Applying for ethics approval

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If your research project involves human subjects you must seek ethical approval, whether you are undertaking a project of clinical or a social / behavioural nature.

Contact
- Local research ethics committee
- Associated with institution involved in the research
- e.g. Universities, Hospitals, Departments of Health, Royal College of GPs

Why do you need ethics approval?
- To ensure relevance of research
- To ensure privacy
- To ensure confidentiality
- To obtain informed consent
- To ensure quality of the research & appropriate dissemination of results

When to apply?
- Before you start your research
- At the time you are planning your project
- Find out about meeting dates of the relevant research ethics committee; generally monthly; applications need to be in a week in advance to the meeting; find out if and how many hardcopies/ electronic copies are required
- Find out if ethics committee charge for their service (e.g. RACGP charges $400)

Guidelines & Proforma
Some ethics committee websites such as the Flinders Social and Behavioural Research Ethics committee: found at http://www.flinders.edu.au/research/Office/ethics/socialbehavioural.html have proforma of frequently required documents such as consent forms. These are usually accompanied by instructions and guidance. This saves a lot of time when preparing applications!

What do you need for the ethics application?
- Research team
- Details on duration, budget, participants, data source & storage
- Recruitment method(s), consequences of research, reporting to participants & publication
- Considerations on groups with special needs, e.g. Indigenous researchers – you might need to seek information from a relevant Aboriginal Health Research Ethics Committee
- Letter of introduction & consent form’ for participants explaining the project in lay language
- Detailed research proposal, including literature review, justification of need for the proposed research, primary hypothesis, project design & methods (e.g. details on randomisation, statistical analysis)
- Copy of study tool(s), e.g. questionnaire
Retrospective ethics approval

• The majority of ethics committees state in their guidelines not to consider retrospective ethics applications.

The Monash University in Melbourne seems to be an exception.

The Standing Committee on Ethics in Research Involving Humans (SCERH) at Monash Uni writes:
"In some cases where data have been collected without obtaining human ethics approval, retrospective approval may be granted for the use of the data. Permission will only be granted where the collection of data was completed in a way that did not give rise to ethical concerns. Where the data were collected in a manner which the Committee would have approved, retrospective approval for the use of the data may be given. Applicants should explain why human ethics clearance was not sought before the data were collected and why they are now seeking approval."

It is better to plan your research thoroughly and with the help of ethics committees, than not be allowed to publish the research and having 'waisted' time and resources.

http://bmj.bmjournals.com/archive/7087e.htm

Circumstances in which informed consent from study participants may not be necessary:

"...But [Prof D] does identify three sets of circumstances in which informed consent may not be necessary. So long as a set of conditions are met then research may be allowed without consent on patients not competent to give consent - including children, patients with learning difficulties, and unconscious or semiconscious patients. Otherwise, such patients will be denied the benefits of research. Secondly, epidemiological research on medical records may be acceptable in certain strict circumstances when, for practical reasons, consent cannot be obtained. Thirdly, research without informed consent may sometimes be acceptable on stored tissue from anonymous donors."

2) Woodcock T, Norman J. Explicit guidance is required on valid exemptions for need for ethical review. BMJ No 7102 Volume 315, Letters Saturday 26 July 1997
http://bmj.bmjournals.com/archive/7102/7102l9.htm

..."In essence, the grounds for exemption could include:

- that the information emerged from clinical practice and so does not constitute research (section 3.1 in the Royal College of Physicians' guidelines)
- that the information concerns innovative treatment applied with the patients' informed consent and so does not constitute research (section 3.2)
- that the investigation was considered to be a quality control or medical audit exercise exempt for the need for ethical review [section 4.8]."

Forum contributions by Liz Farmer & Karin Ried, July 2005

Ethics committees are there to help you. 😊
If you are not sure what ethics committee to apply to, ask the contact person of the committee you most likely think is the right one if they agree with you. 😊
They will also be able to advise you on any other appropriate ethics committee(s). 😊

Forum contribution by Karin Ried, October 2004

Other resources

SARNet Online Discussion Forum – http://som.flinders.edu.au/SARNetForum - To register contact SARNet

The Handbook will assist researchers to design and conduct ethically sound research. The Handbook will be of use not only to members of Human Research Ethics Committees and researchers, but also to research participants, students, research administrators and the public generally in providing useful information and references on most topics relevant to the ethical conduct of research.

Contains useful information and further reading.

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