

July 2026

Human Research Ethics Committee

Standard Operating Procedures

Acknowledgement of Country

The Parenting Research Centre acknowledges and respects the diverse Aboriginal and Torres Strait Islander people of this country and the Elders of the past and present.

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1. Frequency of Meetings

- 1.1 The Human Research Ethics Committee will meet monthly throughout the year, except in January when no meeting will be held.

2. Attendance at Meetings

- 2.1 Every effort will be made to ensure at least one member in each membership category is able to attend a meeting. Where core members cannot be present, the Chairperson will ensure, before a decision is reached on a proposal, that the views of those members who are unable to attend have been received and considered.
- 2.2 The HREC may consult any person considered qualified to provide advice and assistance in the review of any proposal submitted to it, provided that the person has no conflict of interest and provides an undertaking of confidentiality.
- 2.3 The HREC may invite observers to its meetings, provided they are not members of the HREC or members of project teams whose applications are under consideration by the HREC.
- 2.4 Applicants or members of a project team may be invited by the HREC to attend part of a meeting to present their project, provide clarification, or respond to questions regarding an application under review. Applicants and project team members must leave the meeting before the HREC commences its deliberation and decision-making on the application.

3. Logistic Support for HREC

- 3.1 The day-to-day management of the business of the HREC will be the responsibility of the HREC Administrator and any person delegated by the relevant Portfolio Lead.
- 3.2 The relevant Portfolio Lead or HREC Administrator will also be responsible for ensuring:
 - 3.2.1 the preparation and maintenance of written records of the HREC's activities, including agendas and minutes of all meetings; and
 - 3.2.2 the preparation and maintenance of a file for each application received, including a copy of the application and any correspondence between the applicant and the HREC.
- 3.3 Records will be kept securely and confidentially and retained for sufficient time to allow for future reference. A register of all applications received and reviewed will be maintained in accordance with the provisions of the National Statement.

4. Conduct of Meetings and Confidentiality

- 4.1 The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. A significant minority view will be noted in the minutes.
- 4.2 Members of the HREC are responsible for treating matters discussed at meetings as confidential and ensuring that documents are stored securely and/or disposed of in a manner that protects confidentiality. Any unwanted papers must be returned to the PRC at the end of a meeting for secure shredding.

5. Preparation of Agenda and Minutes

- 5.1 A minute taker will be provided by the PRC. Minutes of meetings will be distributed to members

one week prior to the next meeting. The minutes will be reviewed and confirmed by the HREC at the subsequent meeting and their acceptance recorded in the meeting minutes. A copy of the meeting minutes will be forwarded to the Chief Executive Officer as required.

- 5.2 Minute-taking may be supported by AI-assisted tools, such as transcription or summarisation from an audio recording of the meeting, where appropriate. Any such use must comply with the PRC AI Usage Policy and governance arrangements, including requirements relating to confidentiality, privacy and secure handling of information. AI-assisted outputs must be reviewed by a human minute taker for accuracy, completeness and potential bias prior to circulation and formal approval.

6. Distribution of Papers for Meeting

- 6.1 All papers relevant to the agenda for the meeting will be distributed to HREC members at least one week prior to the meeting and will include copies of completed applications and relevant documents.
- 6.2 Agenda items will include at least the following items: i) apologies; ii) minutes of the previous meeting; iii) business arising from the previous minutes; iv) declaration of conflicts of interest; v) new applications; vi) applications to external HRECs; vii) amendments to approved protocols; viii) correspondence; ix) adverse event notifications; x) other business; and xi) close and next meeting.

7. Presentation of Applications for Review

- 7.1 All submissions to the HREC for ethical approval will be presented using the following approach:
 - 7.1.1 Proposals that present potential or significant risk will be submitted using the Human Research Application Form (HREA) developed by the NHMRC.
 - 7.1.2 Proposals that present low or negligible risk will be submitted using the HREC Application for Ethics Approval (Expedited) Form.
- 7.2 All applications for ethical approval must be reviewed by a peer for methodological quality and appropriate handling of risk, and endorsed by the relevant Portfolio Lead.
- 7.3 The endorsed application must be forwarded to the HREC Administrator at least 2 weeks prior to the HREC meeting at which the application is to be considered.
- 7.4 The HREC may request the applicant to supply any further information in relation to the application and/or request the applicant to attend a meeting of the HREC at which the application will be considered for the purpose of providing information to, and answering questions from, the HREC members in accordance with clause 2.4.
- 7.5 Where an ethics application has been submitted by a PRC team to an external Human Research Ethics Committee, the PRC team shall not be required to resubmit the ethics application to the PRC HREC, but the following information on the ethics application to the external HREC must be provided to the PRC HREC:
 - 7.5.1 The Principal Investigator completes the PRC HREC Registration of External HREC Approval Form, together with a copy of the letters of approval from the external HREC; and
 - 7.5.2 A copy of the Final Report on the project submitted to the external HREC on the completion of the project.

8. Timely Consideration and Review of Application

- 8.1 The HREC will consider new applications at its next available meeting provided that the application is received by the relevant closing date. The application will be reviewed by all HREC members present at the meeting or providing written comments and recommendations in lieu of attendance.
- 8.2 The HREC will ethically assess each application in accordance with the National Statement on Ethical Conduct in Human Research (National Statement 2025). The HREC must ensure that it is sufficiently informed on all aspects of a project, including its scientific validity, in order to make an ethical assessment.
- 8.3 The HREC will consider whether an advocate for any participant or group of participants should be invited to the meeting to ensure informed decision-making.
- 8.4 After consideration of an application at a meeting the HREC will make one of the following decisions:
 - 8.4.1 It will approve the project as ethically acceptable as it stands, without conditions;
 - 8.4.2 It will approve the project conditional upon changes being made to the satisfaction of either: a) a sub-committee of the HREC; or b) the HREC Chairperson for minor alterations;
 - 8.4.3 It will defer making a decision on the project until clarification or further information is provided to the HREC; or
 - 8.4.4 It will reject the project.
- 8.5 The HREC will endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered carried by a majority of two-thirds of members who examined the project, provided that the majority includes at least one layperson. Any significant minority view will be noted in the minutes.

9. Management of Conflicts of Interest

- 9.1 Any HREC member who has an interest, financial or otherwise, in a proposal or other related matter considered by the HREC must declare that interest as soon as practicable and in advance of consideration.
- 9.2 If the member is present at a meeting at which the proposal is under consideration, the member may, at the discretion of the Chairperson, be asked to leave the room. If the member remains in the room, they will not participate in the discussion, except to provide clarification if requested, and will not take part in the decision-making process.
- 9.3 If the Chairperson has a potential conflict of interest as described above, the meeting will appoint a Deputy Chairperson to conduct the meeting for the proposal under consideration. All declarations of interest will be recorded in the meeting minutes.

10. Communication with Researchers

- 10.1 The HREC will report in writing to the project team, advising whether the application has received ethical approval (including any conditions of approval), within 10 working days of the meeting, unless otherwise notified. A copy will be forwarded to the relevant Portfolio Lead for information.
- 10.2 If the HREC determines that further information, clarification or modification is required for consideration of a project, correspondence to the project team must clearly state the reasons for this determination and set out the information required. Where possible, requests for additional information will refer to the National Statement or other relevant legislation.

- 10.3 If the requested information is not received from the applicant within three months, the project will be dismissed and the applicant will be required to resubmit the project at a later date.
- 10.4 The HREC will notify the project team of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:
- title of project;
 - date of HREC meeting at which the project was first considered;
 - date of HREC approval; and
 - conditions of HREC approval, if any.

A copy of the notification will be forwarded to the relevant Portfolio Lead for information.

- 10.5 Projects may not commence until written notification that confirms ethics approval has been received.
- 10.6 If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation.
- 10.7 The status of the project will be updated on the HREC's register of received and reviewed applications.
- 10.8 The HREC will notify the project lead of receipt of registration of approval from an external HREC.
- 10.9 The communication requirements for research with external HREC approval will be the responsibility of the project lead.

11. Record Keeping

- 11.1 The HREC Administrator will be responsible for the preparation and maintenance of written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.
- 11.2 In accordance with the National Statement, the relevant Portfolio Lead and HREC Administrator will ensure the preparation and maintenance of a confidential electronic and/or paper record for each application received and reviewed that records the following information:
- unique project identification number;
 - title of the project;
 - ethical approval or non-approval, with date;
 - approval or non-approval of any changes to the project;
 - duration of the approval;
 - the terms and conditions, if any, of approval of the project;
 - action taken by the HREC to monitor the conduct of the project; and
 - relevance, if any, of Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.
- 11.3 All relevant records of the HREC, including applications, membership, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the relevant legislation.
- 11.4 To ensure confidentiality, all hard copy documents provided to HREC members that are no longer required must be disposed of securely, such as by shredding or placement in confidential bins.

Members who do not have access to secure disposal should leave their documents with the HREC Administrator for disposal.

- 11.5 Data pertaining to projects will be retained for sufficient time to allow for future reference and to comply with relevant legislation.

12. Monitoring and Reporting on Activities to PRC

- 12.1 The HREC will monitor all approved projects to ensure compliance with the HREC's ethical approval. In doing so, the HREC may request and discuss information on any relevant aspects of the project with the investigators at any time.
- 12.2 The HREC will require successful applicants to provide a report at least annually, and at the completion of the project. The annual report will contain information on the progress to date of the project, maintenance and security of records, compliance with approved protocols, and compliance with any conditions of approval.
- 12.3 The HREC will determine whether more frequent reporting or monitoring by other means is required for each approved project, taking into account the degree of risk to participants.
- 12.4 The HREC will require, as a condition of approval of each project, that investigators immediately report anything which might warrant a review of the ethical approval of the project, including:
- 12.4.1 proposed changes in the protocol or how it is implemented;
 - 12.4.2 unforeseen events that might affect continued ethical accountability for the project;
 - 12.4.3 serious or unexpected adverse events; and
 - 12.4.4 if the project is abandoned for any reason.
- 12.5 The HREC will report annually to the Chief Executive Officer on the activities of the previous year for inclusion in the annual report required under the provisions of the National Statement.

13. Handling of Adverse Events

- 13.1 The HREC will require, as a condition of approval of each project, that team members report serious or unexpected adverse events to the HREC in a timely manner.
- 13.2 Notification of adverse events must include, as a minimum, advice from the Chairperson as to whether, in their opinion, the adverse event necessitates an amendment to the project.
- 13.3 The HREC will determine the appropriate course of action, which may include a request for an amendment to the project, suspension of ethical approval or termination of ethical approval.
- 13.4 The Chairperson may take the appropriate course of action for adverse events deemed serious and requiring immediate attention. Such action may include a request for additional information, or the immediate suspension or termination of ethical approval.
- 13.5 For projects approved by an external HREC, responsibility for complaint management rests with the approving HREC. The PRC HREC must be notified of any complaints relating to the research.

14. Receiving and Handling of Complaints

- 14.1 Any concern or complaint about the conduct of an approved project should be directed to the attention of the HREC Chairperson.

- 14.2 The Chairperson will initiate an investigation of the complaint and make a recommendation on the appropriate course of action to the HREC. The complainant will be advised in writing of the HREC's decision, if appropriate.
- 14.3 If the complainant is not satisfied with the response of the HREC, the complainant can refer the complaint to the Chief Executive Officer or request the Chairperson to do so.
- 14.4 Any concern or complaint about the HREC's review process or rejection of an ethics application should be directed to the HREC Chairperson, who will investigate the complaint and its validity and make a recommendation to the HREC on an appropriate course of action. If appropriate, the complainant will be advised in writing of the HREC's response.
- 14.5 In reviewing its decision, the HREC will determine whether it acted in accordance with the National Statement, its terms of reference and its standard operating procedures.
- 14.6 If the complainant is not satisfied with the HREC's response, the complainant may refer the complaint to the Chief Executive Officer or request the Chairperson to do so.
- 14.7 For projects approved by an external HREC, responsibility for complaint management rests with the approving HREC. The PRC HREC must be notified of any complaints relating to the research.
- 15. Advising PRC of decision to withdraw Ethics Approval of Project**
- 15.1 Where the HREC is satisfied that circumstances have arisen such that an approved project is not being, or cannot be, conducted in accordance with the approved protocol, the HREC may withdraw approval.
- 15.2 The HREC will advise the relevant Portfolio Lead in writing of any decision to withdraw ethical approval of a project.
- 16. Remuneration of HREC Members**
- 16.1 Members may submit claims for expenses incurred as a result of their participation in the HREC to the HREC Administrator, who will arrange reimbursement of those expenses.
- 17. Completion of Ethics Approval of Project**
- 17.1 One month prior to the ethical approval completion date, the HREC Administrator will notify the project team lead that ethical approval is about to cease and that the final report is due.