CPL HREC - Research Review Procedure

PURPOSE

This document provides procedural guidelines for the review of research proposals in line with the current National Statement on Ethical Conduct in Human Research.

PROTOCOL SUBMISSIONS

Prior to CPL HREC submission, organisational approval from either (i) CPL or (ii) Queensland Cerebral Palsy Register Steering Committee, as appropriate, is required, using the *Organisational Approval Form*. Following submission of the relevant form to the Research Manager, the form will be reviewed by the CPL Executive or Queensland Cerebral Palsy Register Steering Committee. The researcher will then be advised by the Research Manager if organisational approval has been granted and an ethics application can proceed.

Following organisational approval, the Research Manager can provide the researcher with the *CPL HREC Submission Fact Sheet*, a full ethics application (including all relevant documentation) and the date of the next scheduled CPL HREC meeting. All documents must be received by the Research Manager more than two weeks prior to the next scheduled CPL HREC meeting to ensure inclusion.

The Chair, the Research Manager and members of the CPL HREC, as needed, will determine if any additional expert advice is required in relation to review and invite relevant guests to the meeting.

The CPL HREC will assess each project against the principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research:

- Research merit and integrity
- Justice
- Beneficence
- Respect

a) Levels of review

Incoming projects will be reviewed by the Research Manager in consultation with the Chair and other members, as required, to determine the level of review.

Research considered to be of low risk:

Where research carries risks that are perceived by the submitting researcher to be low, that is, the risk is no more than inconvenience (no foreseeable risk of harm or discomfort) and/or the project involves de-identified databank information that does not require new consent, full review by the CPL HREC may not be required.

Based on the guidelines for assessing risk set out in the National Statement, the Research Manager in consultation with the Chair will determine if a submitted project is considered to be of low risk. These studies can be reviewed by the Chair or a delegated subcommittee of the CPL HREC out of session. Alternatively, these projects may also undergo a full CPL HREC review at the discretion of the Chair.

Outcomes from the low risk review processes should be reported to the next scheduled meeting of the CPL HREC. This report should include project description and sufficient detail to enable the CPL HREC to review the decision. However, the project can be conducted during the period between the completion of the review and the ratification by the CPL HREC.

Multi-centre research:

Multi-centre research that another NHMRC-certified ethics committee has approved may be reviewed out of session by the Chair or a delegated subcommittee if there is evidence of current approval by the NHMRC-certified HREC and the protocol conforms to the required standards of the CPL HREC. Alternatively, these projects may also undergo a full CPL HREC review at the discretion of the Chair.

The CPL HREC reserves the right to ratify any previous decision or to instigate its own review process, to request amendments, clarification or to reject the protocol. As above with low risk research, outcomes should be reported to the next scheduled meeting of the CPL HREC.

All other research will undergo full review by the CPL HREC.

b) Managing external and overseas review

External researchers:

External research teams who are not affiliated with the organisation wishing to conduct research at CPL involving either staff or clients, may be eligible for ethical approval through the CPL HREC. After completing the Organisational Approval process detailed above, external researchers may submit their research through the standard procedure.

Research overseas:

CPL HREC approval is required for all staff who wish to conduct research involving participants overseas or for overseas researchers wishing to include any staff or clients in a research project. All research conducted overseas must comply with the National Statement.

c) Amendments, extensions and revisions

Amendments:

Amendments to approved research can be submitted at any time. Amendment submissions require the *CPL HREC – Amendments to approved research form* and any appropriate changed documentation. When amendments to currently approved projects are minor and are submitted between meetings, these may be approved out of session by the Chair or their delegate. When they are received within a two-week period of the next scheduled meeting, they will be reviewed at that meeting. Major amendments will be considered by the CPL HREC as deemed necessary by the Chair. All outcomes will be reported to the CPL HREC at the next scheduled meeting.

Extensions to research:

Applications for extension to approved research must be submitted in writing to the Chair, requesting an updated extension timeframe for completion and any known reasons for required extension. Extensions to approved research may be approved out of session by the Chair or by the CPL HREC if received within two weeks of a meeting. Ethical approval should be awarded for a maximum duration of one year, except for circumstances where this is impractical.

Revisions:

Major revisions to research applications should be reviewed by the Chair and a relevant subcommittee of the CPL HREC or the whole CPL HREC, as appropriate, to determine whether the concerns raised during review have been met by the revision. In the case of a minor revision, these can be approved at the discretion of the Chair.

Flying Minutes:

In the case of applications for full ethical review, flying minutes should only be used in extraordinary circumstances where there is a genuine need to resolve a matter "out of session".

MEETINGS

- Meetings will be held as necessary, at least once per calendar year.
- Notice of meetings will be given to members for the current year at the beginning of that year.
- An electronic copy of the agenda, previous minutes, and all documentation required for research review or other relevant correspondence will be forwarded to all members two weeks before the next scheduled meeting.

a) Meeting protocol

Decisions by the CPL HREC about whether the research protocol meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the CPL HREC.

Where there is less than full attendance of the minimum membership at a meeting, the Chair must be satisfied, before a decision is reached, that those members unable to attend the meeting have received all papers and have had an opportunity to contribute their views and that the views of all members have been recorded and considered. Members who are unable to attend a meeting are thereby asked to contribute and advise their opinion via submission to the Research Manager prior to the meeting.

Meetings are held either in person or online as required.

- The Researcher or a representative may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is made.
- Members of the CPL HREC will be required to declare any conflict of interest prior to or at any time during a meeting, such as where the member is associated with a research protocol under review by the CPL HREC (as per the National Statement).

- Such a declaration may be made: 1) verbally at the meeting 2) verbally prior to the matter being considered or 3) in writing to the HREC Chair prior to the meeting. Where it is deemed necessary and appropriate, members of the HREC with a conflict of interest may be requested to abstain from comment or leave the meeting while the particular project is being discussed.

- Decisions of the CPL HREC will be reached by general agreement rather than simple voting majorities. All content of reviewed applications and deliberations made by the CPL HREC in relation to these applications will remain confidential.
- The appointed Chair will chair every meeting when present. On occasions when the Chair is absent the meeting will appoint a Chair for the duration of the meeting and will be reflected in the minutes of the meeting. On occasions when the Chair declares or it is determined has a conflict of interest regarding a research proposal/project or agenda item will exclude themselves for the duration of the meeting agenda item discussion, the meeting will appoint a Chair for the defined period. This will be recorded within the minutes of the meeting.

b) Secretariat support

Secretariat support will be provided by the Research Manager in collaboration with the Executive Assistant to the CEO.

This will include:

- Managing project submissions to the CPL HREC and associated correspondence/ communication.
- Drafting and distributing the meeting Agenda and Minutes.
- Providing all research project documentation for the CPL HREC within deadlines.
- Maintaining research files and records as per the National Statement.
- Maintain a register of conflicts of interest and declarations of interests as appropriate and as reflected within the minutes of the meetings.
- Coordinating with researchers, study coordinators and CPL HREC members.
- Responding to administrative queries related to research.

c) Decisions from HREC meetings

Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol and where necessary link those reasons to the National Statement.

Notification of the CPL HREC deliberations will be made directly to the Researcher in writing, as per the National Statement, within one month of the proposed meeting date.

The outcomes of ethical review can be categorised as follows:

- Approved without changes.
- Request for minor changes/ clarifications - recommendations from the CPL HREC for minor changes can be reviewed and approved by the Chair or their delegate. These will be reported at the next scheduled CPL HREC meeting.

- Request for major changes/ clarifications - recommendations that are considered major (e.g. involving more significant justification of project protocol or elements of participation) must be reviewed by the CPL HREC. Only the issue(s) identified in the original review are to be reassessed.
- Not approved - the Researcher should be given clear feedback for future resubmission.

d) Post-HREC processes - monitoring of approved research

In accordance with the National Statement the CPL HREC requires the Researcher to:

- Keep adequate records (hard copy and/or electronic) and provide access to the CPL HREC when requested.
- Annually provide the CPL HREC with a written report using the *Annual Research Progress Report Form* provided near the beginning of each calendar year. The object of the report is to verify that the conduct of research conforms to the approved process. The CPL HREC may request more frequent progress reports.
- Notify and provide reports, in a timely fashion, to the CPL HREC of significant events (including SAEs and SUSARs), complications and protocol deviations that occur at any time during the conduct of the research, detailing the course of action taken.
- Provide prospective advice of any proposed changes to be made to the protocol and apply for approval to these amendments prior to implementation.
- Notify the CPL HREC if the research is to be discontinued before the expected date of completion (detailing a justification for the termination of the research).
- Notify the CPL HREC of any complaints received from participants, staff, observers or the community and comply with the *CPL HREC – Research Complaints Procedure*.
- Provide documents of the outcomes of the research to the CPL HREC.
- In addition to receiving and reviewing the above, the Research Manager, Chair and CPL HREC may:
    (a) Request an interview with the researchers
    (b) Request access to research data and records as part of an audit
    (c) Request the opinion of external experts.

Complaints and Adverse Events

SAE reporting: All researchers must comply with the NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials involving therapeutic goods 2016 for the reporting of SAEs and SUSARS in clinical trials.

Complaints Procedure: All complaints relating to research will be managed according to the CPL HREC – Research Complaints Procedure, in alignment with the National Statement.

Suspension or Discontinuation of Research: If the CPL HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of the research participants are not, and will not be protected, the CPL HREC may withdraw approval, inform the Researcher of such withdrawal, and advise that the research project has been discontinued, suspended or other steps be undertaken.

Definitions

Abbreviation/ Acronym	Definition
HREC	Human Research & Ethics Committee
NHMRC	National Health & Medical Research Council
SAE	Serious Adverse Event
SUSARS	Suspected Unexpected Serious Adverse Reaction

Related Documents

Forms

- CPL HREC Organisation Approval Form
- CPL HREC Amendment to Approved Research
- CPL HREC Annual Research Progress Report
- CPL HREC Low Risk Review Assessment

Procedures

- CPL HREC Research Review Procedure
- CPL HREC Research Complaints Procedure

Documents

- CPL HREC Terms of Reference
- CPL HREC Research Review Policy

Compliance

Standards

- National Statement on Ethical Conduct in Human Research | NHMRC