Guidelines for formation of Intuitional Review Committee (IRC) in Manmohan Memorial Institute of Health Sciences

Introduction

Manmohan Memorial Institute of Health Sciences(MMIHS) values and promotes its collaborative role in research and is committed to ensuring that research conducted within the institute's jurisdiction meets the highest scientific, ethical, and legal standards. The review process of the MMIHS-IRC is to ensure that clinical research conducted at Nepal Health Cooperative Ltd (NEHCO) umbrella is adequately funded for any organization resource utilization.The Nepal health Research Council (NHRC) regulation stipulates that an institutional research review committee is required to approve the disclosure of all health related information for research purposes. The IRC review the research projects and retains responsibility for ensuring that compliance with current legislation is in place.

Authority

The Management Board of the Institute vests the IRC with the authority to approve, reject, propose modifications to, or terminate all proposed or ongoing research involving or not involving humans within the institution's jurisdiction on grounds of non-compliance with current legislation, ethics guidelines, or resource feasibility considerations.

Research Policy

1. The review and conduct of research at Manmohan Memorial Institute of Health Sciences (MMIHS) must comply with the guidelines, standards, and regulations of the NHRC and other Nepal government regulations.
2. Ethical review is required for all research involving or not involving human subjects and encompasses both basic and applied research across varied disciplines (Public Health, Pharmaceutical Sciences, medicine, nursing, Medical Lab Technology and other allied health).
3. It is the role of the Intuitional Review Committee (IRC) to ensure that all research projects conducted within the jurisdiction of the institution have undergone the appropriate review processes.

Formation of IRC

MMIHS management committee will form an IRC (having at least five members) with a formal minute decision. In usual practice the committee should include members of sufficiently diverse backgrounds and mostly involved in the teaching learning in the NEHCO institutions and at least one member from outside.

Intuitional Review Committee (IRC) – Terms of Reference

1. Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.
2. All research activities (protocols) proposed for use at MMIHS staff personnel and students that involve or not involved human subjects must be reviewed and approved by an IRB prior to implementation. In addition, all amendments and/or revisions to ongoing, approved activities must be submitted for review and approval prior to implementation.
3. Require that information given to participants as part of informed consent is in accordance with appropriate NHRC regulations, and international standards. The IRB

may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.

4. Require documentation of informed consent or waive documentation in accordance with current laws and regulations.
5. Notify supervisors and/or investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRC approval of the research activity. If the IRC decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the supervisors and/or investigator an opportunity to respond in person or in writing.
6. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than twice per year, (unless the research has been classified as "Exempt") and have authority to observe or have a third party observe the consent process and the research.
7. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants and/or nation. Any suspension or termination of approval shall include a statement of the reasons for the IRC's action and shall be reported promptly to the investigator, appropriate institutional official and the department or agency head.

Administration

All activities requiring IRB review are administered through the Intuitional Review Committee (IRC) Office. This office reports directly to the Vice Chairman NEHCO responsible for MMIHS administration. The office of IRB is situated at the Nakkhu Campus building Lalitpur.

IRC Meetings

IRB meetings are held every month usually first Sunday of Nepali month and meeting will be schedule if necessary in between.

How to Apply for Review

Application for review by an IRC for any new protocol or activity in IRC office. All relevant materials, i.e., consent form(s), approach letters, questionnaires, etc., must be submitted in the appropriate number of copies as indicated in the IRB instruction form.

Each supervisor and/or Principal Investigator is notified of his/her agenda assignment and invited to attend the meeting to answer IRC questions.

Each supervisor and/or Principal Investigator is notified of the results of the meeting by formal memorandum. If modifications are requested, supervisor and/or principal investigators must comply or justify in writing why they feel compliance is not necessary prior to final approval documents being released. If modifications are requested and no response is received within thirty days, the supervisor and/or Principal Investigator will be contacted. If, after 15 working days, no response has been received the activity will be closed. Activities cannot be implemented, nor Certificates of Approval signed, until the IRB has issued approval and all required modifications have been confirmed complete.

Continuing Review

All activities must be reviewed at least once annually (except for studies determined to be exempt or Not Human Subjects). Each Principal Investigator is notified approximately 10 weeks prior to expiration by the IRC Office.

Certifications of Approval

Any grant, fellowship, or contract application (new or renewal, competing or noncompeting) submitted to a funding agency must include an indication of IRB approval for all activities proposing the use of human subjects or not human subject.

The Supervisor's and/or Investigator's responsibility to insure that all forms and other documents are submitted to the IRB so that review may be completed within the time frame. Once completed, the IRC office will send a copy of the subsequent (or follow-up) Certification of Approval to the supervisor or Principal Investigator.

IRB- Terms of reference of Chairman

Chair will usually serve for two years term, but is not limited to it and may be re-appointed. The IRC meeting will appoint a Vice-Chair to assist with the work of the IRC. The Vice-Chair will assume the role of Chair if the Chairperson is unable to attend.

IRB- Terms of reference of Member Secretary

-The role of member secretary is to make the minutes of the meeting under the guidance of the chairman.

-To manage the office of the IRC and execute administrative works

-Receive the research proposals from the researcher and coordinate with the peer reviewer to review the proposal

-Send feedback to the researcher on the proposal as per advised by the reviewer

-Serve as focal person for the IRC and be in continual connection with NHRC

-Do other necessary work as per assigned by the chairperson

IRB- Terms of reference of Member

- To support the committee in strengthening the quality of research proposal
- Support in reviewing of the proposal and provide feed back on the proposals