Monash University Procedure

Procedure Title	Ethical Research and Approvals: Human Research Ethics Committee Procedures
Parent Policy	Ethical Research and Approvals Policy
Date Effective	25-November-2009
Review Date	25-November-2012
Procedure Owner	Manager, Research Ethics and Compliance
Category	Academic Quality and Standards
Version Number	1.0
Content Enquiries	Manager Research Ethics
Scope	Applies to all Monash University staff and students, full time, part time, casual or adjunct, from any Monash University campuses, national and international, who host, conduct, participate in or disseminate the results of research involving human or animal subjects. Visitors to the University who participate in research are also covered by this policy.
Purpose	All Australian research institutions accepting funding from either the Australian Research Council or the National Health and Medical Research Council enter into funding agreements which require in part that all research activities with or about people, or their data or tissue, regardless of the funding source, must be reviewed in accordance with the guidelines set out in the *'National Statement on Ethical Conduct in Human Research'*. Monash University is committed to ensuring maximum compliance with current ethical guidelines and legislative frameworks as they apply to research and therefore has review procedures for such research.

PROCEDURE STATEMENT

1. Research Governance

- The DVC(R) is responsible for ensuring that all human research is conducted ethically and is appropriately reviewed. The DVC(R) has established the Monash University Human Research Ethics Committee (MUHREC) for the purpose of reviewing all human research proposals in accordance with the National Statement and appoints a chair and associate chair(s) to oversee MUHREC's activities. Administrative support to MUHREC is provided by the Monash Research Office.
- MUHREC is a sub-committee of the Monash Research Committee which is charged with, amongst other things, the monitoring of research performance. MUHREC membership is constituted in accordance with the National Statement and includes individuals both internal and external to Monash University.

Responsibility

DVC(R)

Monash University Procedure

2. Appointment of members to MUHREC

- Members are appointed to the Committee for three-year terms by invitation from the Chair.
- Internal members are recruited from Monash faculties and departments to provide appropriate representation of the categories required in the National Statement, and in proportion to the number of proposals submitted to the Committee for review. This ensures the appropriate experience and knowledge in the relevant research disciplines.

Responsibility

MUHREC Chairs

3. Member's Responsibilities

- Each member is responsible for making themselves familiar with the contents of the National Statement.
- Each member is responsible for deciding whether, in their judgment, a proposal submitted meets the requirements of the National Statement and is ethically acceptable.
- Each member is assigned to a sub-committee of MUHREC and needs to prepare for and attend the scheduled meetings of that sub-committee. In the event that a member cannot attend the scheduled meeting they are required to make their opinions about each application before the Committee known to the Chair prior to the meeting.
- Each member must attend continuing education or training programs, such as the MUHREC retreats, at least every three years.
- Members given access to confidential material or information in order to assess an application's ethical merits are bound to maintain that confidentiality.

Responsibility

MUHREC members

4. Appointment of Chair(s)

- The MUHREC Chair and Associate Chair(s) are appointed by the DVC(R) on an annual basis. The DVC(R) may choose to reappoint the existing Chair(s) each year or appoint a new chair.

Responsibility

DVC(R)

5. Chair(s) Responsibilities

The Chair(s) are responsible for:

- the conduct of MUHREC meetings including the appropriate management of members' workloads;
- assisting in the resolution of disputes or complaints emanating from the community, research participants or Monash University researchers;
- overseeing collaborative relationships and Memoranda of Understanding with external organisations;
- advising the DVC(R), Monash Research Committee and the university community on matters concerning the ethical conduct of research involving humans;
- providing advice to the Human Ethics Office of the Monash Research Office regarding policies and procedures;
- recommending reports of the Committee to the Vice-Chancellor, DVC(R) and Academic Board;

- initiating responses on behalf of the University to matters of policy and procedure originating from government and other sources;
- ensuring that a program of education is conducted on matters concerning human ethics for Committee members and the general university community.

Responsibility

MUHREC Chairs

6. Frequency of meetings

- MUHREC is divided into three sub-committees, each constituted in accordance with the requirements of the National Statement. The sub-committees meet on a six-week cycle with a sub-committee meeting every two weeks.

Responsibility

Executive Officer of the Human Ethics Office

7. MUHREC Management Committee

- The administrative and management issues and ongoing strategic direction of ethical review of human research at Monash is overseen by the MUHREC Management Committee. The Committee consists of the Chair and Associate Chair(s), representation from the Monash Research Office/Human Ethics Office, representatives from both Monash Sunway Campus and Monash South Africa and experienced members from within MUHREC, including external members such as lawyers, lay persons and individuals with pastoral care functions within the community.

Responsibility

MUHREC Chairs
Human Ethics Officer

8. Human Ethics Office

- The Human Ethics Office, within the Monash Research Office, provides administrative support for the operation of the MUHREC and is responsible for ensuring that applications are received and processed as described below.
- The Human Ethics Office is responsible for ensuring that all applications and other documentation such as agendas, minutes and comments from reviewers are maintained according to the Monash University Recordkeeping Policy.

Responsibility

Manager, Research Ethics and Compliance

9. MUHREC approval of research proposals

- MUHREC reviews research proposals submitted to the Human Ethics Office from the Monash research community and considers each application, giving due consideration to the merits of the research and the risks to participants as a result of their voluntary involvement in the proposed research. In their consideration of such research proposals, MUHREC members will apply the principles and values of ethical conduct as described in the National Statement, establish that any risk to participants is warranted by the benefits to participants or the broader community and ensure appropriate and informed consent has been obtained.
- Once satisfied that the proposed research will be conducted in accordance with the National Statement the Chair will issue an approval certificate to the researchers.

Responsibility

MUHREC Chairs

10. Withdrawal of MUHREC approval

- Should MUHREC believe it is necessary to withdraw approval of a research project the Committee shall inform the researchers, the Deputy/Associate Dean (Research) of the relevant faculty and the DVC(R) of its decision and the substantive reasons behind its decision. It shall seek the advice of the Deputy/Associate Dean and the DVC(R) regarding any subsequent action to be taken further to the decision to withdraw the approval of research.

Responsibility

MUHREC Chairs

11. Privacy

- Research participant information
  - Protection of privacy in research involving human participants is an important consideration for researchers in developing a research project. Although MUHREC and the Human Ethics Office consider the privacy implications of each proposal, it is the researchers' responsibility to familiarise themselves with the Monash University Conduct and Compliance Procedure - Privacy and the information privacy principles and how they apply to the collection, use and disclosure of any personal, health or sensitive information about research participants collected during the course of their research activities.
- Researcher information
  - The information provided by researchers when submitting an application to MUHREC is collected for the primary purpose of assessing the application. This information will also be entered into a database to assist with administration, correspondence and statistical analyses. These records are accessed by staff in the Monash Research Office and possibly other administrative staff at Monash University (e.g. Occupational Health and Safety, Archives and Records Services) and are kept in a manner to ensure confidentiality and secure storage for seven years after the expiry of the term of approval. Although this information is not usually disclosed to other individuals, there may be some circumstances which require the information to be disclosed (e.g. the Freedom of Information Act).

Responsibility

Monash staff and students conducting research
Human Ethics Office
MUHREC Members

12. Complaints

- All complaints about human research conducted by Monash staff and students should be directed to the Executive Officer of the Human Ethics Office, who may seek to resolve the problem or forward it to the Manager of the Research Ethics and Compliance Unit for resolution.
- Where the complaint cannot be handled by the Executive Officer or Manager of the Research Ethics and Compliance Unit, the complaint is directed to the Chair or Associate Chairs of MUHREC who will act on behalf of the Committee to fully investigate the complaint. This may involve seeking advice from the DVC(R), relevant Deans or Associate Deans, University Privacy Officer, University Solicitor or the MUHREC Management Committee. The investigation will, at all times, be conducted sensitively and within the requirements of relevant privacy legislation.
- The outcome of the investigation will then be communicated to the complainant on behalf of the Committee.

- If the matter is not able to be resolved, a written request for resolution of the matter may be made to the DVC(R) by either the complainant or the person with whom the matter has been discussed.
- The DVC(R) may then attempt to resolve the complaint through further negotiation or mediation, or may advise the complainant in writing that the complaint is considered to be lacking in substance, or frivolous and/or vexatious, and that no further enquiry is to be made.
- A complaint case would be considered closed upon receipt by the DVC(R) of a written withdrawal of the complaint by the complainant, or when the DVC(R) determines that there is nothing further that can be done in order to settle the complaint.
- Decisions of the DVC(R) may be appealed by the complainant in writing to the Vice-Chancellor. An appeal must be made within 28 days of receipt of the decision of the DVC(R), must be in writing and include the grounds for the appeal. It will not be sufficient for a researcher or complainant to ask for a re-consideration of the original complaint. The complainant or researcher must provide some reasons why they consider the decision to be incorrect or unfair.
- The decision of the Vice-Chancellor is considered to be final.

Responsibility

Executive Officer of the Human Ethics Office
MUHREC Chairs

13. Research Misconduct

- The Australian Code for the Responsible Conduct of Research 2007 considers the conduct of research without ethics approval as required by the National Statement an example of research misconduct.
- If MUHREC believes that such research has been conducted without specific approval, it may recommend that the Monash University Procedures for Dealing with Allegations of Research Misconduct be activated.

Responsibility

MUHREC Chairs

14. Conflict of Interest

- Any conflict of interest perceived or real should be managed in accordance with the Monash Conduct and Compliance Procedure - Conflict of Interest.

Responsibility

MUHREC Chairs
MUHREC members

15. Review of Research Proposals from External Organisations

Monash University is occasionally approached by external organisations wishing to have MUHREC ethical review of their research activities. The decision concerning whether MUHREC undertakes the review is at the discretion of the DVC(R) and will generally incur a fee for service. The fee is based on the level of review required for the proposal.

Responsibility

DVC(R)

Responsibility for implementation	DVC(R) MUHREC Chairs

Monash University Procedure

	MUHREC members Executive Officer of the Human Ethics office Human Ethics Office Manager, Research Ethics and Compliance Monash staff and students conducting research
Status	New
Approval Body	**Name:** Academic Board **Meeting:** 06/2009 **Date:** 25-November-2009 **Agenda item:** 17.1.1
Definitions	**Human research**: Broadly, research conducted with or about people, or their data or tissue. **HREC**: Human Research Ethics Committee **MUHREC**: Monash University Human Research Ethics Committee **National Statement**: National Statement on Ethical Conduct in Human Research **DVC(R)**: Deputy Vice-Chancellor (Research)
Legislation Mandating Compliance	Queries may be addressed to Risk and Compliance at: riskandcompliance@monash.edu.
Related Policies	• Recordkeeping Policy
Related Documents	• National Statement • Conduct and Compliance Procedure - Privacy • The Australian Code for the Responsible Conduct of Research 2007 • Monash University Procedures for Dealing with Allegations of Research Misconduct • Monash Conduct and Compliance Procedure - Conflict of Interest