Monash University Procedure

Procedure Title	Ethical Research and Approvals: Research Involving Human Participants 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 part of which require that all research activities with or about people, or their data or tissue, must be reviewed in accordance with the guidelines set out in the 'National Statement on Ethical Conduct in Human Research'. Monash 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

All human research activities involving Monash staff and/or students must be subjected to ethical review and monitoring by the Monash University Human Research Ethics Committee (MUHREC) which is established by Monash University for this purpose. Such review and monitoring will be conducted in accordance with the National Statement.

Responsibility

Monash University staff and students

2. What is human research?

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.

Responsibility

Not applicable

3. Determining the level of ethical review of research

- The National Statement requires that the process of ethical review of human research be determined by the level of risk to participants and the category of research. All research considered to be greater than 'low risk' or including vulnerable participants or sensitive issues is to be reviewed by a fully constituted Human Research Ethics Committee (HREC). Subject to paragraph 3.3 below (see paragraph 5.1.7 of the National Statement) all 'low risk' research may be approved by a mechanism other than a full HREC review.
- The expression 'low risk research' describes research where the only foreseeable risk to participants is not more than one of discomfort.
- Research involving any of the following also requires review by the full Committee:
  - interventions and therapies;
  - human genetics;
  - human stem cells;
  - women who are pregnant and the human foetus;
  - people highly dependent on medical care;
  - people with cognitive impairment, an intellectual disability, or mental illness;
  - Aboriginal and Torres Strait Islander peoples;
  - people involved in illegal activities.

Responsibility

Not applicable

4. Harm, discomfort and inconvenience

- Researchers must be aware of the effects research activities may have on participants and whether their participation in the project may lead to any harm, discomfort and/or inconvenience. From the National Statement, 'harms' to research participants may include the following:
  - physical harms - including injury, illness, pain;
  - psychological harms - including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
  - devaluation of personal worth - including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
  - social harms - including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
  - economic harms - including discovery and prosecution of criminal conduct

- Less than harm is 'discomfort', which can include minor side-effects of medication, the discomforts related to measuring blood pressure, or anxiety introduced by being interviewed.
- Less than discomfort is 'inconvenience', which may include such activities as filling in a form or participating in a street or phone survey, or simply giving up time to participate in research

Responsibility

Not applicable

5. Submission of research proposal for ethical review

- Research requiring full ethical review
  - 'Greater than low risk' research proposals or other research requiring full review, excluding proposals considered under either the Multi-Centre (see paragraph 5.3 below) or Memoranda of Understanding (see paragraph 5.4 below) processes, are to be submitted using the current form as per the instructions, both found on the Monash Research Office website, to the Human Ethics Office.
  - Complete proposals will be receipted and entered into the database by the Human Ethics Office before being assigned to the next available meeting.
  - Incomplete proposals will be returned to the researcher for their attention and will not be considered as having been submitted to the Human Ethics Office.
  - Meeting dates are made available on the Monash Research Office website.
  - Research proposals will be assigned to readers for comment prior to the next meeting date.
  - Readers will assess the proposal confirming the level of risk and identify any ethical concerns.
  - If the readers confirm the proposal as being 'greater than low risk' the application will be circulated to all Committee members for review at the next meeting. If the readers assess the proposal as 'low risk research' the proposal will be processed via the 'low risk' process.
  - Proposals confirmed as being 'greater than low risk' or requiring full review are circulated to the full MUHREC prior to the meeting date with any comments already identified by readers. Such proposals are discussed in detail at the meeting.
  - The readers may collectively decide that the Committee's deliberations as to the suitability of the application would be greatly enhanced by having the researchers attend the meeting. In such cases the researchers are invited to attend an interview.
  - Attendance by researchers or other observers is by prior invitation only.
  - Researchers are notified of the review outcome within one week of the Committee's meeting. Any issues to be addressed are itemised in a letter from the Committee. Proposals with no issues will receive an approval certificate. Proposals that have issues to be addressed will be approved once the issues have been addressed to the satisfaction of the Committee.
  - No human research classified as 'greater than low risk' may commence until MUHREC approval has been obtained.
  - Approvals are granted subject to conditions specified on the approval certificate.

- Low risk research
  - Research that meets the National Statement's criteria to be classified as 'low risk', and which does not require full review, excluding proposals considered under either the Multi-

Centre or Memoranda of Understanding processes, can be submitted at any time to the Human Ethics Office.

- Research proposals are to be submitted using the current form as per the instructions, both found on the Monash Research Office website to the Human Ethics Office.
- Complete proposals will be receipted and entered into the database by the Human Ethics Office before being assigned to one of the delegated readers for review.
- Incomplete proposals will be returned to the researcher for their attention and will not be considered as having been submitted to the Human Ethics Office.
- Readers will review and return any comments or concerns to the Human Ethics Office and researchers will be notified of the outcome approximately two weeks from the date of submission.
- Proposals with no issues will receive an approval certificate. Proposals that have issues to be addressed will be approved once the issues have been addressed to the satisfaction of the reader.
- No low risk human research may commence until written approval has been obtained.
- Approvals are granted subject to conditions specified on the approval certificate.

- Multi-centre research
  - The National Statement encourages HRECs to reduce the duplication of ethical review of research proposals to be conducted at more than one site.
  - In keeping with the intent of the National Statement any research involving Monash staff or students to be conducted at a site under the jurisdiction of an HREC other than MUHREC, that has already been approved at that site, may be reviewed under the Multi-Centre Review Process.
  - In such instances, the researchers may submit a copy of the previously completed application, as approved by the other HREC, with a copy of the approval letter and the Multi-Centre Form to the Human Ethics Office at any time.
  - Such proposals are reviewed by the Chair or Associate Chair(s) of MUHREC who must ensure that the research proposal has been reviewed appropriately according to the National Statement.
  - Unless the level of review is deemed as inappropriate MUHREC will issue an approval based on the other site's HREC's review.
  - Approvals are granted subject to conditions specified on the approval certificate.

- Review under Memoranda of Understanding(MOU)
  - In keeping with the intent of the National Statement to reduce the duplication of ethical review, Monash University has entered into agreements or memoranda of understanding with several hospitals where Monash research is routinely conducted. These agreements or MOUs assign full responsibility of ethical review and monitoring to the hospital HREC.
  - Hospitals participating in the MOU ethics review arrangement can be found on the Monash Research Office website.
  - Where a Monash researcher is conducting or is involved in research conducted at such a hospital the application for ethical approval should be submitted to the hospital's HREC, and not MUHREC.
  - Once the application has been approved by the hospital HREC the hospital's HREC administrator will notify the Monash Human Ethics Office of any approved projects

involving Monash staff. The Human Ethics Office will contact the Monash staff to request a copy of the approval letter and final application for the University records.

- No additional ethical review of the project will be undertaken. However, the application will be assessed for governance issues such as insurance and indemnity arrangements, legal contracts and other regulatory matters, for example Therapeutic Goods Administration requirements

6. Withdrawal of MUHREC approval

- Should MUHREC feel it is necessary to withdraw approval of a research project the Committee will 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.
- Depending on the project it is possible that multiple university processes will be followed, for example where student researchers are involved in the project the Associate Dean (Graduate Studies or Research Degrees) and MRGS will be notified.
- Other university departments may have additional processes which may be instigated as a result of withdrawal of MUHREC approval.
- MUHREC may 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.

7. 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 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 on to 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 for university business, 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, it may be subject to disclosure for the purposes of obtaining legal advice or as appropriate according to law (e.g. the Freedom of Information Act).

8. Complaints

- All complaints about human research conducted by Monash staff and students or the outcome of an ethical review approved by MUHREC should be directed to the Human Ethics Executive Officer, 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 Chair or Associate Chairs of MUHREC will be consulted.

- The Chair or Associate Chairs of MUHREC 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 and the researchers on behalf of the Committee. In addition, the head of the academic unit responsible for the conduct of the researchers will be notified of the complaint and the resolution.
- Depending on the nature of the complaint and the resolution, it is possible that other processes may be instigated such as withdrawal of MUHREC approval, staff misconduct or student misconduct procedures.
- 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). An appeal 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 of the DVC(R) to be incorrect or unfair.
- The decision of the Vice-Chancellor is considered to be final

9. Research Misconduct

- The Australian Code for the Responsible Conduct of Research 2007 considers conducting research without ethics approval as required by the National Statement an example of research misconduct.

If MUHREC believes that research has been conducted without specific approval with intent and deliberation, or has been conducted with recklessness or gross and persistent negligence and has serious consequences, such as having adverse effects on research participants, it will recommend that the Monash University Procedures for Dealing with Allegations of Research Misconduct be instigated.

Responsibility for implementation	Monash University staff and students Monash Human Ethics Office MUHREC Chairs MUHREC members Human Ethics Executive Officer DVC(R) Vice-Chancellor

Monash University Procedure

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	
Related Documents	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