

Avoid common problems and delays with research ethics applications

What can hold up your application?

1 Information sheets and consent forms

As the information sheet and consent form are the formal documents between the University and the participant, the Human Research Ethics Committee is at pains to ensure that there is fulsome, succinct and appropriate information available. The information needs to include the components required under the National Statement and the information sheet needs to have enough detail that a potential participant is able to make an informed decision.

1.1 Double check -

- Name and contact details of the research candidate and the supervisor are provided. Note the research candidate/student must provide their UWS student email contact details.
- It's clear how the research results are to be disseminated
- It's clear whether the participant will be identified or not
- The ethics complaint clause is included
- There are details about what the participant is being asked to do.

1.2 Style

The information sheet's audience – the participants – needs to be considered in terms of the way the project is described. There should be enough detail so someone can make an informed decision to participate – but remember that detail does not mean more technical.

1.3 Proformas

There are proformas for Information sheets and Consent forms – they are fill-able pdf documents with hover text to guide you through each section.

1.4 Web location

http://www.uws.edu.au/research/researchers/ethics/human_ethics/apply_to_human_research_ethics_committee_guide1#3

Notes:

In some instances a consent form is not required, for example an anonymous survey. Consent forms should indicate the person and address the form is to be returned to. The 'Ethics Complaint Clause' should be included on the bottom of all Information sheets and they must be printed on a UWSW letterhead.

2 NEAF Application

HREC's responsibility is to make an informed decision. It is very rare that HREC would decline to approve a project but sometimes it is difficult for the committee members to come to a judgement based on the slight information that they have from the application.

If a NEAF question is relevant - based on the information you enter into the web tool - it will appear on the screen, therefore, none of the Items will be able to be addressed with a N/A response.

In planning their own research, researchers will often consider and address ethical issues automatically as a component of the professional conduct of the proposed research. In making an application for ethical clearance, it's essential that you make this process transparent to the ethics committee. This confirms that you are aware of, and have responded to, the issue, rather than the HREC being unsure whether the "silence" means that you are unaware of the issue.

The NEAF sections that often don't reflect the researcher's consideration and planning of ethical issues are addressed in more detail below.

2.1 NEAF Item 5 (Research aims, plan, benefits etc)

Data collection – if a survey or individual interviews are mentioned, detail about the data instrument, the participant group, the recruitment and the consent process is needed by the Committee. All data collection instruments should accompany your application.

Information sheets and consent forms should be provided to cover this component of the research.

Research to be conducted overseas should be acknowledged.

2.2 NEAF 5.3 Section covering risks.

Risk from an ethical perspective is essentially a specialised understanding of risk in relation to the National Statement (2.1). It's the choices, experience, perceptions, values and vulnerabilities of different populations of participants that are relevant.

Risk is almost always something that can be managed and HRECs do not decline approval because risks are present, rather researchers should advise HREC how they will manage particular risks.

2.3 NEAF 6 Participants

- 6.3 Participant experience – tell what will be done, when, by whom and where
- 6.4. Relationship of researchers to participants, in particular, potential conflict of interest – again this is normally manageable, but how it will be managed needs to be articulated.
- 6.5 and 6.6. Recruitment and Consent– detail needed about how the recruitment process will avoid the possibility of coercion or pressure, including where consent might reflect deference to the researcher's perceived position of power not only as a researcher but in other contexts, e.g. student's using their children or siblings or other relatives as participants. Power as the HREC understands it takes many subtle and indirect forms.

2.4 NEAF 8.4 Ownership of data

University policies govern responses to this section.

In accordance with the UWS Intellectual Property Policy – Part E – (22) in accordance with legal principles, the University, as employer, is the owner of intellectual property created by staff, in the course of their employment.

Part I – Scholarly works and student theses (36) in accordance with conventions in the university community for many years, the University will not claim ownership of copyright in scholarly works. (37) A student will own copyright subsisting in the student's thesis. The University will not claim ownership of copyright in a student thesis

2.5 NEAF 8.5 – Storage and Disposal of the Information

There is a mandatory 5 year period for storage of data. Longer storage is not required. Articulate how the data will be stored in a secure manner.

3 Communicating with the Human Ethics Officer

It is very helpful if in any communication with the Human Ethics Officer, you refer to the ethics protocol/registration number and the name of the project, particularly as funded project titles are not always used for the ethics application.

3.1 Feedback and re-submission of NEAF

You will receive an email advising of issues the committee needs clarification on or information that is missing. In many instances, this will mean that the NEAF also needs revising, plus any attachments that needed revisions. The revised application is sent to the Human Ethics Officer electronically – it is very helpful if a brief summary of the modifications is in your email, ensuring that the revised proposal can be quickly reviewed and approval issued.

4 Other documents

Applications for ethical clearance will often include attachments (eg a copy of the information sheet and consent form. The data collection instruments or some sample questions from the instrument or an indicative line of questioning, or copy of the approval from another organisation). Ensure that all the required attachments are included with your application for ethical clearance.

WEB addresses:

Main Human Ethics page:

http://www.uws.edu.au/research/researchers/ethics/human_ethics

Apply to the Human Research Ethics Committee page

http://www.uws.edu.au/research/researchers/ethics/human_ethics/apply_to_human_research_ethics_committee_guide1

Form: Progress Report; Final Report; notification of an adverse event page

http://www.uws.edu.au/research/researchers/ethics/human_ethics/human_ethics_adverse_eventend_of_project_report

College/Division Peer Review Committee contacts page

http://www.uws.edu.au/research/researchers/ethics/human_ethics/college_committee#3