ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE

The ACT Health Human Research Ethics Committee (HREC) is responsible for ensuring that researchers submitting proposals for its review are awareof their ethical and legal responsibilities to research participants in accordance with the *National Statement on Ethical Conduct in Human Research (2023) – and its most recent updates* (National Statement).

The HREC is a participating committee of the National Mutual Acceptance (NMA) scheme.

Terms of Reference

1. Objectives

The objectives of HREC are to practice and promote the core values of respect,beneficence, justice and research merit and integrity through ensuring research proposals:

1.1 Ask important and answerable questions

1.2 Protect the welfare, rights, dignity and safety of participants

1.3 Provide informed consent procedures and protect the privacy andconfidentiality of participants

1.4 Use valid and appropriate methods in research and data analysis

2. Functions

The HREC functions on behalf of ACT Health Directorate (ACTHD), Canberra Health Services (CHS) and those submitting to it under the NMA scheme or from private organisations to:

2.1 Provide independent review and ongoing monitoring of human research, ensuring competent, timely processes in line with the principles of the National Statement and the NMA agreement

2.2 Grant, withhold or withdraw ethical approval on the basis of a research project's compliance with the National Statement and relevant guidelines and regulations

2.3 Conduct the functions of 2.1 and 2.2 as a participant of the NMA scheme or any such replacement scheme

3. Accountability

3.1 HREC is accountable to the Director-General, ACT Health Directorate (DG), or their delegate. HREC ensures issues of concern are escalated in accordance with its established complaints process

3.2 HREC reports as follows:

3.2.1 Contributes to the ACT Health Directorate annual report

3.2.2 Provides annual report to the NHMRC

3.2.3 Contributes to the National Aggregate Statistics data collection

3.2.4 Other reports as agreed by the DG or delegate

4. Scope of Responsibility

4.1 In accordance with relevant ACTHD and CHS policies, the National Statement, NMA Scheme and other relevant guidelines, HREC is responsible for competent and timely review of human research, including:

4.2 Taking place at any site (organisation, institution/division/department/unit) under the governance of ACTHD, CHS, participating NMA sites or any other organisation choosing to make a submission for ethical review

4.3 Involving the use of ACTHD or CHS personnel, consumers/patients, facilities, resources or information

4.4 Assessing responses to HREC queries

4.5 Amendments to currently approved projects

4.6 Under section 19(5) of the *Medicines, Poisons and Therapeutic Goods Act 2008*, and in line with guidance from the Therapeutic Goods Administration (TGA) applications to become an Authorised Prescriber

4.7 Urgent ethical review and approval of new projects or amendments to existing projects

4.7.1 As per available guidelines, items deemed as urgent patient safety matters may be considered by the Chair, their delegate, or by the Chair and a relevant Sub-Committee, to be later ratified by the full HREC

4.8 Any or all of these responsibilities may be delegated from the HREC or the LRSC to the relevant Chairperson or committee secretariat

4.9 HREC will ensure the formation and use of expert sub-committees to perform specialist scientific review, including Research Merit and Integrity. These committees will provide advice and regular reports to the HREC.

4.9.1 Sub-committee members are appointed by the HREC chair.

4.9.2 Reporting of sub-committees to the HREC may be via meeting minutes provided to the HREC

4.10 Sub-Committees will provide competent and timely review of:

4.10.1 Scientific and technical review by a Clinical Research Sub- Committee (CRSC) or Social Research Sub-Committee (SRSC)

a) The CRSC and SRSC are advisory committees and are not approving bodies

4.10.2 Low or negligible risk research review by a Low Risk Sub-Committee (LRSC)

a) The LRSC is an approving body, with all activity subsequently reported to the next available meeting of the full HREC

b) The LSRC will conduct ongoing review and monitoring of low and negligible risk research with the same scope of responsibility that the HREC carries for greater than low risk research

4.10.3 Any or all of these responsibilities may be delegated from the HREC or the LRSC to the

relevant Chairperson or committee secretariat

5. Membership

5.1 In accordance with the National Statement (NS5.1.30), the Committee shall consist of the following minimum membership:

a) a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement (NS5.1.30(a))

b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution (NS5.1.30(b))

c) a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional (NS5.1.30(c))

d) a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader (NS5.1.30(d))

e) a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters (NS5.1.30(e))

f) two people with current research experience that is relevant to research proposals to be considered at the meetings they attend (NS5.1.30(f))

5.2 In addition to the minimum requirements of the National Statement, ACT Health HREC will include:

a) At least one member with knowledge and experience in research involving people of Aboriginal and Torres Strait Islander background

b) At least one member with knowledge and experience in social science research methodologies

c) At least one member with knowledge and experience in clinical pharmacy operations

d) At least one member who identifies as a health consumer or carer of a health consumer*

*the health consumer member is appointed in addition to the laypersons required under the National Statement

5.3 HREC may maintain a pool of inducted members who are able to attend meetings as needed and provide knowledge and experience relevant to research proposals considered at HREC meetings

5.4 HREC may seek advice from qualified persons provided there is no conflict of interest

5.5 A quorum for any meeting of HREC will consist of eight members and will include:

5.5.1 The Chair, Deputy Chair, or if unavailable, a member appointed as Acting Chair

a) Acting Chair may be appointed by HREC Chair or, in exceptional circumstances, by the Secretariat

5.5.2 At least three members from outside ACTHD and CHS

5.5.3 Taken together, at least two people from NS categories 5.1.30 (b),(c), (d) and (e)

5.6 To satisfactorily reach quorum, the minimum membership must reflect that prescribed in the National Statement. However, where there is less than full attendance of the minimum membership at a meeting, the Chair should be satisfied, before a decision is reached, that those present represent a reasonable cross-section of the minimum membership. When possible, the views of those not present will have been received and considered before the meeting or as soon as possible after the meeting

6. Appointment, Re-Appointment and Termination of Chairperson:

6.1 ACT Health Directorate may recruit a Chairperson for the HREC in such manner and shall appoint them for such periods and on such terms and conditions as it determines, however in ordinary circumstances:

6.1.1 A Chairperson will be appointed using open and transparent processes. These may include by nomination, through advertisement or via direct approach. Conditions of appointment, including potential for renumeration, will be determined and agreed; such conditions will be confirmed on completion of the appointment process

6.1.2 Rates of remuneration for the Chairperson will be at a rate deemed appropriate by the Health Directorate

6.1.3 The Chairperson will be independent of ACT Health Directorate and Canberra Health Services

6.2 Duties of the HREC Chair will include:

6.2.1 Attend and chair meetings of the HREC

6.2.2 Attend and chair meetings of the LRSC

6.2.3 Availability between meetings to liaise with the Secretariat, to fulfil administrative tasks as required, including tasks delegated by the HREC and those considered appropriate for out of session review

6.2.4 Participate in ad-hoc activities, that may include sub-committees, special working groups or other activities requested by the Health Directorate

7. Appointment, Re-Appointment and Termination of Members:

7.1 ACT Health Directorate may recruit members for the HREC in such manner and shall appoint them for such periods and on such terms and conditions as it determines, however in ordinary circumstances:

7.1.1 HREC members will be appointed using open and transparent processes. These may include by nomination, through advertisement or via direct approach

7.1.2 Prospective members may be invited to observe a meeting of HREC

7.1.3 Prospective members are to provide an expression of interest and copy of their

curriculum vitae to a selection panel for consideration. The selection panel will comprise, at a minimum, of the Chair and Secretariat. The selection panel may make decisions based on EOI and CV only or it may conduct interviews with prospective members before providing recommendations to the Director-General or delegate

7.1.4 Members will be appointed to a category of membership (refer 5.1 and 5.2) for a term of three years. A member may be re-appointed for a second term of three years on recommendation of the HREC Chair without additional advertising. While recognising that some positions on the committee may be difficult to fill, membership of any one category should not generally be extended beyond two consecutive terms

7.1.5 Towards the end of a member's first term the Chair will submit a recommendation to the DG or delegate on the suitability of offering a second term

7.1.6 A member may be re-appointed to a second term in the same category where the member continues to meet the criteria for appointment to that category

7.1.7 Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion

7.1.8 Members are appointed by the DG or delegate

7.1.9 Members will be provided with a formal notice of appointment including the start and end dates of their term

7.1.10 Members who are not substantively employed by ACT Health Directorate or Canberra Health Services may be eligible to receive an honorarium per meeting attended

a) Members electing to receive such honorarium shall be responsible for liaising with the Australian Tax Office or other financial advisors regarding any potential tax implications relating to the receipt of this honorarium

7.2 Upon appointment, members will be asked to declare any known conflicts of interest, undertake to declare conflicts of interest that may arise and sign a confidentiality agreement

7.2.1 Conflict of Interest Declarations will be renewed each year

7.2.2 Confidentiality agreements will be renewed each year

7.3 HREC members are expected to become familiar with the National Statement and other relevant guidelines and legislation required for ethical review of research projects

7.4 Upon appointment, members will be provided with induction materials and an opportunity to meet with the Chair and/or secretariat to discuss the responsibilities of members and introduce processes and procedures

7.4.1 ACTHD, via the committee secretariat, will seek out appropriate training opportunities and where necessary, will provide funding for members to attend and receive training

7.5 Members may be expected to participate in sub-committees or special working groups

7.6 Membership may be terminated if:

7.6.1 A member fails to attend three consecutive meetings without prior notice or reasonable apology

7.6.2 A member fails to attend at least two thirds of all scheduled HREC meeting in a calendar year without prior notice or reasonable apology

7.6.3 The member has failed to carry out their duties as HREC member

7.6.4 The member is not a fit and proper person to serve on HREC

7.6.5 The Chair is of the opinion that it is necessary for the proper and effective function of HREC

a) The Chair will provide a brief and recommendation to the DG or delegate outlining the member's performance (7.2-7.5) and providing reasons for the proposal to terminate membership

b) Where the DG or delegate supports the proposal to terminate membership, this support will be provided in writing via a letter to the relevant member, copied to the Chairperson and committee secretariat

c) Where the DG or delegate does not support the proposal to terminate membership, further review of the member's performance will be undertaken and performance management and/or mediation will occur as appropriate

7.7 Members seeking to resign or take extended leave of absence are asked to give notice to the Chair and secretariat. Notice is to be provided in writing giving as much lead time as possible

7.8 ACT Government provides indemnity for HREC members for liabilities that arise as a result of the members' exercising their duties in good faith. Such indemnity is provided through the ACT Insurance Authority (ACTIA)

7.9 HREC membership will be published on an ACT Government website and in annual reports as required. See 3.2 above.

8. Secretariat:

8.1 Secretariat functions will be provided by Research Ethics and Governance Office

8.2 The secretariat will make public a schedule of meeting and submission dates

8.3 The secretariat will make public a schedule of fees relating to HREC review process

8.3.1 Fees shall be reviewed annually and may be increased as of 1 July in any given year

8.4 Minutes of meetings will be included in the next available set of agenda papers

8.5 Members will receive agenda papers seven calendar days prior to the meeting date

8.6 The secretariat will communicate decisions of the meeting to applicants in writing within seven calendar days of the meeting date

8.7 The secretariat will ensure compliance with established policies, processes and procedures to enable the effective and efficient work of the HREC

9. Meetings

9.1 HREC will meet at least 11 times each year. Meetings will usually be held on the first Monday of the months February-December

9.2 Meetings may be held in person, virtually or a combination of these

9.3 Meeting dates, including submission deadlines, will be published on the Health Directorate web site

9.4 Agenda papers are delivered to members in digital format

9.5 All matters relating to the HREC and its proceedings are confidential between the committee, the secretariat and the researcher

10. Decision making

10.1 HREC endeavours to reach agreement by consensus

10.2 Where consensus is not reached, the matter will be determined by vote. A majority vote of members present at the meeting will secure a decision, provided the majority includes at least one lay person

10.3 In ordinary circumstances, the Chairperson will not cast a vote. However, where a vote is tied, the casting vote of the Chair will break the tie

10.4 Any dissenting view will be noted in the minutes

10.4.1 Where requested by the dissenting member/s the reasons for the dissent will be recorded in the minutes

10.5 Where the Secretary has been notified in advance that a member will be absent from a meeting where that member's expertise would otherwise be required, the Secretary will request a written review from the member to be tabled at the meeting. Where the member is unable provide a written review, a verbal review may be provided to the Secretary who will record the member's views for tabling at the meeting

10.6 Where the member is not available in any capacity, the HREC may, in accordance with the National Statement, seek input from a suitably knowledgeable and experienced person outside the membership, preferably from the pool of inducted members

11. Declaration of interest

11.1 Declarations of interest are to be completed by each member on appointment and are to be renewed annually.

11.2 HREC members are to declare any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at a meeting. A conflict of interest includes:

a) Personal involvement or participation in the research

b) Financial or other interest or affiliation

c) Involvement in competing research

11.3 HREC will consider the interest declared and determine actions to be taken subject to the provisions of 11.4 and 11.5 below

11.4 Where a member is a participant in a proposal or a resubmission of a proposal (either as an investigator, a team member or a student supervisor), the member will leave the meeting for

the discussion and decision-making on the item

11.5 Where a member is not a participant in a proposal but has been involved in formal or informal discussions of the proposal prior to its submission or, as head of a department or division, has approved the allocation of resources to the proposal, the member:

a) May not act as a lead reviewer for the item;

b) May participate in the discussion of the item; and

c) If the chair calls for a vote on the item, may not participate in the vote

11.6 Declaration of a conflict of interest and the actions taken in relation to the conflict of interest must be recorded in the minutes of the meeting

11.7 Where a member was excluded from discussion of an item or a vote on an item, this will be included in the advice to the researcher on the outcome of the meeting

12. Record keeping

12.1 The secretariat will ensure records of all HREC meetings are maintained, including agendas and minutes

12.2 The secretariat will ensure files are kept securely and confidentially in accordance with ACTHD/CHS Policy and the requirements of the *Territory Records Management Act 2002*

13. Appeals and Complaints

13.1 Appeals regarding HREC non-approval

13.1.1 Where HREC has not approved an application, the investigator may request the Chair seek review of the application from another NHMRC certified HREC. The certified HREC will be supplied with the original application in full plus a confirmed minute of the original HREC debate and decision together with the letter of appeal

13.2 Appeals regarding HREC approval

13.2.1 Any individual or group may appeal, in writing to the Chair, the decision to approve a project when:

a) The individual or group, subsequent to HREC approval, have identified a significant ethical or scientific issue they believe the HREC was unaware of

b) It is believed that the decision to approve was based on inconsistent application of policy and guidelines

13.3 Complaints about the conduct of HREC members

13.3.1 Complaints about the conduct of HREC or an HREC member may be directed to the secretariat, the Chair or the DG

13.4 Complaints about the conduct of an approved research project

13.4.1 Complaints about the conduct of an approved research project, including allegations of research misconduct, are reported in the first instance to the secretariat

13.4.2 The secretariat will report to the Chair who will take action to address and resolve the complaint

13.4.3 If the matter cannot be resolved to the satisfaction of all parties, the Chair will escalate the complaint in accordance with the ACTHD/CHS Research Policy

13.4.4 As an NMA participating HREC, complaints will be managed in accordance with these Terms of Reference and any complaint handling procedures specific to the site to which the complaint relates

14. Termination of HREC responsibility

14.1 Where HREC has ceased to function, the relevant Public Health Organisation will notify the relevant ACT Minister and the NHMRC

14.2 Prior to ceasing its functionality, the HREC, in conjunction with the Public Health Organisation, will ensure the transfer of ethical responsibility for all continuing projects to a suitable NHMRC certified HREC

Revision History			
Version	**Date**	**Reviewed/Amended by**	**Endorsed by**
1.0	Jan 2010	August Marchesi John Biggs, deputy chairperson	Paul Gatenby, Director of Research
2.0	Sept 2014	August Marchesi Louise Morauta, chairperson HREC members	Paul Gatenby, Director of Research
2.1	Aug 2015	August Marchesi Louise Morauta, chairperson HREC members	David Brewster, Director of Research
2.2	Nov 2016	August Marchesi Louise Morauta, chairperson HREC members	Bruce Shadbolt, Deputy Director of Research
3.0	Dec 2023	August Marchesi Paul Gatenby, chairperson HREC members	Jade Redfern, Executive Branch Manager, Research, Programs & Scientific Services