

# Nepal Health Research Council and its role in ethics

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- Need of Ethical guidelines?
- Relationship between societies and science
- -government and communities values have an influence through settings of funding priorities
- -Researchers are shaped by their cultural background( gender research, health service research etc)
- These values can potentially bias the research





























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### INTRODUCTION TO NHRC

- Nepal Health Research Council (NHRC), was established in 1991 by the Government of Nepal (GoN)
- In 1995, NHRC published its first document on research ethics, "NHRC's Ethical Guidelines", which was primarily for research proposal reviewers, ethical committee members, health and medical researchers, health professionals and students of health and medical sciences.
- In 2001, NHRC published the National Ethical Guidelines for Health Research in Nepal
- Revised guideline was disseminated in a workshop on April 26, 2010.















- The ERB has delgated its power to the Institutional review Committees( IRCs)boards at health facilities, academic institutions and research institutions
- Every IRC has a muliti disciplinerary team, holds regular meetings and submits semi annual reports to NHRC
- An IRC is authorized to give clerance for research proposals within an Institution associated with a specific IRC, NOT for national or international researches, externally funded reaearches or clinical trials involving humans/animals.
- They follow the guidelines and SOP















"National Ethical Guidelines for Health Research in Nepal and SOP"-January 2011.

Assists the Ethical Review Board (ERB) of NHRC in achieving its commitment to promote and protect the dignity, rights, safety and wellbeing of all involved in health research in the culture and environment of Nepal















#### National Ethical Guidelines For Health Research in Nepal And Standard Operating Procedures



Nepal Health Research Council (NHRC) Ramshah Path, Kathmandu, Nepal

January 2011















#### 2005, there were three publications:

- -Ethical Guidelines for the Care and Use of Animals in Health Research in Nepal
- National Guidelines on Clinical Trials with the Use of Pharmaceutical Products
- -Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal















## The U.S. Government's Global Hunger & Food Security Initiative Elements of the Ethics Review Process

- Technical Review by the Reviewers: Submitted proposals are screened for completeness and reviewed by the internal reviewer. The proposal is then assigned to external subject experts to review the the scientific and technical content.
- Communication of review to the researcher: Reviewers' feedback is given to the researcher(s) who must then respond to the comments.
- **Ethical Review:** Technically and scientifically sound proposals that have addressed reviewers' comments are then submitted to the Member-Secretary of the Ethical Review Board (ERB) for a thorough discussion in an ERB meeting for ethical approval.
- **Decision Making:** Normally the ERB will make approval decisions by consensus, but the majority will rule if the timely agreement is not reached. The ERB may offer conditional approval with specific suggestions to the researcher or may disapprove the proposal with clear and compelling reasons.
- Communicating a Decision: The Member Secretary, on behalf of the ERB, will
  deliver the decision to the researchers in written form within two weeks of ERB
  meeting.
- Follow-Up: ERB monitors the progress of all approved studies. ERB has the right to monitor approved studies from the time the approval until the completion or termination of the research.







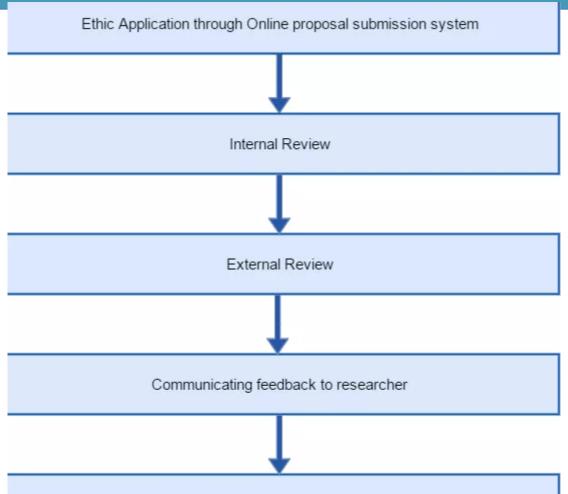








### The U.S. Government's Global Hunger Flood Security Initiative of Ethical Review Process

















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