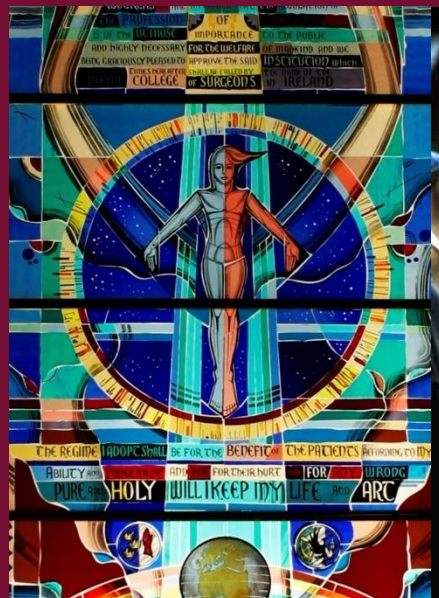
Royal College of Surgeons in Ireland
Coláiste Ríoga na Máinleá in Éirinn

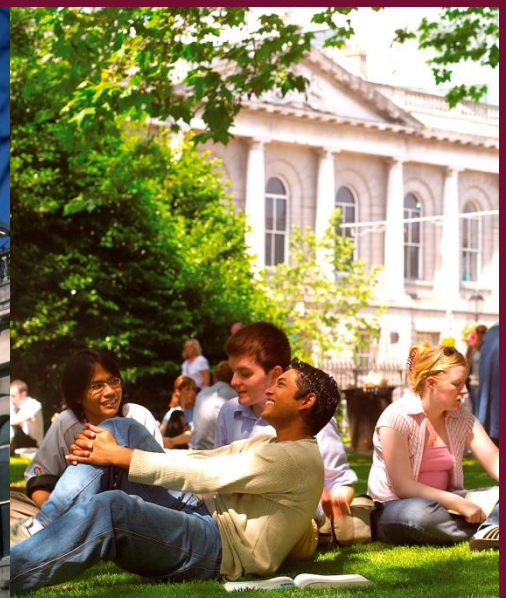
RCSI

Federation of European Academies of Medicine

Issues for Remit, Composition and Effectiveness of Research Ethics Committees

Prof David Smith





OUTLINE

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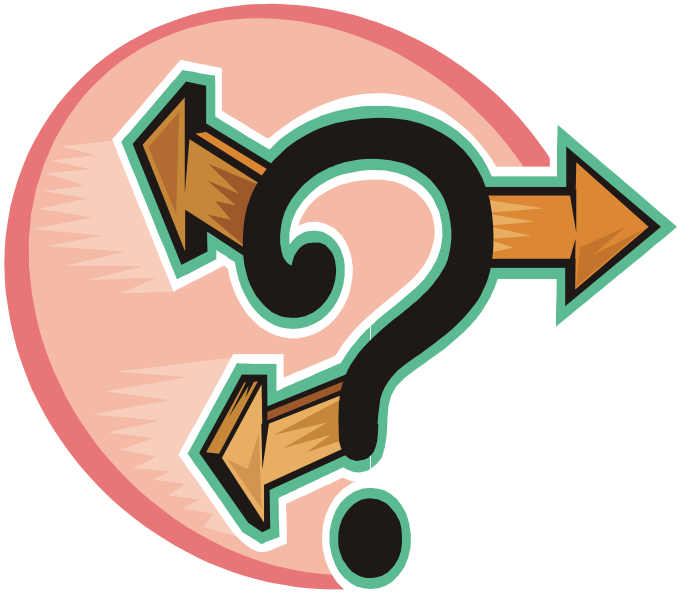
1. Remit
2. Composition of Research Ethics Committees
3. The Effectiveness of Research Ethics Committees



The Remit of Research Ethics

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- Derived from *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* – updated 2013
- No. 23 states:
- The research protocol must be submitted for consideration, comment, guidance and approval **to the concerned** research ethics committee before the study begins. **This committee must be transparent in its functioning**, must be independent of the researcher, the sponsor and any other undue influence and **must be duly qualified**. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The Remit of Research Ethics

- The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No **amendment** to the protocol may be made without consideration and approval by the committee.
- **After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions**

The Remit of Research Ethics

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- **While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.** No. 8
- **Medical research should be conducted in a manner that minimises possible harm to the environment.** No. 11
- Medical research involving human subjects must be conducted only by individuals with the appropriate **ethics** and scientific **education**, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. No. 12
- 2001 Directive Member States shall take the measures necessary for establishment and operation of Ethics Committees … (Article 6)

Function of Research Ethics Committees

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- ***Protection***: to protect the rights and welfare of human subjects of research from any physical and mental discomfort, harm and danger from research procedures; to protect your rights as a researcher to carry out legitimate investigation; and the University's/hospital's reputation for research conducted and sponsored by it
- ***Advice***: can advise individual researchers on whether a project is likely to be harmful or offensive to subjects or the broader community
- ***Education***: has the task of increasing knowledge and awareness of ethical issues and regulations/directives
- ***Research Quality***: For research to be ethical, it must be scientifically sound
- ***Conciliation***: conciliation and adjudication of conflicts between investigators and participants

FUNDAMENTAL CONCERNS FOR ETHICAL RESEARCH

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- ***Integrity***: a commitment to the search for knowledge, honest, ethical conduct of research and dissemination and communication of results
- ***Respect for Persons***: regard for the welfare, rights, beliefs, perceptions and customs of the person involved in research
- ***Beneficence***: researcher's responsibility to minimise risk of harm or discomfort to research participants
- ***Justice***: fair distribution of the benefits and burdens of participation in research for any research participant

Composition and Effectiveness of RECs

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- **General RECs or Specialised RECs**
- The increased complexity of data sets and advances in data-mining capabilities have serious data protection implications - this raises questions around the composition of RECs and whether RECs require members with specific professional expertise (e.g. in data protection).

Composition and Effectiveness of RECs

- **RESEARCH – AUDIT**
- Ethical considerations should apply to all medical practice, but many people act as if they apply only to research.
- For example, all research studies have to be scrutinised by an ethics committee, but most ethics committees specifically exclude audit studies from their remit.
- Consequently, the distinction between audit and research can have important implications, and the temptation to label research as audit is considerable.

Composition and Effectiveness of RECs

- **Variations in the EU**
- In contrast to the intention of the Directive to centralise and harmonise the work of RECs, the number of RECs, the appointment of members to RECs, the timelines for obtaining research permission from them, and the procedures for obtaining informed consent from vulnerable persons are all varied across Europe.
- There is no uniform method of implementing European legislation in the different countries. This situation raises doubts about the feasibility of international multicentre studies in the EU.
- Therefore, harmonisation should be considered as regards legislation on clinical drug trials and also on other types of research, and should cover the working principles of RECs.

Composition and Effectiveness of RECs

- **Membership**
- Members with clinical practice experience (physicians and nurses) are mandatory for all surveyed ethics committees, together with specialists in activities related to medical research (epidemiologists, pharmacists, pharmacologists and/or biostatisticians).
- This is a legal requirement in Austria, Germany, Italy and Spain.
- Lawyers and other lay members (ethicists, social workers and religious leaders) are the second group of mandated representatives.
- One of the biggest differences among the target countries is the representation number of those experts.

Composition and Effectiveness of RECs

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- The same is true for the participation of lay persons.
- In Denmark they represent the majority of all committees
- In Austria, France, Sweden and the United Kingdom they represent half of the membership
- In Hungary, Ireland, Italy and Spain one third or less.
- Representation of patients or patient groups is unevenly perceived as an ethical requirement.

Composition and Effectiveness of RECs

- **Monitoring and Auditing of Research**
- The involvement of RECs in upholding research integrity
- The inadequacy of current systems of monitoring research projects by ethics committees, widely recognized in the literature.
- Possible resistance amongst researchers.
- An obstacle to more comprehensive monitoring procedures often cited is lack of resources.

Composition and Effectiveness of RECs

- **A Way Forward? A report from the European Forum for Good Clinical Practice Drafted by the Research Integrity Subgroup of the EFGCP Ethics Working Party (June 2010)**
- Follow Denmark and the Nordic Countries and in the USA (with the ORI) for a **National Body on Research Integrity**. The case now had to be made for establishing such a body in other countries.

Points for Discussion

1. These differences have resulted in immense variations regarding RECs working practices and workload.
2. The efficiency of a review system depends on a clear regulatory framework.
   - There is a need for a common regulatory framework on other categories of research not involving medicinal products.
3. There is a need for formal training of ethics committee members and researchers.

Points for Discussion

4. Different national practices
   - Regulatory legislation applied only to clinical trials on drugs and medical devices
   - In other states various types of research is also regulated but by laws which are different from those concerning trials
   - In many countries, some research areas were not controlled by legislation at all.
5. Who are these Committees responsible to?
6. In many countries there is no appeal mechanism after a negative decision by an REC.

Points for Discussion

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7. There is a need for a fundamental debate regarding whether and which kinds of changes are needed for the further harmonisation of medical research governance in the EU and how cross-country medical research could be facilitated in the future.
   - Key members of the medical research community have expressed the opinion that changes should be made at the European level and not by national governments.

THANK YOU