

Ethics Submissions: Keeping it Simple¹

An ID PHD Program Tip Sheet

By Sandra K. Znajda, November 2006

If you're doing research that involves humans, you will have to acquire the approval of an Ethics Review Board before you carry out your research. For many of us, this seems like an incredibly daunting task. However it doesn't have to, nor should it, be complicated. This tip sheet provides practical information and tips on how to navigate the ethics review process efficiently and "painlessly".

Purpose of Ethics Review Boards

Over and above everything else, the purpose of an ethics review board is to ensure the protection of human research participants. This is done by following the guidelines set out in the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Human (TCPS, 1998)*. Ethics reviews need to be done before research is conducted.

The specific functions of Ethics Review Boards are to review your research and ensure that the proposed study demonstrates:

- Respect for human dignity;
- Respect for voluntary and informed consent;
- Respect for vulnerable persons;
- Respect for privacy and confidentiality; and
- Respect for welfare and rights of research subjects by minimizing harm and maximizing benefits.

Other Benefits

Going through an ethics review process can provide several additional benefits that will strengthen your research overall, including: (1) increasing your awareness of issues and problem areas you may not have previously considered; and (2) forcing you think clearly through the logic of your proposal, by way of needing to explain your proposal to someone else clearly and simply.

Important Things to Consider In Writing Your Application

Some essential tips to keep in mind when writing your application:

- Use simple language.
- Tell the story of your research.
- Keep it concise: e.g. one paragraph per question. 10-12 pages is often sufficient for the entire application, not including appendices (e.g. interview questions).
- Always justify your statements. What you say can get you into trouble; not what you don't say. If you put a one-line sentence in your application without justification, you will get flagged for further inspection.
- Follow the guidelines. Use the exact headings suggested in the guidelines for putting together your application.

¹ This tip sheet is based on a workshop delivered by Hendricus Van Wilgenburg, PhD Candidate, entitled "Ethics Submissions: Keeping it Simple", on November 16th, 2006. Version 1.1.

Writing Your Ethics Application

Each ethics review board will have their own set of guidelines for that particular ethics proposal. However, there are several areas that are common across all ethics review processes.

Risk-Benefit Analysis

- Ethics proposals are about minimizing potential risks to research participants.
- Think carefully about these potential risks and put *something* down – there are risks involved in any activity. In the ethics proposal, you will need to show what kinds of risks may be involved *and* how you are going to minimize these risks. Putting down “zero to minimal risk” will get your application flagged for further inspection.
- Describe what attempts will be made to ensure confidentiality and anonymity of your research subjects. It is not possible to guarantee anonymity, so it is sufficient to use phrases such as “every effort will be made to...”

Subject Selection

- How will you recruit your participants? What eligibility criteria will you use? Make sure to justify the reasons behind your choices.
- If you will be conducting research on a vulnerable population, justify in your proposal why this is necessary.

Informed Choice

- An *informed choice* is an intentional choice by a person with mental capacity, made with a reasonable understanding of the nature and consequences of available options and without undue influence.
- It is important that in your research your participants have a reasonable understanding of the nature and consequences of participating, and that they know they can leave at any time.
- Consent can take the form of written/signed consent forms, or verbal consent. If verbal consent is required over written, justify why this is so in your proposal (e.g. increases risk to participants in countries with political turmoil, literacy issues, culturally unacceptable, apprehension to bureaucracy will skew recruitment strategy).

Regardless of the form taken, informed consent should include the following:

- An invitation to participate;
- Research purpose (enough for participant understanding but not so much that it will skew your research results because participants know what you are looking for; if deception is necessary, explain this in the proposal, not the consent form);
- The identity of the researcher, including any actual/potential conflicts of interest;
- The nature and duration of participation;
- Description of procedures;
- Foreseeable harms, benefits, and consequences of participating;
- Potential uses of the data; and
- Contact details for further information if needed

Data collection and storage:

- What methods will you use to collect your data? Where will the data be stored? If you are bringing results back to the community, justify why you believe this to be necessary.

As a final tip, don't underestimate the importance of reviewing successful submissions as templates for your own proposal. At Dalhousie these can be found in the Office of Research Services, 3rd floor Henry Hicks.