



Ethical-Legal Context

Establishing guidance and legislation that will create an enabling normative and legal environment for the regulation of research.

This could start at the simplest level with ethical guidelines, and work towards the development of a legislative act or policy:

1. Based on existing international guidelines, develop national guidelines for ethics review
2. Legally mandating the ethical review of all human subjects research
3. Establish statutory requirements for the conduct and regulation of human subjects research

BUILDING

ESTABLISHING A RESEARCH ETHICS COMMITTEE (REC)

Structure

- Semi-autonomous within institution
- Representative membership

Functions

- Ethical review of research protocols

EQUIPPING

CAPACITATING THE RESEARCH ETHICS COMMITTEE

Human Resource Requirements

- Multidisciplinary and multisectoral representation
- Relevant scientific expertise
- Skills in ethical review of research protocols
- Balanced age and gender distribution
- Community representation (lay person membership)
- Administrative staff and resources
- Policy on payment and incentives for members

Logistics

- Infrastructure (meeting space, internet etc.)
- Meetings (periodic committee meetings)

Financing

- Develop mechanisms for sustained financing

ENHANCING

BUILDING UP TO A NATIONAL RESEARCH ETHICS COMMITTEE OR COUNCIL

As national capacity and research activity increases and there may be a need for more than one ethics committee, consider building the existing REC up to a national committee or council, with additional functions of oversight and monitoring over other local IRBs that might be established subsequently.

National Committee or Council Structure

- Autonomous
- Legally mandated to exercise authority and oversight of research regulation

National Committee or Council Functions

- Performs a leadership role for local RECs and independent review boards (IRBs)
- Supports and trains local RECs
- Establishes a registration and accreditation system for local RECs
- Reviews and amends existing guidelines for local contexts
- Monitors and audits RECs
- Arbitration of grievances
- Creates awareness of the role of RECs to enhance buy-in among researchers and the public