium for their work in the Jose R. Reyes Memorial Medical Center 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 an honorarium to all IRB members.

### 1.5.4. Process Flow/Steps



ACTIVITY		RESPONSIBILITY	
NO.	ACTIVITY	RESPONSIBLE	TIMELINE
1	Explore administrative mechanisms and precedents to provide honorarium for IRB work	Chair/ Member-Secretary	Every 6 months
2	Discuss feasibility options and prepare a recommendation	Members/Chair	
3	Endorse IRB recommendation to the Training & Research Office, then to CMPS, then to the Hospital Director	Chair	
4	Approval	Hospital Director	
5	Dispensation of honorarium	Disbursing	Upon approval
6	Acknowledgement of honorarium	Member/Reviewer	upon notice or availability

### 1.5.5. Detailed Instructions:

- 1.5.5.1. The Chair/Member-Secretary explores possible financial and administrative mechanisms and precedents to be able to provide an honorarium for IRB work.
- 1.5.5.2. The Chair includes the topic in the IRB meeting agenda for discussion among IRB members.
- 1.5.5.3. The IRB may suggest other schemes, endorse or modify the recommendation.
- 1.5.5.4. The Chair makes a recommendation for the specific amount of honorarium or its adjustment to the Hospital Director.
- 1.5.5.5. All IRB mMembers shall be compensated based on their attendance at IRB meetings. The allowable honorarium for members per meeting is P1,000.00 – P3,000.00 and P3,000 – P5,000 for the Chair. IRB Members who are staff of the institution may receive honorarium provided that the meetings are undertaken after office hours.
- 1.5.5.6. The IRB members are informed of the decision.
- 1.5.5.7. IRB members or consultantreviewers acknowledge in writing any honorarium that may be received from the IRB.

## LETTER OF APPOINTMENT OF IRB MEMBER (FORM 1.1)

Date

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Dear \_\_\_\_\_

I have the honor to appoint you as a **Member** of the **Jose R. Reyes Memorial Medical Center IRB** for a period of one year, effective \_\_\_\_\_ until \_\_\_\_\_. As a member, you will have the following roles and responsibilities:

- Serve as Primary Reviewers for research protocol documents within their area of expertise, and as General Reviewers for all researches discussed at convened meetings of the REC.
- Submit on time (within 14 working days) to the Secretariat the completed Protocol and ICF Assessment forms when they are designated as Primary Reviewers
- Conduct expedited review on behalf of the REC of protocols assigned by the REC Chair/Member Secretary and submit the assessment forms on time (within 7 working days)
- Perform post-approval review procedures of protocol-related documents within 14 working days
- Update CV and training record every time appointment is renewed
- Conform at all times with the legal and ethical principles accepted by the REC
- Attend basic and continuing education on Research Ethics at least once a year
- Perform other tasks assigned by the REC Chair.

*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 Jose R. Reyes Memorial Medical Center IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.*

Very truly yours,

\_\_\_\_\_  
Hospital Director  
Jose R. Reyes Memorial Medical Center

Conforme:

\_\_\_\_\_  
**Print name and Sign**

\_\_\_\_\_  
**Date**

**CURRICULUM VITAE (FORM 1.2)**

Last name		First name	
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Position in IRB		Address	
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Date of Appointment		Contact No.	
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Educational Background:	
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Research Ethics Training/s:	
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**WORK EXPERIENCE**

A. Occupation	
---------------	--

B. Previous work experience	
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C. Present work experience	
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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 & Address)

as a member of the **Jose R. Reyes Memorial Medical Center 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 is~~ conducted ~~in a humane and ethical manner~~ **humanely and ethically**, 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 **Jose R. Reyes Memorial Medical Center IRB** is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as to 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 Jose R. Reyes Memorial Medical Center 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~~ Reviewer of the **Jose R. Reyes Memorial Medical Center 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 Jose R. Reyes Memorial Medical Center'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~~reviewer may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRB.

The **Undersigned** will immediately disclose to the Chair of the Jose R. Reyes Memorial Medical Center 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/consultantreviewer 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 areis not limited to any of the following:

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

## **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 **Jose R. Reyes Memorial Medical Center IRB**.*

*A copy will be given to you for your records.]*

In the course of my activities as a member of the **Jose R. Reyes Memorial Medical Center 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 the 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 accepted the aforementioned terms and conditions as explained in this Agreement.

\_\_\_\_\_  
Title/Name

\_\_\_\_\_  
Date

IRB Chair  
Jose R. Reyes Memorial Medical Center

Date

## TRAINING RECORD OF AN IRB MEMBER (FORM 1.4)

Last name		First name	
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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.				



INVITATION TO INDEPENDENT ~~CONSULTANT REVIEWERS~~ (FORM 1.5)

*To be attached to appointment document from the Hospital*

(Name of Independent ~~Consultant Reviewer~~)  
Jose R. Reyes Memorial Medical Center  
Manila

Date

Dear: \_\_\_\_\_

We hereby invite you to serve as Independent ~~Consultant Reviewer~~ for the following protocol:

(Title of Protocol), Protocol Number), (Name of PI), (Sponsor)

Please review the technical and ethical issues in the protocol based on the assessment forms that we hereby attach. Please forward your assessment/comments to the Secretariat within 14 working days. Please attend the full board meeting on \_\_\_\_\_ at \_\_\_\_\_.

Thank you for your support and cooperation.

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 Jose R. Reyes Memorial Medical Center IRB Secretariat. Please sign, date, and submit your latest curriculum vitae and the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

\_\_\_\_\_  
Chair, IRB  
Jose R. Reyes Memorial Medical Center

Conforme:

\_\_\_\_\_  
Print Name and Sign

\_\_\_\_\_  
Date