



TERMS OF REFERENCE **(ALTERNATE MEMBERS)**

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection. In accordance to provisions set forth in the national and international guidelines, it has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance of its researchers with all relevant procedures after approval of trials.

Membership

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 CGHMC RERB shall be composed of a pool of at least 8 members.

The RERB membership shall allow for multidisciplinary and multisectoral representation to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. The RERB also includes a person who will represent the interest and concerns of the community, have at least one member who is in a non-medical/non-scientific area, and one who is non-affiliated to the institution. It shall aim for gender balance in its membership, with representation from both old and young generation. An independent consultant may also be invited to provide expert opinion and expertise to protocols under review, with no voting privilege.



Appointment of Alternate Members and Terms of Office

RERB members shall nominate qualified candidates for new members to the Chair. The Chairman of DMER selects from the list of nominees for RERB members and issues an appointment letter.

Members are appointed for a maximum period of two (2) years on the initial appointment. The appointments may be renewed by the Appointing Authority for another term for a maximum period of three (3) years.

Training of Alternate Members

It is the responsibility of all the RERB officers, members and staff to have themselves educated and trained regularly. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in RERB standard operating procedures (SOP). In addition, they should be provided with external training opportunities at least once a year from information on courses/conferences gathered from various media channels in coordination with the Secretariat.

Review of Research Proposals

The CGHMC RERB accepts the following protocols for review: 1) CGHMC funded researches, 2) researches done in CGHMC by medical house staff, 3) research proposals submitted by CGHMC personnel for thesis defense, 4) industry sponsored researches to be conducted by CGHMC active/visiting medical staff to be conducted off-site (in the event the institution does not have ethics review board in place). In consideration to multi-center trials or studies, each Center/trial site has to have an independent or its own RERB approval for the said protocol.

Other than obtaining RERB approval, researches to be conducted by trainees that entail retrospective review of charts/medical records (with no actual participant/subject contact in whatever manner) will need to be approved by the Medical Director prior to implementation. All clinical study agreement (CSA) of externally supported/funded studies/trials should undergo approval by the Legal Division of the Hospital. RERB approval letter will not be released until CSA is approved by the office of the legal counsel.

Protocols submitted for RERB review (either for full board or expedited reviews) should follow the detailed steps set forth in the SOP. The RERB conducts regular reviews of approved protocols until end-of-study period. The Secretariat keeps close communication with the principal investigator for any concerns that need further clarification or actions.



Meetings

Monthly RERB meeting is held to discuss all concerns related to new protocols and ongoing studies. Notice of meeting as well as agenda set for the date will be closely coordinated to all by the Secretariat. For each meeting, an invitation to more than half of the general membership shall constitute a quorum, which includes community representative/lay member who is independent of the institution or research site. 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.

Post Approval Responsibilities

The RERB will continue to monitor approved projects in terms of compliance with national and international as well as local ethical approval. The RERB requires researchers to provide regular reports (frequency depends upon manner of review – full board or expedited review) and on completion of the study. It may request for additional information from the researchers on any relevant aspects of the project at any time. It will also require the researchers to report any form of protocol amendments, serious adverse events, protocol violation and deviation, early termination, as well as participant's requests or queries as soon as possible. Appropriate mechanism for site monitoring and random audits are also in place.

Amendments to the Terms of Reference

The Board may amend the Terms of Reference at anytime or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)

CGHMC RERB Member

Date:

Chair, Research Ethics Review Board
CGHMC

Chair, Department of Medical Education and Research
CGHMC