Research ethics review committees

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Disclaimer

- The opinions expressed are the author's own. They do not reflect any position or policy of the National Institutes of Health, Public Health Service, or Department of Health and Human Services

Background

- Established principle of research ethics that there should be independent review
- Some system of research ethics review established in most countries that do clinical research
- Requirement for drug approval: increase in interest in increased competence of review
- Continued deficiencies in system, both in developed and developing countries

Legislative/regulatory framework

- Based on funding
  - US: Federally funded research
- Based on drug regulation
  - US: FDA
  - Europe: GCP directive
- National legislation
  - Regulation within broader legislative framework
  - Most European countries, Brazil
- Semi-official bodies
  - Medical Council, Thailand
- Indirectly: Journal editors, outside rules

Organizational issues

- Institution based systems
  - Institution is responsible for its activities
  - Possibility for conflict of interest
- Regional committees
- Independent, private committees

Challenge

- To propose a system of research ethics review that
  - Ensures that all research in a country is reviewed
  - In such a way that allows committees to carry out their task

Composition

- Number: 5-12
- Different professional backgrounds
- Non-medical and non-science representation
- Gender
- Representation from outside institution
- Key: Independence

Challenge of “ideal composition”

- Research ethics committees in the Scandinavian countries
  - Sweden – Majority of physicians until 2004, now majority of biomedical researchers/physicians, but with judge as chair
  - Norway – Physicians in minority, majority with university backgrounds
  - Denmark – True majority lay representation

Lack of empirical data

- We do not know which specific composition is ideal
- Countries with very similar cultural backgrounds have chosen very different structures
- Two models:
  - A body with expertise: Sweden. The experts always have the decisive say. Brazil: at least half of members must have experience in research
  - A jury body: The committee consults experts

Tasks, US

- Evaluate risks and benefits of research
- Ensure equitable selection of subjects
- Review informed consent procedures and documentation
- Review adequacy of data and safety monitoring
- Review procedures to ensure confidentiality
- Review special safeguards for vulnerable populations

Tasks, Europe

- Relevance of clinical trial and trial design
- Risks and benefits of research
- Protocol, investigator’s brochure, quality of facility, suitability of staff
- Informed consent procedures

Tasks, EU,II

- Insurance provisions
- Amounts of compensation for trial subjects and investigators and agreement between sponsor and site
- Arrangements for recruitment of subjects

ICMR

- Advice on all aspects of safety and welfare of research participants
- Ensure scientific soundness of research proposal
- Protect dignity rights and well being of participants
- To ensure that universal values are expressed in terms of local community values and customs
- To assist in the education of the research community

Basic tasks

- Ensure that research ethics regulations are followed
- Ensure an appropriate risk-benefit ratio in trial
- Ensure that research conforms with appropriate standards and values

Different types

- Institutional
- Regional, National
- Belonging to International agencies or organizations
  - UNAIDS
  - EU
  - WHO

National Committee

- Policy setting body
- Appeal procedure?
  - Denmark, Sweden, Brazil
  - Norway: Advisory only
- Review research of particular types?
  - Externally sponsored research
  - Sensitive research: stem cell research
  - Brazil: human genetics, indigenous population

Multisite research

- Often there is a requirement that all local ethics committees approve research
  - Problem of time and conflicting recommendations on same protocol
- EU GCP guideline
  - For multi-centre clinical trials within single member states a procedure for the adoption of a single opinion state shall be adopted

Multisite research

- In the case of multi-centre clinical trials carried out in more than one member state simultaneously, a single opinion shall be given for each member state concerned by the clinical trial
- Both provisions are problematic
  - Spain
  - Why not one review for multi-country research?

Multi-site, US

- US: Each institution is responsible but may enter into an agreement with another IRB.
- US: Assurance of equivalent protection. But a separate requirement that US informed consent regulation be followed