INTRODUCTION

The Chinese General Hospital and Medical Center (CGHMC RERB) started last 2004 as an Ethics Committee headed by Dr. Antonio Periquet. In 2011, Chinese General Hospital and Medical Center Institutional Review Board (CGHMC IRB) was established and chaired by Dr. Leonor Cabral-Lim. It's function is to review and document approvals of all clinical researches conducted at the Chinese General Hospital and Medical Center. Four years later, the IRB was renamed to Chinese General Hospital and Medical Center (CGHMC RERB).

The CGHMC RERB reviews researches conducted by hospital and medical staff, residents, fellows-in training of the Chinese General Hospital and Medical Center (CGHMC) and also industry-sponsored clinical trials by principal investigators who are consultants of CGHMC. The CGHMC RERB is an independent body under the Department of Medical Education and Research (DMER). Its main responsibility is to safeguard the rights, safety, and well-being of human participants involved in health-related research and to provide public assurance of that protection. It operates in accordance with national and/or local regulations as well as with ICH-Good Clinical Practices (GCPs) guidelines.

The CGHMC has been granted Level III Ethics Review Committee Accreditation effective February 2016 until 2019 and has been re-accredited and granted Level III Ethics Review Committee effective June 1, 2019 until June 30, 2023.

The CGHMC RERB has been granted recognition by the Strategic Initiative for Developing Capacity in Ethical Review – Forum for Ethical Review Committees in the Asian and Western Pacific Region (SIDCER-FERCAP) on November 24, 2015 in Nagasaki, Japan. SIDCER-FERCAP renewed its recognition to CGHMC at Chang Gung Memorial Hospital, Taoyuan, Taiwan last November 21, 2018. The CGHMC RERB is also one of the members of the Philippine Health Research Ethics Network (PHREN) since 2017.

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 19, 2018	RERB Members	Role and responsibilities of RERB officers were revised Flowcharts
6	Sep 19, 2018	RERB Members	Added the ff as functions of the Chair Approves the agenda Prepares budget plan for the RERB Ensures that RERB members receive orientation and undergo basic research ethics training immediately after their appointment and continuing education thereafter
6	Sep 19, 2018	RERB Members	Removed from the Chair and officers the responsibility of sourcing funds

1.1. Ethical Framework and Constitution of the RERB

1.1.1. Purpose

To describe the composition and structure of the CGHMC Research Ethics Review Board (RERB) in compliance with national and international guidelines in ethical research

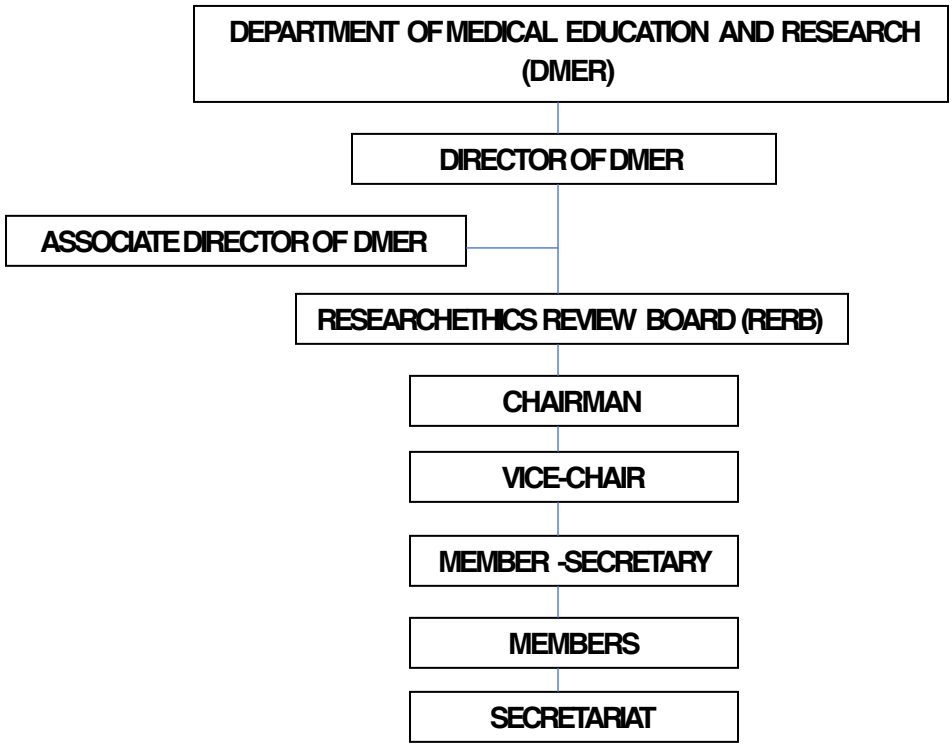
1.1.2. Specific Objectives

To describe the RERB procedures and define the terms of reference for the CGHMC RERB related to: Composition of the RERB, Confidentiality/Conflict of Interest Agreement with RERB members and independent consultants, Training of personnel and RERB members, Selection of independent consultants and incentives for RERB members and independent consultants

1.1.3. Scope

The CGHMC RERB is an independent body under the Department of Medical Education and Research (DMER).

Organizational Structure



1.1.3.1. Its main responsibility is to safeguard the rights, safety, and well-being of human participants involved in health-related research and to provide public assurance of that protection. In accordance to provisions set forth in the national/international regulations, the CGHMC RERB has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant policies and procedures after a research is given approval.

1.1.3.2. This Standard Operating Procedures (SOP) provide the Terms of Reference (TOR) that describes the framework for the constitution of the CGHMC RERB, the responsibilities and activities of its officers, members, staff and consultants.

1.1.4. Responsibility

It is the responsibility of the RERB Members, Officers, and Secretariat to understand and implement the SOP of the RERB in the conduct of its functions.

1.1.5. Ethical basis

The CGHMC RERB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents:

- World Medical Association Declaration of Helsinki (2008 and subsequent revisions)
- Council for International Organizations of Medical Sciences (CIOMS) 2002 and 2009

1.1.5.1. The RERB will function in accordance with national laws, regulations, and guidelines.

1.1.5.2. The RERB provides its own standard operating procedures based on:

1.1.5.2.1. 2000 Operational Guidelines for Ethics Committees that Review Biomedical Research by the World Health Organization (WHO)

1.1.5.2.2. 2011 Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants by the WHO

1.1.5.2.3. International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)

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

1.1.5.2.5. Philippine Food and Drug Authority regulations and other relevant laws and regulations

1.1.5.3. The RERB 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 their implementation in specific localities.

1.1.5.4. In evaluating protocols and ethical issues, the RERB is cognizant of the diversity of laws, cultures, and practices governing health research in various countries around the world.

1.1.5.5. The RERB strives 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 research is being considered.

1.1.5.6. The RERB will take the initiative to be informed, as appropriate, by national/local ethics committees and researches of the impact of the research that it has approved.

1.2. Appointment and Duties and Responsibilities of RERB Members

1.2.1. Purpose

To describe the appointment procedures of the members of the RERB and to identify the roles and responsibilities of its officers and members

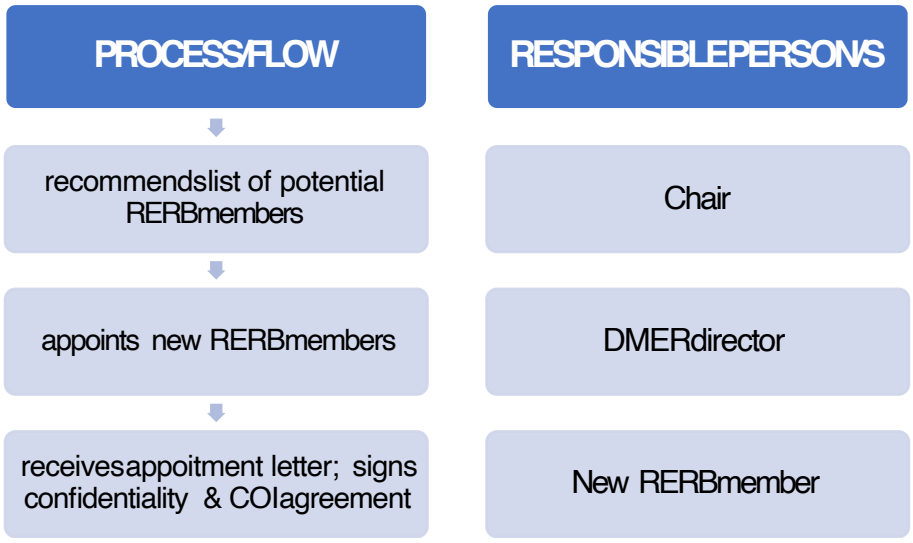
1.2.2. Scope

While the RERB remains under the authority of the DMER, 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 RERB members, officers, and independent consultants.

1.2.3. **Responsibility**

It is the responsibility of the DMER Director to appoint the members and officers of the RERB after the recommendation of the Chair.

1.2.4. Process Flow/Steps



1.2.5. Requirements for Membership

1.2.5.1. The CGHMC RERB is comprised of at least 8 regular members including a pediatrician/child development specialist. All members including alternates will be invited to attend monthly meeting. The pediatrician/child development specialist will be invited to specifically review studies pertaining to children.

1.2.5.2. For each meeting, all regular members, including alternate members will be invited with a quorum requirement of 50%+1. Moreover, at least 1 member whose primary area of interest is 1 non-medical and at least 1 member who is independent of the institution (who can be represented by the non-medical as the case may be) must be present.

1.2.5.3. In any case that an RERB member has conflict of interest to a particular protocol, s/he may give insights/inputs during deliberation but should inhibit her/himself from voting.

1.2.5.4. In case when the RERB Chair is the principal trialist of a study/trial for review, s/he shall disclose conflict of interest and inhibit her/himself in the protocol review and decision process, including but not limited to all documents submitted to RERB. All communications pertaining to the protocol need to be addressed to the Vice-Chair. The Vice-Chair is hereby given the authority to preside on matters related to the protocol and sign on all documents/ communications.

1.2.5.5. The RERB membership shall allow for multidisciplinary and multisectoral representation. Members should come from diverse background and experiences. This is to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations.

1.2.5.6. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the RERB should include a person who will represent the interest and concerns of the community.

1.2.5.7. One of the members in attendance should be a non-medical (lay member) who is not a practicing medical doctor, but may be an allied health professional, or non-scientific, or not institutionally related.

1.2.5.8. The RERB 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.

1.2.5.9. The RERB shall have representatives from both the older and younger generations.

1.2.5.10. The RERB shall invite independent consultants, whenever necessary, to provide expert opinion related to protocols under review, with no voting privilege.

1.2.6. Terms of Office

1.2.6.1. Members are appointed for two (2) years on the initial appointment. Thereafter, the appointment may be renewed by the Appointing Authority every three (3) years.

1.2.7. Appointment of Members

1.2.7.1. The DMER Director is responsible for appointing RERB members upon the recommendation of the RERB 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 and commitment to perform their functions in the RERB.

1.2.7.3. Members shall have valid certificate of Good Clinical Practice (GCP), training in research methodology and research ethics, or should be willing to undergo such training during their term.

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 (2) years.

1.2.8. Conditions of Appointment of Members

1.2.8.1. All prospective RERB members shall be willing to:

1.2.8.1.1. Make public his/her full name, profession, and affiliation as an RERB member

1.2.8.1.2. Disclose all financial accountability, reimbursement for work and expenses related to their work in the RERB. RERB Secretariat shall record and publicly disclose its financial records upon request.

1.2.8.1.3. Sign the confidentiality/conflict of interest/agreements regarding meeting deliberations, applications, information on research participants, and related matters.

1.2.8.1.4. The Secretariat and Administrative Staff is likewise expected to sign a similar document.

1.2.8.1.5. The Confidentiality Agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the RERB in the course of its work.

1.2.9. Resignation, Disqualification, and Replacement of Members

1.2.9.1. Members may resign from their positions by submitting a letter of resignation to the DMER Director.

1.2.9.2. Disqualification criteria considered, but not limited to:

1.2.9.2.1. through the conduct of his/her duties blatantly disrespects the RERB in any form

1.2.9.2.2. over-utilizes resources or make unnecessary referrals of goods or service for his own personal financial benefit

1.2.9.2.3. consistently shows biased judgment and viewpoints contrary to the ethical principles of human research

1.2.9.3. Members who resigned or were disqualified maybe replaced by following the appointment procedures previously stated.

1.2.9.4. The terms of replacement shall be limited to the remaining term of the member who shall be replaced.

1.2.10 Duties and Responsibilities RERB Officers

1.2.10.1 The Chair shall

1.2.10.1.1 Shall be appointed by the DMER director

1.2.10.1.2 Finalize and approve the agenda and preside in all RERB meetings.

1.2.10.1.3 Conduct a preliminary review of all protocols and decide on the nature of review – expedite, exempt or full board

1.2.10.1.4 Assign primary reviewers to initial protocols submitted

1.2.10.1.5 Ensure that a final decision on all protocols reviewed is made and break a tie whenever a deadlock in RERB voting occurs

1.2.10.1.6 Sign the following communications: Notice of Meetings, Notice of Action to Principal Investigators and Sponsors

1.2.10.1.7 Represent Chinese General Hospital and Medical Center in ethics-related symposia or meetings that require institutional participation

1.2.10.1.8 Ensure that appropriate decisions/actions are made by the RERB on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator, etc.

1.2.10.1.9 Submit annual reports on the accomplishments of the RERB to PHREB

1.2.10.1.10 Communicate decisions of the RERB to research proponents

1.2.10.1.11 Ensures that all RERB members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter

1.2.10.1.12 Prepares budget plan for the RERB

1.2.10.2 The Vice Chair shall

1.2.10.2.1 Be appointed by the Chair and selected based on experience and expertise from among the current RERB members

1.2.10.2.2 Have the authority to perform all the duties of the Chair when the latter is unavailable or unable to perform them

1.2.10.2.3 Perform other tasks as delegated by the Chair

1.2.10.3 The secretary shall

1.2.10.3.1 Be appointed by the Chair

1.2.10.3.2 Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair

1.2.10.3.3 Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting

1.2.10.3.4 Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions

1.2.10.3.5 Supervises the RERB Secretariat in the preparation of the agenda and minutes

1.2.10.1.1 Review minutes of the meeting

1.2.10.1.2 Accurately record (real-time) minutes of the meeting of the RERB

1.2.10.2 The Secretariat shall

1.2.10.2.1 Organize an effective tracking procedure for each proposal received

1.2.10.2.2 Prepare, maintain, and distribute study files

1.2.10.2.3 Organize RERB meetings regularly
1.2.10.2.4 Prepare and maintain meeting agenda and minutes of meeting
1.2.10.2.5 Maintain good RERB documentation and archiving procedures
1.2.10.2.6 Communicate with the RERB members and investigators
1.2.10.2.7 Arrange training for personnel and RERB members
1.2.10.2.8 Organize the preparation, reviews, revision, and distribution of SOPs and guidelines;
1.2.10.2.9 Provide the necessary administrative support for RERB related activities to the Chair of the RERB
1.2.10.2.10 Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the RERB members
1.2.10.2.11 Maintain a library of relevant resource materials and references
1.2.10.2.12 Ensure that all relevant documents are kept in order, maintained locked and secured in the cabinets

1.2.11 **Roles and Responsibilities of RERB Members**

1.2.11.1 Attend RERB meetings regularly
1.2.11.2 Review, discuss and participate in the evaluation and approval of research protocols
1.2.11.3 Assess serious adverse event reports and recommend appropriate action
1.2.11.4 Review progress reports and monitor ongoing studies as appropriate
1.2.11.5 Evaluate final reports
1.2.11.6 Maintain confidentiality of the documents and deliberations during RERB meetings
1.2.11.7 Declare any conflict of interest
1.2.11.8 Participate in continuing educational activities in health research and ethics

1.2.12 Confidentiality/ Conflict of Interest Agreement

1.2.12.1.1 The Secretariat shall provide a copy of the appointment letter with conforme signature (Form 1. See Appendix) to each member of the RERB.

1.2.12.1.2 It is the responsibility of all RERB 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 RERB.

1.2.12.1.3 Newly appointed members will obtain two copies of the Conflict of Interest Agreement Form (Form 2. See Appendix). They should read the text carefully, fill in their names, sign, and date the forms. The members keep a copy for their records. The Secretariat keeps a copy of the signed Agreement in the membership files. Any member may ask questions, or clarifications from the Chair or Secretariat in relation to the contents of the document.

1.2.12.1.4 The RERB 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 Agreement

1.3. Selection of Independent Consultants

1.3.1. Purpose

To describe the procedures for the appointment of RERB independent consultants

1.3.2. Scope

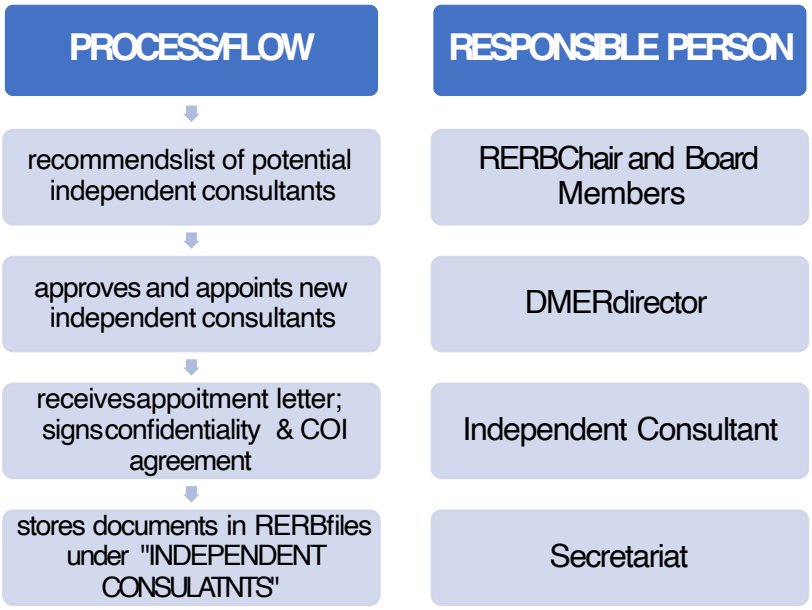
This SOP describes the procedures for engaging the services of a professional/expert as an independent consultant to the RERB.

In studies that involve procedure/s not within the area of competence or expertise of board members, they may invite from the pool of independent consultants an expert who could assist them in the review.

1.3.3. Responsibility

The RERB Chair and RERB board members are responsible recommend members of the pool of independent consultants for approval by the DMER Director.

1.3.4. Process Flow/Steps



1.3.5. Detailed Instructions

1.3.5.1. Selection of the Independent Consultants

1.3.5.1.1. The RERB Chair and Board members recommends independent consultants to help review research where the RERB lacks expertise.

1.3.5.1.2. The Chair finalizes and approves a list based on expertise and availability criteria and submits them to the Director of DMER.

1.3.5.1.3. The DMER Director appoints independent consultants to help the RERB Cinprotocol review.

1.3.5.2. Independent Consultant signs agreements

1.3.5.2.1. The Secretariat contacts the independent consultant, who will be asked to provide:

1.3.5.2.1.1. A signed Confidentiality/Conflict of Interest (Form 2. See Appendix)

1.3.5.2.1.2. An updated curriculum vitae (Form 3. See appendix)

1.3.5.2.1.3. A signed Terms of Reference (Form 4. See Appendix)

1.3.5.2.2. The Secretariat keeps the pertinent documents in an independent consultant's file. S/He prepares and files a roster of independent consultants and the areas of their expertise.

1.3.6. Independent Consultants render services

1.3.6.1. The RERB Secretariat provides study protocol documents to the concerned independent consultant for review, after the latter has signed the Terms of Reference and the Confidentiality/Conflict of Interest Agreement.

1.3.6.2. The independent consultant must complete the assessment form to be reviewed by the RERB at the time the study is reviewed.

1.3.6.3. The independent consultant shall attend the RERB meeting, present his/her assessment, and participate in the discussion but without voting rights. The report becomes a permanent part of the study file.

1.3.7. Termination of Services

1.3.7.1. Independent consultant's services may be terminated by either the consultant or by the DMER Director upon recommendation of the Board.

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

1.3.8. Store documents in the RERB folder under **Independent Consultants File** in alphabetical order.

1.4. Training of RERB Members

1.4.1. Purpose

To properly describe CGHMC RERB procedures in order to ensure initial and continuing training of RERB members and staff

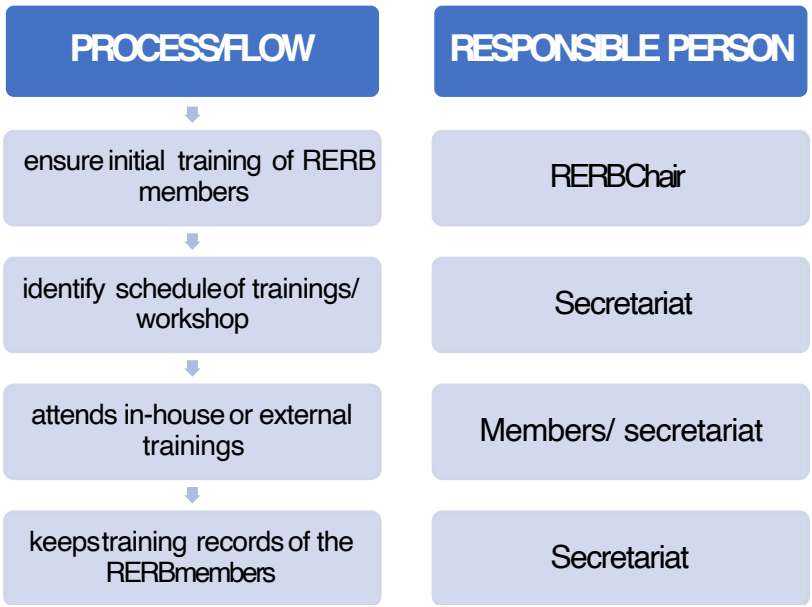
1.4.2. Scope

This SOP describes the training requirements of RERB members and staff from initial training to continuing ethical education. This is to maintain and update RERB competence in the task of reviewing different types of protocols.

1.4.3. Responsibility

It is the responsibility of all the RERB Chair, members and staff to have themselves educated and trained regularly. The Secretariat keeps track of the training records of all members.

1.4.4. Process Flow/Steps



1.4.5. Detailed Instructions

1.4.5.1. RERB members should maintain competence by ensuring that they have updated knowledge of the following:

1.4.5.1.1. Good Clinical Practice (GCP)

1.4.5.1.2. Declaration of Helsinki

1.4.5.1.3. CIOMS

1.4.5.1.4. Ethical Issues

1.4.5.1.5. Relevant laws

1.4.5.1.6. Development in relevant science, technical and environmental, health and safety aspects

1.4.5.1.7. Relevant requirements of health, safety and environmental laws, regulations and related documents

1.4.6. Initial Training of RERB Members

1.4.6.1. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in CGHMC RERB standard operating procedures.

1.4.7. Continuing Ethical Education of RERB Members

1.4.7.1. Members should have training in RERB SOPs. In addition, they should be provided with external training opportunities at least once a year.

1.4.7.2. The secretariat shall regularly obtain information on the availability and schedule of training courses, workshops or conferences on ethics

1.4.7.3. The RERB Chair shall identify members of the RERB who will attend seminars/ training/ workshop or conferences

1.4.8. Keeping the Training Records

1.4.8.1. The RERB Secretariat shall

1.4.8.1.1. Prepare attendance sheet of in-house training with relevant information about the topic, duration, date and venue.

1.4.8.1.2. Ask member attendees to sign the attendance sheet and keep a copy in the membership files.

1.4.8.1.3. Keep copies of Training Records (Form 5. See Appendix) of RERB members and staff in the membership and staff files.

1.4.8.1.4. Update the CV of individual member/staff to reflect attendance of training activities.

1.5. Incentives for the RERB Members and Independent Consultants

1.5.1. Purpose

To ensure that members of the RERB and independent consultants are granted honoraria for their work in the RERB

1.5.2. Scope

This SOP describes how RERB members and independent consultants be given honorarium for their work in the CGHMC RERB.

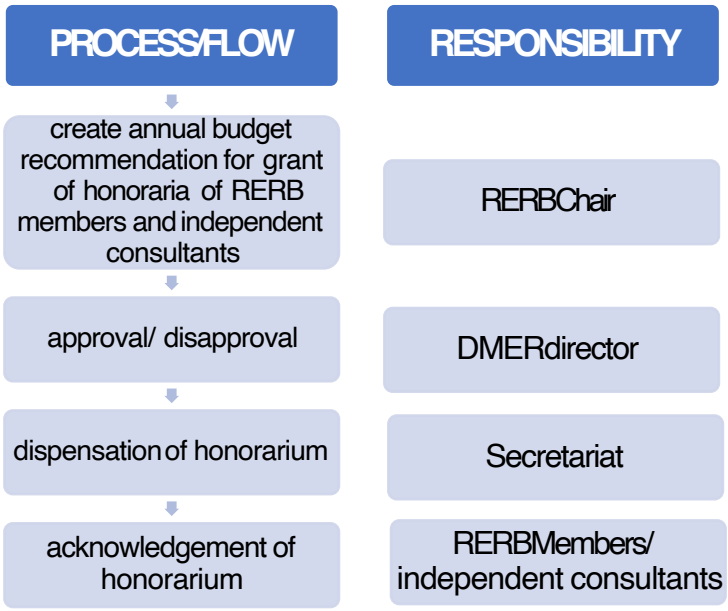
1.5.3. Responsibility

It is the responsibility of the RERB Chair to create a separate annual budget for RERB's operation and recommend grant of honorarium to RERB members and independent consultants to the DMER director

It is the responsibility of the secretariat to dispense the approved honorarium to members

It is the responsibility of the RERB members/ independent consultant to acknowledge receipt of honorarium

1.5.4. Process Flow/Steps



1.5.5. Detailed Instruction

1.5.5.1. Chair shall create an annual budget for RERB operation including the honorarium and other expenses.

1.5.5.2. Chair shall recommend to the DMER director the granting of honorarium to the RERB members and independent consultants for their work in the RERB. The honorarium shall cover attendance and review of protocols

1.5.5.3. The DMER Director may approve or disapprove the budget and recommendation.

1.5.5.4. The secretariat shall dispense the honorarium.

1.5.5.5. The RERB members or independent consultants shall sign a voucher upon receipt of honorarium