## Purpose

Reviewing research projects by the CPL Human Research Ethics Committee

## Scope

To provide procedural guidelines and standards for the review of research proposals.

This procedure addresses the ethical conduct of research involving humans, which confers special ethical responsibilities by both CPL and individual researchers. CPL is committed to the highest ethical standards of research involving humans, in conformance with the National Statement on the Ethical Conduct of Research (2023).

## Procedure

### PROTOCOL SUBMISSIONS

Prior to HREC submission, Organisational approval from either (i) CPL or (ii) Queensland Cerebral Palsy Register Steering Committee is required as appropriate for the research project, using the *Organisational Approval Form* for each.

Following organisational approval, a full ethics application including all relevant documentation meeting the requirements of section 3.1 of the National statement must be submitted to the HREC in a timely manner. All documents must be sent to the Research Manager more than two weeks prior to the next meeting to ensure inclusion.

The Chair along with the Research Manager and members of the Committee will determine if any additional expert advice is required in relation to scientific review and invite relevant guests to the meeting as needed (Section 5.1.38 of the National Statement).

The HREC will assess each project against the principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research (2023):

- Research merit and integrity
- Justice
- Beneficence
- Respect

### a) Procedures for managing low/negligible risk applications

A sub-Committee of the CPL HREC will be available as required to assess the risk level of research ethics applications. This sub-Committee will comprise of the Chair, the Research Manager, and other members of the HREC at the discretion of the Chair of HREC, in order to facilitate timely responses to ethics applications. Research that is potentially considered exempt from review will also be considered by this committee, as per section 5.1 of the National Statement. Decisions of the sub-Committee will be reviewed and ratified by the HREC at its regular meeting.

### b) Levels of review

The ethical review structure should target the level of ethical scrutiny to the ethical sensitivities of individual research projects. The process should be transparent, demonstrate consistent standards of excellence, and be timely.

There are three levels of ethical review:

- Expedited Level 1 – Applies to human research where there are no significant ethical risks - 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. These studies can be reviewed by the Chair out of session or by a Committee review at the discretion of the Chair.
- Expedited Level 2 – Applies to human research where there may be some ethical issues (but these are easily managed), the research involves the use of standard instruments, or the research has already been approved by a HREC at the "primary or host site" (e.g. hospital or other educational institution). These studies can be reviewed by the Chair out or session or by a Committee review at the discretion of the Chair.
    - Outcomes from the Expedited Review processes should be reported to a meeting of the CPL HREC. This report should include project description and sufficient detail to enable the HREC to revisit, revise or replace an expedited decision. However, the project can be conducted during the period between the completion of the expedited review and the ratification by the Committee.
- Full Review Level Three – Reserved for those projects with significant ethical sensitivity, risk and/or legislative dimensions and projects where CPL is the host institution. In practice, this means that projects that do not fall into either of the Expedited Review categories One and Two.

### c) 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 CPL staff or clients, may be eligible for ethical approval through the CPL HREC. After completing the Organisational Approval process detailed above and having their research endorsed by the relevant CPL Executive or management staff, external researchers may submit their research through the standard procedure.

**External ethical review:** Consistent with the National Statement, CPL HREC will recognise approvals issued by other NHMRC-registered HRECS and their delegated review bodies. Evidence of the external review and approval, along with any Progress Reports, Variation requests and Final Reports and well as report any behaviour, activity or incidents that may cause harm to researchers and/or participants or put CPL staff or clients at any risk must be provided to the CPL HREC. The Chair of the HREC may decide on review of submitted documents that a full review by the CPL HREC is still warranted. Where an external review has been completed an external HREC or review body is not registered with the NHMRC, the CPL HREC will perform a full review.

**Research overseas:** CPL HREC approval is required for all CPL staff who wish to conduct any level of research involving human participants overseas or for overseas researchers wishing to include any CPL staff or clients in research project. All research conducted overseas by all named researchers must comply with the National Statement. To fail to do is considered breach of Research Integrity.

### d) Amendments, extensions and revisions

**Amendments:** When amendments to currently approved projects are minor and are submitted between meetings, these may be approved out of session by the Chair. When they are received within a two-week period of the next meeting, they will be reviewed at that meeting. Major amendments will be considered, similar to an expedited review, with the Chair being able to refer the review to the committee at the next HREC meeting. All outcomes will be reported to the HREC for ratification at the next meeting.

**Extensions to research:** Extensions to approved research may be approved out of session by the Chair of the HREC or by the HREC committee if received within two weeks of a meeting.

**Revisions:** Major revisions to research applications should be reviewed by the Chair of the HREC and a relevant subcommittee of the HREC 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.

**Reciprocal Arrangements:** CPL should establish reciprocal review arrangements with other key institutions (e.g. "partner" hospitals). Reciprocating institutions may have a much greater discipline specific understanding of the ethical risks associated with a research project while other institutions will look to CPL to initiate an ethical review of a joint research proposal. A CPL researcher doing work at a reciprocating institution can submit that institution's ethical clearance form (with a single sheet covering form) and receive review via the Expedited Review Level 1. In the event that the Chair conducting the Expedited Level 1 Review considers that the project still involves significant ethical risks that have not been addressed by the reciprocating institution then the application may be referred to a higher level of review.

**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".

### e) Meetings

- Meetings will be held as necessary, at least once per calendar year and up to six times.
- 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, new protocols for consideration, including the ethics application forms, participant information & consent form, questionnaires or other relevant correspondence and the written advice for any meeting will be forwarded to all members two weeks before the meeting.

### f) Meeting protocol

Decisions by the 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 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 Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is taken.
    - Members of the Committee 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 Committee (as per section 5.6 of the National Statement).
    - In general, decisions of the HREC will be reached by general agreement rather than simple voting majorities.
    - The appointed Chair will chair every meeting when present. On occasions when the Chair is absent or excluded because of a conflict of interest, the meeting will appoint a chair.

g) **Secretariat support**

Secretariat support will be provided by the Research Manager in collaboration with the CEO's Executive Assistant. This will include:

- Manage project submissions to the HREC and associated correspondence/communication
- Draft and distribute the meeting agenda and correspondence arising out of meetings and subsequent HREC activities
- Provide all research project documentation for the committee within deadlines
- Properly maintain files, records as per section 5.2.15 to 5.2.20.
- Coordinate with researchers, study coordinators, other HREC staff
- Record receipt of documents, progress of project review/approval/monitoring and other matters as appropriate in a timely fashion
- Respond to administrative queries from researchers, staff and committees

h) **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 Committee's deliberations will be made directly to the Principal Investigator in writing as per section 5.2.11 to 5.2.14 of the national statement.

The outcomes of ethical review can be categorised as follows:

- Approved without conditions.
- Approved with conditions involving minor amendments to be dealt with administratively and reported to the HREC granting the approval.
- Approved with conditions, the response to which could be considered and resolved executively by the Chairperson of the ethics committee and reported to the next meeting of the HREC.
- Provisionally approved, the response to which must be considered and resolved by the body which originally conducted the review. This is a more rigorous approach than "Approved with conditions" above as it requires the project to be reconsidered by the relevant body (HREC/Expedited Ethical Review Panel). In terms of administrative efficiency only the issue(s) identified in the provision approval are reassessed.
- Not approved and invited to resubmit to the same level of review. The applicant should be given clear feedback and advised what – if any – additional information to provide to inform the subsequent review.

As noted above, under the expedited review process once a project is approved and any conditions satisfied then the project may commence in the period between expedited approval and ratification by full committee. In the event that the specified conditions are not met then approval is not given. If a researcher subsequently breaches specified conditions, then approval is revoked and enforcement processes would apply. Ongoing dialogue and working through problems would largely be done outside of a meeting.

i) **Post-HREC processes - monitoring of approved research (as per section 5.4 of the national statement)**

The Institution and the HREC acts in accordance with the National Statement in relation to monitoring approved research and requires the Principal Researcher (including co-ordinating principal investigator for multi-centre research) to:

- Keep adequate records (hard copy and/or electronic) and provide access to the HREC when requested.

- The Principal Investigator must annually provide the HREC with a written report using the form provided near the beginning of each calendar year. The object of the report is to verify that the conduct of research confirms to the approved process.
- Notify and provide reports, in a timely fashion, to the HREC of significant events (including SAEs and SUSARs), complications and protocol deviations that occur at any time during the conduct of 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 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 HREC of any complaints received from participants, staff, observers or the community and comply to the Complaints Procedure.
- Provide documents of the outcomes of the research to the HREC.
- The HREC may:
- (a) Request an interview with the researchers if required.
  (b) Request access to research data and records (including consent documentation as part of a random audit).
  (c) Request the opinion of external experts if considered necessary.

The following specific processes apply:

*Progress reports:* Progress reports on all approved research protocols are to be submitted to the HREC at least annually. The annual reports are provided to researchers of all approved projects near the beginning of the year and are required for submission by March 31st. The Committee may request more frequent progress reports, primarily based on the level of risk associated with the particular research protocol.

*Application for amendment and extension:* Any changes to the approved research must be submitted as a request for amendment using the '*Amendment to approved research*' form as per the procedure listed above. Extensions may be applied for in writing to the chair of the HREC.

*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. All researchers must comply to the CPL Reviewing Research Complaints procedure.

*Extension of ethical approval:* Ethical approval should be awarded for a maximum duration of one year, except for circumstances where this is impractical. Extensions within the one-year limit will be processed administratively. Renewal applications beyond the one-year limit will be considered executively. Renewals which involve an extension beyond five years will be considered via an Expedited Ethical Review Panel with the option of referral to the HREC.

*Complaints and Procedures*: All complaints from other interested parties will be managed normally according to the procedure as outlined in our 'Reviewing Research Complaints Procedure', in alignment with Chapter 5.7 of the National Statement.

*Suspension or Discontinuation of Research:* If the 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 HREC may withdraw approval, inform the Principal Investigator 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

### Form

- Application for Organisational Endorsement for Research Support Organisational Approval for Research.docx (sharepoint.com)
- Amendment to approved research Amendment to Approved Research.docx (sharepoint.com)
- Annual Research Progress Report Annual Research Progress Report.docx (sharepoint.com)

### Procedure

- Reviewing Research Complaints Procedure Reviewing Research Complaints Procedure.docx (sharepoint.com)
- Terms of Reference HREC TOR - Human Research Ethics Committee.docx (sharepoint.com)

### Policy

- Reviewing Research Projects Policy Reviewing Research Projects Policy.docx (sharepoint.com)

## Compliance

### Standards

- National Statement on Ethical Conduct in Human Research | NHMRC