

CPL Human Research Ethics Committee – Research Complaints Procedure

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 HREC. This procedure outlines the process for handling complaints related to research at CPL.

What constitutes a research complaint?

Research complaints may include:

- complaints or concerns from human research participants about the ethical conduct of research carried out through CPL or its approved Researchers.
- 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 from a Researcher / applicant; or
- requests from a member of the HREC for review of a decision of the committee.

Responsibility of Researchers

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

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.

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

The Researchers must always:

- immediately advise the Chair of the HREC or the Research Manager 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 if unexpected pain, discomfort and anguish occurs, and immediately advise the Chair of the HREC or the Research Manager of this action;
- withdraw any human research participant from the project if continuation may be harmful to that person, and immediately advise the CPL HREC Chair or the Research Manager of this action; and
- respond in a timely manner to any instructions or requests from the CPL HREC.
- provide reports on the progress of the project (including at the completion of data collection / testing / experimentation), as requested by the CPL HREC.

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

Who conducts the investigations?

All research complaints will be reported to the CPL HREC and the Chair (or their nominated delegate) will carry out the initial investigation. Further involvement from other members of the CPL HREC may be requested as required.

Responding to concerns and complaints about the ethical conduct of research by the CPL HREC

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 CPL HREC Chair. This response will be communicated in writing to the complainant.

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 acceptable research practices, such as those outlined in the National Statement. These complaints should be in formal writing and should indicate the matters that the complainant feels are still outstanding following the initial response of the CPL HREC Chair.

c. Stage 3 Research Complaint: These include escalated complaints where other cognate organisations may be involved (such as universities).

Responding to an alleged research ethics breach or participant complaint

Identification of a potential breach

Upon receiving an allegation of a potential breach, the CPL HREC Chair will then contact the Researcher to obtain a response to the issues raised. If it is possible (e.g. 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 CPL HREC Chair 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 detailing 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.

Conducting the review of a potential breach

A formal complaint will be investigated in a manner determined by the Chair of the CPL HREC.

However, the following general principles must be observed in the conduct of such an investigation:

- The CPL HREC Chair 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.
- Other parties may be interviewed 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 CPL HREC Chair will liaise with the CEO (or their proxy) and the organisational legal representative.
- Notification of the outcome of the investigation must be provided in writing to the complainant, the Researcher, and the CPL HREC.

Requesting a review of a CPL HREC decision from a Researcher/Committee member

The process below articulates how a Researcher can seek a review of a CPL HREC decision or a member of the CPL HREC can seek a review of that HREC's decision.

Receipt of request for review

A request for a review of the decision of the CPL HREC should be made in writing. This should be submitted to the Chair of the CPL HREC. However, in some circumstances the person requesting the review may feel that they wish the review to be conducted without any involvement by the CPL HREC Chair. 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

The CPL HREC Chair 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 complaint.

Conducting the review of the HREC decision

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 HREC 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 HREC.

Outcomes of the review of the HREC decision

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

- Uphold the original decision.

- Uphold the original decision, however the CPL HREC should be instructed to consider clarification to avoid a recurrence of the situation which resulted in the request for a review.
- Request the CPL HREC to revisit the original decision, with commentary from the review process.
- Set aside the original decision of the CPL HREC and replace this with a decision of the review.

Required response by researchers to complaints

One responsibility of a researcher is to respond in a timely manner to the instructions of the CPL HREC. 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 CPL HREC Chair 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 HREC for their comment.

First request

The first request will be issued by the CPL HREC Chair on behalf of the HREC. 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 CPL HREC 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 HREC 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.

Outcomes of the investigation of a formal complaint about a Researcher

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

- No further action is required.
- The Researcher is instructed to modify the design and / or conduct of their project.
- The ethical clearance for the particular project is withdrawn and/or all other clearances held by the Researcher are suspended pending further investigation.
- The matter is to be referred to the relevant external party.