



Child and Adolescent Health Service

Low Risk Ethics Committee

Terms of Reference

1. Purpose

The Child and Adolescent Health Service Human Research Ethics Committee (**CAHS HREC**) will appoint a Low Risk ethics committee (**LREC**) to review ethics submissions that are considered low risk according to the definition described in the *National Statement on Ethical Conduct in Human Research*, 2007, updated 2018 (National Statement).

This committee will assess the scientific merit and integrity and ethical acceptability of low risk research as per the National Statement.

Low risk research is defined in National Statement as *research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk* (Section 2.1.6).

Negligible risk is defined in the National Statement as *research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience* (Section 2.1.7).

The National Statement allows a non-HREC review process to be used for the review and approval of low or negligible risk research (Sections 5.1.18-5.1.21). Low risk approval pathways are also accepted by the National Mutual Acceptance Scheme (NMA Standard Principles for Operation).

Low or negligible risk research projects submitted via the Research Governance Service (RGS) system will follow an expedited pathway for ethical review. The Ethics team within the Department of Research will triage ethics submissions and assess whether a research project qualifies for a low risk review.

2. Functions

- 2.1. The LREC will determine that all low-risk human research proposals submitted for CAHS HREC approval meet the requirements of the National Statement, that they have scientific merit and integrity and are ethically acceptable.

3. Authority

- 3.1 The LREC is a committee functioning under the authority of the CAHS HREC and reporting to the CAHS HREC.
- 3.2 The LREC may recommend further HREC review if issues of concern are identified.
- 3.3 These Terms of Reference shall be available upon written request and shall be posted upon the CAHS website.

4. Membership

- 4.1. The LREC will consist of a pool of members from varied and experienced scientific and clinical backgrounds, the LREC will also pull from the HREC membership.
- 4.2. Members will be drawn from a list of nominations and expressions of interest from all departments/clinical areas of Child and Adolescent Health Service, collaborating institutions such as Telethon Kids Institute and academic institutions
- 4.3. Members of the LREC shall be approved and appointed (or re-appointed) by the Director - Research Operations upon the recommendation of the Manager – Ethics & Compliance.
- 4.4. The term of appointment of each member of the LREC shall be three years from the date of that member's appointment. Members of the LREC may be reappointed for up to three terms (nine years).
- 4.5. All new members to the LREC are oriented to their role and receive copies of Terms of Reference, Conflict of Interest declaration documents and any other documents required for ethics review. This is the responsibility of the Manager – Ethics & Compliance.
- 4.6. CAHS shall indemnify members of this panel for any liabilities that arise because of the member exercising his or her duties as a member in good faith.

5. Low Risk review procedure

- 5.1 Projects will be reviewed by members of the LREC as per the CAHS Standard Operational Procedures for the Approval of Research SOP (Research SOPs) and checklist provided by the Ethics team.
- 5.2 There are no submission deadlines for low risk research and applications may be submitted at any time.
- 5.3 Once received, the project will be reviewed by the ethics team within 3 working days, if suitable, it will then sent to a low-risk panel comprising at least three members.
- 5.4 The review of low-risk projects will be conducted by the three individuals within 7-10 working days. These individuals will include members of the LREC and appropriately qualified staff from the Department of Research.
- 5.5 The ethics team will compile any queries from the panel and correspond with the Principal Investigator.



- 5.6 Once a low-risk research project receives approval, the project will be ratified by CAHS HREC at the next scheduled HREC meeting.

6. Conflict of Interest

- 6.1 Committee members are required to comply with Department of Health policy on [Conflict of Interest](#).
- 6.2 No members of the LREC may review projects in which they may be personally involved.

7. Post-approval amendments and reporting

- 7.1 All research projects must be monitored according to the National Statement requirements (Section 5.5).
- 7.2 Post-approval management of these projects should be managed in line with the CAHS Research SOPs.
- 7.3 Annual progress reports are required to be submitted by the anniversary of approval date via RGS.
- 7.4 Annual safety reports are not required for low and negligible risk projects.
- 7.5 Amendments will be reviewed by the Ethics team for minor amendments or the LREC for substantial amendments.
- 7.6 Amendments elevating potential risk to beyond what can be considered low, will be reviewed by the full HREC.

8. Key Performance Indicators

The LREC expected outcomes for the next twelve (12) months are listed below.

Evaluation of committee administrative processes against the following administrative KPIs:

1.	Rate of correct triage to low risk review process	100%
2.	Rate of reviews completed by panel members within 7-10 working day KPI	100%
3.	Rate of approvals completed by 20 working day KPI	100%

The LREC shall be evaluated annually against its expected outcomes and KPIs. This evaluation shall be tabled and presented annually to the CAHS HREC.



11. Approval

These Terms of Reference may be altered on the recommendation of the Director of Research Operations or HREC Chair. Amended Terms of Reference shall be brought by the Director of Research Operations to the CAHS Executive Committee for approval.

The LREC members are responsible for the adoption of the Terms of Reference as ratified by CAHS Executive Committee.



Signature of Chairperson on behalf of HREC

Simon Erickson

Name of Chairperson on behalf of HREC

12th June 2023

Date

Document History

Version	Date	Changed by	Nature of amendment
1	22.05.2023	Natalie Giles	NA
2	12/06/2023	Natalie Giles	Low risk panel (LRP replaced with Low risk ethics committee (LREC))

