

SOP 2.5: Complaints

A. Complaints about the AH&MRC Ethics Committee

1. a. Appeals regarding Ethics Committee rejection

(NB: Outright rejection of an application to the Ethics Committee is a rare occurrence and the *National Statement* is silent on mechanisms to deal with this circumstance.)

Where the Ethics Committee has rejected an application, the investigator may:

- a) Submit a new application, taking due account of the Ethics Committee's concerns; or
- b) Lodge an appeal with the Ethics Committee Chairperson specifying the grounds of the appeal in writing.

b. Appeals regarding Ethics Committee approval

Where the Ethics Committee has given a favourable decision on an application and an ethical or scientific issue is subsequently identified by any party, or it has become apparent that either (i) the application contained inaccurate content or (ii) the decision was based on inconsistent application of policy and guidelines, the concerned party may lodge a written appeal with the Ethics Committee Chairperson in the first instance.

2. Appeals to the Chair of AH&MRC Board

If, after making an appeal in line with steps outlined above, the appellant is dissatisfied with the outcome, he or she has the discretion to lodge an appeal with the Chief Executive Officer or the Chair of the AH&MRC Board or request that the Ethics Committee Chairperson do so.

3. Complaints about the conduct of Ethics Committee members

Any complaint about the conduct of an Ethics Committee member should be made in writing to the Chair of the Ethics Committee, who will raise the matter with the Chair of the AH&MRC Board or Chief Executive Officer to decide upon an appropriate course of action. The complainant will be informed of the outcome.

B. Complaints about the conduct of an approved research project

4. Complaints information to be provided to participants

- 4.1 It is a requirement for all applications to the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee ('the Committee') that the full name of the Committee be included on the Participant Information Statement as a body to which participants may raise concerns or complaints. The following paragraph has been suggested for use:

If at any stage you have complaints or concerns about this research, you may contact:
The Chairperson
AH&MRC Ethics Committee
Aboriginal Health & Medical Research Council of NSW
PO Box 1565
STRAWBERRY HILLS NSW 2012
Phone 02-9212 4777 or email: ethics@ahmrc.org.au

For research conducted at Aboriginal medical services, the following wording may be preferable:

If at any stage you have complaints or concerns about this research, you may contact the CEO of (insert name of Aboriginal medical service). Alternatively, or if your concerns are not able to be resolved at the local level, you may contact:
The Chairperson
AH&MRC Ethics Committee
Aboriginal Health & Medical Research Council of NSW
PO Box 1565
STRAWBERRY HILLS NSW 2012
Phone 02-9212 4777 or email: ethics@ahmrc.org.au

4.2 Initial steps on receipt of a concern/complaint:

4.2.1 On receipt of the complaint, the Executive Officer of the Committee will ascertain whether it might be possible to resolve the concerns raised without initiating a formal investigation procedure (eg. if the concerns are based on a factual error).

4.2.2 If action under 4.2.1 does not resolve the matter, the grounds for the complaint should, ideally, be provide in writing before the procedures set out in this document can begin. The Committee may choose to accept a verbal complaint where the complainant is reluctant to provide a written statement.

4.2.3 A letter of acknowledgement is to be sent once the complaint has been received in writing. A further letter may be sent once the Committee decides to accept the complaint and initiate action as below.

4.2.4 The complaint is to be initially referred to the legal member of the Committee for advice as to whether the facts present *prima facea* grounds for further action to take place.

- 4.3 The Chairperson will then determine the appropriate investigative action. This may include the Chairperson or her/his nominee:
- convening a sub-committee to investigate the matter;
 - seeking advice from other members of Committee or from external persons;
 - seeking a response from the Chief Investigator of the project which is the subject of the complaint; and/or
 - interviewing any relevant party.
- 4.4 If an investigation is conducted, the Chairperson will send a letter of notification to the Chief Investigator of the project, outlining the complaint and the mechanism for investigating the complaint.
- 4.5 The CEO of the AH&MRC is to be informed that the complaint has been made if it involves a member organisation of the AH&MRC or staff of the AH&MRC.
- 4.6 If the complaint is substantiated, action may include:
- a requirement to amend the project (eg. the research protocol) which may include increased monitoring by the Committee; and/or
 - temporary suspension of the project pending resolution of the concern/complaint; and/or
 - termination of the project; and/or
 - other action to resolve the complaint.
- 4.7 The complainant shall be informed of the outcome of the Committee's investigation.
- 4.8 Where ethical approval for a research project is withdrawn by the Ethics Committee, the researcher, the institution(s) and, where possible, the participants should be informed of the withdrawal.
(Refer also to SOP2.6 *Monitoring research projects*, Section 4. Suspension or cessation of research.)
- 4.9 If the complainant or Chief Investigator is not satisfied with the outcome of the Committee's investigation, and wishes further action to be undertaken, the Chairperson may refer the complaint to the Chair of the AH&MRC Board, together with a copy of all relevant information and documents. The Chair of the AH&MRC Board will determine whether there is to be a further investigation by the AH&MRC of the complaint.
- 4.10 Where no further investigation is to be undertaken, the Chair of the AH&MRC Board or delegate will inform the complainant and Ethics Committee Chairperson.
- 4.11 Where the Chair of the AH&MRC Board determines a further investigation is necessary, she/he will establish a panel to consider the complaint. The panel will include, at least, the following members:
- The CEO or her nominee as convenor of the panel;
 - Two nominees of the CEO (not members of the Committee);

- The Executive Officer of the Committee.
- 4.11.1 The panel will have access to all documents relating to the project. The panel may interview or seek submissions from, the Committee Chairperson, the complainant, the Chief Investigator of the project, or any other relevant party. The panel may also seek internal and external expert advice.
- 4.11.2 The Chair of the AH&MRC Board will notify the complainant and the Chairperson of the outcome of the panel's investigation.
- 4.12 Documentation in relation to a complaint is kept in the relevant project file. The complaint is also logged in the complaints register and a copy of documentation placed in the complaints folder.