

ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE

Terms of Reference

The ACT Health Human Research Ethics Committee (HREC) is responsible for ensuring that researchers submitting proposals for its review and approval are aware of their ethical and legal responsibilities to research participants in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* (National Statement).

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 and confidentiality of participants
- 1.4 Use valid and appropriate methods in research and data analysis

2. Functions

The HREC functions on behalf of ACT Health to:

- 2.1 Provide independent oversight of human research, ensuring competent, timely review and ongoing monitoring of research projects and compliance with acceptable ethical and scientific practices for the duration of the project
- 2.2 Grant, withhold or withdraw ethical approval on the basis of a research project's compliance with the National Statement

3. Accountability

- 3.1 HREC is accountable to the Director of Research as delegate for the Director General, ACT Health

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- 3.1.1 Under this delegation the Director of Research may approve amendments to these terms of reference
- 3.2 HREC ensures issues of concern are raised with the Director of Research
- 3.3 HREC reports as follows:
 - 3.3.1 Annual reports to the Executive Council, ACT Health
 - 3.3.2 Contributes to the ACT Health annual report
 - 3.3.3 Contributes to the biennial Research Review
 - 3.3.4 Provides annual report to the NHMRC

4. Scope of Responsibility

- 4.1 In accordance with the ACT Health Research Practice Policy, HREC is responsible for competent and timely review of applications for human research:
 - 4.1.1 Taking place at any institution/division/department/unit under the governance of the ACT Health
 - 4.1.2 Involving the use of ACT Health personnel, clients/patients, facilities, resources or information
 - 4.1.3 Any externally located/governed institution/organisation or researcher choosing to submit a proposal to the ACT Health HREC
- 4.2 Competent and timely review by the HREC sub-committees of applications for:
 - 4.2.1 Scientific, technical and regulatory review by a Clinical Trials Sub-Committee or Social Research Sub-Committee
 - 4.2.2 Low or negligible risk research proposals by a Low Risk Sub-Committee
 - 4.2.3 Responses to HREC queries approved by the full HREC for review by the chair or sub-committee
 - 4.2.4 Amendments to currently approved projects deemed by the HREC as not requiring full HREC review and as delegated by the HREC to the Chair
 - 4.2.5 Under section 19(5) of the Medicines, Poisons and Therapeutic Goods Act 2008 applications to become an Authorised Prescriber
 - 4.2.6 Urgent ethical approval by HREC chair or sub-committee – to be later ratified by the full HREC – in the interests of protecting research integrity
- 4.3 HREC may utilise the expertise of sub-committees to perform specialist review and give advice to the next sitting of the full HREC. Sub-committee

members are appointed by the HREC chair. Minutes of all sub-committee meetings are submitted to the next sitting of the full HREC

5. Membership

- 5.1 In accordance with the National Statement (NS5.1.30), the Committee shall consist of the following membership:
- A Chairperson (NS5.1.30(a))
 - At least two laypersons, one male and one female (NS5.1.30(b))
 - At least one person with knowledge of, and current **experience in**, the professional care, counselling or treatment of people; for example a nurse or allied health professional (NS5.1.30(c))
 - At least one person who performs a pastoral care role in the community (NS5.1.30(d))
 - At least one lawyer – not employed by the ACT Health (NS5.1.30(e))
 - At least two members with current research experience relevant to the type of research proposals considered at HREC meetings (NS5.1.30(f))
- 5.2 In addition to the requirements of the National Statement, ACT Health HREC will include:
- At least one member with knowledge and experience in research involving people of Aboriginal and Torres Strait Islander background
 - At least one member with knowledge and experience in social science research methodologies
- 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
 - Acting Chair may be appointed by HREC Chair or Director of Research
 - 5.5.2 At least three members from outside ACT Health
 - 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 present will have been received and considered, as per section 5.2.30 of the National Statement

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

ACT Health 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:

- 6.1 HREC members will be appointed using an open and transparent process of either direct approach, nomination or through advertisement
- 6.2 Prospective members may be invited to observe a meeting of HREC
- 6.3 Prospective members are to provide an application letter and copy of their curriculum vitae to a selection panel for consideration. The selection panel may conduct interviews with prospective members before providing recommendations to the Director of Research
- 6.4 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 and Director of Research and 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
- 6.5 Towards the end of a member's first term the Chair will submit a recommendation to the Director of Research on the suitability of offering a second term
- 6.6 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
- 6.7 Members are to be appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion
- 6.8 Members are appointed by the Director General of ACT Health
- 6.9 Members will be provided with a formal notice of appointment
- 6.10 Members who are not employed by ACT Health receive remuneration for attendance at meetings
- 6.11 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
 - 6.11.1 Conflict of Interest Declarations will be renewed each year

- 6.12 HREC members are expected to become familiar with the National Statement and other relevant guidelines and legislation required for ethical review of research projects
- 6.13 Members may be expected to participate in sub-committees or special working groups
- 6.14 HREC Chair is expected to be available between meetings to fulfil administrative tasks as required
- 6.15 Membership may be terminated if:
 - 6.15.1 A member fails to attend three consecutive meetings without prior notice or reasonable apology
 - 6.15.2 A member fails to attend at least two thirds of all scheduled HREC meeting in a calendar year without prior notice or reasonable apology
 - 6.15.3 The member has failed to carry out their duties as HREC member
 - 6.15.4 The member is not a fit and proper person to serve on HREC
 - 6.15.5 The Chair is of the opinion that it is necessary for the proper and effective function of HREC
 - 6.15.6 The Chair will provide a brief and recommendation to the Director of Research outlining the member's performance (6.15.1-6.15.5) and providing reasons for the proposal to terminate membership
 - 6.15.7 Where the Director of Research supports the proposal to terminate membership, a brief and recommendation will be provided to the Director-General who is responsible for the appointments to HREC, including termination of appointments
 - 6.15.8 Where the Director of Research 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
 - 6.15.9 The decision to terminate membership or not is a matter for the Director-General
- 6.16 Members seeking to resign or take extended leave of absence are asked to give notice to the Chair. Notice is to be provided in writing giving as much notice as possible
- 6.17 ACT Health 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
- 6.18 HREC membership will be made public on the HREC web site and through annual reports

7. Orientation and training for members

- 7.1 New members are provided with induction and training as determined appropriate by the HREC Chair
- 7.2 Induction may include:
 - 7.2.1 Meeting with HREC Chair and/or the Secretary of the Committee to explain responsibilities of members and introduce processes and procedures
 - 7.2.2 Provision of an induction package which includes copies of the National Statement, institutional guidelines/policies and table of relevant legislation across all Australian jurisdictions
 - 7.2.3 Attendance at a meeting of HREC prior to appointment
- 7.3 Ongoing training may include:
 - 7.3.1 In-house training conducted at HREC meetings, and support to attend external training which will be managed on a rotational basis

8. HREC Management

- 8.1 HREC will consider the ethical implications of proposed research projects, submitted through the secretariat office, to determine their ethical acceptability
- 8.2 HREC will refer clinical trials and social science research to specialist sub-committees for review and advice on the scientific, technical and regulatory aspects of the project
- 8.3 HREC will delegate the review and approval of low-risk research projects, defined by the National Statement as "research in which the only foreseeable risk for participants is one of discomfort" to the Low Risk Sub-Committee (LRSC)
 - 8.3.1 The LRSC comprises the HREC Chair and/or Deputy Chair or delegate and two HREC members (one medical researcher and social science researcher) as permitted by the National Statement Section 5.1.19
- 8.4 HREC will consider and advise ACT Health on ethical matters arising from research activity, which require determination. The Committee will have particular regard to the importance of informed consent procedures for participants and to the ongoing best interests of research participants
- 8.5 The secretariat office will maintain a register of proposed research projects, approved and not approved, so that the following information is readily available

- 8.5.1 Name of the responsible institution
- 8.5.2 Notification of Indemnity
- 8.5.3 Project identification number
- 8.5.4 Principal Investigator(s)
- 8.5.5 Short title of the project
- 8.5.6 Ethical approval or non-approval with date
- 8.5.7 Dates designated for review

(Protocols of research projects shall be preserved in the form in which they were approved.)

- 8.6 HREC will abide by the principles laid down in the National Statement in regard to research involving people of Aboriginal and Torres Strait Islander background and seek assessment of the research from:

- 8.6.1 HREC membership will include at least one member with knowledge and experience in research involving people of Aboriginal and Torres Strait Islander background. Recruitment of this member will include discussions with the Aboriginal and Torres Strait Islander Health Unit, Winnunga Nimmityjah Aboriginal Health Service and Aboriginal and Torres Strait Islander Health research units at local universities

- 8.6.2 In addition to a member appointed specifically in consideration of their knowledge and experience in research involving people of Aboriginal and Torres Strait Islander background, HREC will encourage its membership to be or become familiar with the culture and practice of Aboriginal and Torres Strait Islander peoples, especially in regards to research participation. In supporting this aim, HREC will provide access to reading materials and training opportunities

- 8.7 HREC will provide surveillance and monitoring of the ongoing ethical conduct of research projects (see section 13)
- 8.8 HREC will ensure that its membership is made public on its web site and within annual reports
- 8.9 HREC will ensure that researchers can request direct discussion with HREC Chair regarding proposed or ongoing research projects
- 8.10 HREC will ensure processes are in place to minimise the duplication of ethical review of research projects as per the National Statement (NS 5.3)

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 of HREC will be held at the dates and times agreed by the Committee. The meeting dates, including submission dates, will be published on the web site
- 9.3 All matters relating to submissions and HREC proceedings are confidential
 - 9.3.1 Agenda papers are delivered to members in electronic format (USB and network drive)
 - 9.3.2 USB drives are to be returned to the secretariat at the conclusion of each meeting and all files deleted
 - 9.3.3 Agenda papers received in hard copy are stored in official government files and kept in a locked room with restricted access
 - 9.3.4 Archiving is carried out in accordance with institutional policy
 - 9.3.5 Hard copy paper documents being disposed of are to be placed in a secure, locked, confidential recycling bin

10. Declaration of interest

- 10.1 Conflicts of interest are declared on appointment of members and are renewed annually. Members are to declare any potential conflicts as and when they arise (ref 6.9)
- 10.2 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 the meeting. A conflict of interest includes:
 - a. Personal involvement or participation in the research;
 - b. Financial or other interest or affiliation; or
 - c. Involvement in competing research
- 10.3 HREC will consider the interest declared and determine actions to be taken subject to the provisions of 10.4 and 10.5 below
- 10.4 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 room for the discussion and decision-making on the item
- 10.5 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

- 10.6 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
- 10.7 Where a member was excluded from discussion of an item or a vote on an item, this should also be included in the advice to the researcher on the outcome of the meeting

11. Decision making

- 11.1 HREC endeavours to reach agreement by consensus concerning the ethical and scientific acceptability of applications
- 11.2 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
- 11.3 Where a vote is tied, the casting vote of the Chair will break the tie
- 11.4 Any significant minority view (more than 3 members) will be noted in the minutes
- 11.5 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
- 11.6 Where the member is not available in any capacity HREC may, in accordance with the National Statement, seek input from a suitably knowledgeable and experienced person outside the membership

12. Record keeping

- 12.1 Records of all HREC meetings are maintained, including agendas and minutes
- 12.2 Files are kept securely and confidentially in accordance with ACT Health Administrative Records Management Policy DGD14-022
- 12.3 HREC maintains a database of all applications it has received

13. Monitoring research projects

- 13.1 HREC monitors approved research projects to ensure continued compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of:
 - Annual progress reports
 - Final reports
 - Safety reports (at least annually)

- Site specific serious adverse events and protocol deviations/violations (as they occur)
- Changes to the participant information sheet and consent forms (as they become available)
- Protocol updates (as they become available)
- Investigator brochures updates (as they become available or a statement of no change provided at least annually)
- Data safety and monitoring board reports (as they become available)

13.2 HREC has the discretion to adopt other appropriate monitoring mechanisms depending on the complexity, design and risk perceived

14. Guidelines for the Management of Research Proposals

14.1 HREC and sub-committee meeting dates, including submission dates, will be published on the website

14.2 Applications for research projects to be considered by HREC must be submitted in the name of the Principal Investigator

14.3 HREC will only receive electronic submissions

14.4 HREC members will receive meeting papers not less than seven days prior to the meeting date

14.5 The Principal Investigator will be advised of the outcome of consideration within 14 days of the meeting

14.6 Notification of approved research proposals will include instructions in relation to length of approval, compliance, reporting, monitoring of adverse outcomes and complaints procedures

14.7 No research may commence until the Principal Investigator has received formal notification of approval from HREC

15. Appeals and Complaints

15.1 Appeals regarding HREC non-approval

15.1.1 Where HREC has not approved an application, the investigator has the discretion to request the Chair seek review of the application from another 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

15.2 Appeals regarding HREC approval

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

- The individual or group, subsequent to HREC approval, have identified a significant ethical or scientific issue they feel HREC was unaware of
- It is believed that the decision to approve was based on inconsistent application of policy and guidelines

15.3 Complaints about the conduct of HREC members

15.3.1 Complaints about the conduct of HREC or an HREC member should be directed to the Secretary of the Committee, the Chair or Director of Research

15.4 Complaints about the conduct of an approved research project

15.4.1 Complaints about the conduct of an approved research project, including allegations of research misconduct, are reported in the first instance to the Secretary of the Committee

15.4.2 The Secretary of the Committee will report to the Chair who will take action to address and resolve the complaint

15.4.3 If unsuccessful, the Chair will refer the complaint to the Director of Research

15.4.4 All complaints will be managed in accordance with site specific complaint handling procedures

16. Termination of HREC responsibility

16.1 Where HREC has ceased to function, the Public Health Organisation, in this case ACT Health, notifies the ACT Minister for Health and the NHMRC

Version	Date	Endorsed by
V2.1	23 July 2015	A/g Chief Medical Administrator
Signature		