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Writing Tips: Ethics Application

Planning and time allowance

Writing an ethics application is an essential part of a research project that involves human participants, which can be time consuming. As such, the ethics component of your research project requires time and planning. Researchers should allow sufficient time to develop a well-written ethics application that addresses all relevant ethics issues.

Ethics application – the HREA

The ethics application process at TUA is online, using the online platform Ethics Review Management (ERM). The form is based on the Human Research Ethics Application (HREA), which highlights the ethical principles with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

Refer to guidance documents

There are numerous guidance documents available via the Human Research Ethics page, including links to relevant policies, legislation and the National Statement.

Also available are exemplars to provide an overview of template usage including the **project description and PICF.**

Clear communication and plain language

An ethics application should be written in plain language to ensure it can be easily understood. This is relevant for the application as well as the attached documents. All participant recruitment documentation should be in plain language to support informed consent (such as the PICF, recruitment flyers, introductory letters, etc).

Write for the participants

When considering the ethics issues that may arise, and in writing your ethics application and recruitment documentation, place yourself in the role of a potential participant. Write the application and documentation respectfully, appreciating a participant's viewpoint and needs; consider what information and reassurances would be important to you, and provide clear guidance regarding what participants are being asked to consent to.

Complete and self-explanatory

The ethics application and attachments must provide a comprehensive description of the research proposal. Researchers should ensure documentation is consistent and complete, to enable ease of review and approval by the HREC. Incomplete or missing information may delay the review process.

Ethics application attachments

There are a number of documents that are usually required to complete your ethics application. Each document should be attached and clearly labelled according to the content.

Such documents include (not limited to):

1. Project Description
2. Research Team CVs
3. TUA Management support (staff researchers)
4. Participant Information & Consent Form (PICF)
5. Recruitment documentation, for example flyers, introductory letters, organisational permission.
6. Survey/Interview/Focus Group questions

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Ethical concerns

There are a number of ethical concerns to consider when writing an ethics application, including:

1. **Participant involvement:**
    a. **Participant risk:** designing the research project and participant involvement to minimise risk, offer mitigating strategies and disclose this information.
    b. **Participant recruitment:** participants must be recruited to enable voluntary participation, self-selecting against the selection criteria provided and without coercion.
    c. **Participant informed consent:** participants should have clear information provided to enable informed consent.
    d. **Participant remuneration:** In addition to the National Statement, the NHMRC has published advice regarding payment of participants, available at NHMRC: Payment of participants in research: information for researchers, HRECs and other ethics review bodies
    e. **Participant feedback:** Participants can be provided with the opportunity to receive outputs/outcomes of the research, which should should be stated within the PICF: *"Researchers should advise participants on the format and medium or media that will be used to disseminate outputs or outcomes of research to them (such as a lay summary, a research manuscript or published paper, or both) and, to the extent known, when such information about the outcomes will be made available to them. Dissemination of outputs or outcomes of research should occur in a timely fashion".* National Statement 3.1.71
2. **Confidentiality and privacy:** *"Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities."* National Statement 1.11
TUA researchers are bound by the Privacy Act 1988, which employs a broad definition of personal information:
Further information and examples of 'personal information' can be found at the Office of the Australia Information Commissioner (OAIC).
3. **Ethical data management:** Research data should be managed in accordance with TUA data management policies and the Privacy Act 1988, and the approach should be consistently described throughout the ethics application and attachments. Also the data management approach should be conveyed to participants in the PICF: *"In any information provided to potential participants during the consent process, researchers should include information on data management and storage..."* National Statement 3.1.31

Responding to the compliance review by the HRE Office

Once your ethics application has been submitted within ERM, the HRE Office will conduct an administrative compliance review, and provide feedback.

The objectives of this compliance review are to:

1. Provide constructive feedback to researchers to facilitate ethical research.
2. Ensure that research projects align with the National Statement, relevant legislation and TUA policies.
3. Ensure that participants are treated with respect.

The compliance review feedback will be provided within ERM at 'comments', with guidance statements and recommendations. Researchers should carefully consider and address all comments before resubmitting the application. The compliance review, including researcher responses, will be accessed by the HREC when considering the application.