Terms of Reference
for

Ramsay Health Care Human Research Ethics Committees:

RHC WA|SA HREC (EC00266)
RHC HREC A (EC00279)
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ACRONYMS AND DEFINITIONS

AP	Authorised Prescriber
EO	Executive Officer (or delegate)
CEO	Chief Executive Officer
HREA	Human Research Ethics Application (form) – located on the Research Ethics, Governance and Grants (REGGS) online portal
HREC	A Human Research Ethics Committee of RHC
Lower Risk Research	Research which is considered to meet the criteria for 'Lower-risk' research as defined in the *National Statement* as having no risk of harm or discomfort
Minimum Membership	Membership categories of the HREC listed under *NS 5.1.30*
National Statement (NS)	The *National Statement on Ethical Conduct in Human Research* (as updated from time to time)
NHMRC	National Health and Medical Research Council
NHMRC-Certified HREC	A HREC which has been certified to meet criteria stipulated by the NHMRC that allows it to undertake ethical review of multi-centre research
NHMRC-Registered HREC	A HREC that has notified the NHMRC of its existence and meets the standards of the *National Statement*.
NRU	Ramsay Health Care National Research Unit
RHC	Ramsay Health Care
RHC Facility	A hospital or day procedure centre of Ramsay Health Care
SOP	Standard Operating Procedures
TGA	Therapeutic Goods Administration
Unapproved Goods	Therapeutic goods that are not included on the Australian Register of Therapeutic Goods (ARTG)

1 ACCREDITATION OF THE HREC

1.1 The HREC will be registered with the NHMRC at all times and will operate in accordance with the *National Statement.*

1.2 The HREC will comply with all accreditation requirements stipulated by the NHMRC to ensure registration is maintained, including any reporting requirements.

2 FUNCTION OF THE HREC

2.1 The HREC shall have the following functions:

2.1.1 To consider the ethical implications of any proposed research project it reviews and to determine whether or not the project is acceptable on ethical grounds in a timely and independent manner;

2.1.2 To monitor approved research projects until completion to ensure that the project conforms to ethical standards, that risks are monitored and that the research does not deviate from the approved protocol;

2.1.3 To suspend or withdraw ethical approval for the conduct of research which does not conform to ethical standards;

2.1.4 To endorse applications by medical practitioners accredited at RHC facilities to become Authorised Prescribers.

3 SCOPE OF RESPONSIBILITY

3.1 Except as specified in 6.5, all research at Ramsay Health Care (RHC) facilities must undergo some level of ethical review. In this context research is considered to involve human participants or their data.

3.2 A HREC will undertake ethical review of a project where:

3.2.1 the Principal Investigator is an accredited health professional at the Ramsay Facility where it is proposed the Research will be conducted (including Multi-Site Research projects);

3.2.2 the Principal Investigator wishing to undertake the Research is a Ramsay Health Care employee; or

3.2.3 the Research which is proposed to be conducted within a business co-located within a Ramsay Health Care Facility (e.g. the Private Rooms of an Accredited Practitioner) is Low Risk Research

3.3 Requests for the HREC to review research outside of the above criteria (including non-affiliated researchers) must be approved by the National Research Unit (NRU) prior to submission to the HREC.

3.4 Approval granted by the HREC constitutes ethical approval only. Research must not commence at any RHC site until final, written approval has been granted by the CEO (or delegate) of the facility at which the research will take place.

4 ACCOUNTABILITY AND REPORTING OF THE HREC

4.1 The HREC is accountable to Ramsay Health Care (RHC) through the RHC National Research Unit (NRU) in the conduct of its business.

4.2 The HREC shall make an annual report available to the NRU: this will include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcomes, and general issues raised.

4.3 As required under the *National Statement*, the HREC will make publicly accessible summary descriptions of all its research projects for which the requirement for consent has been waived.

4.4 The HREC Terms of Reference (TOR), membership, and complaints procedure will be made publicly available.

5 MEMBERSHIP

Composition

5.1 The HREC shall maintain a minimum membership of no less than eight members and be constituted in accordance with the requirements of the *National Statement*:

- 5.1.1 A Chairperson with suitable experience, including previous membership of a HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- 5.1.2 Two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- 5.1.3 A person with knowledge of, and current experience in, the professional care or treatment of people;
- 5.1.4 A person who performs a pastoral care role in the community, including, but not limited to, an Aboriginal and/or Torres Strait Islander Elder or community leader, a chaplain or a minister of religion or other religious leader;
- 5.1.5 A qualified lawyer, who may or may not be currently practicing and, where possible who is not engaged to advise the institution on research-related or any other matters; and
- 5.1.6 Two people with current research experience that is relevant to research proposals to be considered at the meetings that they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

5.2 No member may be appointed in more than one of the categories listed at any meeting.

5.3 HREC members are required to:

5.3.1 Be familiar with the *National* Statement and other relevant policies;
5.3.2 Prepare for and attend scheduled HREC meetings (or if unavailable, provide opinions on the ethical acceptability of research proposals);
5.3.3 Decide whether in his/her judgement, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable.
5.3.4 Attend continuing education or training programs in research ethics at least every three years.
5.3.5 Disclose any actual or perceived conflict of interest, including any financial or other interest or affiliation that may have bearing on the research reviewed.

5.4 Where there is insufficient clinical or scientific expertise amongst the HREC members for the review of an application, the HREC Chairperson may elect to seek scientific review from a suitably qualified person who will be subject to the same confidentiality requirements as HREC members. The process of obtaining scientific review may be arranged through the NRU or the Executive of the HREC. Any conflicts of interests declared by external reviewers will be managed as per the process for HREC members.

5.5 The members of the HREC will not be remunerated.

5.6 The HREC will be supported by an Executive Officer (EO) who is familiar with the *National Statement* and has an understanding of the ethical issues that may arise in research and other guidelines and policies governing human research. The EO will be responsible for the day-to-day operation of the HREC and will manage all communication with applicants and monitoring activities. The EO will be allowed to participate in discussion at meetings but will not have voting rights.

Appointment of Members

5.7 In accordance with the *National Statement*, members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion.

5.8 The NRU will receive and review nominations for HREC Chairperson who may be derived from within RHC. A Deputy Chairperson may be appointed by the same process to perform the duties of the Chairperson when the Chairperson is not available.

5.9 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Membership of the HREC will be reviewed by the NRU.

5.10 Length of membership on the HREC shall be three years, with the option of extension following this term.

5.11 Members will be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of *bona fide* conduct of their duties as an HREC member and responsibilities as an HREC member. New members will also be provided with the current version of the *National Statement*, relevant Privacy Guidelines and other relevant policies and procedures.

5.12 Members must agree to their name being made publically available.

5.13 Members will be required to sign a statement undertaking: that all matters of which s/he becomes aware during the course of her/his work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during her/his tenure on the HREC will be declared; and that s/he has not been subject to any criminal conviction or disciplinary action, which may prejudice her/his standing as an HREC member.

5.14 Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson/EO to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The HREC will notify the member of such lapse of membership in writing.

5.15 A member may resign from the HREC at any time upon giving notice in writing to the HREC Chairperson (via the EO).

5.16 The HREC Chairperson (in conjunction with the EO and NRU) may terminate in writing the appointment of any member of the HREC if it is considered that termination is necessary for the proper and effective functioning of the HREC, that the person is not a fit and proper person to serve on an HREC or that the person has failed to carry out his/her duties as an HREC member. The NRU will be notified of the termination of any HREC member.

6 CONDUCT OF BUSINESS

Procedures and Guidelines

6.1 The HREC will perform its functions according to written Standard Operating Procedures (SOPs). These procedures shall be reviewed at least every three years and amended and updated as necessary. All HREC members shall have access to copies of the procedures upon request.

6.2 Guidelines shall be available from the HREC to assist researchers in the preparation of the applications.

Circumstances where HREC approval is required

6.3 In accordance with the *National Statement,* ethical review by an HREC review is required in circumstances for all research that involves more than a low level of risk to participants. This includes:

6.3.1 Most genomic research;
6.3.2 Xenotransplantation research;
6.3.3 Research involving active concealment/planned deception or illegal activity;
6.3.4 Research involving a waiver of consent
6.3.5 Most research involving: women who are pregnant and the human fetus; people highly dependent on medical care who may be unable to give consent; people who have a cognitive impairment, intellectual disability or mental illness or Aboriginal and Torres Strait Islander peoples.

6.4 In accordance with the *National Statement*, only an HREC may grant waiver of consent for research using personal information in medical research.

6.5 Ethical review for research conducted at a RHC Facility is not required where the proposed project will involve:

6.5.1 the use of existing data/records that contain non-identifiable personal information where re-identification will not be reattempted or will be prevented,
6.5.2 or the use of identifiable data for a reasonably expected, related purpose (eg audit/QC project) where the project is considered low-risk.

Meetings

6.6 The meeting frequency for each HREC will be overseen by the NRU and the frequency will be determined based on the anticipated volume of applications being submitted to the HREC. Meeting dates and submission deadlines will be available via the NRU website.

6.7 For urgent matters that cannot wait for the next scheduled meeting, the Chairperson may:

6.7.1 have the matter referred out of session to HREC members by email or

6.7.2 convene an unscheduled meeting of the HREC.

6.8 The EO shall be responsible for preparing and distributing the meeting agenda and papers. Meeting papers will be made available to HREC members at least one week prior to the meeting.

6.9 The EO will be responsible for taking minutes of each meeting. The minutes of the meeting will be ratified as a true record of proceedings and decisions made by the HREC at the subsequent meeting. The HREC Chairperson may provide interim approval between meetings to allow timely communication with researchers.

6.10 For the purposes of holding a meeting of the HREC, a quorum shall exist when the number of members present is at least one more than half of the minimum membership.

6.11 Those in the minimum membership who cannot attend a meeting must submit their views in writing, or by telephone, at least one business day prior to the HREC meeting at which they cannot attend, to either the EO or Chairperson of the HREC.

6.12 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

6.13 If any member of the HREC has a potential conflict of interest when considering a particular research application, this must be declared beforehand and that member must not be present when a decision on that application is being made. The potential conflict of interest and departure of the member will be noted in the minutes.

6.14 Where possible, any comments or concerns with respect to the project should be linked to relevant sections of the *National Statement*.

6.15 Before giving a favourable opinion, the HREC should determine that the submission adheres to the values and principles of ethical conduct as described in the *National Statement.*

6.16 The HREC will endeavor to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. Any significant minority view (i.e. two or more members) shall be noted in the minutes.

Attendance as Observers, of People Other Than Members or Researchers at Meetings

6.17 It will not be usual for observers to attend meetings of a HREC. Any requests to attend meetings should be directed to the Chairperson of the relevant HREC (via the EO). If permission to attend is granted, the observer will be asked to sign an agreement stating that they may not divulge any confidential information arising from the meeting to any other person.

Communication with Researchers

6.18 The EO will communicate any decision made or any clarification requested by the HREC to researchers with regards to their application.

Fees

6.19 Fees will be charged for the review of applications submitted for assessment by the HREC in accordance with the HREC fee schedule. The fee schedule will be made publicly available.

Legal liability

6.20 The activities of all HRECs will be covered by insurance policies maintained by RHC.

7 ALTERNATIVE REVIEW PATHWAYS

Management of Lower- Risk Research

7.1 Where the researchers have identified that the foreseeable risks to participants meet the criteria for lower-risk research as per the *National Statement*, then the researchers may seek to have the proposal reviewed under the Lower-risk pathway.

7.2 The proposal is reviewed by a Lower-risk review committee comprised of the HREC Chairperson, the EO and one other member of the HREC. After any initial feedback provided by the EO to the researchers is actioned, the HREC member will provide a review to the HREC Chair and EO.

7.3 If the group unanimously agrees that the activities to be undertaken in the research project constitute no greater than lower risk to research participants and is satisfied that the proposal meets the requirements of the *National Statement*, the HREC Chairperson has delegated authority to provide approval for the research project on behalf of the HREC.

7.4 In circumstances where the HREC Member, the HREC Chairperson and the EO do not agree that the research meets the criteria of a lower risk research project, the full application will be submitted to the HREC for consideration.

7.5 Projects approved under this pathway will be subject to the usual monitoring and reporting requirements of the HREC. Any approval granted under this pathway will be noted at the next HREC meeting.

Authorised Prescriber Scheme

7.6 The HREC may consider applications from Ramsay Accredited Practitioners to supply and prescribe unapproved therapeutic goods under the Authorised Prescriber (AP) Scheme.

7.7 When considering a proposal by a medical practitioner to become an AP, the HREC shall undertake an assessment of the following, in accordance with regulations stipulated by the TGA, including (but not limited to):

7.7.1 the clinical justification for the use of the goods;
7.7.2 the safety of the product in relation to its proposed use;
7.7.3 the suitability of the medical practitioner; and
7.7.4 information to be given to the patient about the product and the informed consent form.

7.8 If the application for AP status is approved, the HREC will provide a letter to the applicant with the HREC Chairperson as signatory. The HREC Chairperson has delegated authority to provide approval for the AP application on behalf of the HREC.

7.9 The HREC will monitor the medical practitioner's use of the unapproved goods to ensure continued approval is appropriate and consider any available information to determine whether it would be appropriate to continue the approval.

8 POST APPROVAL RESPONSIBILITIES

8.1 The HREC will monitor approved projects in terms of compliance with the HREC's ethical approval. In so doing, the HREC may request and discuss information on any relevant aspects of the project with the investigators at any time.

8.2 The HREC may adopt any additional appropriate mechanism for monitoring as deemed necessary.

8.3 Progress reports on all approved research protocols are to be completed by the researcher and submitted to the HREC for consideration at least annually. The Committee may request more frequent progress reports, based on the level of risk associated with the particular research protocol. In the event of a report being unsatisfactory, approval for the project may be reconsidered.

Advising the Researcher and the Institution of Decisions to Withdraw Ethical Approval of a Research Project

8.4 In the event it becomes necessary for the HREC to withdraw ethical approval of a research project the Chairperson will immediately notify the researcher and if the research is occurring at a RHC Facility, the relevant facility CEO and the NRU of this decision and outline the justifications for the withdrawal.

9 COMPLAINTS AND REVIEW

Complaints concerning the conduct of a project

9.1 A local, independent contact person to receive complaints about the conduct of research project shall be listed on all study participant document/s. Where the research is conducted at a RHC Facility, this person will be an employee of RHC but must not be involved in the conduct of the research project. The local contact may consult with the EO or Chairperson of the overseeing HREC to obtain further information about the project and/or to provide the HREC with information as to the nature of the complaint and to facilitate resolution. Such complaints will be noted in the annual report made by the HREC to the NRU.

9.2 Where the complaint is unable to be resolved by the overseeing HREC, the local contact may escalate the complaint to a representative of the NRU who will liaise with the CEO of the relevant Facility to determine the appropriate course of action.

9.3 Where researchers are unable to identify an appropriate contact person within the relevant RHC Facility, a member of the NRU may be asked to receive complaints regarding research activities.

Complaints concerning the HREC's review process

9.4 The NRU will oversee the activities of all Ramsay HRECs. Any complaints or concerns regarding the operation, management and ethical review decisions of a HREC, which cannot be resolved at the local level, should be escalated to the NRU for further management.

10 AMENDMENT TO THE TERMS OF REFERENCE

10.1 These terms of reference may be amended by a HREC member or by the NRU as follows:

10.1.1 The proposal must be in writing and circulated through the EO to all HREC members for their consideration.

10.1.2 The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing or assign her/his proxy to another member.

10.1.3 The proposal shall be approved if two-thirds of the members agree to the amendment.

10.1.4 The Chairperson, through the EO, shall send the amendment to the NRU for review and approval if appropriate.

10.2 These Terms of Reference are to be reviewed every three years or sooner if necessary.