

SOME THOUGHTS ON HOW TO SURVIVE THE RESEARCH ETHICS REVIEW PROCESS

Maureen H. Fitzgerald, PhD
School of Occupation and Leisure Sciences
The University of Sydney
Faculty of Health Sciences
PO Box 170
Lidcombe NSW 1825
Telephone +61 2 9351 9216
Fax +61 2 9351 9197
m.fitzgerald@fhs.usyd.edu.au
<http://www.ethicsproject.com>

Adapted from material prepared for The University of Sydney's College of Health Sciences
Fourth Research Conference 2004: "From Cell to Society 4", 3-4 November 2004.

The research ethical review process can be a daunting experience, but it is an inherent part of research in contemporary times. It is not going to go away so how can we survive this experience with our sanity intact. And, how can we get through the process in a timely fashion so our research funds or candidatures do not run out before we get ethics approval and, at the same time, have a project that is ethically and methodological sound. This paper provides a preliminary guide on developing an application and managing the ethical review process. It is based on research on anthropological, ethnographic research on the ethical review process as culture and cultural process.

Put your ego aside

This process can be an assault on your ego, but it does not have to be. During the process you may receive enquires and responses from the ethics review committee that will (or at least seem to) challenge your perceptions of yourself as an intelligent, responsible, knowledgeable person. Try not to take these things personally. Sometimes your response will not be to the question or comment, but to the way it is presented to you. Some committees have better communication skills and mechanisms than others.

Know your research and methodology

You need to be the expert in your research area and have a firm grasp of the methodology and data collection methods you intend to use. Your research question/topic must be clear in your mind before you can communicate it to others, particularly those who have no knowledge or experience in this area or only think they do.

Support your argument for why this research is important, but do not over-reference. Select your references with great care, but you can let the committee know through your writing that you know these are only a few examples of relevant references. The same goes for presenting your methodology and data collection methods. It is up to you to make a case that how you propose to do this research is not only the best way to do it in this instance, but that what you proposed to do is within the guidelines for best practice or, if the approach is new

or innovative, that you can support this approach. Again, use the literature to support your argument, but do not over-reference. Use your references for the greatest effect.

Unless there is a compelling reason to do so (like your audience will expect it to be named), do not label your methodology, particularly if your research involves an alternative paradigm or the kind of research many refer to as qualitative research. It is safer to describe and support what you propose to do than to name it. There is too much variation in understandings of many research terms, particularly in what is called qualitative research. The result may be that the same term can result in you and your reader thinking about different things. People will respond to the label. If you do not provide a description or your description does not match with the reader's understanding of the term, then you will have problems.

Know the potential ethical issues associated with your research topic and the methods you plan to use

The ethical review process can be used to your advantage and thus to the advantage of the potential participants. Use it as an opportunity to think through all the potential ethical implications of your research from the research questions to situations that might occur when you are collecting data to writing the research and disseminating it. Be your own most critical audience. Use your mentors, supervisors, friends and colleagues to help you think through the potential ethical issues. In most fields there are now texts that outline common ethical issues in relation to particular methodologies and data collection methods. Use them to help you think about potential ethical issues for your research and then try to think about them from the perspective of someone who does not know anything about this type of research. This is where your colleagues can be very helpful. You might also want to ask some people who know nothing about your research to get their perspective. Ask them how they would react if someone came to them and asked them to participate in a project like this. What kinds of concerns might they have? What questions do they have? Then be sure you consider them when you write your application.

You should also be familiar with the guiding documents for research in the places where you intend to do it. For example, in Australia you should be aware of the *National Statement* and the expectations it sets for ethically responsible research and the review of research. Use these documents to your advantage to not only identify potential ethical issues and concerns, but how they are addressed in the guidelines and any relevant legal documents, like the privacy legislation.

And last, but by no means least, review your professional code of ethics and any others that are potentially relevant to your work. Nearly all professional codes of practice today give some ethical guidance in relation to research in that discipline.

Know your review committee

This is not always an easy task. Committees vary in the amount of information they provide on the members of the committee and the processes they use in the review of applications. They also vary in terms of the issues and concerns upon which they focus.

Although you may not be able to identify particular members of a committee, all committees are made up of a group of experts that includes researchers and lay people. The membership of the committee is guided by a set of national guidelines. The kind of expertise available on a committee is not always easy to identify, but most committees, even those devoted to the review of behavioural and social science research, usually have a clinician and all have lay men and women. In some countries the committee may also be required to include a lawyer and a religious or cultural leader. Even when a committee is not required to include people from these categories, people from these categories may still be members.

Obviously, if you know who the actual people are on the committee you have the opportunity to identify whether or not a member has expertise in your specific area. You may also be able to identify their particular peccadillos. If you know that a member has particular concerns about certain issues, then you know better what kinds of things you need to take care to address in your applications. However, as we often do not know who the members of the committee are, write for the more general audience.

Write to your audience

Assume that the people reading your application are intelligent people who know little or nothing about your topic or the methodology you plan to use, but do so being aware that these people have often reviewed many applications. Even if they have not been on your particular topic, they have probably read applications on related topics. They may or may not be familiar with the methodology or data collection methods you plan to use. Even if some members are knowledgeable about these things, many members are not. Write to the person who is not knowledgeable, but do not write “down” to them. Again, just as you want to be treated as a reasonably intelligent person, so too do members of the committee. Considering how much power they have over your research, you want to communicate with them in a respectful way.

Use the proper form

Ethics committees are pedantic about forms and how they are filled out. One quick way to get on the bad side of an ethics committee is to use the wrong form or to not fill it in the way they expect.

Ethics committees often change their forms. You need to be sure you use the most recent version of the application form. Even if you just submitted your last application a month ago, check to be sure you are using the most recent version of the form. Submission on the wrong form (or version of the form) irritates committee members to the point that it actually influences how some will review your current application, even whether or not they will review the application.

Most committees provide downloadable versions of the most current ethics form on the committee’s website. If the committee does not have a website or you cannot download a form, then contact the ethics officer.

Many of the questions on a form may seem inappropriate or not applicable to your research, particularly if you are not going to be doing medical research. Most committees’ forms are designed for medical and behavioural research, with the clinical trial the core model. You

must still deal with each question, even if it is to note that it is not applicable. However, do not assume that you and the committee will agree on what questions are applicable. When in doubt, contact the ethics officer or other designated member of the committee. Do this before you submit the form or it might be sent back to you unreviewed.

Be consistent

As you work through an application form it is easy to lose track of what you have already written, particularly when several questions seem to address the same issue. Working through the form may also encourage you to think about how you will do the research and you may actually make changes to your methods as you fill out the form. Before you submit the application be sure that the responses are consistent across all sections of the form. Ethics committee members will almost certainly pick up any inconsistencies in your application. So check your application to be sure there are none for them to find.

Proof the final form

The quality of the writing on your application form can influence the committee's impression of the quality of your work — not just this application, but the general quality of your work. There is no way to overemphasize the impact the quality of the writing has on the response of ethics committee members. One of the pet peeves of committees is poorly written forms. They become easily irritated by spelling and grammatical errors. This does influence their reviews.

You must proof the final copy, and then do it again. Use the spelling and grammar checking program on your computer — and ask several people to read the application. If possible, use the services of a professional editor, particular for information sheets and consent forms.

Ethics committees often spend an inordinate amount of time reviewing and critiquing informational sheets and consent forms. Get this part right. It needs to be in clear and concise language and it needs to be grammatically correct and with the appropriate punctuation. You should write these forms in language understood by someone with a Grade 6 education. Some committees suggest a higher level, but at the Grade 6 level the information should be understandable to most literate people in that language, including highly educated people who tend to read such materials very quickly.

Translations and Verbal Consent

If the population or populations you will be working with are more fluent in another language, be sure the forms are appropriately translated. There are standard procedures for obtaining high quality conceptual translations that are appropriate to the population. When possible use the skills of a professional translator. Consider providing a form that includes English and the other language/s on the same sheet. Many people are bilingual and many find it useful to be able to read the information in more than one language to be sure they understand the material.

In some cases it may be more appropriate to provide the information that would commonly appear on an information sheet in another medium, for example verbally or on a video or

audiotape. Committees will expect you to provide the basic information that will be included in the consent process no matter what media will be used. In some cases it will not be possible to provide a script, but you do need to let the committee know basically what kinds of information the person will receive before making a decision to participate in the research.

Ethnographic research and things like participatory research present particular challenges for the consent process and convincing committee of the appropriateness of the process to be used. Obtaining consent is one of the most contentious issues in the review process. This means that methods other than a written consent form are often more appropriate, but it is your responsibility to convince the committee of this.

Think ahead

The time it takes to get through the review process varies from country to country and committee to committee. For example, minimum times can vary from a few days to two months. Some projects can take up to a year to get through the process. If the committee has questions or concerns about the research or the application this will expand the time required. If this project requires review by more than one committee then the time required often increases exponentially. If you can, find out how long it normally takes an application to go through the review process with the committee or committees involved and then use that information to help you plan when you have to submit your application. Sooner is better than later. It is safe to assume that you will not get through in the minimum time reported. So plan ahead.

Planning ahead also means thinking about the kinds of questions the committee is likely to ask. If you can deal with them in the initial application, all the better. Assume that no matter how good your application, the committee will have questions or will demand some changes. This is not a personal attack; it is just the way they do things.

In the meantime

Do not just sit and wait for the ethics committee's response. Get on with all the related work for the project so you are ready to begin when the approval finally comes through. Do not let the waiting time be wasted time.