

REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

Guidance on Making an Amendment to an Approved Project

When are amendments to existing projects required?

Many projects will require amendments to the project post approval. This may be for relatively simple things like a change of team member or an extension of time. Or they may be more substantial changes such as the addition of a new data collection tool, research site or group of participants, or a change to the recruitment procedure.

The important point is that the research project must proceed as it was approved by the ethics committee until after a request for an amendment is submitted and approved. (Except in the case of a project Adverse Event when it may be necessary for the researcher to amend the project prior to reporting it to the Committee.)

Which HREC can approve an amendment?

The HREC which provided the original approval for the project must be the approval entity for the life of the project. Therefore, for researchers who have their original ethics approval from a non-Western Sydney ethics committee, all amendments must be made to that other entity.

Where a project has been given external ethics recognition by Western Sydney University copies of the approved amendments should be sent for the Western Sydney file, but the Western Sydney HREC does not actually approve them. The information below relates to the processes at Western Sydney University when it was the approving HREC. These processes may not be the same at other HRECs.

How is an amendment request made?

The form to complete for an amendment request is at <http://www.westernsydney.edu.au/research/researchers/forms>

As well as identifying information about the project the form asks for details such as:

- A brief explanation of what the specific amendment is
- Why the amendment is being requested
- The ethical implications of the amendment.

The form must be submitted alongside documents that have been changed because of the amendment, i.e. a new or changed data collection tool and a corresponding new participant information sheet and/or consent form. Email the documents to humanethics@westernsydney.edu.au

How do I determine the ethical implications of the amendment?

To answer this question, consider whether this amendment would change or add anything to your already approved ethics application.

For example:

- If the amendment includes an overseas site you may need to add a new group of participants and address issues related to overseas research eg cultural sensitivity and/or researcher safety.
- If the amendment is for a new group of participants you need to address issues about the group itself (number of people, age range, characteristics etc.) and what the group will be doing in the research. You may also need to provide new information sheets and consent forms and perhaps new data collection tools.

An amendment request that does not provide this level of detail will not be suitable for assignment to a meeting for assessment.

Risk levels of amendments

The research project will have been assigned a risk level in its original review. However, an amendment may increase the risk level of a project and once increased that risk rating remains with the project until its completion.

For example, if the project was originally risk rated as Low 1 and assigned to the LNR committee, a later addition of children as a participant group will increase the risk rating for the project as a whole to at least Low 2, and the initial amendment request will go to the HREC for review and all future assessments will be made by either the HREC or the Executive.

All projects that are risk rated as High risk must have all amendments, even the more minor ones that might otherwise be handled administratively, reviewed by at least the HREC Executive.

What happens to the amendment?

Once received, the amendment will be screened by the ethics staff and if ready for review will be assigned to the next available committee meeting.

Amendments are required by COB Wednesday to make the meeting in the next week, except for amendments that go to the HREC.

If the amendment is approved an amendment approval letter will be sent to the project CI. Alternately, a request for more information may be sent.

Occasionally an amendment request may be rejected by the Committee because the assessors believe that the amendment goes beyond the original project scope or intent and the research described in the amendment should form part of a new application. The statement the ethics officers use to help determine this issue is:

The research project is comprised of: the participants' involvement and/or the data collection that is done to answer the research question(s) posed by the approved NEAF; which is done by analysing the data in the ways outlined in the approved NEAF; and which results in outputs in line with the approved NEAF (and/or any subsequent approved amendments.)

If the amendment goes beyond this it may be necessary to make a new application.

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

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