

## 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.

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

It is unusual for an ethics application to be approved following the first review at any HREC. 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 aspects of the application which need to be clarified. Some of these queries or recommendations will be related to specific application questions and they will be noted to correspond to the application form and/or attachments. Others may be general comments.

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

1. Use the summary sheet provided in the email to you that contains the initial reviewers' comments. This is laid out as a table in a Word document. Row 2 *Issue Description* will list the reviewers' comments as separate items, in separate rows. In row 3 *Researcher Response*, write your feedback in relation to the comments in that row. If you change text in the application form or attachments, you should note what the text now says as well as any general comments. If you need to add new issues you can add rows to the table but ensure your response text is in row 3.
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 reviewers 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 new copies of all the documents, even those that haven't been adjusted. If you are submitting with documents from the HREA website, you will send the complete zip file.
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 new 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. Send the documents via email to [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au), including the Western Sydney HREC 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 meeting.

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 the Wednesday before the meeting in the next week, except for responses that go back to the HREC. For all meeting and submission dates see [https://www.westernsydney.edu.au/research/research\\_ethics\\_and\\_integrity/human\\_ethics/apply\\_for\\_human\\_research\\_ethics\\_review](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/apply_for_human_research_ethics_review)

This link is also provided in the email sent to you with the reviewer comments as well as an indication of which committee will review the response.

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 Research Services**

- Guidance for Researchers New to Human Ethics Review
- Guidance Human Research Ethics Protocols for Coursework Masters
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Completing the Project Description
- Guidance on Creating Research Project Flyers
- Guidance on Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Issues with Informed Consent in Research
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- Guidance on Organisations in Research
- 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 Research Involving Young People
- Guidance on Research Projects and DFAT Advice
- Guidance on Using Focus Groups in Research

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