

National Institute of Integrative Medicine Human Research Ethics Committee

TERMS OF REFERENCE

1. Background

1.1 The National Institute of Integrative Medicine (NIIM) Human Research Ethics Committee (HREC) has been established by NIIM in exercise of its commitment to the conduct of human research according to the highest scientific and ethical standards.

1.2 The NIIM HREC act by way of delegated authority of the Board of Directors of NIIM and have executive authority conferred upon them to carry out the functions detailed in these Terms of Reference.

1.3 The Board of Directors may, consider, recommend and implement changes to the structure and operations of the NIIM HRECs including dissolution, streamlining, re-configuration and establishment as deemed appropriate from time to time, provided that any changes do not compromise the capacity of the HREC to meet all relevant standards and procedures.

1.4 The duly constituted NIIM HREC shall operate in accordance with these Terms of Reference as amended from time to time.

2. What is human research?

2.1 From the National Statement, human research is described as research conducted with or about people or their data or tissue. There is no generally agreed definition but human research can be understood broadly to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to people's personal documents or other material;
- the collection and use of their body organs, tissues or fluids or exhaled breath;
- access to people's information, in individually identifiable, re-identifiable or non-identifiable form, as part of an existing published or unpublished source or database

3. Roles and responsibilities

3.1 The HREC has been established to conduct scientific and ethical reviews of:

3.1.1 proposals for human research to be undertaken at or under the guidance of NIIM; and

3.1.2 proposals for human research received by the HREC in the performing of its function as an accredited HREC within the streamlined ethical review of multi-site research; and

3.1.3 proposals for human research received by the HREC in the performance of review processes accepted, accredited or certified for the purposes of any other system designed to eliminate unnecessary duplication of ethics review of human research.

3.2 The role of NIIM HREC shall be to:

3.2.1 promote ethical, high quality human research and this includes:

- i. ensuring participants be accorded the respect and protection that is due to them; and
- ii. fostering research that is of benefit to the community.

3.2.2 Ensure that the design and conduct of any human research that it reviews within the scope of its responsibilities conforms with the National Statement on Ethical Conduct in Human Research (NHMRC, ARC, UA, 2007 – updated May 2015) (National Statement) and other relevant national codes of human research ethics as amended from time to time and also with the ethical standards that NIIM is committed to.

3.2.3 Ensure that participants in any human research that the NIIM HREC reviews and approves are accorded the respect and protection that is due to them.

3.2.4 Ensure that any decision it makes complies with relevant Victorian and Australian laws.

3.3 The NIIM HREC act by way of delegated authority from the Board of Directors of NIIM and have executive authority conferred upon them to carry out the functions detailed in these Terms of Reference. The HREC is accountable to the NIIM Board of Directors for the exercise of its functions and the fulfilment of its roles.

3.5 The HREC, through the Chair, may at any time bring to the attention of the NIIM Director and CEO any issues of significant concern that merit prompt consideration and attention.

3.6 The HREC will establish an Executive comprising at least the Chair or Deputy Chair, the HREC administrator, and two members of the HREC, one of which must have experience in research

3.7 The NIIM HREC may delegate to the HREC Executive and HREC Administrator any of its powers and functions which are capable of being delegated in order to assist in the expeditious ethical review of a research proposal.

3.7.1 The NIIM HREC delegates to the HREC Executive the authority to review and approve low and negligible risk research projects. Any decisions of the HREC Executive will be ratified at the next HREC meeting.

3.7.2 The HREC Executive will undertake expedited review of business that does not require full HREC Review, including:

- Minor amendments to current HREC approved projects;
- Responses to HREC queries, as approved by the full HREC for Executive review and approval;

4. Functions of NIIM HREC

4.1 In fulfilling these roles, the NIIM HREC will:

4.1.1 conduct ethical and scientific review of research projects in a timely fashion and to ensure that the proposed research project strikes an appropriate balance between protecting the rights and wellbeing of research participants and facilitating research;

4.1.2 operate and act at all times in accordance with the National Statement and other relevant NHMRC guidelines and legislation as amended from time to time;

4.1.3 decide whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them;

4.1.4 ensure that they are sufficiently informed on all aspects of a research proposal, including its scientific and statistical validity, before deciding whether a proposal is both acceptable on ethical grounds and conforms with the National Statement;

4.1.5 receive advice and reports including from expert reviewers to assist in determining if a research project is acceptable on ethical grounds and meets all necessary scientific, legal, insurance and regulatory requirements;

4.1.6 determine, in relation to each reviewed and approved research project, that there will be mechanisms to monitor the conduct of the research and that the frequency and type of those mechanisms reflect the degree of risk to participants;

4.1.7 advise NIIM and researcher applicants whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons;

4.1.8 monitor approved research projects;

4.1.9 provide an avenue for handling queries and complaints in relation to approved research projects;

4.1.10 offer relevant advice and assistance to other institutions without formally constituted HRECs;

4.1.11 implement systems to promote the efficient ethical review of research projects including mutual acceptance in the case of multi-centre research or acceptance of single ethical review processes for approval of multi-site clinical trials in order to minimise any unnecessary duplication in the review of that research;

4.1.12 submit a report of its activities on an annual basis to the Board of NIIM;

5.1.13 have the authority to delegate to a subcommittee any of its powers and functions that are capable of being delegated in order to assist in the expeditious and effective ethical review of research proposals. The HREC will remain responsible and accountable for the activities and recommendations of any subcommittees;

4.1.14 consider issues referred by the Board of Directors of the NIIM and, where appropriate, provide advice to the Board of Directors especially on policy issues with ethical implications;

4.1.15 provide a forum in which staff, patient, carer, student concerns regarding ethical issues in research can be considered and investigated; and

4.1.16 promote a deeper understanding of ethical issues related to research within NIIM through educational activities.

5. Membership

5.1 NIIM HREC shall be constituted as prescribed by the National Statement and will include at least eight (8) members, both men and women, namely:

5.1.1 a Chairperson, appointed by the NIIM Board of Directors, with suitable experience in HREC operations, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;

5.1.2 at least two (2) members of the public, one (1) man and one (1) woman who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, legal or academic work, and who are preferably from the community in which the institution or organisation is located;

5.1.3 at least two (2) members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;

5.1.4 at least one (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people;

5.1.5 at least one (1) member who performs a pastoral care role in a community eg is a minister of religion or an Aboriginal elder;

5.1.6 at least one (1) member who is a lawyer;

5.1.7 additional members as required from time to time to assist in ethical decision-making;

5.2 A Deputy Chairperson will be appointed by the Board of Directors from the HREC. The Deputy Chairperson will also have suitable experience in HREC operations.

5.3 The Board of Directors will ensure that two or more of the appointed members are experienced in reflecting on and analysing ethical decision-making, in accordance with the requirements of the National Statement.

5.4 NIIM may recruit members for an HREC in such manner and shall appoint them for such a period and on such terms and conditions as it determines, however in ordinary circumstances:

5.4.1 NIIM will adopt open and transparent processes including advertising for applications for membership and making appointments of members.

5.4.2 members will receive a formal notice of appointment that will include an assurance by the institution of legal protection for any liability that may arise in the course of the bona fide conduct of their duties.

5.4.3 the term of office shall be three (3) years, with the option for renewal of membership by the Board of Directors

5.5 NIIM shall appoint HREC members for their expertise and not in a representative capacity.

5.6 NIIM may add to the membership such other persons as is necessary to ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider.

5.7 Members will receive formal communication of their appointment to the HREC from the NIIM Board of Directors.

5.8 Members may resign their membership by written notice to the HREC administrator.

6. Standing Arrangements

6.1 As far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend. The quorum at the NIIM HREC meetings is six (6) members present either in person or via other electronic/technical means and is inclusive of all categories of membership. Where a member cannot physically attend, they may attend via phone-link up

or videoconferencing and are counted as in attendance. Where a quorum is not reached, the meeting will be adjourned to another date.

6.2 The Secretary will circulate an agenda and meetings papers at least five working days before the meeting.

6.3 Conduct of meetings

- The Chair shall conduct the meeting according to the standing orders; ensure order is maintained; and give members an opportunity to speak and vote on matters tabled at the meeting.
- The order of business shall follow the agenda unless agreed otherwise.
- Matters for discussion or to move a motion must be on the agenda and seconded, unless otherwise approved.
- Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether present at a face to face meeting, by teleconference or videoconference.
- The HREC will endeavour to reach decisions by general agreement, which need not involve unanimity.
- Voting shall be by show of hands. Each member has one vote.
- Members may vote by proxy if they are unable to attend. Notice of proxy must be submitted in writing 5 days before the meeting.
- Matters will be passed by a majority of members.
- The Chair shall have the deciding vote if there is a tie.
- Members may speak more than once at the discretion of the Chair.

6.4 Minutes

a. The Secretary shall accurately record the minutes of each meeting. The following details shall be recorded in the minutes:

- Date, time and venue of the meeting
- Names of members present and apologies and the name of the Chair
- An overview of discussions and business conducted; decisions about approval, amendment or rejection of proposals in written or electronic form; action items and persons responsible
- Date, time and venue of next meeting

b. The minutes of the preceding meeting shall be circulated to members. The Chair will:

- Approve the minutes for circulation as soon as possible after the meeting
- At the next meeting move that the minutes be confirmed as a true record
- Sign the confirmed minutes

6.5 Adjournment

The Chair may adjourn the meeting from time to time with the consent of the HREC. Business at the adjourned meeting shall be confined to business that was left unfinished at the meeting

where the adjournment took place. If a meeting has been adjourned for more than 10 working days, notice shall be given as for an ordinary meeting.

6.6 Code of Conduct

An HREC member shall:

- Keep their comments to matters before the HREC
- Attend meetings and be punctual
- Act in the best interests of the HREC and not bring the HREC into disrepute
- Exercise appropriate care and diligence
- Not make false statements or falsify records
- Act appropriately to not gain advantage for themselves or others
- Not make offensive statements or comments or behave improperly
- Shall cease speaking when called to order by the Chair
- Declare any potential conflicts of interest and stand aside from discussions and voting on such matters deemed to be a conflict of interest
- Keep all matters in confidence and not disclose any matters of business to the general public or other persons not associated with the research projects under review

6.7 Dismissal of members

a. Members are required to adhere to the Code of Conduct listed above. Non-compliance with the code of conduct could result in the removal of the individual/s from the HREC. Such inappropriate conduct includes, but is not limited to:

- not adhering to the Code of Conduct listed above
- not attending meetings; being unreliable; or not being punctual
- having a criminal record
- making commercial misrepresentations

b. If a member's conduct is in question, and it appears to be a minor issue, then the Chair should contact the member and discuss the matter to determine if it can be resolved. If it cannot be resolved or the matter is deemed to be serious, then a formal notice should be sent by the Chair to the member outlining the issue. Evidence should be included where relevant, and/or details of a complaint if appropriate. Members should be given an opportunity to respond to the notice. After the second written notice, the member is dismissed from the HREC. Members may appeal the proposed action and should be given the opportunity to meet with the Board of Directors. Members may bring a representative to any appeal meetings. The outcome of the appeals meeting is final.

c. If the matter is considered extremely serious, then only one notice is necessary; such as having a criminal record that has not been disclosed. Other disciplinary action may include temporary dismissal for a period of time.

6.8 Amendment of standing orders

These standing orders may be amended by a motion which has been presented according to these standing orders.

7. Meeting Notices and Frequency

7.1 The HREC shall meet at least every 3 months or when required.

7.2 Notices of meetings will be sent out at least two weeks prior to the meeting date. Agenda and papers will be sent out at least five days prior to the meeting date.

8. Members Responsibilities and Entitlements

8.1 Each member will be provided with an induction and orientation to the functions of the HREC and be offered the opportunity of being assisted by a current HREC member as a mentor.

8.2 Each member is responsible for ensuring that they have read all HREC documentation to be considered at a HREC meeting prior to the meeting;

8.3 Each member is responsible for deciding whether, in his or her judgment, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable.

8.4 Where a member is not able to attend a meeting, the member is responsible for sending any comments on HREC proposals and others matters to the HREC administrator prior to the meeting, unless circumstances do not permit this.

8.5 Each member is responsible for:

- disclosing to the HREC any conflicts of interest that may affect the HREC's review of a research proposal;
- protecting the confidentiality of information received in the exercise of his or her duties;
- becoming familiar with the National Statement and other relevant guidelines;
- preparing for and attending HREC meetings or, if unavailable, provide opinions on ethical acceptability of research proposals;
- undertaking continuing education in human research ethics at least once every three years.

9. Chair and Deputy Chair Responsibilities

9.1 In addition to the responsibilities and entitlement as members, the Chair (and where relevant, in the absence of the Chair, the Deputy Chair) will have the following responsibilities as set out in clauses 7.2-7.5.

9.2 The Chair must not have other responsibilities that will impair the HREC's capacity to fulfil its obligations under the National Statement and fulfil the roles and carry out the functions set out in these Terms of Reference.

9.3 The Chair is responsible for ensuring that HREC decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of feedback from those members who cannot be present. Achieving such decisions requires that the Chair:

- actively engages all members;
- elicits their views; and
- communicates their responses to other members.

9.4 As the HREC endeavours to reach decisions by general agreement, which need not involve unanimity (National Statement 5.1.31), the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

9.5 The Chair of the HREC will review and approve any reports of activities of the HREC to the NHMRC and the NIIM Board of Directors.

9.6 The Deputy Chair should support the Chair in the performance of, and be capable of fulfilling, the responsibilities of the Chair whenever the Chair cannot attend meetings or perform any other function.

10. Reporting

10.1 The NIIM HREC shall report to the NHMRC and the NIIM Board of Directors annually.

11. Handling of Complaints and Avenue of Appeal Against NIIM HREC Decisions

11.1 Complaints about the conduct of NIIM researchers or NIIM higher degree by research students are managed under NIIM's policies and procedures.

11.2 Complaints by researchers against NIIM HREC decisions are handled under the Appeals Against HREC Performance and Decisions Procedures (**Attachment 1**).

Attachment 1 Complaints About HREC Performance and Decisions Procedures

1. Procedures Statement

These procedures set out the processes for receiving and handling of complaints against the performance of, and appeals against decisions made by, the NIIM Human Research Ethics Committee (HREC).

2. Scope

These procedures relate only to the management of complaints in relation to the processes, decisions and actions of the NIIM Human Research Ethics Committee. They do not relate to the handling of complaints about research misconduct of NIIM staff or higher degree by research students- these are handled under NIIM's internal research policies and procedures

3. Definitions

HREC Human Research Ethics Committee

4. Appeals Against HREC Decisions

- 4.1 Researchers have the right to appeal against a decision made in relation to a HREC application.
- 4.2 Informal resolution should be attempted in the first instance. This may include the researcher(s) meeting with the Chair of the HREC to discuss the points of contention.
- 4.3 Where attempts at informal resolution are not successful, the researcher(s) should submit a complaint in writing to the Board of Directors. In the case of an appeal against a decision of the HREC, this should be within ten working days of receipt of the HREC decision.
- 4.4 An independent academic will be appointed by the Board of Directors as an Independent Adjudicator to investigate and make decisions in relation to appeals against HREC decisions.
- 4.5 The Independent Adjudicator will communicate with the researcher(s), members of the HREC and do anything reasonable to resolve the issue.
- 4.6 After due consideration of the facts, the Independent Adjudicator will recommend a decision to:
 - Dismiss the appeal, or
 - Uphold the appeal in whole or in part
- 4.7 The Independent Adjudicator will submit a report of the findings of the investigation to the Board of Directors within 10 working days of completion of the investigation.
- 4.8 The NIIM Board of Directors will communicate the findings of the investigation and decision to the complainant. This constitutes the last internal process of appeal at NIIM.

5. Complaints About HREC Performance By the Public

5.1 The public, including participants of research, have a right to make complaints against the performance of an HREC in relation to its handling of concerns and complaints about research projects.

5.2 HREC Participant Information Forms include the contact details for correspondence and complaints in relation to research.

5.3 Complaints about performance of the HREC are handled by an Independent Adjudicator appointed by the NIIM Board of Directors.

5.4 The Independent Adjudicator will communicate with the Chair of the HREC and the complainant and do anything reasonable to resolve the issue.

5.5 After due consideration of the facts, the Independent Adjudicator will make a recommendation to:

- Dismiss the complaint, or
- Uphold the complaint in whole or in part

5.6 The Independent Adjudicator will submit a report to the NIIM Board of Directors in relation to his/her findings.

5.7 In the case where the complaint is dismissed, the NIIM Board of Directors will communicate the findings of the investigation and decision to the complainant. This constitutes the last internal process of appeal at NIIM. Complainants who are dissatisfied with the decision of the Independent Investigator may appeal to the Victorian Ombudsman.

5.8 In the case where the complaint is upheld, the NIIM Board of Directors will:

- Communicate with the Chair of the HREC and the complainant the findings of the investigation and decision.
- Initiate restorative or disciplinary action against the HREC or individual HREC member(s) where appropriate. This may include removal of an HREC member from the HREC.

6. Approvals Summary

Policy/Procedure Code & Name	Complaints About HREC Performance and Decisions Procedures
This Version Number	1.0
Date of Original Version	13 April 2016
Approving Authority	NIIM Board of Directors
Approval Date	20 April 2017
Next Review Date	20 April 2022
Contact Officer	Chief Executive Officer

Appendix 1 Independent Adjudicator

Name	Relevant Experience	Appointment Date
Professor Ian Wallace	Previous Vice Chancellor Swinburne University of Technology; experienced researcher	27 August 2013