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Version 1.5

# Human Research Ethics Committee Terms of Reference

This document was developed by Macquarie University Human Research Ethics Committee



## Historical Notes:

### Table of Amendments

Amendment	Date	Short Description	Version
Draft current terms of reference	12/11/2012	Terms of Reference drafted	1.0
Revision of full document	13/11/2012	Reviewed by Director, Research Ethics	1.1
Submitted to the DVC(R)	16/11/2012	Reviewed by DVCR	1.2
Submitted to the Vice-Chancellor	23/11/2012	Approved by Vice-Chancellor	1.2
Terms of Reference Revised	09/04/2015	Reviewed by Director, Research Ethics and Integrity and HRECs	1.3
Submitted to the Vice-Chancellor	12/06/2015	Approved by Vice-Chancellor	1.3
Terms of Reference Revised	05/08/2015	Reviewed by the Director, Research Ethics and Integrity	1.4
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Terms of Reference Revised	09/06/2017	To HREC's for review	1.5

# Human Research Ethics Committee

## Terms of Reference

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## Definitions and Acronyms

### Acronyms:

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FMHS	Faculty of Medicine and Health Sciences	HREC	Human Research Ethics Committee
MUH	Macquarie University Hospital	MQ	Macquarie University
DVC(R)	Deputy Vice Chancellor: Research	TGA	Therapeutic Goods Administration
NHMRC	National Health and Medical Research Council	SAE	Serious Adverse Event
SUSAR	Suspected Unforeseen Serious Adverse Reaction	RO	Research Office
HDR	Higher Degree Research	SOPs	Standard Operating Procedures

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### Definitions:

**NHMRC** – National Health and Medical Research Council. Australia’s peak body for supporting health and medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research.

**The National Statement** – *The National Statement on Ethical Conduct in Human Research (2007)*. The *National Statement* consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992. It is intended for use by researchers conducting research with human participants, HREC members reviewing that research, those involved in research governance, and potential research participants.

The *National Statement* is developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

**The Code** – The *Australian Code for the Responsible Conduct of Research (2007)* guides institutions and researchers in responsible research practices and promotes integrity in research for researchers. The *Code* shows how to manage breaches of the *Code* and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.

The *Code* is developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia and has broad relevance across all research disciplines.

## 1. Preamble

- 1.1 The *National Statement* sets out that institutions must ensure that all research involving human participants is designed and conducted in accordance with *The Code* and ethically

reviewed and monitored in accordance with the *National Statement*.<sup>1</sup> Organisations that regularly undertake research involving humans may establish a HREC to review this research.

- 1.2 To provide timely review of research protocols that involve human participants from Macquarie University and MUH as required, Macquarie University has established two HRECs, the Human Sciences and Humanities HREC and the Medical Sciences HREC. As well, there are a number of faculty-based HRECs that assess low and negligible risk research. All HRECs operate in accordance with the *National Statement* (Sec. 5.1.33).

## 2. Objectives

The objectives of the Macquarie University The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) are:

- 2.1 To protect the rights and welfare of research participants by ensuring that research projects are designed in accordance with the following values:
  - a. Respect for human beings
  - b. Research merit and integrity
  - c. Justice
  - d. Beneficence
- 2.2 To facilitate ethically good research through efficient and thorough review processes developed in accordance with the *National Statement*.
- 2.3 To minimise the risk of harm arising from research studies involving humans.
- 2.4 Promote the development of an 'ethical consciousness' through education of the academic and professional community.

## 3. Functions

- 3.1 Provide independent, sound and timely review of research projects which involve human research participants.
- 3.2 Ensure that researchers comply with the relevant guidelines on the conduct of human research, including the *National Statement* and *The Code*, and other appropriate guidelines and legislation as required.
- 3.3 Conduct regular monitoring processes to ensure that ethical standards are maintained.
- 3.4 Provide ethics related advice to researchers and their students, visiting academics and other personnel involved in the conduct of health research.
- 3.5 To develop a policy and provide oversight of innovative surgery at MUH in order to provide guidance to clinicians when assessing whether an innovative surgery constitutes research. This is in accordance with the *National Statement* Ch. 3.3.

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<sup>1</sup> Australian Government, National Health and Medical Research Council (NHMRC), *The National Statement on Ethical Conduct in Human Research (National Statement)* s 5.1.1 <<http://www.nhmrc.gov.au/book/chapter-5-1-institutional-responsibilities>>

- 3.6 Receive complaints from research participants, researchers or others regarding the conduct of human research projects and to deal with these in accordance with Macquarie University policies and procedures.
- 3.7 Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the storage, security and disposal of confidential data collected during the conduct of research involving humans.
- 3.8 Promote an understanding of human research ethics within Macquarie University and the broader community.
- 3.9 Provide advice to the other departments within the University including HDR, the DVC(R) on matters relating to human research ethics.

#### **4. Scope of Responsibility**

- 4.1 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) are responsible for reviewing, approving and monitoring research protocols where humans are involved in research and where this research:
  - a. Is undertaken by researchers and their students, visiting academics or medical personnel and other personnel formally recognised by the University.
  - b. Involves human participants recruited from Macquarie University, being staff or students, or recruited externally.
  - c. Is carried out using University or MUH equipment, facilities or premises owned by the University or MUH or otherwise under control of the University or MUH.
  - d. Is undertaken by individuals not affiliated by the University or MUH provided that an agreement exists between the University/MUH and the external researchers that defines the role of the HREC in providing ethical approval and ethical monitoring of the research. The agreement will specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC.
- 4.2 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) can accept another HREC ethical approval to allow both the release of funds and the commencement of a research project, provided that such other HREC is properly constituted and registered with the National Health and Medical Research Council.
- 4.3 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will provide education and training to MACQUARIE UNIVERSITY and MUH researchers and their students.

#### **5. Accountability and Reporting**

- 5.1 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) are an advisory Committee of the DVC(R) mandated to:
  - a. Approve human research on ethical grounds
  - b. Withhold human research approval on ethical grounds
  - c. Suspend human research approval on ethical grounds
  - d. Withdraw human research approval on ethical grounds
- 5.2 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) are accountable to the VC through the DVC(R). They shall bring to the attention of the DVC(R)

any issues relating to human research ethics that may constitute breaches of the Macquarie University Academic Honesty Policy, Macquarie University Code of Conduct, *National Statement* and *The Code*.

- 5.3 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will make the Terms of Reference, Standard Operating Procedures and membership information publicly available by posting them on the Research Office website.
- 5.4 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will provide annual reports to:
  - a. The NHMRC
  - b. The NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW)
  - c. The DVC(R)
- 5.5 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will liaise with the Dean, HDR on matters of significant ethical concern regarding student research projects.

## 6. Membership

- 6.1 In accordance with the *National Statement*, Sec. 5.1.29 the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will have a minimum membership of eight. As far as possible, this will include:
  - a. Equal numbers of men and women
  - b. A least one third of the members should be from outside of the institution
- 6.2 In accordance with the *National Statement*, Sec. 5.1.30 (a-f), the membership of the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will constitute the following:
  - a. A Chairperson, with suitable experience and whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*.
  - b. At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.
  - c. At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, an allied health professional.
  - d. At least one person who performs a pastoral care role in the community.
  - e. At least one lawyer, where possible who is not engaged to advise the institution.
  - f. At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- 6.3 No member may be appointed in more than one of the above categories. The University may establish a pool of inducted members in each category. These members may attend meetings as needed to make a quorum and may also be available to provide expertise for the research under review.
- 6.4 Wherever possible one or more of the members listed in 6.2 should be experienced in ethical decision-making.

- 6.5 The HREC (Medical Sciences) will have access to scientific expertise, via the Scientific Review sub-Committee in order to facilitate ethical issues arising from the protocol design. Where necessary the HREC (Medical Sciences) may access the relevant expertise by going outside the HREC membership.
- 6.6 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will maintain an Executive per HREC, consisting of the Chair, two Deputy Chairs, the Director, Research Ethics (if this is not the Chair) and one other (rotating) member of the HREC as required. This Executive will be responsible for issues that may arise outside of session.

## 7. Appointment of Members

- 7.1 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) members may recruited by direct approach from the Research Office. MUH and MACQUARIE UNIVERSITY members will be formally nominated by the Faculty Dean. Members will be appointed by the DVC(R) and the VC will formally approve all memberships.
- 7.2 Prospective lay members will be recruited by word of mouth or direct approach. Lay members will be asked to submit a curriculum vitae to the Research Office before formalising membership. Lay members will be formally appointed by the DVC(R).
- 7.3 Members are appointed for their expertise and not in a representative capacity.
- 7.4 All members including the Chairperson and Deputy Chairs will receive a letter of appointment. The letter of appointment will include the date of appointment, length of tenure, indemnity and termination. Members will also be provided with an orientation package and will be asked to sign a confidentiality agreement which indicates that all matters of which the member becomes aware during the course of their work on the HREC (Medical Sciences) will be kept confidential and that any conflicts of interest will be declared.
- 7.5 Members will be provided with appropriate induction and support. Members will receive a copy of the *National Statement*.
- 7.6 Members will be appointed for a period of three years with an opportunity to renew at the end of this period.
- 7.7 Members are expected to participate in education and training as required. Members are expected to be familiar with the *National Statement* and other guidelines and legislation as required.
- 7.8 The Chairperson of the HREC (Medical Sciences) and the Chairperson of the HREC (Human Sciences and Humanities) will be available between meetings to undertake ethics business and provide advice as required.
- 7.9 Membership will lapse if a member fails, without providing reason, to attend three consecutive meeting or fails to attend at least five meetings in any one year. The Chair will notify the member in writing prior to any lapse in membership. Termination of a member's appointment will be in writing.
- 7.10 A member may resign at any time upon giving notice in writing to the Chair.
- 7.11 The DVC(R) may terminate the appointment of any member if the DVC(R) is of the opinion that:
  - a. It is necessary for the proper and effective functioning of the HREC



- b. The person is not a fit and proper person to serve on the HREC
- c. The person has failed to carry out their duties as a HREC member.

## **8. Liability and Coverage**

- 8.1 The University will provide indemnity for members of the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) for any liabilities that may arise as a result of the member exercising their duties as a member in good faith.

## **9. Applications, Review and Approvals**

- 9.1 Applications are to be submitted for review in accordance with the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) Policy for the submission of ethics applications.
- 9.2 All applications are to be submitted to the Ethics Secretariat, in hard or soft copy, by the relevant closing date in a format approved by the Ethics Office.
- 9.3 Guidelines to assist applicants as well as document templates and policies and procedures will be made available on the Research Office website.
- 9.4 The Ethics Secretariat will check applications for completeness and may request additional information or corrections before submission to either the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities)
- 9.5 The HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) may request the applicant supply further information in relation to an application to clarify issues that may arise during the course of review.
- 9.6 The HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) may request an applicant attend a meeting with a Committee Executive in order to facilitate review of a research protocol. The HREC may also request an applicant attend a meeting of the HREC for the purpose of providing information to, and answering questions from, HREC members.
- 9.7 The Ethics Secretariat will circulate the meeting agenda, previous meeting minutes and associated documents and any new applications to all members of the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) at least 7 days prior to the meeting.
- 9.8 The HREC (Medical Sciences) may delegate consideration of certain scientific/technical matters to the Scientific Sub-Committee or a particular HREC member. The HREC (Medical Sciences) may also obtain independent scientific or technical advice, subject to paragraph 6.5.
- 9.9 The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) may take into account the views and opinions of another properly constituted HREC in relation to a research protocol.
- 9.10 The HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) will notify the applicant by email advising whether the application which it has considered was approved in accordance with the *National Statement* within 10 working days following a meeting.
- 9.11 The HREC (Medical Sciences) or the HREC (Human Sciences and Humanities)) will notify the applicant by email advising whether the application which it has considered needs

amendments before it can be approved. Applicants will be advised that they have six weeks in which to forward a response to the Committee. If a response is not received after six weeks, the Ethics Secretariat will send one reminder email advising that the file will be closed, and a new application will need to be submitted for review, if a response is not received within two weeks of the final reminder. If a file is closed due to no response having been received the applicant must complete a new application to be submitted for review.

- 9.12** If the application was rejected the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) will inform the applicant in writing citing the relevant sections of the *National Statement*.

## **10. Meetings**

- 10.1** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) meetings will be conducted once a month between February and November.
- 10.2** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) meeting dates, and closing dates for the receipt of applications, will be advertised on the Research Office website.
- 10.3** As set out in the *National Statement* Sec 5.1.29, the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) meetings will require a minimum attendance of eight members, with at least one third of these members from outside the institution, in order to have a quorum.
- 10.4** Any member of the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) who has a conflict of interest associated with a proposal or other related matter being considered by their HREC should declare such an interest at the earliest opportunity. The member shall absent themselves from the meeting when the project is the subject of consideration, and any related documentation regarding the project will be distributed to other members of the relevant HREC separately. Once the HREC has considered the matter and a decision has been reached, the member will be asked to return to the meeting. A permanent item will be added to the meeting agenda whereby members can declare a conflict of interest. All declarations of interest and absences of members will be minuted.
- 10.5** Where an institutional conflict of interest arises, this should be declared by a designated officer at the request of the Chairperson. External expert reviewers will be recruited. These reviewers will be required to declare an absence of conflict of interest and sign a confidentiality agreement prior to undertaking review.
- 10.6** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will endeavour to reach a unanimous decision concerning the ethical acceptability of a research protocol. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one layperson. Minority views will be recorded in the minutes.
- 10.7** Meetings will be conducted in such a way to encourage discussion, debate and the exchange of ideas.

## **11. Fees**

- 11.1** A fee will not be charged for applications submitted for assessment by the HREC (Medical Sciences) from researchers who are full-time, part-time or visiting appointees to the University, unless engaged in sponsored research.
- 11.2** A fee will be charged for applications submitted for assessment by the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) from researchers who have no formal affiliation with the University and researchers who are appointees of MUH. These researchers will be invoiced according to the Macquarie University fee structure which is made available on the Research Office website. These researchers will also be required to sign an agreement with Macquarie University detailing the terms and conditions under which the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) will review the application and monitor the protocol (once approved).

## **12. Low and negligible risk research and research requiring expedited review**

- 12.1** Research that is considered to be negligible or low risk will be submitted to the relevant Faculty sub-Committee for consideration.
- 12.2** Research that requires expedited review, in accordance with the Macquarie University policy regarding the submission of ethics applications for health research, will be distributed to the relevant committee between meetings via a secure online review system.
- 12.3** Expedited review requests will be reviewed by the Chair, or the Chair's delegate, and by a nominated number of Committee members.
- 12.4** Records will be kept of all expedited review applications. The Committee may decide to defer an expedited review application to the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) meeting for further review if considerable ethical issues arise.
- 12.5** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) may defer an expedited review application to the Scientific Sub-Committee for further review if technical/scientific issues require further consideration.

## **13. Records**

- 13.1** The Ethics Secretariat will prepare and retain written records of the HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) activities, including agendas and minutes of all meetings. Meeting minutes will be retained in a Minutes file in accordance with the State Records Act.
- 13.2** The Ethics Secretariat will prepare and maintain an official University file for each application received. This will include a copy of the application, any relevant correspondence including that between the applicant and the HREC in accordance with the State Records Act.
- 13.3** Files will be kept securely and confidentially in accordance with the state and federal privacy legislation and the State Records Act. Files will remain open until a final report has been received and the project closed off. A file may also be closed after two unsuccessful attempts to contact the research personnel by email or by phone. An applicant may request in writing

that an application is withdrawn. The Ethics Secretariat will close and archive the file in accordance with the State Records Act.

- 13.4** Records will be held for sufficient time to allow for future reference. The minimum period of retention will be in accordance with The Code and the State Records Act.
- 13.5** The Ethics Secretariat will maintain a database of all applications received and reviewed.
- 13.6** The Ethics Secretariat will maintain a record of all complaints received regarding the activities of the Committee. This record will include the complaint, the outcome of the complaint, and any related investigations. A record of complaints received regarding HREC (Medical Sciences)-approved research will also be maintained. This will include the complaint, the outcome of the complaint and any related investigations.

## **14. Monitoring and Reporting Requirements**

- 14.1** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will monitor approved projects in accordance with the *National Statement* Ch. 5.5 to verify that the conduct of the research conforms to the approved proposal.
- 14.2** Mechanisms for reporting include:
  - a. Annual progress reports from researchers. If a project is deemed to be of considerable risk to participants researchers may be requested to provide more frequent progress reports.
  - b. Reports from safety or other monitoring boards
  - c. Review of adverse event forms
  - d. Other forms in accordance with the *National Statement* and at the discretion of the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities)
- 14.3** Researchers will be advised in the letter of final approval that they are required to submit reports as a condition of approval.
- 14.4** The Ethics Secretariat will send reminders to the Chief Investigator when a report is due.
- 14.5** The HREC (Medical Sciences) and the HREC (Human Sciences and Humanities) will require, as a condition of final approval, that investigators immediately report any of the following:
  - a. Proposed changes to the protocol or project in the form of a request for amendment
  - b. Other unforeseen events that may affect the continued ethical acceptability of the project
  - c. If the project is discontinued for any reason

## **15. Complaints regarding approved research**

- 15.1** Complaints about the conduct of an approved research project, whether from the research participants, the general public or university staff or students, should be directed in writing in the first instance to the Director, Research Ethics.
- 15.2** If a complainant provides their consent, the complainant's contact details will be recorded in the Complaints file maintained by the Ethics Secretariat so that the outcome of the investigation can be reported to the complainant.

- 15.3** The complaints procedure will be made clear to research participants on the participant information and consent form.
- 15.4** The Ethics Officer will notify the HREC (Medical Sciences) or the HREC (Human Sciences and Humanities) members of the complaint immediately after it has been received.
- 15.5** Complaints considered to raise the possibility of research misconduct, as outlined in the Code, will be referred immediately to the DVC(R).
- 15.6** Where a complaint alleges serious misconduct that falls outside of the range of research misconduct as described in *The Code*, the matter will be dealt with in accordance with the Macquarie University Grievance Management Policy and other relevant policies and procedures.

## **16. Complaints regarding the HREC review processes**

- 16.1** Complaints regarding the process of review should be directed in writing in the first instance to the Director, Research Ethics. If this is not successfully resolved, the complaint should be managed in accordance with the Macquarie University grievance procedure.
- 16.2** The complaint may be referred to the DVC(R) in accordance with these procedures.

**Notes:**

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# HUMAN RESEARCH ETHICS

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<http://www.mq.edu.au/research/about-research-at-macquarie/research-integrity-and-ethics>*

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