

Human Research Complaints Guidelines

In accordance with the Western Sydney University Research Code of Practice, Western Sydney University expects its staff, students and other individuals acting in its name or using its facilities to demonstrate integrity and professionalism in the conduct of their research. Integrity means that researchers primarily serve scholarly and public interests and have an obligation to achieve and maintain the highest standards of intellectual honesty and ethical practice in all aspects of their research.

All persons involved in research that is undertaken by, at, or on behalf of Western Sydney University are expected to act in a manner that serves to promote the good name of the University and augment the confidence of the public in its research credentials.

Integrity also requires researchers to only participate in work that they are competent to perform and which conforms to accepted ethical standards, Western Sydney University policies and procedures, and all prevailing legislation.

The University has established mechanisms for receiving and promptly handling queries and/or complaints about the conduct of research projects approved by the Western Sydney University Human Research Ethics Committee (HREC), including those approved by the Low and Negligible Risk Committee (LNR).

Reciprocal and Joint Approvals

University researchers who have their ethics approval from an external ethics committee should approach that committee in relation to any complaints about the project or about how the application has been reviewed by the ethics committee.

Where a project has joint ethics approval (Western Sydney University and another ethics entity are both actively monitoring the project) it may be necessary to approach both committees.

Process for communicating a complaint

Providing contact information

Complaints may arise from participants in the research, or people and communities connected with participants. Complaints may also be received from researchers about HREC decisions. Any of these persons may express concerns or direct complaints during the research process, particularly about situations where the welfare of participants may be jeopardised, to the Human Research Ethics Officer, or other person as nominated by the HREC.

In order to communicate this process, all parties to a research project should be advised of the contact details of the person nominated to deal with complaints prior to the commencement of the research.

To assist participants and other parties the following clause should be at the end of a Participant Information Sheet provided to participants when gaining informed consent. (This clause is on the University information sheet templates.)

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Services on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

When research is conducted overseas it may be necessary to also have a local contact who can facilitate the complaints process.

Complaints handling process

Complaints about the conduct of the research (usually from research participants)

1. The Human Research Ethics Officer on receipt of a complaint will:

- a. make a clear and full written record of the complaint
- b. seek further information from all relevant parties with a view to resolving the matter.

All efforts will be made to seek a resolution to the complaint to the satisfaction of the complainant with minimum distress to the complainant and without unnecessarily jeopardising the research project.

2. Where resolution has not been achieved, the Human Ethics Officer will refer the matter to the HREC Chair, who has been delegated the authority to deal with such matters. The HREC Chair will:

- a. seek further information from all relevant parties as necessary, and ensure that no conflict of interest is evident
- b. in writing, invite the researcher(s) to recommend a resolution to the complaint in a manner that is in the best interests of the complainant. Researchers may elect to respond in writing or in person, and must do so within 10 days. When responding in person, researchers should be advised that they may be accompanied by a support person. This may be a fellow researcher, another member of staff, or a friend or family member but may not be a person who is a currently practising solicitor or barrister.

The Human Research Ethics Officer will take a record of any meeting called to discuss the complaint and its recommended resolution. This outcome may result in confirmation, amendment or withdrawal of the approval protocol for the project.

3. On behalf of HREC Chair, the Human Research Ethics Officer will communicate the outcome of the investigation of the complaint to both complainant and researchers within 5 working days of the written response or meeting.

4. If the complaint remains unresolved the Human Research Ethics Officer will:

- a. advise the Deputy Vice-Chancellor & Vice-President (Research & Innovation) and, where a research student is the researcher, the Dean, Graduate Studies.
- b. the Deputy Vice-Chancellor & Vice-President (Research & Innovation) and/or the Dean, Graduate Studies may refer the matter as appropriate for advice and resolution.

Amendment or withdrawal of the approval protocol

- Where the decision requires amendments to the original research proposal or to the conduct of the research these will be finalised in a timely fashion by the researchers.
- A decision to withdraw approval of the research protocol must be recommended by the HREC Chairperson and endorsed by the Deputy Vice-Chancellor & Vice-President (Research & Innovation), on behalf of the Vice-Chancellor.
- Withdrawal of the approval protocol will necessitate stopping the project (where this does not cause harm or undue distress to any participant).

Researcher appeal against HREC including LNR review decisions of an application or amendment

1. If researchers (staff or students) have a concern about decisions made by the University HREC committees in relation to a research project (excluding decisions resulting from participant complaints), they should contact the Human Research Ethics Officer. Upon receipt of a complaint, the Human Research Ethics Officer will:

- a. provide the complainant (verbally or in writing, as required) with reasons for the decision with a view to resolving the appeal.
- b. make a record of the receipt of a complaint.

All efforts will be made to seek a resolution to the satisfaction of the complainant with minimum distress to the complainant and without unnecessarily jeopardising the research project.

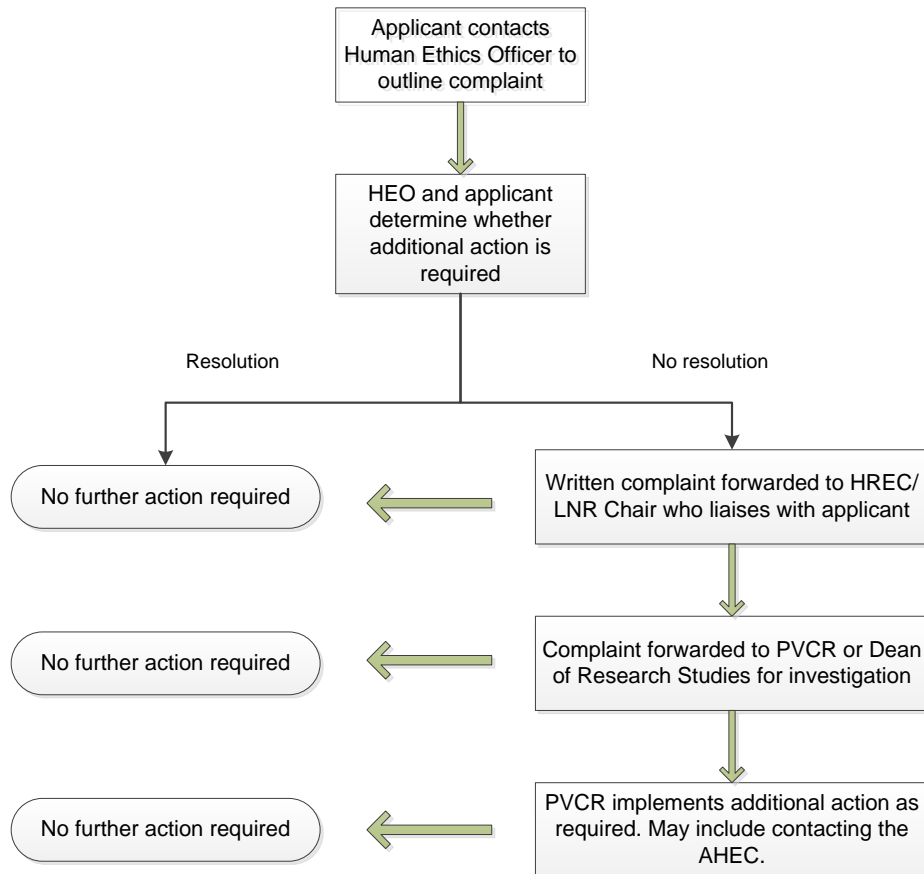
2. If the appeal cannot be resolved, it will be referred to the HREC Chair, who has been delegated the authority to deal with such matters.

3. The HREC Chair will seek further information from all relevant parties as necessary, either in writing or by requesting a meeting, and ensure that no conflict of interest is evident.

4. The Human Research Ethics Officer will take a record of any meeting called to discuss the complaint and its recommended resolution.

5. The HREC Chair will communicate the recommended resolution to the complainant. This outcome

- may result in confirmation, amendment or withdrawal of the approval protocol for the project.
6. If the matter is not resolved to the satisfaction of the complainant, the Chair will forward the complaint and correspondence to date to the Deputy Vice-Chancellor & Vice-President (Research & Innovation), for staff researchers, or the Dean, Graduate Studies for student researchers.
 7. The Chair, Deputy Vice-Chancellor & Vice-President (Research & Innovation) or the Dean, Graduate Studies may contact the Australian Health Ethics Committee for advice on interpreting NHMRC Guidelines in order to reach an appropriate decision or to help a complainant understand the reasons for the Committee's decision.
 - 8.



Decision chain: researcher appeal against HREC decisions

Resources

Western Sydney University Research Code of Practice:

<http://policies.uws.edu.au/view.current.php?id=00166>

Western Sydney University Media, Social Media and Public Commentary Policy:

<http://policies.uws.edu.au/view.current.php?id=00109>

Western Sydney University Privacy Policy: <http://policies.uws.edu.au/view.current.php?id=00108>

NHMRC National Statement on Ethical Conduct in Human Research: <https://www.nhmrc.gov.au/guidelines-publications/e72>

Western Sydney University Research Code of Practice:

<http://policies.uws.edu.au/view.current.php?id=00166>

Australian Health Ethics Committee: <https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/australian-health-ethics-committee-ahec>

Human Research Ethics Guidance Documents available from Research Services

- Guidance for Researchers New to Human Ethics Review

Complaints Guidance – V2 – January 2020
Chair Approved

- 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
