Human Research Ethics Committee

Terms of Reference

Document history

Version	Issue date	Changes
01	30 November 2017	Rebrand to Bolton Clarke & update internal research review governance processes.
02	26 August 2019	NHMRC National Statement 2007 Version updated to 2018. Internal research review governance processes updated. 'Low risk' renamed 'Negligible risk' throughout document.
03	1 March 2021	Names of internal research governance committees updated.
04	6 November 2024	Rebrand with new company logo National Statement Version updated to 2023. ATSI clauses added.

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1. Purpose

The purpose of the Bolton Clarke Human Research Ethics Committee (**HREC**) is to protect the welfare and the rights of Bolton Clarke individuals, groups or communities who participate in research projects conducted by members of the Bolton Clarke Group (**Group**) or external researchers.

The Group supports and promotes the conduct of clinical research which will assist the Group to provide services which improve the health, wellbeing and lifestyle of its consumers. Members of the Group undertake research individually and in collaboration with other parties.

The Group's Board has responsibility for research governance and has delegated that responsibility to the Executive Research Management Committee (ERMC). The HREC will provide a copy of its minutes to the ERMC after each meeting, together with any additional information that may be requested. The Group acknowledges its responsibilities in supporting and monitoring the functions and operations of the HREC as set out in these Terms of Reference.

Capitalised terms used in these Terms of Reference are defined in the Glossary (see clause 21).

2. Privacy and ethical framework for HREC

The HREC operates within:

- the Guidelines set out in the National Health and Medical Research Council's (2007) National Statement on Ethical Conduct in Human Research 2023
  National Statement on Ethical Conduct in Human Research 2023 | NHMRC
- NHMRC Australian Code for the Responsible Conduct of Research 2018
- the Office of the Health Services Commission Statutory Guidelines (Victoria) (2002) on Research issued for the Purposes of Health Privacy Principles 1.1 (e) (iii) and 2.2 (g) (iii) (); and similar Guidelines in other States
- any relevant amendments made to the above documents.

3. Privacy legislation underpinning HREC activities

The Privacy Act 1988, the Health Records Act and similar legislation in other States direct the collection and use of personal information in research and other applications. The HREC must confirm that applications for ethical approval conform to all relevant legislative requirements.

The Privacy Act, the Health Records Act and similar legislation in other States mandate that research involving a person's health information will be conducted wherever possible with the knowledge and consent of the individual. Where this is not practicable, only non-identifiable health information will be collected. Both Acts recognise that in

some circumstances, obtaining consent may not be practicable or possible. In such a case, other priorities will need to be balanced against the public interest in maintaining an individual's privacy. Both Acts have provision for the collection, use and disclosure of health information (that cannot be deidentified) which is necessary for research and compilation or analysis of statistics that is either 'relevant to public health or public safety' (Privacy Act) or 'in the public interest' (Health Records Act):

- where the data is identifiable and/or it is impracticable to obtain consent of the individual;
- the information is collected by or under an Australian law;
- the information is collected in accordance with rules established by competent health or medical bodies or in accordance with any guidelines issued; and
- in the case of disclosure, the research body reasonably believes that the recipient will not disclose the information, or personal information derived from that information.

In the situation where the aims of the research cannot be achieved if those aims and/or the research methods are fully disclosed to participants, the HREC will be guided by Chapter 2.3 Qualifying or waiving conditions for consent of the NHMRC National Statement. The HREC will require evidence from the applicant that limiting or concealing disclosure to participants is required for research integrity, is not in breach of any state, federal or international law and that the potential risk to participants is low.

4. Ethical principles underpinning HREC activities

The NHMRC National Statement has determined that the following values and principles will underpin the conduct of research with human participants:

4.1 ***Research merit and integrity***: This includes the commitment to ensuring that:

- Research is justifiable by its potential benefit and contribution to knowledge and understanding.
- Studies build on the existing knowledge base.
- Research methods are appropriate to the aims of the study.
- Studies are adequately resourced.
- Researchers have suitable experience and training to conduct studies they are conducting and provide supervision to students/novice researchers.
- The aims of the study do not compromise respect for persons.
- Principles of research integrity are applied.

4.2 ***Justice*****:** Justice is described as fairness in the distribution of research burdens and benefits, including selection and exclusion of participants, recruitment, protection from unreasonable burden on participants, and access to the benefits of research.

4.3 ***Beneficence***: Researchers are obliged to justify and minimise the risk of harm or discomfort to participants and the community. Harm, in this context, extends

beyond physical harm to a wide range of psychological or emotional distress, discomfort and economic or social disadvantage.

4.4 ***Respect***: Researchers and their institutions have an obligation to respect the inherent dignity, privacy and rights of people. That respect includes a commitment never to use a person only as a means to an end and a commitment to respecting an individual's right and responsibility to make decisions about his or her life.

5. HREC functions and responsibilities

The HREC will:

5.1 Consider the ethical implications of all research proposals involving Group staff, consumers, formal carers, volunteers or students. All such proposals must be reviewed by the HREC and must not be undertaken unless and until approval has been granted. The HREC may approve, require amendment of, or reject a research proposal on ethical grounds. HREC shall record its decisions in writing and include reasons for rejection.

5.2 Comply with the ethical principles and associated guidelines for research outlined in the NHMRC National Statement and relevant state and federal law.

5.3 Protect the welfare and the rights of participants in research. The primary responsibility of each member is to decide, independently, whether in his or her opinion the conduct of each research proposal submitted to the HREC will not infringe upon the welfare and rights of participants.

5.4 Protect the confidentiality and privacy of individuals by requiring that researchers undertake rigorous measures regarding the security, storage and disposal of confidential data collected during the conduct of research involving Group staff, consumers or students in accord with the Australian Code for the Responsible Conduct of Research (2018).

5.5 Maintain confidentiality of HREC deliberations.

5.6 Review all research applications which involve or impact upon Indigenous Peoples in line with the NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander (ATSI) Peoples and communities.

5.7 Establish collaborative relationships with ATSI peak bodies and local HRECs with Indigenous membership representation to enable engagement with Indigenous elders/community leaders if/as required.

5.8 Request advice from, and consult with, recognised experts in Research involving Indigenous Peoples who are familiar with the cultural practices of the Aboriginal and Torres Strait Islander Peoples, for research specifically seeking to target/recruit Indigenous Peoples at Bolton Clarke.

5.9 Promote understanding within the Group and the broader community of the ethical issues raised by research. The HREC will also monitor and, if applicable, implement any subsequent amendments made to HREC Terms of Reference and guidelines for conducting research within the Group.

5.10 Establish, implement and review procedures for evaluating, approving and monitoring the acceptable conduct of research involving human participants. These procedures will be applicable to:

5.10.1 any Group staff and/or students, within Group facilities, who want to use any Group name, premises, equipment, data, staff, students or consumers for the purpose of research.

5.10.2 any Group staff and/or students outside Group facilities who want to use any Group name, premises, equipment, data, staff, students or consumers for the purpose of research, and;

5.10.3 any researchers without affiliation to the Group or to an organisation with a human research ethics committee, who want to use any Group name, premises, equipment, data, staff, students or consumers for the purpose of research, taking into consideration the resources of the HREC and the Group to respond to researcher requests.

5.11 Ensure that legal responsibility for research projects is properly defined and does not expose the Group unnecessarily to litigation.

5.12 Ensure that all projects approved by the HREC are completed in accordance with relevant Group policies.

5.13 Report to the ERMC and the Board any significant matters relating to research involving Group staff, consumers or organisations or individuals undertaking or wishing to undertake research with the Group, including:

- matters that may have a negative impact on the Group or may affect the legal standing or reputation of the Group;
- matters that present any actual or potential conflicts of interest;
- matters impacting on the performance of the HREC; or
- matters impacting on the performance of the Research Institute.

5.14 Endeavour to ensure the results of HREC approved research and the methods used are made public in ways that permit scrutiny and contribute to public knowledge.

5.15 Provide copies of meeting minutes to the ERMC and the Board after each meeting, together with any additional information that may be requested.

6. Membership of HREC

6.1 Composition

The requirements for membership of the HREC, as defined by the NHMRC National Statement, are as follows:

- a minimum of eight members, with equal numbers of men and women, at least one third of whom are external to the Group and wherever possible, one or more of the members listed below to be experienced in reflecting on and analysing ethical decision making;
- No member may be appointed in more than one of the categories listed below:
  - a Chair, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the NHMRC National Statement;
  - at least two members who are lay people, one man and one woman, who have no affiliation with the Group, and do not currently engage in medical, scientific, legal or academic work;
  - at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
  - at least one member who performs a pastoral care role in a community, for example, an Aboriginal elder or a minister of religion;
  - at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant experience; and
  - at least one lawyer who is not engaged to advise the Group in any other capacity.

6.2 Additional members

Co-opted members: when decisions require specific expertise beyond that of the HREC Members, the HREC may co-opt additional members or seek advice from external advisors. (NHMRC National Statement, Chapter 5.1.33).

6.3 HREC Secretariat

The Group shall provide an HREC Secretariat to:

- Assist the Chair and members in the functions of the Committee.
- Receive and distribute papers and documents of relevance to the HREC.
- Correspond where necessary with researchers.
- Ensure maintenance of all HREC documentation including Terms of Reference, Committee membership, HREC meeting minutes.
- Arrange HREC meetings.

6.4 Rationale for appointing members

6.4.1 Members of the HREC will be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.

6.4.2 The HREC shall ensure that its membership will equip it to address all relevant considerations arising from the categories of research likely to be submitted to it. For example, an experienced medical practitioner should be included if the HREC considers research proposals which involve any physically invasive procedures or medical interventions, (e.g. surgical, pharmacological, physiological, technological or nutritional intervention).

6.4.3 The HREC shall ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific and statistical validity, that are relevant to deciding whether the proposal is both acceptable on ethical grounds and conforms with the NHMRC National Statement. The HREC may request a written report from the Research Institute and/or may co-opt additional invitees with specific expertise.

6.5 Disclosure of Conflict of Interest

6.5.1 The HREC shall require that members declare any actual or potential conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research. Where a real or perceived conflict of interest arises, the HREC member will absent themselves from deliberation and decision making in relation to the relevant application and their absence will be recorded in the minutes. Specific guidelines are detailed in Section 5, Chapter 5.6 of the NHMRC National Statement.

6.6 Appointment of Chair and Deputy Chair

6.6.1 The NHMRC National Statement states that the Chair of the HREC requires "suitable experience" and must be in a position where their "…other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement" (Chapter 5.1.30 (a)). The Chair will not be a Group employee. The Chair will be confirmed by the CEO and the Board on the advice of the HREC.

6.6.2 The Deputy Chair shall be approved by the CEO on the advice of the HREC.

6.6.3 The terms of appointment of the Chair and Deputy Chair shall not be completed in the same year.

6.7 Responsibilities of Deputy Chair

Responsibilities of the Deputy Chair are:

- To fill in as Chair if the Chair is an apology at a meeting of the HREC.
- Induction of new members of the HREC.

- To meet as required with the Chair to discuss matters arising in between HREC meetings.
- To undertake any further tasks as directed from time to time by the Chair.

6.8 Appointment and removal of members

An open and transparent process should be employed for the appointment of members to the HREC (NHMRC National Statement, 5.1.34). Committee members are appointed by the CEO on the advice of the HREC for a period of two (2) years, and are eligible for ongoing re-appointment of two year terms.

Up to half of the membership of the HREC shall be eligible for re-appointment each year in June.

The process for appointing new members to the HREC is as follows:

- The Chair seeks suggestions and recommendations of potential candidates from HREC members.
- The Chair makes an approach to potential candidates seeking an initial level of interest, explaining the purpose of the HREC, outlining the anticipated commitment and determining the candidate's availability.
- If both parties are interested in pursuing possible membership, a CV is requested from the potential candidate.
- The CV and outcomes of the approach are forwarded to the Deputy Chair and Secretary for review. The Chair seeks feedback on the potential candidate and the membership position is matched to one of the NHMRC membership categories.
- The potential candidate is interviewed by the Chair and Deputy Chair or Secretary.
- If all parties are wishing to proceed, the Secretary drafts a letter of appointment and Deed of Confidentiality, which are submitted to the CEO's office, along with a copy of the CV, for signing by the CEO.
- The length of term for the candidate's appointment is determined by the expiration dates of current membership to balance half of the committee retiring/being re-appointed each year.

A member may be removed by notice from the Group if:

- they fail to attend at least half of the Committee meetings held during a year; or
- the CEO reasonably considers that the member has brought the Group or the HREC into disrepute.

6.9 Induction of new members

The Deputy Chair, assisted by staff of the Secretariat, shall be responsible for induction of new members.

6.10 Responsibilities of HREC members

It is expected that HREC members will be familiar with the NHMRC National

Statement and other relevant documents, attend continuing education and training in research ethics at least every three years, prepare opinions on the ethical acceptability of applications for HREC meetings and attend meetings to discuss said applications. If a member is unable to attend a meeting they will provide their opinions on the ethical acceptability of the research proposals before the meeting, either by submitting a completed Research Proposal Approval form or providing comment in an email.

HREC members will determine whether applications submitted to the HREC conform to the requirements and standards of the NHMRC National Statement.

HREC members will undertake to disclose potential or actual conflict of interest in accordance with section 6.5.1 of this Terms of Reference document.

HREC members' responsibilities will be limited to reviewing the ethical implications of applications:

- the scientific merit of internal and student research applications will be reviewed by the Research Institute's Research Review Governance Committee (RRGC) prior to submission of the application to the HREC, and
- resource impact, clinical merit and support for the conduct of research at the Group will be determined by the relevant Bolton Clarke Business Stream leader independent of scientific merit and ethical approval.

6.11 Indemnity of HREC members

The Group shall indemnify and keep indemnified each member of the HREC against all actions, suits, claims and demands whatsoever (whether arising during or after the term of office of that member) in respect of any act or thing done by that member in good faith during his or her term of office in the exercise or purported exercise of any power or duty conferred or imposed upon the HREC.

6.12 Remuneration of HREC members

Involvement in the HREC is entirely voluntary and HREC members will not be remunerated for their HREC activities in any form whatsoever.

7. Quorum for meetings

A quorum of the HREC shall consist of 50% of its members.

8. Meetings

8.1 Frequency of meeting

Meetings of the HREC shall be held at least five (5) times a year with the option of an additional meeting. The dates of these meetings and closing dates for submission of agenda items will be established on an annual basis by 30 November

of the previous year and published on the Group's website by 31 December.

All members of the HREC should strive to attend all meetings and must attend at least half of the Committee meetings each year.

8.2 Circulation of agenda and minutes of meetings

The HREC Secretariat shall circulate the agenda, relevant papers and minutes of the previous meeting to committee members at least seven (7) days prior to each meeting.

9. Submission of applications for ethics approval

9.1 Researchers are required to complete and submit the NHMRC Human Research Ethics Application (**HREA**) form to the HREC if it is their intention to undertake a research project within the Group or using Group resources. All relevant sections of the form must be completed before the HREC will consider the proposal. The form must be submitted in a typed format accompanied by a completed HREC Application Checklist.

9.2 Documentation that must accompany the HREA

9.2.1 The completed and signed HREA should be accompanied by all documents and other materials used to inform potential research participants (including plain language statements, Protocols, consent forms, questionnaires, advertisements and letters of invitation). All materials are to be approved by the HREC before research commences.

9.2.2 Written notification of the decision of another human research ethics committee shall be provided to the HREC where relevant. The HREC aims to minimise duplication of ethical review in accord with the Chapter 5.5 of the NHMRC National Statement .

NOTE: When another Human Research Ethics committee has approved a research activity that seeks health information from the Group in accordance with guidelines under the Privacy Act or the Health Records Act, the Group can either:

- require the researcher to go through the HREC process and submit a HREA,
- choose not to approve the application even though it has been approved by another human research ethics committee, or
- may accept the application subject to HREC specific conditions.

9.3 Disclosure of sources of funding

A researcher must disclose to the HREC the amount and sources or potential sources of funding for the research and declare any affiliation or financial interest when proposing and when reporting the research.

10. Processing applications for ethics approval

10.1 Reviewing applications

The HREC must be satisfied that a research application gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage both individual and collective.

10.1.1 All research projects will be required to obtain approval from the Bolton Clarke RRGC, and the relevant Bolton Clarke Business Stream leader and responsible Executive, before applications will be accepted by the HREC for review.

10.1.2 The HREC may only approve, require amendment of, or reject a research application on ethical grounds. The HREC will record decisions in writing and shall include reasons for amending or rejecting a proposal in the written report.

10.1.3 When considering proposals in accordance with guidelines relating to either the Privacy Act or the Health Records Act, irrespective of whether they satisfy the HREC's procedural requirements, the HREC shall weigh the public interest consideration set out in Section D.5 of the NHMRC Statutory Guidelines as approved under Section 95A of the Privacy Act, and Section 4 of the Statutory Guidelines on research issued for the purposes of Health Privacy Principles 1.1 (e)(iii) and 2.2 (g)(iii) HPP Statutory Guidelines .

10.1.4 The HREC may invite the researcher(s) to be present at the meeting to clarify any aspect of the research and may request amendments to the research applications.

10.1.5 The HREC may not communicate directly with a research sponsor on matters relating to the proposal or ethics of a project, but the HREC and the sponsor may have direct communication on matters relating to administration, indemnity and insurance.

10.1.6 HREC members should endeavour to reach decisions by general agreement. This need not involve unanimity, but failure to agree may require an extension of time to reconsider the research proposal and its possible amendment, especially when any member is not satisfied that the welfare and rights of participants are protected. If the HREC requires an extension of time to consider a research application, the Chair will ensure that the authors of the application are notified regarding this decision.

10.2 Notification of decisions

If HREC members are given sufficient time to review a research application, the respective researchers should be able to expect written notification of the HREC's decision within seven (7) clear business days of the meeting at which the application was discussed.

11. Expedited review for negligible or low risk research

11.1 Definition of expedited review

Expedited review involves a departure from the usual HREC requirement that all materials are considered by all members of the Committee. The justification for this type of review is that the research involves negligible or low risk to the participants and not that speedy approval is needed. Under the NHMRC National Statement research with the potential for physical or psychological harm shall not be considered for expedited review. This includes drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues. Further, where the Chair of the HREC considers that research may involve a departure from any of the ethical principles in the NHMRC National Statement, the proposal must be considered by the full HREC and cannot be dealt with by expedited review. This includes where research involves participants from cohorts identified in NHMRC National Statement Chapter 5.1, as well as Chapter 4.3: People in dependent or unequal relationships.

11.2 Reasons for research being considered for expedited review by HREC

The Chair of HREC shall instigate the process of expedited review only if all relevant aspects of the documentation required for ethics approval have been completed by the intending researchers, is of negligible or low risk to the participants as defined in the NHMRC National Statement Chapter 2.1, has been reviewed by RRGC and is funded by a recognised agency.

11.3 Process for expedited review

The Chair of the HREC is empowered to decide whether a HREA is to be considered for expedited review. An expedited review must be undertaken by no less than three HREC members, nominated by the Chair.

12. Monitoring of HREC-approved research projects

12.1 Responsibility of the HREC in regard to monitoring

The HREC has a responsibility to ensure that the conduct of all research that it approves is monitored by procedures as determined by the Group and the HREC.

The frequency and type of monitoring required by the HREC should reflect the degree of risk to participants in the research project.

12.2 Basic monitoring requirements

The HREC must receive as requested, and at least annually, written reports from Principal Researchers that include information about:

- progress to date or outcome(s) in the case of completed research;
- maintenance and security of records; and
- compliance with the approved proposal
- compliance with any conditions of approval

12.3 Additional monitoring requirements

12.3.1 The HREC may recommend and/or adopt any additional appropriate mechanisms for monitoring HREC-approved research projects, including random inspections of research sites, research data, signed consent forms and interview transcripts or recordings (with the prior consent of research participants).

12.3.2 The HREC has an obligation to monitor approved projects in accordance with NHMRC National Statement.

12.4 Criteria that might warrant review of ethics approval

The HREC shall, as a condition of approval of each research application, require that researchers immediately report, verbally and in writing, anything which might warrant further review of ethical approval of the project, including:

- serious or unexpected adverse effects on participants,
- proposed changes in the project, and
- unforeseen events that might affect continued ethical acceptability of the project.

12.5 Responsibility of researchers to notify HREC if the research project is discontinued or there is deviation from the approved research timetable.

The HREC shall, as a condition of approval of the research proposal, require researchers to inform the HREC, in writing, reasons why there is a deviation from the approved research timetable or the research project is discontinued before the expected date of completion.

12.6 Advising institution(s) or organisation(s) to discontinue a research project

Where the HREC is satisfied that circumstances have arisen such that a research project is not being, or cannot be, conducted in accordance with the approved proposal and that, as a result, the welfare and rights of participants are not, or will not be, protected, the HREC may withdraw approval, inform the researcher(s) and the institution(s) or organisation(s) of such withdrawal, and recommend to the

institution(s) or organisation(s) that the research project be discontinued, suspended, or that other necessary steps be taken. A researcher must not continue the research if ethical approval has been withdrawn and must comply with any special conditions required by the HREC.

13. Reporting and handling of complaints about researchers

13.1 A detailed Research Complaints Procedure is available on the Group's website Complaints Procedure

13.2 Nomination of person to receive complaints

13.2.1 Complaints from research participants, family members of research participants, researchers and other interested persons should be made in writing to the Chair.

13.2.2 If the Chair has been able to resolve a complaint, he or she shall provide advice regarding this to the Committee. In the case of unresolved complaints, the Chair shall request the Committee to be involved in resolution processes.

13.3 Referral of unresolved complaints to third party

If the HREC cannot resolve a complaint, the Chair of the HREC will refer the matter to the CEO.

14. Reporting and handling of complaints from researchers about the HREC

14.1 A detailed Research Complaints Procedure is available on the Group's website Complaints Procedure

14.2 Any complaints from researchers about the conduct of the HREC must be referred to the CEO in writing. The complainant will receive a written acknowledgement of receipt of the complaint. The CEO shall arrange for an investigation of the complaint, if necessary providing the complainant(s) with the opportunity to present the complaint in person. The decision of the CEO or their delegate in relation to the outcome of the complaint shall be final and shall be communicated to the complainant(s) in writing.

14.3 Complaints about an activity approved under Commonwealth or State privacy guidelines.

Irrespective of the complaints mechanism outlined in 13, 14.1 and 14.2 above, an individual may complain directly to the Health Services Commissioner or Information Commissioner if they believe that procedures set out in either sets of

Guidelines are not followed or that the conduct of the approved activity may interfere with their privacy.Recording of decisions and storage of HREC documentation

14.4 Nature of record to be maintained by HREC

The HREC is required by the NHMRC National Statement to maintain a record of all research proposals received and reviewed including:

- the name of the responsible institution or organisation
- the project identification number(s)
- the principal researcher(s)
- the title of project
- ethical approval or non-approval with date
- approval, or non-approval, of any changes to the proposal
- the terms and conditions, if any, of approval of any proposal
- whether approval was by expedited review
- whether the opinion of another HREC was considered,
- the action(s) taken by the HREC to monitor the conduct of the research.

For decisions made regarding proposals to conduct research or compilation or analysis of statistics relevant to public health or public safety, the HREC must record additional details cited in (a) – (f) of paragraph D.6 of the Statutory Guidelines approved under Section 95A of the Privacy Act.

For decisions made regarding proposals to conduct research or compilation or analysis of statistics, in the public interest, the HREC must record additional details cited in (a) – (f) of Section 4.5 of the Statutory Guidelines issued for the purposes of Health Privacy Principles 1.1 (e)(iii) and 2.2 (g)(iii).

The HREC shall retain on file a copy of each research application for HREC approval, including any information sheets, consent forms or relevant correspondence, in the form in which they are approved.

14.5 Multi-centre research proposals

For multi-centre research proposals, the HREC shall also record, from information provided by the researcher(s):

- details of other centres involved
- the ethical approval status of the study at each centre; and
- details of any amendments required at other centres.

14.6 Confidentiality of the content of proposals and of committee proceedings

HREC members shall at all times protect the confidentiality of the content of proposals and of committee proceedings. At appointment, members will be asked to sign an agreement in relation to confidentiality.

All documentation related to the workings of the HREC shall be stored in a secure location and shall not be revealed to persons without proper authorisation.

The Chair of HREC, assisted by the Secretariat, shall be responsible for securing the confidentiality of the proceedings of the HREC. In order to minimise the amount of confidential documentation that HREC members store in their homes, members are requested to leave all documentation no longer required for decision-making purposes with the Secretariat for destruction. Additionally, unnecessary files related to HREC proceedings should be deleted from their personal computers or computer disks.

All outgoing HREC members will be requested, in writing, to return all documentation related to the Committee to the Secretariat as soon as possible on the completion of their tenure.

15. Advocates and interpreters

15.1 Indications for advocates/interpreters

15.1.1 The HREC shall consider whether an advocate for any research participant or group of participants should be invited to the HREC meeting to try to assist participants in understanding the project and support their decision-making.

15.1.2 Where research involves the participation of persons unfamiliar with the English language (or the language in which the research is to be conducted), the HREC shall ensure that:

- The participant information has been translated into the participant's language, and then translated back into English for the HREC by a second independent person to provide the HREC Members with confidence that there is fidelity of the translation. The second translator must verify the accuracy of the translation with a statement that is dated and signed.
- An interpreter is present during discussions with participants about the project.

Normally interpreters should be independent, but when the research proposed is of minimal risk, an English-speaking relative or friend may be justified by the researcher in the HREC application.

The cost of the interpreter(s) must be borne by the researcher(s).

16. Compliance reports to the NHMRC

16.1 NHMRC auditing of HREC activities

The NHMRC may audit the activities of the HREC to ensure compliance with the NHMRC National Statement and Section 95A of the Privacy Act.

The HREC shall provide information from its records to the NHMRC upon request.

16.2 Annual report by HREC

The HREC shall report annually to the NHMRC information relevant to its procedures including:

- membership/membership changes
- number of meetings
- confirmation of participation by required categories of members
- the number of proposals presented, the number approved, and the number rejected
- monitoring procedures in place and any problems encountered
- complaints procedures and number of complaints handled

Decisions and details of these decisions as required by paragraph D.6 of Guidelines approved under Section 95A of the Privacy Act.

17. Reporting on privacy issues to the Victorian Health Services Commissioner

The HREC will report annually or as required to the Health Services Commissioner on those decisions it has made where it has applied the Health Services Commissioner's Guidelines.

The report will consist of:

- the information required to be recorded by paragraphs (a) – (f) of Section 4.5 of the Guidelines,
- the information specified in and on the form provided and at the time specified in Appendix 4 of the Guidelines.

The HREC shall provide information in relation to Sections 4.5, 4.6, and 4.7 of the Guidelines to the Health Services Commissioner on request at any time.

18. Consideration of other NHMRC requirements on the ethical conduct of research involving humans

The HREC shall consult the NHMRC National Statement in regard to research involving:

- multi-centre approval
- children and young people
- persons with an intellectual or mental impairment
- persons highly dependent on medical care
- persons in dependent or unequal relationships
- collectives

- Aboriginal and Torres Strait Islander peoples
- ionising radiation
- reproductive technology
- clinical trials
- innovative therapy or intervention
- epidemiological research
- use of human tissue samples
- human genetic research, and
- deception of participants, concealment or covert observation.

19. Revision of HREC Terms of Reference

The HREC shall review the HREC Terms of Reference when there are changes to the NHMRC National Statement or any relevant legislation and provide a copy of the amended Terms of Reference to the CEO and ERMC.

21 Glossary

Term	Definition
Board	Board of Directors of RSL Care RDNS Limited.
CEO	Chief Executive Officer of RSL Care RDNS Limited.
ERMC	Executive Research Management Committee
Group	The Bolton Clarke group of companies consisting of RSL Care RDNS Limited ACN 010 488 454, Royal District Nursing Service Limited ACN 052 188 717 and its subsidiaries.
HREA	NHMRC Human Research Ethics Application.
HREC	Bolton Clarke Human Research Ethics Committee.
NHMRC National Statement	National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2023
Research Institute	Bolton Clarke Research Institute.
RRGC	Research Review Governance Committee