Table of Amendments

Amendment	Short Description	Version Dated
Draft terms of reference	Terms of Reference drafted	18 March 2022
Revision	Minor revisions of draft by OfR	9 June 2022

Contents

1 Acronyms

Acronym	Definition
AH	Austin Health
CMO	Chief Medical Officer
COO	Chief Operations Officer
HDR	Higher Degree Research
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
OfR	OfR
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration

2 Functions and Responsibilities of the HREC

2.1 The Austin Health Human Research Ethics Committee (HREC) operates in accordance with the National Statement on Ethical Conduct in Human Research (2007) Updated 2018 (the National Statement) and the Australian Code for the Responsible Conduct of Research 2018 (the Code). The primary responsibility of the HREC is to ensure research proposals are designed in accordance with the following values:

a. respect for human beings
b. research merit and integrity
c. justice
d. beneficence

2.2 In accordance with the National Statement Austin Health has established a HREC and a Low Risk Sub-Committee. From hereon, any function of the HREC is also a function of its Sub-Committee unless stated otherwise.

2.3 The functions and responsibilities of the HREC and its Low Risk Sub-Committee are to:

a. Review applications for projects and approve only those projects that are ethically acceptable as defined by section 2.1.3 of the National Statement and conform to the requirements of the National Statement.
b. Review applications for activities associated with research conducted with or about people, or their data or tissue.
c. Conduct follow-up review of approved projects and activities, and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the National Statement.
d. Take appropriate actions regarding non-compliance.
e. Provide advice and recommendations to the Institution.
f. Report on its operations to the Institution per Austin Health Clinical Trials & Research Governance Framework.

2.4 The HREC may refer applications to its Sub-Committees for review and vice-versa.

3 Responsibilities of the Institution

3.1 The primary responsibility of Austin Health, acting as an Institution are defined in the National Statement (Section 5.1) and the Austin Health Clinical Trials & Research Governance Framework.

3.2 OfR acting on behalf of the Institution is responsible for:

a. Any human research designed and conducted in accordance with the Australian Code for the Responsible Conduct of Research 2018 (the Code); and ethically reviewed and monitored in accordance with the National Statement
b. Creating and managing research governance processes as outlined in Section 5.1 of the National Statement and the Austin Health Clinical Trials & Research Governance Framework
c. Managing conflicts of interest
d. Monitoring research
e. Handling complaints
f. Ensuring accountability
g. Promoting clearly documented, accessible and current policies and procedures for research governance and ethical review
h. Ensuring these Terms of Reference are available for access by the general public
i. Providing adequate resources to allow proper function of the HREC
j. Facilitating education of HREC members and assisting in conflict resolution as necessary
k. Conducting an annual review of the function of the HREC
l. Appointing a chairperson and deputy chairperson to the HREC
m. Providing advisory support to the HREC and its Low Risk Sub-Committee

4 Responsibility of HREC and its Low Risk Sub-Committee Members

4.1 Each member of an ethical review body is responsible for deciding whether, in their judgement, a proposal submitted to the review body meets the requirements of the National Statement and the Code, and other appropriate guidelines and legislation as required.

4.2 To fulfil that responsibility, each member of a review body should:
a. become familiar with this National Statement, and consult other guidelines relevant to the review of specific research proposals;
b. prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences; and
c. attend continuing education or training programs in research ethics, where possible, this training will be included as a standing agenda item.

4.3 Sign a confidentiality agreement that agrees to maintain confidentiality regarding the content of applications, deliberations, correspondence between the HREC and any other party/institution.

4.4 Conflicts of interest will be declared before any deliberations of the HREC. Members are obliged to declare any interests that could influence the objectivity of their decision making. The procedure for managing conflicts of interest is:
a. Conflicts of interest and how each was managed will be recorded in the meeting minutes
b. Members must remove themselves from the HREC's decision making on matters that relate to the conflict of interest
c. In the case the member is an Investigator, the member concerned is required to leave the room (or sent to a breakout room or equivalent if using videoconferencing). The committee member with the conflict of interest may be asked to respond to questions directed to them upon returning to the room. This member will not participate in voting.

5 Membership of the HREC and Low Risk Sub-Committee

5.1 The Institution will appoint a chairperson with suitable experience as per the National Statement (Section 5.1.30).

5.2 In accordance with the National Statement (Section 5.1.29), the HREC will have a minimum membership of eight. As far as possible, this will include:
   a. equal numbers of men and women
   b. at least one third of the members should be from outside of the Institution.

5.3 In accordance with the National Statement (Section 5.1.30), the membership of the HREC will consist of the following:
   a. A Chairperson, with suitable experience and whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
   b. At least two lay people, one man and one woman, who have no affiliation with the Institution and do not currently engage in medical, scientific, legal or academic work.
   c. At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, an allied health professional.
   d. At least one person who performs a pastoral care role in the community.
   e. At least one lawyer, where possible who is not engaged to advise the Institution.
   f. At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

5.4 The minimum membership for the Low-Risk Committee is:
   a. a) A Chairperson, with suitable experience and whose other responsibilities will not impair the Low Risk Sub-Committee capacity to carry out its obligations under the National Statement.
   b. At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.
   c. At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, an allied health professional.
   d. At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

5.5 No member may be appointed in more than one of the above categories (National Statement 5.1.31). Austin Health may establish a pool of members in each category. These members may attend meetings as needed to meet quorum and may also be available to provide expert advice for the research under review.

5.6 Wherever possible one or more of the members should be experienced in reflecting on and analysing ethical decision-making.

5.7 The HREC will have access to scientific or content expertise, via the HREC and the Low Risk Sub-Committee in order to facilitate ethical issues arising from the research proposal. Where necessary the HREC may access the relevant expertise outside the HREC membership.

5.8 The HREC will maintain the Low Risk Sub-Committee, consisting of the Chair, Deputy Chair, members with current research experience relevant to research proposals considered at meetings and/or knowledge of and current experience in care, counselling or treatment of people and lay members. The Sub-Committee will be responsible for the review of low and negligible risk research proposals. Members with relevant research experience must be current researchers experienced in ethical decision-making.

5.9 A Deputy or Acting Chairperson will be appointed by OfR from the HREC and Sub-Committee membership, to act for the Chairperson in their absence.

5.10 The HREC or Sub-Committee may co-opt other persons with relevant experience or expertise as required, including persons with experience in field of research being reviewed and members from the Austin Health Department of Quality and Safety. Co-opted members of the HREC or Sub-Committee cannot exercise voting rights but must adhere to the principles of confidentiality as per voting members.

5.11 Appointment of Members:
   a. Austin Health may recruit new HREC or Sub-Committee members by calling for Expressions of Interests, which include a Duty Statement in the form of an Ethics Committee Position

Description. Applicants must respond to the Expressions of Interest by providing a covering letter and current curriculum vitae. Internal applicants must also provide written approval from their Head of Area supporting their application.

b. All applicants (except for the Chair) will be interviewed at a minimum by the OfR Manager or delegate, the Chair of the HREC or Low Risk Sub-Committee and any other stakeholders as deemed appropriate.
c. Members will be appointed by the Manager, OfR under the advisement of the interview panel.
d. Applicants for Chair will be interviewed at a minimum by the Manager, OfR, Director of Research, and relevant representative from Research Safety, Quality, Risk & Strategy Committee. The Chair will be appointed by the Manager, OfR, after the Chair has been endorsed by the Research Safety, Quality, Risk & Strategy Committee.
e. All members including the Chair and Deputy Chairs will receive a letter of appointment. The letter will include the date of appointment, length of tenure, indemnity and termination.
f. New members will be provided with an orientation package and will be required to attend an induction session.
g. Before appointment, all members of the HREC or Low Risk Sub-Committee must acknowledge in writing their acceptance of the terms of reference of the HREC and will be asked to sign a Confidentiality Agreement.
h. Members will be appointed for a period of three years with an opportunity to renew at the end of this period for a maximum second term, unless an Expression of Interest fails to find a suitable candidate.

5.12 Varying and Replacing Members:

a. The Institution on the advisement of the OfR may elect to vary membership or replace members at any time per the terms of the members' appointed letter.
b. The HREC may recommend to the Institution via the Ethics, Integrity and Governance Advisor that membership be amended.
c. In the event a member is obliged or elects to retire or resign during the term of the HREC or Low Risk Sub-Committee, the Institution will seek nominations for a replacement member via an Expression of Interest process as outlined in Section 9 of this document.

5.13 Absentee, Termination and Resignation of Members:

a. Where a member fails to attend three consecutive meetings of the HREC or Low Risk Sub-Committee without providing an apology or reasonable reason or has demonstrated an inability to maintain an adequate level of participation or meet the responsibilities of HREC or Low Risk Sub-Committee membership, the HREC or Low Risk Sub-Committee shall recommend to the Institution via the Ethics, Integrity and Governance Advisor that the member be replaced by a new appointee of the same category.
b. The Ethics, Integrity and Governance Advisor will notify the member in writing prior to any lapse in membership.
c. The Institution via the Manager, OfR (or delegate) may terminate the appointment of any member if they believe:
    - It is necessary for the proper and effective functioning of the HREC or Low Risk Sub-Committee
    - The person is not fit and proper to serve on a HREC or Low Risk Sub-Committee
    - The person has failed to carry out their duties
d. A member can resign in writing to the OfR at any stage during their term.

6 Ethics, Integrity & Governance Advisor to the HREC and Low Risk Sub-Committees

6.1 The OfR will provide an Ethics, Integrity and Governance Advisor to provide administrative and advisory support (in terms of providing research on best practice) to the HREC and Low Risk Sub-Committee. The Ethics, Integrity and Governance Advisor will be the first point of contact for HREC and Low Risk Sub-Committee members, Institutions or investigators wishing to access the HREC or Low Risk Sub-Committee.

6.2 The Ethics, Integrity and Governance Advisor will ensure distribution of meeting papers in a confidential manner to the members prior to each meeting, as well as maintaining records of HREC business. Records of applications and associated documents will be maintained indefinitely to meet record retention requirements.

6.3 The Ethics, Integrity and Governance Advisor should aim to circulate no less than seven working days prior to a scheduled meeting or a special meeting, an agenda setting out standing business before the HREC or Low Risk Sub-Committee meetings, all relevant proposals and related correspondence.

6.4 The Ethics, Integrity and Governance Advisor will be responsible for coordinating and drafting policies and procedures in accordance with the Code and other relevant legislation and codes of practice for review by the HREC.

6.5 The Ethics, Integrity and Governance Advisor will foster open communication between the committee and researchers to facilitate the review process as per the National Statement (Section 5.2.14).

6.6 The Ethics, Integrity and Governance Advisor will develop documentation per the National Statement (Section 5.1.5) and coordinate and conduct annual reviews of the operation of the HREC and the Low Risk Sub-Committee as pre section 14 of this document.

6.7 The Ethics, Integrity and Governance Advisor will coordinate an annual HREC self-review report in conjunction with the Chair.

6.8 The Ethics, Integrity and Governance Advisor in conjunction with the Chair and the Manager, OfR will prepare an annual report of HREC and Low Risk Sub-Committee operations for the Research Safety, Quality, Risk & Strategy Committee and other relevant external institutions.

7 Review and Approval of Pre and Post Approval Documents

7.1 Activities associated with research conducted with or about people, or their data or tissue must not start before written approval is given (National Statement 5.2.26(h))

a. The HREC may only approve applications that comply with The National Statement and other relevant legislation.

b. For research involving humans, applications must also comply with the requirements of the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (R2), Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice (ISO 14155), and the Therapeutic Goods Administration (TGA).

7.2 Applications are to be submitted for review in accordance with the OfR website.

7.3 Guidelines to assist applicants as well as document templates and policies and procedures will be made available on the Austin Health OfR website.

7.4 New proposals must be considered and approved only at quorate meetings of the HREC or the Low Risk Sub-Committee and meet the requirements outlined in The National Statement (Section 5.1.30).

7.5 The HREC or the Low Risk Sub-Committee may request the applicant to supply further information in relation to an application to clarify issues that may arise during review.

7.6 The HREC or the Low Risk Sub-Committee may request an applicant attend a meeting with the HREC or the Low Risk Sub-Committee Executive to facilitate review of a research protocol. The HREC or the Low Risk Sub-Committee may also request an applicant to attend a meeting of the HREC or Low

Risk Sub-Committee for providing information to, and answering questions from, HREC or Low Risk Sub-Committee members.

7.7 Following consideration of each application, the HREC or the Low Risk Sub-Committee may decide that an application to commence a project or activity is approved with or without conditions, deferred to the next meeting, subject to clarifications reviewed by the Ethics, Integrity & Governance Advisor, or not approved.

7.8 Applicants will be notified of HREC or Low Risk Sub-Committee decisions within five (5) business days from the date of the advertised meeting.

7.9 The HREC may establish a HREC or Low Risk Sub-Committee Executive from the available members at any time. The Executive must include the Chair and if deemed appropriate any other membership category as required.

7.10 The HREC or the Low Risk Sub-Committee Executive:

a. May approve modifications to approved projects or activities for ratification at the next quorate committee meeting
b. May specify urgent action required in response to reports of adverse events or emergencies
c. Consistent with HREC meetings, Executive members must declare if they have a conflict of interest with an item and another member must be appointed for consideration of the item.
d. Agenda items must be distributed in a safe and confidential manner.

8 HREC and Low Risk Sub-Committee Meetings

8.1 Meetings shall be conducted in accordance with operating procedures established by the OfR.

8.2 The HREC meetings will be conducted at least once a month between February and December.

8.3 The Low Risk Sub-Committee meetings will be conducted at least once a month between February and December.

8.4 The HREC and the Low Risk Sub-Committee meeting dates, and closing dates for the receipt of applications, will be advertised on the Austin Health OfR website.

8.5 The Committee may elect to conduct special meetings, if circumstances or the nature of business is urgent or extraordinary.

8.6 The HREC and the Low Risk Sub-Committee must have a quorum of members in attendance to conduct meetings. Such quorum must comprise at least one member from each category.

8.7 The HREC will not make decisions unless a quorum is in attendance. A non-quorate meeting of the HREC may discuss matters for future approval by a quorate meeting.

8.8 Attendance of quorate meetings may be facilitated by submission of written comments, video linking or teleconferencing of some members.

8.9 Any duly convened meeting at which a quorum is in attendance shall be able to consider and resolve any business of the HREC and shall have and may exercise all the functions of the HREC.

8.10 Any member of the HREC or the Low Risk Sub-Committee who has a conflict of interest associated with a proposal or other related matter being considered by the HREC or the Low Risk Sub-Committee should declare such an interest at the earliest opportunity. The member shall remove themselves from the meeting or being a reviewer when the project is the subject of consideration. Once the HREC or the Low Risk Sub-Committee has considered the matter and a decision has been reached, the member will be asked to return to the meeting. All declarations of interest and their management and absences of members will be minuted. Where there are no declarations of interest, this will also be minuted.

8.11 The HREC or the Low Risk Sub-Committee will endeavour to reach a unanimous consensus decision concerning the ethical acceptability of a research protocol. Where a unanimous decision is not reached, the HREC or the Low Risk Sub-Committee should explore with the applicant(s) ways of modifying the project that may lead to consensus. If necessary, the investigators should be invited to attend the next meeting.

8.12 If consensus is still not achieved, the HREC or the Low Risk Sub-Committee should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion. In this instance the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one layperson. Minority views will be recorded in the minutes.

8.13 Meetings will be conducted in such a way to encourage discussion, debate, and the exchange of ideas.

9 Fees and HREC Review

9.1 A fee will be charged per the fee structure outlined on the OfR website.

9.2 External researchers wishing to access the HREC or the Low Risk Sub-Committee must contact the OfR and book a consultation prior to submitting an application.

10 Record Keeping

10.1 The OfR will prepare and maintain an official file for each application received. This may be electronic, and will include a copy of the application, any relevant correspondence including that between the applicant and the HREC or HREC Executive in accordance with the Public Records Act 1973 (Vic). Meeting minutes will be retained in a Minutes file in accordance with the Public Records Act 1973 (Vic).

10.2 The OfR will also maintain the following records (The Code 2.2.30 and 2.3.22):

a. A register of all applications to the HREC, including the outcomes of deliberations.
b. Minutes that record decisions and other aspects of the HREC's operation.
c. Records of inspections conducted by the HREC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes.

10.3 Files will be kept securely and confidentially in accordance with the Commonwealth and State privacy legislation and the Public Records Act 1973 (Vic)

10.4 The OfR will close and archive the file in accordance with the Public Records Act 1973 (Vic).

10.5 Records will be held for sufficient time to allow for future reference. The minimum period of retention will be in accordance with the Code and the Public Records Act 1973 (Vic).

11 HREC monitoring and Reporting Requirements

11.1 The HREC will monitor approved projects in accordance with the National Statement Section 5.5 and the Austin Health Clinical Trials Governance Framework to verify that the conduct of the research conforms to the approved proposal.

11.2 **Mechanisms for reporting include:**

a. Annual progress reports from researchers. If a project is deemed to be of considerable risk to participants researchers may be requested to provide more frequent progress reports;
b. Reports from safety or other monitoring boards;
c. Review of adverse event reports;
d. Risk Based Monitoring and/or Auditing of Research; and
e. Other forms in accordance with the National Statement and Austin Health Clinical Trials & Research Governance Framework.
f. Researchers will be advised in the letter of final approval that they are required to submit reports as a condition of approval.

11.3 The OfR will send reminders to the Principal Investigator when a report is due.

11.4 The HREC will require, as a condition of final approval, that investigators immediately report any of the following:

a. Proposed changes to the protocol or project in the form of a request for modification.

b. Other unforeseen events that may affect the continued ethical acceptability of the project, including compliance with the approved protocol protocol, conduct of research investigators, emerging conflict of interest or conditions of the approval.
c. If the project is discontinued for any reason.

12 Complaints or appeals

12.1 All complaints, concerns or enquiries will be treated confidentially and sympathetically. Complaints must be addressed in writing to the Manager, OfR.

12.2 If a member of a HREC or Low Risk Sub-Committee or a researcher has any grievance about the operation of that committee, they should discuss this, in confidence, with Ethics, Integrity & Governance Advisor.

12.3 If the grievance cannot be resolved they should then take their concerns to the Manager, OfR who may on-refer the complaint to the Research Director, OfR or Research Safety, Quality, Risk & Strategy Committee. The referral pathway will depend on the nature of the complaint.

12.4 Conscientious objection - If a staff member or student wishes to conscientiously object to participation in an activity occurring under Austin Health, then this should be first addressed with the Principal Investigator. If a resolution is not apparent, the objection can be provided in writing to OfR who will on-refer it to the appropriate person/s.

12.5 **Resolution of Complaints will be handled in the following manner:**

a. If the complaint is of a serious nature, or if the matter cannot be resolved, then the Manager, OfR should be notified in a timely manner. Under these circumstances the Manager, OfR will commence an initial investigation into the complaint to determine the severity and validity of the complaint, obtain in writing the grounds of the concern or complaint and where possible categorise it. A letter of acknowledgement to the complainant and a letter of notification to the principal investigator (where relevant) will be sent, outlining the complaint and the mechanism for investigating the complaint.
b. The complainant will be informed of the outcome of the investigation. If the complainant is not satisfied with the outcome of the investigation, then they can refer the complaint to the Research Safety, Quality, Risk & Strategy Committee or request the Manager OfR/Director of Research or HREC or Low Risk Sub-Committee Chairperson to do so.
c. Complaints considered to raise the possibility of research misconduct, as outlined in the Code, will be referred immediately to the appropriate person as per relevant institutional policies and procedures.
d. Where a complaint alleges a type of misconduct that falls outside of the range of research misconduct as described in the current version of the Code, the matter will be dealt with in accordance with the relevant Austin Health policies or procedures.

12.6 During monitoring of an approved project or investigation of adverse events/safety reports, OfR and/or HREC may uncover potential matters of concern to participant safety or use of their data and/or biological specimens, or misconduct or research misconduct. These will be handled in a similar manner to that described above.

12.7 OfR will maintain a record of all complaints received regarding the activities of the Committee. This record will include the complaint, the outcome of the complaint, and any related investigations. A record of complaints received regarding HREC approved research will also be maintained. This will include the complaint, the outcome of the complaint and any related investigations.

12.8 If there is a grievance between the HREC and the Independent External Review, the complaint shall be submitted in writing by the HREC to the review body.

12.9 All attempts should be made to resolve the matter between the parties, but if this is unsuccessful then the matter shall be referred to an external independent mediator. If appropriate, the regulatory Department will also be informed.

13 Business Operations

13.1 The HREC or the Low Risk Sub-Committee will examine applications for approval with the following decisions:

a. **Approved** The HREC or the Low Risk Sub-Committee is satisfied that the application is ethically acceptable and complies with the National Statement. The application is approved by the HREC, as submitted, with no changes required.

b. **Approved with condition(s)** The HREC or the Low Risk Sub-Committee is satisfied that the application will be ethically acceptable and comply with the National Statement, subject to a specific correction or defined alteration. Alternatively, where outcomes or effects of procedures are not well known, the HREC or the Low Risk Sub-Committee may wish to receive reports at specified time points to ensure the project remains ethically acceptable. The agreed and exact condition(s) are recorded in HREC or the Low Risk Sub-Committee meeting minutes as a decision of the committee. The investigator is made aware that exact conformity with specified alterations is a condition of approval. The condition(s) of approval must be defined in the letter of approval. For example, the HREC may require six monthly progress reports or require completion of one stage of the research before approving for the next stage to commence.

c. **Subject to changes to the satisfaction of the HREC or the Low Risk Sub-Committee**: The HREC or the Low Risk Sub-Committee is satisfied that the application has in-principle justification but requires additional information and the required modifications meet the committee's criteria for minor changes. In that instance the revised application may be considered out of session and the approval is delegated to an executive of the committee or the OfR.

- If the HREC or the Low Risk Sub-Committee Executive or the OfR is satisfied with the resubmitted application, the executive or the OfR may approve the revised application; subject to ratification by the HREC at the subsequent quorate meeting of the HREC. The approval date is the date approved by the executive of the HREC.
- If the HREC or the Low Risk Sub-Committee Executive or the OfR determines that the resubmitted application contains modification(s) outside of the criteria for a minor amendment it must refer the application to a quorate meeting of the HREC or the Low Risk Sub-Committee.

d. **Deferred**: The HREC or the Low Risk Sub-Committee is satisfied that the application has in-principle justification, but requires additional information, clarification or changes to make a decision that are outside of the scope of a minor amendment. In that instance the resubmitted application must return to the full committee for appraisal at a quorate meeting. Changes to the project that have potentially high impact on participant safety or their data or biological specimens must be considered by a quorate meeting of the HREC.

e. **Not approved** This situation will arise where, in the judgment of the HREC or the Low Risk Sub-Committee, the potential effects on the wellbeing of human participants, their data or biospecimens involved is not justified by the potential benefits of the project. In this circumstance the HREC or the Low Risk Sub-Committee should clearly communicate its decision and require the applicant to withdraw the application.

13.2 Amendments to approved projects

a. An investigator may apply to have an amendment to an approved project approved during the period of its approval provided the proposed changes do not alter the substantive procedures or processes to such a degree that a new project application is warranted.

b. The HREC, the Low Risk Sub-Committee or their delegate will determine if a new application is required.

c. The HREC, the Low Risk Sub-Committee or their delegate must approve in writing any proposed amendments to an approved project before the change is implemented.

14 Financial Arrangements

14.1 External committee members will be paid a monthly sitting fee as outlined in their appointment letters.

14.2 OfR will provide parking vouchers for all external members.

14.3 OfR will provide indemnity for members of the HREC or the Low Risk Sub-Committee in respect of liabilities that may arise during the conduct of their HREC or Low Risk Sub-Committee duties.

15 Annual Report and Review of Operations

15.1 The HREC will produce an annual report of its operations for submission to Research Safety, Quality, Risk & Strategy Committee, any regulatory agency and eligible institutions.

15.2 The HREC Chair and/or the Manager, OfR will make themselves available to meet with the relevant regulatory agency to review the HREC annual report.

15.3 The report should include:

a. Confirmation that all research governance and ethical oversight processes remain compliant with the National Statement and the Code.
b. Numbers and types of projects and activities assessed and approved or not approved.
c. Actions that have supported the educational and training needs of HREC members.
d. Administrative or other difficulties experienced in HREC operations.
e. Any complaints, grievances and adverse events.
f. Any matters that may affect relevant eligible institution's ability to maintain compliance with the Code.
g. Any matters that may affect the HREC's ability to maintain compliance with the Code.
h. Appropriate recommendations to address matters of non-compliance and measures for effective, remedial change.

16 Revision of Terms of Reference

16.1 These Terms of Reference will be reviewed as necessary in response to changes in legislation, policies or upon the request of the HREC, or every three years, whichever occurs first.

17 Related Documents

17.1 Australian Code for the Responsible Conduct of Research 2018

17.2 National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)

17.3 Privacy and Data Protection Act 2014 (Victoria)

17.4 Privacy Act 1988

17.5 Public Records Act 1973 (Vic)