

# REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

## Receiving and Responding to Ethics Committee Assessor Comments

### Review of applications

After your human ethics application has been assessed by the Low and Negligible Risk (LNR) or the Human Research Ethics Committee (HREC), you will receive feedback from the Committee. This will usually be that:

- the application has been approved, or
- the Committee requires more information from you before being able to approve the application.

Very occasionally the Committee will feel that the application requires a substantial redraft and the researchers will be asked to 'resubmit' the application.

Ethics approval following first review is not the norm in any HREC. Therefore, please don't feel discouraged if you receive a request for more information.

### Responding to review

The request for more information will set out the queries or suggestions on which the Committee needs clarification. Some of these will be related to specific application questions and they will be noted to correspond to the application form. Others may be general comments.

### When responding to HREC's review you are asked to do the following.

1. Create a summary sheet in a Word document that sets out the Committee's feedback and how you are responding. Ideally this is done in a table – review comments in the left column, your summary of responses in the right column. If you change text in the application form or attachments you should note what the text now says.
2. You may accept the Committee's commentary and make the relevant change or you may not agree with the comment or suggested change. In the latter case, please provide the Committee with the relevant clarifying information or put a case back to the Committee, providing more information that helps the assessors understand what you are doing and why you are wanting to do it in the way originally outlined. Be assured the Committee is open to reasoned argument for practices that meet the principles of ethical research as outlined in the *National Statement*.
3. Reflect all changes in the application form and attachments, e.g. information sheet and consent form, and provide copies of the revised documents.
4. Ensure that the revised version of the application form has been signed by all the researchers to acknowledge their agreement to the new version.
5. If the principal investigator is a student or PhD candidate, evidence of the Principal Supervisor's agreement with the changes must be provided. Note: if it's impossible to get a signature in a timely manner, an email from the Principal Supervisor stating that they have reviewed the changes and accept them going forward can be included instead of a signature.
6. Add any other documents that are needed, e.g. if you were asked to show evidence of an organisation's agreement to be part of the research, you will need to attach a copy of the agreement.
7. All documents that make up the revised application, both documents that have changed and/or been added, plus any other original documents should be sent via email to

[humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au), using the reference number in the subject line of the email. This reference number will have been provided in the email sent to you with the feedback.

### **What happens to responses?**

Once received, the response will be screened by the ethics staff and if ready for review by the Committee, it will be assigned to the next available review.

Note: review may be delegated to the HREC Executive or the Chair or, infrequently, be required to go back to the full HREC. Responses for LNR applications are reviewed weekly by members of the LNR committee.

Responses are required by COB Wednesday to make the meeting in the next week, except for responses that go back to the HREC.

You are welcome to discuss the process and/or the Committee's comments you received with the Human Ethics Officers. Please contact them at [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au), or their phone contacts are on the website.

### **Human Research Ethics Guidance Documents available from REDI**

- Guidance for Researchers New to Human Ethics Review
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- Guidance on Questions Related to Cultural Sensitivities
- Guidance on Questions Related to Restrictions on Publication of Results
- Guidance on Receiving and Responding to Ethics Committee Assessor Comments
- Guidance on Research Projects Seeking to use Western Sydney Staff as Participants
- Guidance on Reimbursements
- Guidance on the use of 'Opt Out' or Passive Consent in Human Research
- Guidance on Writing Participant Information Sheets and Consent Forms
- Guidance on Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Research Involving Young People
- Guidance on Using Focus Groups in Research
- Guidance on Complaints
- Guidance on Research being done with, or for, Organisations

Human Research Ethics Team Contact: [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au)