

त्रिभुवन विश्वविद्यालय
चिकित्सा शास्त्र अध्ययन संस्थान
डीनको कार्यालय, महाराजगंज
पो.ब.नं.: १५२४, काठमाडौं, नेपाल।
फोन नं. ४४१०९११, ४४१२०४०, ४४१३७२९, ४४१८१८७



Tribhuvan University
Institute of Medicine
Office of the Dean
Maharajgunj, P.O. Box: 1524
Kathmandu, Nepal
Ph.# 4410911, 4412040, 4413729, 4418187

पत्र संख्या / Ref.:-

शै.अ. फा.नं.

२०२१/१९७२
(२४६) च.नं. ००९६

मिति / Date:- २०७८/११/२३

श्री **Institutional Review Committee (IRC)**,
चि.शा.अ.सं., महाराजगञ्ज।

विषय : निर्णय पठाइएको बारे।

उपरोक्त सम्बन्धमा यस अध्ययन संस्थानको मिति २०७८/११/१२ मा बसेको विद्यापरिषद् स्थायी समितिको बैठकको निर्णय नं. २ त्यस कमिटीसँग सम्बन्धित भएकोले आवश्यक कार्यार्थ पठाइएको व्यहोरा अनुरोध छ।

प्रस्ताव : **Institutional Review Committee (IRC) Operating Procedures (Karyabidhi)**
स्वीकृत गर्ने बारे।

निर्णय :

चिकित्साशास्त्र अध्ययन संस्थान अन्तर्गत Institutional Review Committee (IRC) सञ्चालनका लागि निम्न बमोजिमको "**Institutional Review Committee (IRC) Operating Procedures (Karyabidhi)**" स्वीकृत गर्ने निर्णय गरियो।

Institute of Medicine
Dean's office, Maharajgunj
Institutional Review Committee (IRC)
Operating Procedures (Karyabidhi)

1. INTRODUCTION

Institutional review committee is an independent and autonomous body of the Institute of medicine. It has the responsibility of reviewing all ethical aspects of health related research proposals, and hence provide approval for the conduction of the research. The ethical review process is based on the ethical principles of health research –respect for the autonomy of research participants, beneficence and non-maleficence, justice and respect for environment. It will provide independent, competent and timely review. IRC will be free of bias and influence (political, institutional, professional, financial, etc).

2. ROLE OF IRC

- To safeguard the dignity, rights, safety and well being of all actual or potential research participants and ensure that animals, if used for research are treated humanely.
- To provide full review and evaluation of all ethical aspects of health related research proposals.

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3. FORMATION OF IRC

- The IRC will be composed of 15 members.
- The chairman will be appointed by the Dean of IOM.
- The members will be appointed by the Dean on the recommendation of the chairman.
- The member secretary will be appointed by the Dean, from the IRC members, on the recommendation of the chairman.
- The Committee member composition should balance gender and representation of various disciplines.
- The committee should include at least one member who is not affiliated with the institution.
- The tenure of IRC will be of 2 years.

4. ROLE and RESPONSIBILITIES of the CHAIR PERSON, MEMBER SECRETARY and MEMBERS

- Chair Person –
 - Organize, overview and participate in the overall ethical review process.
 - Chair and conduct IRC board meetings.
 - Work as a liason between IRC and Dean's office, NHRC and IRCs of other institutions.
 - Update IRC regularly on the ethical principles of health research.
 - Monitor all activities of IRC.
- Member Secretary –
 - Coordinate the internal review of the research proposals submitted.
 - Coordinate meetings of IRC.
 - Call IRC board meetings, prepare the list of research proposals for the board presentation and other agendas for discussion in the board.
 - Prepare minutes of the board meetings and approval letters.
 - Communicate and provide feedback/explanations to the researchers regarding proposals submitted.
 - Monitor the record keeping of the research proposals, approval letters and other communications of IRC.
 - The member secretary will be assisted by the staffs of IRC and the research department.
- Members
 - Participate proactively in all the activities of IRC.
 - Attend the IRC board meeting.
 - Provide feedback/opinion on the proposal presented to the full board.
 - Participate in the internal review process.
 - Provide input, suggestion and recent information regarding ethical review process.

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5. REVIEW PROCESS

- All research proposals submitted for ethical approval will go through internal review first.
- The proposals are then categorized as –
 - exempt – which do not need IRC approval
 - expedited – internal review is sufficient for approval
 - Full board– presentation and discussion in the IRC board meeting is required for approval
- External expert/s can be invited for the review process.
- The duration of the review process will be within four weeks.

6. BOARD MEETINGS

- The board meeting will be held at least once a month, or as required by the number of proposals to be presented to the board.
- More than 50% of board members must be present for the quorum to be complete.
- During the board meeting the PI/Co-PI will make a presentation of the research proposal.
- A consensus will be reached to approve, reject or revise the proposal.
- The board member must withdraw from the meeting during the decision making, if conflict of interest arises.

7. **SUPERVISION and MONITORING** - IRC has the responsibility to supervise and monitor researches approved.

8. **RIGHT to APPEAL** – A researcher who receives an unfavourable decision from IRC has the right to appeal.

9. **RECORDING and REPORTING** – Records of submitted research proposals, approval letters, meeting minutes, monitoring and communications should be kept.

10. **IRC office** – IRC office will share the same building with the Dept. of Research. The chair person and the member secretary will be provided an office each.

11. **ADMINISTRATION, LOGISTICS and FINANCE** – The member secretary will coordinate for the logistics, administrative and financial support required for IRC with the Dean Office.

12. **IRC ethical review fee** – IOM will charge 2% of the total research fund for externally funded research.

सहायक डीन (शैक्षिक)