

Human Research Ethics Committee – Procedure for reviewing research complaints

Background

The National Statement stipulates that an institution must establish the following arrangements for the handling of complaints or concerns about the ethical conduct of a project or the decisions of the Ethics Committee.

An HREC must nominate a person to whom complaints from research participants, researchers, or other interested persons may be made in the first instance. This person or the HREC shall attempt to resolve these complaints.

Where a complaint made cannot be resolved, the HREC must refer the matter to a person nominated by the institution or organisation to handle and resolve such complaints.

When information on the research is first provided to participants, the name or position and contact details of the person nominated by the HREC to receive complaints must be included together with the procedures for raising concerns or obtaining additional information on the research.

What constitutes a research complaint?

Complaints about the conduct of research are made to the HREC. These include:

- complaints or concerns from human research participants about the ethical conduct of research carried out through CPL or its approved researchers.
- complaints or concerns about the ethical conduct of animal-based scientific work;
- allegations of potential breaches of either the *National Statement*, the Australian Code or CPL's research ethics arrangements;
- requests for review of a decision of the HREC or AEC from a researcher / applicant; or
- requests from a member of the HREC or AEC for review of a decision of the committee.

Responsibility of researchers

Researchers have principle responsibility for the ethical conduct of their research with people. In practice, and to comply with the requirements of the National Statement and Australian Code:

1. A researcher conducting human research must immediately report:
 - (a) serious or unexpected adverse effects on participants;
 - (b) proposed changes in the protocol; and
 - (c) unforeseen events that might affect continued ethical acceptability of the project.
2. A researcher conducting scientific work with animals should promptly notify the HREC of any unexpected or adverse effects that occur during the period of the approved project and which impact on the welfare of the animals.

The following are the standard conditions of CPL's ethical clearance, which relate to reporting / monitoring.

The researchers must always:

- immediately advise the Secretary of the relevant ethics committee if any complaints are made, or expressions of concern are raised, in relation to the project;
- suspend or modify the project if the risks are found to be disproportionate to the benefits, or in the case of animals, if unexpected pain, discomfort and anguish occurs, and immediately advise the Secretary of this action;
- withdraw any human research participant from the project if continuation may be harmful to that person, and immediately advise the Secretary of this action; and
- suspend any work with animals where unexpected deaths occur, immediately advise the Secretary of the HREC of this action, and await advice about the continuation of the research; and
- respond in a timely manner to any instructions or requests from the relevant ethics committee.
- provide reports on the progress of the project (including at the completion of data collection / testing / experimentation), as requested by the relevant ethics committee.

Researchers who are in any way unclear of their responsibilities in this regard should consult the Chair of the Ethics Committee.

Who conducts the investigations?

The Chair of the Ethics Committee will attempt to resolve the matter informally. In the event that these matters cannot be so resolved, the complainant will be able to lodge a formal Stage Two complaint/application for review.

All Informed Consent materials for human research must include the contact details of the Chair of the Ethics Committee as the contact person for any complaints or concerns about the ethical conduct of the research.

Stage Two complaints may require the involvement of other involved Ethics Committees who may have given ethics clearance as well (as is the case with Expedited Level one and two applications).

All research complaints will be reported to the Ethics Committee.

Concerns and complaints about the ethical conduct of research

There are three categories of formal complaint:

- a) **Stage 1 Research Complaint (response within five working days):**
These are communicated expressions of dissatisfaction, which can be dealt with promptly and to the complainant's satisfaction at the point of service. They will usually involve some form of correspondence from the complainant and a response from the Chair of the Ethics Committee. This response will be communicated in writing to the complainant,

with some commentary on whether CPL's policy / guidelines have been followed, whether any changes to this policy / guidelines will arise from the complaint, and / or whether the researcher will be advised to modify their project.

The complainant will be invited to indicate whether or not they are satisfied with this response, whether they wish to clarify matters further, or if they wish to lodge a formal complaint.

Every reasonable effort should be made to resolve the issue at the informal stage.

- b) Stage 2 Research Complaint (investigation within four weeks and first response within 10 days):

These include all written complaints and any communicated complaints, which cannot be dealt with as Stage 1 complaints. They may involve major departures from the Code of Conduct for responsible research and the National Statement. These complaints should be in formal writing and should indicate the matters that the complainant feels are still outstanding following the work of the Chair of the Ethics Committee.

The CEO (or their proxy) will be notified and briefed on a such a complaint.

- c) Stage 3 Research Complaint: These include all written complaints and any communicated complaints, which have not been satisfactorily resolved at Stage 2 and which the complainant wishes further reviewed.
- d) Stage 4 Research Complaint: These include escalated complaints where other cognate organisations may be involved (such as universities).

Processing a formal complaint

A formal complaint will be investigated in a manner determined by the Chair of the Ethics Committee. However, the following general principles must be observed in the conduct of such an investigation:

- The Chair of the Ethics Committee will confirm receipt of the formal complaint, and this will include an indication of the investigation process that will be followed and the anticipated timeframe for the investigation.
- The researcher should have the opportunity to respond to the details of the formal complaint.
- During the course of the investigation, the ethical clearance for the project will be suspended, and no further work (recruitment or data collection) will be undertaken until the outcome of the investigation is known.
- The relevant person may interview other parties in relation to the project (e.g. relevant Head of School or external expert).
- In the event that the complaint relates to any potential harm to the participants, the Chair of the Ethics Committee will liaise with the CEO (or their proxy) and the organizational legal team.
- Notification of the outcome of the investigation must be provided in writing to the complainant, the researcher and the Ethics Committee.

Outcomes of the investigation of a formal complaint

A typical outcome of the investigation of a formal complaint might include one of the following recommendations:

- No further action is required.
- No further action on the complaint is required, however the ethics committee should be instructed to consider a clarification of the relevant policy to avoid a recurrence of the situation that resulted in the complaint.
- The researcher is instructed to modify the design and / or conduct of their project. The ethics committee may also need to be instructed to consider a clarification of the relevant CPL policy to avoid a recurrence of the situation which resulted in the complaint.
- The ethical clearance for the particular project is withdrawn.
- The ethical clearance for the particular project is withdrawn, and all other clearances held by the researcher are suspended pending further investigation.
- The matter is to be considered further under relevant policies and procedures.

Failure to respond to instructions from an ethics committee

One responsibility of a research team is to respond in a timely manner to the instructions of an ethics committee. Typically, such instructions will include:

- a request for further information about an application for ethical clearance, or a modification to the project to enable the issue of an authorisation to commence the activity;
- a request for a progress or final report on an ethical clearance; or
- a request for information about the conduct of a project.

Such requests are always made either by email or in writing, and will specify a timeframe in which a response must be received. It is accepted that there can be circumstances beyond the control of a researcher that make responding within the specified timeframe problematic. A researcher who is unable to provide a requested response should contact the Chair of the Ethics Committee to indicate the reasons for the delay and the expected timeframe for a response. In most cases, an extension will be granted – although successive extensions or extended delays may be referred to the relevant ethics committee for their comment.

First request

The first request will usually be issued by the Chair of the Ethics Committee on behalf of the ethics committee. It will be sent to the listed contact for ethical clearance. The request will specify what action is required, provide links to any guidelines, forms or policies that may be of assistance in the preparation of a response, and specify a timeframe for the response.

First reminder

A reminder will be sent to any researcher who the Ethics Committee has sought a response from within the two weeks following deadline. This reminder will articulate again what action is required and will specify a new timeframe for a response. This correspondence will be copied to any relevant heads of department (e.g. research centre director or head of school).

Final reminder

One month following the first reminder, a final reminder will be sent to any researcher who the Ethics Committee has not received a response from and will articulate again what action is required and specify a new timeframe for a response. The final reminder will explain that, if a response is not received to the final reminder, the matter will be handled as a potential breach of the CPL's research ethics arrangements. This correspondence will be copied to the relevant heads of department (e.g. research centre director or head of school).

Breach action

If, following the first request, first and final reminder there has been no contact, the researcher's project will be suspended until compliance is achieved.

Alleged breaches to CPL's ethics arrangements

Identification of a potential breach

Upon receiving an allegation of a potential breach, the Ethics Committee Chair will then normally contact the researcher to obtain a response to the issues raised. If it is possible (eg in the case of an outstanding report) the researcher should be afforded the opportunity to address the issues prior to the commencement of the next phase of the process.

Documentation

If the matter cannot be informally resolved, a formal investigation should be initiated. The Chair Research Ethics will compile the following documentation for the CEO (or their proxy):

- A copy of the original application, and any reports or modifications to the project.
- A report from the CPL's ethics database, that provides details of the operative dates of the project, the outcomes of the original ethics review, and any other matters relevant to the approval status of the project.
- Details of the initial action taken.
- A copy of the allegation about the potential breach.
- A covering briefing note providing commentary on the potential breach.

Processing of an alleged breach

An alleged breach will be investigated in a manner determined by the Chair of the Ethics Committee. However, the following general principles must be observed in the conduct of such an investigation:

- The Chair Ethics will confirm receipt of the formal complaint, and this will include an indication of the investigation process that will be followed and the anticipated timeframe for the investigation.
- The researcher should have the opportunity to respond to the details of the allegation.
- During the course of the investigation, the ethical clearance for the project will be suspended, and no further work (recruitment or data collection) will be undertaken until the outcome of the investigation is known.
- The Chair Ethics Committee may interview other parties in relation to the project (eg relevant Head of School or external expert advice).

- Notification of the outcome of the investigation must be provided in writing to the complainant, the researcher and the Ethics Committee.

Outcomes of the investigation of an alleged breach

A typical outcome of the investigation of an alleged breach might include one of the following recommendations:

- No further action is required.
- No further action on the allegation is required. However, the relevant ethics committee should be instructed to consider a clarification of the relevant CPL policy to avoid a recurrence of the situation that resulted in the allegation.
- The researcher is instructed to modify the design and / or conduct of their project. The relevant ethics committee may also need to be instructed to consider a clarification of the relevant CPL policy to avoid a recurrence of the situation which resulted in the allegation.
- The ethical clearance for the particular project is withdrawn.
- The ethical clearance for the particular project is withdrawn, and all other clearances held by the researcher are suspended pending further investigation.
- The matter is to be considered further under relevant CPL policies and procedures.

Requesting a review of an ethics committee decision

The process below articulates how a researcher can seek a review of an ethics committee decision or a member of the ethics committees can seek a review of that committee's decision.

Receipt of request for review

A request for a review of the decision of an ethics committee should be made in writing. Normally this should be submitted to the Chair of the Ethics Committee. However, in some circumstances the person requesting the review may feel that they wish the review to be conducted without any involvement by the Chair of the Ethics Committee. In this case, the request may be submitted to the other members of the CPL executive team. If the latter, reasons for this direct submission must be provided.

Documentation

Normally, the Chair of the Ethics Committee will compile the following documentation for CEO/ Executive team (or their proxy):

- A copy of the original application, and any reports or modifications to the project.
- A report that provides details of the operative dates of the project, the outcomes of the original ethics review, and any other matters relevant to the approval status of the project
- A copy of the request for review.
- A covering briefing note providing commentary on the potential breach.

Where the request for review has been received directly by the CEO (or their proxy), s/he will liaise with them to have this documentation compiled.

Conducting the review

A review will be conducted in a manner determined by the CEO (or their proxy). However, the following general principles must be observed in the conduct of such an investigation:

- The review may be conducted by a small panel that includes some internal and external expertise, as well as at least one individual with significant understanding of the regulatory frameworks of CPL's Research and Ethics Program.
- The Chair of the Ethics Committee will confirm receipt of the formal complaint and this will include an indication of the investigation process that will be followed and the anticipated timeframe for the investigation.
- The relevant researchers should be afforded the opportunity to respond to the details of the allegation.
- The panel may interview other parties in relation to the matter (e.g. relevant Head of School or external expert advice).
- Notification of the outcome of the investigation must be provided in writing to the person seeking the review and CPL's Ethics Committee.

Outcomes of the review

A typical outcome of the review might include one of the following recommendations:

- Uphold the original decision.
- Uphold the original decision, however the ethics committee should be instructed to consider a clarification of the relevant CPL policy to avoid a recurrence of the situation which resulted in the request for a review.
- Request the ethics committee to revisit the original decision, with commentary from the review process. The relevant ethics committee may also need to be instructed to consider a clarification of the relevant CPL policy to avoid a recurrence of the situation which resulted in the allegation.
- Set aside the original decision of the ethics committee and replace this with a decision of the review.