Composition of Ethics Committees

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An ethics committee is an independent body of people from diverse backgrounds, professions and values chosen from a community to oversee or enhance the ethical conduct of biomedical research within that community or jurisdiction.
Ethics Committees in Different Jurisdictions

- Institutional Review Boards (IRBs)
- Research Ethics Committees (RECs)
- Ethics Review Committees (ERCs)
- Health Research Ethics Committees (HRHCs)
Types of Ethics Committees

• Research Review Committees
  ○ Human subject research
  ○ Research with animals etc....
  ○ Stem cell research

• Clinical Ethics Committee
Establishment of RECs

- Some highlights of the Nuremberg Code (1949)
  - voluntary consent of the human subject is absolutely essential
  - the experiment should be such as to yield fruitful results for the good of society
  - the experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
Establishment of RECs

- Some highlights of the Nuremberg Code (1949)
  - the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved
  - the human subject should be at liberty to bring the experiment to an end if ....
  - the scientist in charge must be prepared to terminate the experiment at any stage if ..... a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject
• But How are These to be Ensured?
Establishment of RECs

- World Medical Association: Declaration of Helsinki (1964)

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental **protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor** provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
What Makes Research Ethical
In order for an institution to be able to conduct health research, the institution must have a registered health research ethics committee (HREC).

The authority to establish a HREC and the procedure of selecting members is vested in the Headship of the proposing institution.
Qualification of Committee Members

- The HREC shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of age, gender, socio-cultural backgrounds, religion and sensitivity to such issues as community attitudes.
Qualification of Committee Members

- Members should have varying academic and professional backgrounds to promote complete and adequate review of health research conducted by the promoting institution.
Qualification of Committee Members

- All members of the proposed HREC must have completed NHREC approved training programs in research ethics
  - Research methodology
  - Research administration  Recommended
Membership of RECs

- At least five members, and if more, the total membership must always be an odd number

- At least one member whose primary concerns are in non-scientific areas

- At least one member who is not affiliated with the institution
Membership of RECs

- **Chair of the RECs**
  - Must be respected members of the community
  - Community oriented

- **Other members** should represent various interests, scientific disciplines etc
Membership of RECs

- Non-affiliated members

  ✓ Ministers, teachers, attorneys, business persons etc
  ✓ Alternate members may be appointed to substitute

  ✓ Community members may be co-opted based on the particular research interests.
Membership of RECs

- Each HREC member must pledge to maintain confidentiality regarding
  - all meetings,
  - deliberations,
  - applications,
  - information on research participants
  - related matters
Resources & Further Readings

- The Nuremberg Code
- WMA Declaration of Helsinki
- CIOMS Guidelines
- REC Administrator 101