

Tips, Hints and Frequently Asked Questions regarding Human Ethics Applications

The Faculty of Business and Economics Human Ethics Advisory Committee meets monthly from February to November to consider applications for Human Ethics approval submitted by Faculty researchers and students. The Committee has noted that applicants commonly experience problems with particular questions on the form, or that applicants do not provide enough detail in their responses to enable the Committee to make a decision as to whether or not the study meets ethical guidelines. Without adequate detail the Committee will have to return the application to you for revision, and this will slow down the ethics approval process and delay the commencement of your research.

We have prepared a list of these that may prove helpful when completing your Minimal Risk application form.

THEMIS – MINIMAL RISK APPLICATION SUMMARY Section E: Additional Questions - a) Sponsored Projects

Applicants seeking to identify the Australian Research Council as a sponsor of their research should be aware that in order to find this sponsor you will only be able to find 'Australian Research Council' as an option and you will not be able to specify individual ARC funding schemes (e.g. Linkage, Discovery). You can use the description field to list more detail. If you have been funded by another sponsor and are unable to locate them in the Themis look-up tables of sponsors, you can list the grantor in the description field.

APPLICATION FORM

1.3 METHOD

What data collection technique(s) will be used?

2.1 TARGET PARTICIPANT GROUP

2.2 NUMBER, AGE RANGE AND SOURCE OF PARTICIPANTS

Provide number, age range and source of participants.

2.3 JUSTIFICATION OF PARTICIPANT NUMBERS

2.4 PARTICIPANT RECRUITMENT

Please indicate the method of recruitment by ticking the appropriate boxes.

Applicants often **fail to provide enough detail** of the data collection methods proposed and the ways in which participants will be recruited to the study for the Committee to make an assessment of their application. Please be **very specific about the size of the sample** (and justify why you think it is adequate for your study objectives), **how you will collect the data** (is it via interview, questionnaire or a range of methods) and provide clear details about **how you will recruit study participants**.

If you are planning to recruit students to your study provide detail as to how you will seek the necessary approvals before you approach students (e.g. emailing lecturers seeking approval to distribute a questionnaire in their class, etc).

2.4 PARTICIPANT RECRUITMENT

If you are not going to use an **advertisement, third party recruitment** or **contact details from private sources** as means of participant recruitment, **please ensure that you select ‘N/A’ at each question**. Applicants tend to assume that if the first option doesn't apply to them that they are not required to complete any of the boxes that follow. The Committee needs to be sure that you have read all potential recruitment options and have answered each one as appropriate.

2.5 DEPENDENT RELATIONSHIPS

Great care needs to be taken in those projects where the research involves persons in dependent or unequal relationships (e.g. teacher/student, doctor/patient, student/lecturer, client/counsellor, warder/prisoner, and employer/employee). Should this apply to your research project please **explain to the Committee how this issue will be dealt with throughout the course of your research** (i.e. a lecturer sampling students in his Department/Faculty might respond 'students will be advised when being asked to participate in the study and also in the Plain Language Statement that there will be no adverse outcomes for them should they decide not to participate in the project, or withdraw from the project after it has commenced'). **Consider whether it might be best to approach students in another Faculty or University to ensure that there is no potential for a dependent relationship to influence participation.**

3.2 PLAIN LANGUAGE STATEMENT

When preparing a Plain Language Statement please **ensure that all information you have indicated at 3.2 you will include is actually included in your Plain Language Statement!**

Applicants frequently fail to include:

- clear identification of the Department, the project title, the researchers and their contact details and the level of study if it is a student project (e.g. Honours, PhD)
- advice that the project has received clearance from the HREC
- a statement that involvement in the study is voluntary and that participants are free to withdraw previously supplied unprocessed data
- advice as to whether or not data is to be destroyed after a minimum period (see 5.1 Data Security)
- a footer with the project HREC number (i.e. your Ethics ID from your Themis submission), date and version of the PLS
- advice that any concerns about the conduct of the project can be taken up with the Executive Officer, Human Research Ethics, and contact details

Please use **the checklist at 3.2 to ensure that you have included all the necessary information in your PLS and ensure that is printed on University letterhead**. Applicants are frequently asked to re-visit their PLS as it is incomplete.

You might it useful to look at the following examples of Plain Language Statements from approved projects when preparing your own for your project

(<http://www.ecom.unimelb.edu.au/research/ethics/>)

Small sample size

3.2 (7) on the PLS checklist it is stated: 'if the sample size is small – confirm that this may have implications for protecting the identity of the participants' - this causes confusion for applicants. Applicants only need to select this option (and make mention of the risks for identification in the PLS) when they have a **small sample from one organisation** where there would be issues about identification. If you have a small sample size that is made up of people from **different organisations** you do not need to select 'yes' at 3.2 (7) as there are not the same risks regarding identification.

4 PRIVACY AND CONFIDENTIALITY

4.3 WILL THE RESEARCH INVOLVE:

- | | YES | NO |
|---|--------------------------|--------------------------|
| • complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)? | <input type="checkbox"/> | <input type="checkbox"/> |
| • de-identified samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)? | <input type="checkbox"/> | <input type="checkbox"/> |
| • potentially identifiable samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)? | <input type="checkbox"/> | <input type="checkbox"/> |

Applicants frequently select 'Yes' to more than one of the above options when completing this section of the form, **when it is most likely that there will be only one method** in place (e.g. if you are asking participants to complete an anonymous survey and no details are collected then you should answer 'Yes' to 'complete anonymity of participants', and 'No' to the remaining two options). Applicants often **make contradictory responses to these questions** (e.g. they select 'Yes' to both complete anonymity, AND potentially identifiable samples or data). It is very rare that you would have both anonymous and identifiable data (e.g. you were undertaking the project in two phases with two different data collection processes in place) – please **select 'Yes' to the one option that applies to your research, and 'No' to those that aren't applicable.**

5 DATA STORAGE, SECURITY AND DISPOSAL

There are a series of questions that relate to how you will securely store and eventually confidentially dispose of your research data. When you answer these questions please bear in mind that the **minimum retention period for research data and records is five years after publication, or public release, of the work of the research** (as stated in the University of Melbourne Code of Conduct for Research). Your response to 5.3 should reflect this minimum period (e.g. ‘the questionnaires will be kept for a minimum of five years after release of my Honours thesis, and then they will be confidentially disposed of’). Also ensure that **your PLS contains this information** as well.

6 POTENTIAL CONFLICT OF INTEREST

If you have not indicated a potential conflict of interest at 6.1 please select ‘Not Applicable’ box at 6.2.

Applicants often get confused completing this section and tick the ‘Yes’ or ‘No’ boxes unnecessarily – you only need to make a yes/no response if you have identified a conflict of interest.

SIGNATURES

Please ensure that **all researchers sign the application form at Section 7**, and that you **obtain a signature from your Head of Department at Section 9**.