TERMS OF REFERENCE
HUMAN RESEARCH ETHICS COMMITTEE

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Contents

Numbered sections:

1 Background

1.1 Relationships Australia NSW (RANSW) conducts research and evaluation to contribute to the production of knowledge, and the ongoing development of good practice in human service delivery. In undertaking this research and evaluation work, the organisation recognises ethical challenges and potential risks to participants, researchers, the organisation and the broader community

1.2 RANSW has established a Human Research Ethics Committee (HREC) in order to support the ethical conduct of research involving clients, staff, and community stakeholders

1.3 Specifically, in establishing the HREC the organisation's aim is to ensure research conducted by or in partnership with RANSW is accountable to independent review, in accordance with the principles of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) – the 'National Statement'

1.4 Our focus is to protect the dignity, welfare and rights of research participants and uphold professional standards in the conduct of human research, while supporting legitimate investigation of services and human experience

1.5 This is a social sciences HREC with expertise in human services, including policy and practice related to: child and family wellbeing, dispute resolution, counselling, family therapy, casework, child protection, educational and therapeutic group work and family violence. Our scope does not cover research outside the expertise of the committee. Applications outside of scope will be screened out by the convenor

1.6 We offer the professional services of the RANSW HREC to other organisations within the human services field that seek formal ethics review of human research projects within our scope.

2 Purpose of these Terms of Reference

2.1 These Terms of Reference (ToR) for the RANSW HREC guide the committee in meeting its obligations under the National Statement and the Australian Code for the Responsible Conduct of Research (the Code of Conduct). They also identify the responsibilities of the committee towards RANSW, and ensure the operation of the committee is consistent with RANSW policy

3 Overview and principles of the RANSW Human Research Ethics Committee

3.1 The RANSW Human Research Ethics Committee facilitates the ethical conduct of research involving services, clients and staff

3.2 In carrying out its task the HREC will apply the principles described in the National Statement (S1) of: research merit and integrity; justice; beneficence; and respect

3.3 RANSW has determined that all human research involving **'greater than low risk'** and **'low risk'** will be reviewed by the HREC; while negligible or no risk research will be referred to the RANSW Quality, Service and Outcomes leadership group (QSO)

3.4 In line with the National Statement, chapter 2.1, 'risk' means 'a potential for harm, discomfort or inconvenience. Levels of risk are defined in the following table:

TERMINOLOGY	SUMMARY OF NATIONAL STATEMENT DEFINITIONS	RANSW APPROACH	Which committee
Research	'Human research' is investigation undertaken to gain knowledge and understanding with or about humans	Including surveys, interviews, focus groups, psychometric testing, observations and analysis of information	**NA**
Greater than low risk research	Where there is risk of **harm** to participants [such as distress, humiliation, pain, damage to relationships, stigmatisation, financial costs and other negative effects] Including *all* research specifically focused on: pregnant women; people unable to give consent; people with cognitive impairment, intellectual disability or mental illness; Aboriginal and Torres Strait Islander peoples	All formal academic research intended for publication	**HREC**
Low risk research	Where the only foreseeable risk is one of **discomfort** [a negative effect, less serious than harm – such as anxiety, but not distress]	As above plus formal evaluations intended for academic publication	**HREC**
Negligible risk research	Where there is no foreseeable risk of harm or discomfort and any foreseeable risk is of **inconvenience** only [a minor negative effect such as time to be interviewed, or filling in a form]	Routine data collection and evaluation for quality improvement purposes and not for general publication	**QSO**
Exemption from review	Research exempted from review may include negligible risk research that involves the use of existing collections of data or records, that contain only non-identifiable data	Routine reporting of de-identified data for use by funding bodies Anonymous client feedback processes	**QSO**

4 The responsibilities of the HREC and individual members

4.1 The HREC operates in accordance with these terms of reference, in order to:

a) Assess all research proposals in relation to the values and principles outlined in the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and the Australian Code for the Responsible Conduct of Research 2018. Available at: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/national-statement-2018.pdf
b) Determine whether the research design addresses the research question
c) Identify potential risks and burdens to participants of all research activities
d) Ensure the research design minimises risks, taking into account the balance of potential benefits to participants
e) Specifically review research procedures for informed consent, to ensure compliance with the National Statement
f) Specifically review confidentiality of data storage, and in the dissemination of results and findings
g) Inform each unsuccessful research applicant of the grounds for declining to issue an ethics clearance statement, and outline the ways in which the proposal would need to be revised to remedy this
h) Advise the RANSW Board or its delegated work group of all approved projects
i) Monitor all approved research activities to ensure adherence to the relevant values and principles, through receiving reports and conducting audits of compliance where deemed appropriate
j) Withdraw or suspend approval of any project where non-compliance has been identified or the safety of participants has been adversely impacted
k) Inform the RANSW Board or its delegated work group as soon as practicable, of any research-related ethical issues that may come to the committees' attention
l) Maintain records of all decisions and correspondence.

4.2 Members of the HREC are individually responsible for:

a) Becoming familiar with the National Statement
b) Deciding upon a chair person through democratic nomination and voting until consensus is reached
c) Preparing for and attending a minimum of three meetings annually, either in person or by telephone, or when unable to attend providing opinions on the acceptability of research proposals to the Chair
d) Sending apologies when unable to attend meetings
e) Keeping all information that comes to the committee confidential
f) Declaring any conflicts of interest and withdrawing from meetings when decisions about relevant projects are being made.
g) Respecting the expression of a diversity of viewpoints and allowing time to consider all members' concerns
h) Participating in training on research ethics at least every three years

5 Conflict of interest

5.1 A conflict of interest exists when 'an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest' (Australian Code for the Responsible Conduct of Research 2018 p5)

5.2 No member of the committee is entitled to adjudicate research in which they have, or could be seen to have, a conflict of interest. A committee member in this position should not discuss the project with other members, nor attempt to influence the committee in any way

5.3 Members must declare any conflicts of interest prior to joining the committee and in relation to each ethics application

5.4 Conflict of interest will be a standing item on the committee agenda

6 Composition and term

6.1 Composition of the HREC must include at least 8 members in the following categories:

a) A chairperson (not in any other role and not a member of RANSW staff of Board)
b) At least 2 lay members (male and female) who have no affiliation to RANSW and are not currently involved in medical, scientific or legal work
c) At least 1 professional with knowledge and experience in professional care, counselling or treatment of people
d) At least 1 person who performs a pastoral care role in the community (Aboriginal Elder or minister of religion)
e) At least 1 lawyer, who is not engaged to advise or represent RANSW
f) At least 2 people with current research experience that is relevant to the research proposals being considered

6.2 The committee may access additional expertise by co-opting individuals for specific purposes

6.3 Members will be appointed for a term of three years with the possibility to renew this upon review

6.4 The HREC must strive for:

a) Equal male/female representation
b) One third of members to come from outside the institutions for which the HREC is reviewing proposals
c) RANSW staff should not exceed half of the committee membership at any one time

6.5 Quorum

6.5.1 As far as possible at least one member in each category must be present for decisions to be made. This should ideally be in person, however telephone attendance can also be accepted at the discretion of the Chair

6.5.2 Where there is less than a quorum in attendance, the Chair may record a decision, provided they are satisfied the minimum number of members' views have been received and considered

6.5.3 The committee may delegate minor decisions for follow up or action, in-between meetings

7 Maintenance of Research Ethics Knowledge

7.1 All new members will be expected to undertake training in human research ethics prior to commencement. Basic training is free of charge and can be undertaken at the members pace and in their own time. The training package is provided by Macquarie University online. The ethics committee secretary or convenor will supply details of this research ethics training. The online address is: http://www.mq.edu.au/ethics_training/

7.2 Long standing members are invited to request additional training, as needed and once annually. This training will be provided by RANSW and will take the form of seminars with invited speakers who will provide information on particular and relevant issues that relate to research ethics. Committee members will have input to appropriate topics and guest speakers.

8 Structure and procedures of the HREC

8.1 Meetings will be held four times annually. Members will be informed of scheduled dates well in advance. Prior to the meeting, all members will receive the agenda and copies of research proposals/protocols with time for their consideration.

8.2 Formal minutes will be taken at each meeting to record deliberations in brief; decisions; and actions. These will be circulated to each member of the committee. Time will be allotted on the agenda to discuss matters arising from the previous minutes.

9 Ethics applications for consideration

9.1 Applications by interested parties are to be submitted on the Human Research Ethics Application form (HREA) available online at https://hrea.gov.au/ and sent to the convenor of the HREC, who is the GM: Quality, Outcomes and Research

9.2 The HREC will consider applications from researchers with no affiliation to RANSW provided they are within the scope of the committee (as per paragraph 1.5) and the committee deems this to be an appropriate use of their resources

9.3 All applications must be accompanied by copies of proposed advertising material, questionnaires, interview schedules, information sheets, consent forms, observational criteria, surveys, approval letters from other ethics committees, and letters of support

9.4 Applications will be circulated to HREC members three weeks prior to the meeting

9.5 Consideration of whether RANSW participates in the research project in any form is the responsibility of QSO and will not be part of the HREC deliberations

9.6 In accordance with the National Statement the RANSW HREC will recognise approvals issued by other NHMRC-registered HRECs to minimise duplication of ethical review.

10 Decision-making

10.1 The committee should endeavour to reach decisions by general agreement. This need not involve unanimity. A two-thirds majority will be deemed sufficient. Where members of the committee have strong objections to granting approval to a particular protocol, their views should be respected and every effort made to reach an accepted resolution. This may require an extension of time to seek further information, to reconsider the research proposal and possible amendments

10.2 Approval will be granted to a proposal when the committee determines:

a) The study has clear aims, research questions and scope
b) The study has sound methodology that will achieve the research aims
c) The researchers have an appropriate level of competence, qualifications and experience

d) Research procedures facilitate a process of informed consent
e) The benefits of the research balance the risks and burdens to participants
f) The rights and welfare of the participants will be protected throughout the study
g) Measures for ensuring confidentiality of data during and after the study are clear and sufficient
h) Strategies for communication of findings adhere to the principles of research merit and integrity; justice; beneficence; and respect

10.3 A written statement of approval signed by the chairperson or nominee will be issued to the researcher/s clearly indicating the conditions and the duration for which this approval is given

10.4 Conditional approval may be granted when amendments are required. Research will not be approved for commencement before all necessary amendments occur. Proposals may also be rejected, at any stage of the review process.

11 Maintenance of records

11.1 A copy of each research ethics application including consent forms, information sheets and relevant correspondence will be kept for a minimum period of 7 years and then destroyed in a confidential manner

11.2 Minutes of HREC meetings will be kept for a minimum of 7 years and then destroyed in a confidential manner

12 Monitoring of research projects and withdrawal of approval

12.1 The Human Research Ethics Committee has responsibility for monitoring approved research projects to determine they are being carried out according to the terms of approval

12.2 As a condition of approval the HREC requires researchers to immediately report anything that is contrary to the approved protocol, and any serious adverse events that might warrant the project's review (such as any sort of unexpected harm to participants; and complaints of 'research misconduct' as defined in the Code of Conduct)

12.3 A final report is required at the closure of all research projects

12.4 The Committee requires an annual report from primary researchers on matters including:
a) The progress to date or outcome of the project
b) The maintenance and security of records
c) Compliance with the approved protocol

d) Compliance with the conditions of approval

12.5 If the HREC has any concern about the manner in which the research project is being conducted, it may consider additional means of monitoring progress including audits, site visits or other means

12.6 If the HREC is satisfied that circumstances are such that the project cannot be conducted in accordance with the approved protocol, the HREC may withdraw its approval. The researcher/s will be informed that the project is to be discontinued, suspended or other necessary steps taken.

13 Complaints

13.1 RANSW is committed to the fair and efficient resolution of complaints. Research participant information should outline complaints procedures and state that complaints may be lodged with the chairperson of the HREC. The chairperson must follow the guidelines for handling complaints outlined in the National Statement and the Code of Conduct

13.2 Where a complaint relates to RANSW services or staff it will be referred to the Executive General Manager of Practice, Quality and Innovation, and follow normal RANSW complaints procedures.

14 Annual report to the NHMRC

14.1 The HREC shall report annually to the National Health and Medical Research Council on all aspects of its procedures including: membership and membership changes, number of meetings, the number of protocols considered, approved and rejected, monitoring of projects and complaints handled.

15 Governance structure and agreed pathways for applications

15.1 The RANSW HREC is an independent review body, established and supported by RANSW (the organisation)

15.2 The HREC has responsibility to inform the RANSW Board of its operations and any issues or risks arising as a consequence of its conduct. In order to comply with this requirement the committee will:

15.2.1 Communicate regularly with the QSO leadership group through the GM: Quality, Outcomes and Research, to provide information on: day-to-day operations; approvals; research complaints; any suspected breaches of the Code of Conduct; any adverse events and; the outcomes of completed

research projects. QSO will in turn, provide monthly reports on HREC activities to the RANSW executive

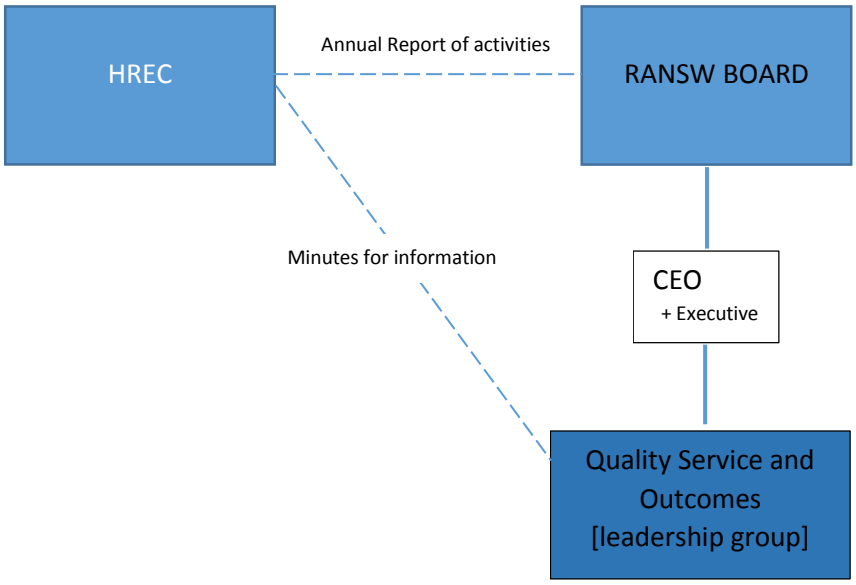
15.2.2 Provide a copy of HREC minutes to QSO

15.2.3 Report annually to the RANSW Board on all aspects of its activity

15.3 The HREC is accountable for compliance with the National Statement through its registration with the NHMRC

15.4 The governance structure and agreed pathways for research ethics approvals are outlined in the table and diagram below:

RANSW HREC Governance structure:



TYPE OF APPLICATION	WHICH COMMITTEE	
	QSO	**HREC**
1. External applications not approved elsewhere	✓	✓
2. External applications with other HREC approval	✓	**X**
3. Internal proposals - low risk and above	✓	✓
4. Internal proposals - negligible or no risk	✓	**X**