

Process for Managing Complaints

1. Complaints concerning research involving humans:

- a. The *National Statement on Ethical Conduct in Human Research* specifies that “An institution or organisation with an HREC shall establish mechanisms for receiving and promptly handling complaints or concerns about the conduct of an approved research project.”
- b. The University’s Human Research Ethics Officer is the nominated person to whom complaints from research participants, researchers, or other interested persons may be directed in the first instance.
- c. All potential participants in research involving humans which is conducted under the auspices of the University are advised in writing by way of the participant information statement, that should they have a complaint relating to a research project they may refer it to the investigator, or if an independent person is preferred, to the Human Research Ethics Officer for whom contact details are provided.
- d. Complaints may be anonymous. Where complainants are identifiable, their personal details shall remain confidential to the Human Research Ethics Officer, Chair of the HREC, and authorised senior officers of the University.
- e. Complainants, except where anonymous, shall receive acknowledgement of their complaint within two (2) working days.
- f. On receipt of a complaint, the Human Research Ethics Officer shall within two (2) working days advise the Chair of the HREC who will invite a response from the chief investigator.
- g. The Human Research Ethics Officer and/or the Chair shall attempt to resolve the complaint. The nature of the complaint and the action taken by the Human Research Ethics Officer and/or the Chair shall be reported to the full Committee at the next scheduled meeting.
- h. The Human Research Ethics Officer and/or the Chair may at any time refer a complaint to the full Committee for determination.
- i. Where a complaint cannot be resolved by the above means, the HREC shall refer the complaint to the Deputy Vice-Chancellor, Research & Innovation for determination and resolution of the complaint. This may involve referral of the complaint to the University’s Complaints Office or other institutional processes.
- j. Except in the case of anonymous complaints, complainants shall receive written notification of the outcome of their complaint. This notification shall be issued by either the Human Research Ethics Officer, the Chair, the HREC, the Deputy Vice-Chancellor, Research & Innovation or the University’s Complaints Office, depending on the level of investigation.
- k. Where complaints raise the possibility of a ‘research breach’ as described in the *Australian Code for the Responsible Conduct of Research*, they will be handled in accordance with the University’s Research Breach Investigation Procedure.

2. Disputes regarding decision of the HREC

- a. An investigator may lodge a written request with the Human Research Ethics Officer for reconsideration of a decision of the HREC within 14 working days of the date of the notification of the decision.
- b. The request must outline the reasons for the request and the evidence upon which the request is based.
- c. The request shall be considered by the HREC at its next scheduled meeting.
- d. Following consideration of the request, the HREC may decide to:
 - i. Uphold its decision.
 - ii. Vary its decision.
- e. The HREC shall notify the investigator in writing of its decision and detailed reasons for the decision, within 10 working days of the meeting.
- f. If the investigator is dissatisfied with the procedures followed by the HREC in reconsidering its decision, the investigator may refer the matter to the Deputy Vice-Chancellor, Research & Innovation.
- g. The Deputy Vice-Chancellor, Research & Innovation may review only the procedures followed by the HREC in reaching its decision, rather than the actual decision of the Committee.
- h. The Deputy Vice-Chancellor, Research & Innovation may require the HREC to provide documentation or any other evidence of the procedures followed by the Committee in reaching its decision.
- i. The Deputy Vice-Chancellor, Research & Innovation shall:
 - i. Notify the parties in writing of the date of receipt of the request for a review.
 - ii. Examine the documents in 2.h.
 - iii. Invite the investigator to make any representations on the matter, in writing or in person.
 - iv. Invite the Chair of the HREC, or nominee, to make representations on behalf of the Committee, in writing or in person.
 - v. Make a decision and notify the parties in writing of the decision within 20 working days from the date of receipt of the request for a review.
- j. The Deputy Vice-Chancellor, Research & Innovation shall:
 - i. Uphold the procedures followed by the HREC in reaching its decision; or
 - ii. Request the HREC to review its procedures in reaching its decision, and to review its decision if procedural deficiencies are identified.
- k. If any party is dissatisfied with the decision of the Deputy Vice-Chancellor, Research & Innovation, or the dispute is unresolved, the Deputy Vice-Chancellor, Research & Innovation may then refer the matter to a mediator.
- l. The role of the mediator is to:
 - i. Bring the disputing parties together to discuss the grievance.
 - ii. Assist the parties to clarify the issues and to recognise areas of common interest and points of agreement as well as points of disagreement.
 - iii. Explore with the parties possible solutions to the grievance.

- iv. Assist the parties to agree on a solution to be applied.
- m. The mediator shall not:
 - i. Render judgement or act as a judge.
 - ii. Apportion blame.
 - iii. Impose solutions or penalties.
 - iv. Act as an advocate for either party or offer legal advice.

The Human Research Ethics Officer can be contacted on (02) 4921 6333 or via human-ethics@newcastle.edu.au.