Human Research Ethics Committee

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Definitions and Acronyms

Acronyms:

<table>
<thead>
<tr>
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<th>Definition</th>
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<tr>
<td>FMHS</td>
<td>Faculty of Medicine and Health Sciences</td>
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<td>MUH</td>
<td>Macquarie University Hospital</td>
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<td>DVC(R)</td>
<td>Deputy Vice Chancellor: Research</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>SUSAR</td>
<td>Suspected Unforseen Serious Adverse Reaction</td>
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<td>HDR</td>
<td>Higher Degree Research</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<td>MQ</td>
<td>Macquarie University</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>RO</td>
<td>Research Office</td>
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<td>SOPs</td>
<td>Standard Operating Procedures</td>
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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 details how to manage breaches 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.

The Macquarie University Code – The Macquarie University Code for the Responsible Conduct of Research (2015) outlines standards of responsible and ethical conduct expected of all persons engaged in research under the auspices of Macquarie University. The University has developed this Code to meet the standards set out in the Australian Code for the Responsible Conduct of Research (2007).
1. **Preamble**

1.1 The *National Statement on Ethical Conduct in Human Research* (2007 – Updated May 2015) (The *National Statement*) sets out that institutions must ensure that all research involving human participants is designed and conducted in accordance with *Australian Code for the Responsible Conduct of Research* (2007) (*The Code*) and ethically reviewed and monitored in accordance with the *National Statement*.\(^1\) Organisations that regularly undertake research involving humans may establish a Human Research Ethics Committee (HREC) to review this research.

1.2 In order to provide timely review of research involving human participants Macquarie University has established two fully constituted HRECs in accordance with the *National Statement*.\(^2\)

2. **Objectives**

2.1 To protect the rights and welfare of research participants by ensuring all research projects involving human participants and conducted under the auspices of Macquarie University 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 To monitor ethically approved research in accordance with the *National Statement*.

3. **Functions**

3.1 Provide independent ethical review of research projects in accordance with the *National Statement*.

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 the HREC requires.

3.3 Conduct regular monitoring processes in accordance with the *National Statement* to ensure that ethical standards are maintained.

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\(^2\) Ibid, 5.1.33.
3.4 Provide advice to researchers and their students, visiting academics or medical personnel and other personnel involved in the conduct of research.

3.5 Provide ethical oversight of innovative surgery at Macquarie University Hospital (MUH) in order to provide guidance to clinicians when assessing whether an innovative surgery constitutes research.³

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 the Higher Degree Research Office (HDRO) and the Deputy Vice-Chancellor; Research (DVCR) on matters relating to human research ethics.

4. **Scope of Responsibility**

4.1 The Macquarie University HRECs will be responsible for reviewing, approving and monitoring research involving human participants 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 the University, being staff or students, or recruited externally.

c. Is carried out using University equipment, facilities or premises owned by the University or otherwise under control of the University.

d. Is undertaken by individuals not affiliated by the University provided prior agreement exists between the University and the external entity.

4.2 The Macquarie University HRECs will provide education and training to University researchers and students.

5. **Accountability and Reporting**

5.1 The Macquarie University HRECs are advisory Committees to the Vice-Chancellor (VC) via the DVCR and are thereby mandated to:

a. Approve human research on ethical and scientific grounds

b. Withhold human research approval on ethical and scientific grounds

c. Suspend human research approval on ethical and scientific grounds

³Ibid, ch 3.
d. Withdraw human research approval on ethical and scientific grounds

5.2 The Macquarie University HRECs are accountable to the VC through the DVCR. Where a complaint alleges research misconduct, the HRECs shall report these matters to the Director, Research Ethics and Integrity to be managed and investigated in accordance with the Macquarie University Code for the Responsible Conduct of Research.

5.3 The HRECs will make these Terms of Reference and Standard Operating Procedures publically available by posting them on the Research Office website.

5.4 The HRECs 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 DVCR

5.5 The HRECs will liaise with the Dean, Higher Degree Research on matters of significant ethical concern regarding student research projects.

6. Membership

6.1 In accordance with the National Statement, the HRECs 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 from outside of the institution

6.2 In accordance with the National Statement, the membership of the HRECs 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.

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4 Ibid s 5.1.29.
5 Ibid s 5.1.30 (a-f).
6.4 Wherever possible one or more of the members listed in 6.2 should be experienced in ethical decision-making.

6.5 The HRECs will have access to scientific expertise, via the University’s Scientific Advisory Committee in order to consider issues of research merit and integrity. Where necessary the HRECs may access the relevant expertise by going outside the HREC membership.

6.6 The HRECs will establish an Executive, consisting of the Chair, two Committee members, the Director, Research Ethics and Integrity (if this is not the Chair) and the Committee Secretary. This Executive will be responsible for issues that arise out of session.

7. **Appointment of Members**

7.1 Committee members are recruited by direct approach from the Research Office. Macquarie University members will be formally nominated by the Faculty Dean. Members will be approved by the DVCR. Members will be asked to submit a resume to the Research Office.

7.2 Prospective lay members will be recruited by advertisement and interview. 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 DVCR.

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 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 and any other relevant policies, guidelines and legislation.

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 HREC Chairs will be available between meetings to undertake HREC 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 of the HREC 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 Membership will not be renewed after a three year term if, at the end of their term, a member has not engaged in at least one education and training activity. The Committee Secretary will advise members of upcoming training and education opportunities.
7.11 A member may resign from the HREC at any time upon giving notice in writing to the Chair and the Director, Research Ethics and Integrity (if this is not the Chair).

7.12 The DVC may terminate the appointment of any member of the HREC if the DVC 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.

7.13 Members of the HREC who are external to Macquarie University may be offered an Honorarium for their pre-meeting preparation and attendance at the HREC meetings. The payment of the Honorarium will be subject to review by the Director, Research Ethics and Integrity.

8. Liability and Coverage

8.1 The University will provide indemnity for members of the HRECs 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 University Ethics Policy.

9.2 All applications are to be submitted to the Ethics Secretariat by the relevant closing date in a format approved by the HRECs.

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 an HREC meeting.

9.5 The HRECs 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 HRECs 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 Committee meeting 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 HREC members at least 7 days prior to the meetings.

9.8 The HRECs may delegate consideration of certain scientific/technical matters to the Scientific Advisory Committee or a particular HREC member. The HRECs may also obtain independent scientific or technical advice, subject to paragraph 6.5.
9.9 The HRECs may take into account the views and opinions of another properly constituted HREC in relation to a research protocol.

9.10 The HRECs will notify the applicant by email advising whether the application which it has considered was approved in accordance with the *National Statement* within four weeks following a meeting.

9.11 The HRECs will notify applicants by email advising whether their application needs amendments in order to ensure it meets the requirements of the *National Statement*. 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.

9.12 If the application was rejected the HRECs will inform the applicant in writing citing the relevant sections of the *National Statement*.

10. **Meetings**

10.1 HREC meetings will be conducted once a month between February and November.

10.2 The HREC 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, HREC 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 HREC member who has a conflict of interest associated with a proposal or other related matter being considered 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 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 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 HRECs 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 HRECs from researchers who have no formal affiliation with the University and for sponsored research projects. These researchers will be invoiced according the Macquarie University fee structure which is made available in the Standard Operating Procedures.

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

12.1 In accordance with s 5.1.18 of the National Statement, the University will establish Faculty ethics sub-committees to undertake ethical review of low risk research. The sub-committees will have the necessary resources and capacity to carry out such review competently and professionally.

12.2 Research that has been assessed by the Ethics Secretariat as negligible or low risk will be submitted to the Faculty Ethics sub-committees for consideration.

12.3 In accordance with the National Statement Faculty sub-committee members will be familiar with the National Statement have an understanding of the ethical issues that can arise in the research under review.

12.4 In undertaking ethical review of low risk research, Faculty sub-committee members will be informed by the following sections of the National Statement: Section 1: Values and Principles of Ethical Conduct, Section 3: Ethical Considerations Specific to Research Methods or Fields and Section 4: Ethical Considerations Specific to Participants. Low risk ethical review will also take account of researchers’ judgements as to whether their research is suitable for review by a non-HREC process and have due regard to relevant privacy regulation.

12.5 Prior reviewed ethics applications will be reviewed by an expedited process, either online or by the Committee Executives.

12.6 Expedited review requests will be reviewed by the Chair, or the Chair’s delegate, and by a nominated number of Committee members.

12.7 During non-HREC levels of review, an application may be deferred to a HREC meeting for further review if considerable ethical issues arise.

12.8 The HRECs may defer an expedited review application to the Scientific Advisory Committee for further review if technical/scientific issues require further consideration.

12.9 The Ethics Secretariat will maintain a record of all expedited review applications. Faculty sub-committee staff will maintain records of low risk applications sent for review.
13. Records

13.1 The Ethics Secretariat will prepare and retain records of the HRECs’ activities, including agendas and minutes of all meetings of the HRECs and the Committee Executives. Meeting minutes will be retained in a minutes file in accordance with the State Records Act 1998 (NSW).

13.2 In accordance with the State Records Act 1998 (NSW) the Ethics Secretariat will retain a record of all ethics applications submitted for review by the HRECs. This will include the application and appendices and any relevant correspondence between the applicant and the HRECs.

13.3 Files will remain confidential and will be kept securely. The University will maintain its records in accordance with its obligations under existing privacy legislation and University policy.

13.4 Files will remain open until a final report has been received and the project closed or the Ethics Secretariat have been advised by the Principal Investigator that the application has been withdrawn. The Ethics Secretariat will close and archive the file in accordance with the State Records Act 1998 (NSW).

13.5 Records will be held for sufficient time to allow for future reference. The minimum period of retention will be in accordance with University policy, The Code and the State Records Act 1998 (NSW).

13.6 The Ethics Secretariat will maintain a database of all applications received and reviewed.

13.7 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-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 HRECs will monitor approved projects in accordance with the National Statement Ch. 5.5 in order 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 University or the HRECs

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 Principal Investigator when a report is due.

14.5 The HRECs will require, as a condition of final approval, that investigators immediately report any of the following:
   a. Proposed changes to the protocol in the form of a request for amendment
   b. Serious or unexpected adverse events within 72 hours of the event occurring
   c. Other unforeseen events that may affect the continued ethical acceptability of the project
   d. If the project is discontinued for any reason

15. **Complaints regarding HREC-approved research**

15.1 Complaints about the conduct of a HREC-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 and Integrity.

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 Secretariat will notify the HREC Chairs of the complaint immediately after it has been received.

15.5 The Chair will decide on the appropriate course of action in consultation with the Ethics Secretariat, Director Research Ethics and Integrity and relevant personnel as required.

15.6 Complaints considered to allege research misconduct will be dealt with in accordance with the procedures outlined in the *Macquarie University Code*.

15.7 Where a complaint alleges serious misconduct that falls outside of the range of research misconduct as described in *the Macquarie University Code*, the matter will be dealt with in accordance with the Macquarie University Grievance Management Policy and other relevant University 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 and Integrity. If this is not successfully resolved, the complaint should be managed in accordance with the Macquarie University Grievance Management Policy and any other relevant University policies and procedures.

16.2 The complaint may be referred to the DVCR in accordance with these procedures.