



A well-functioning research ethics committee is essential for ensuring the ethical conduct of research for health. This guide outlines key considerations for building, equipping and enhancing research ethics committees as part of the national research for health system.

Effective ethics review of research requires 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. Developing national guidelines for ethics review, based on international guidelines
2. Legally mandating the ethical review of all research for health
3. Establishing statutory requirements for the conduct and regulation of research for health

## BUILDING

ESTABLISHING A RESEARCH ETHICS COMMITTEE (REC)

### Role

- Promotion of ethical conduct of research for health
- Protection of rights, safety and welfare of human participants

### Structure

- Linked to an institution or in a private capacity
- Autonomous or semi-autonomous within an institution
- Representative membership that is independent, multidisciplinary and inter-sectoral
- Established and supported by institutional policy and national guidelines

### Functions

- Independent, objective ethical review of research protocols
- Grant approval in cases where proposals meet ethical standards
- Oversight of approved and ongoing research

## EQUIPPING

CAPACITATING THE RESEARCH ETHICS COMMITTEE

### Human Resource Requirements

- Multidisciplinary, multisectoral and independent representation
- Leadership (appointment of a chairperson)
- Relevant biomedical, scientific and sociobehavioural expertise
- Skills and training in ethical review of research protocols
- Balanced age and gender distribution
- Community representation (non-institutional representation by member of local community)
- Administrative staff and resources

### Documentation

- Terms of reference
- Standard operating procedures
- Confidentiality agreements
- Conflict of interest agreements
- Formal notice of membership appointment
- Policy on payment and incentives for members

### Logistics

- Infrastructure: meeting space, secretariat office space, filing systems and space, equipment (computers, printer/copier, telephone, fax), internet connectivity
- Periodic committee meetings
- Opportunities for member training

### 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 a national research ethics committee or council, with additional functions of oversight and monitoring over other local RECs that might be established subsequently.

### National Committee or Council Structure

- Autonomous and independent
- Legally mandated to exercise authority and oversight of research regulation and research ethics committees
- Accountable to government through relevant ministry or department

### 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
- Implements and manages an REC information management system
- 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