Human Research Ethics Committees

Terms of reference

* **Human Ethics Advisory Groups**

The primary function of a Human Ethics Advisory Group (HEAG) is to provide preliminary assessment of human research projects submitted by staff and students in a department, school or faculty; and to advise the relevant Human Ethics Sub-Committee (HESC) and the Central Human Research Ethics Committee (CHREC) on issues pertaining to human research ethics in the department, school or faculty.

**1. Membership**

A HEAG should comprise at least three members of academic staff of a department or centre, including one senior member of staff (e.g. Associate Professor). Where possible a post-graduate student should also be appointed to the HEAG.

In the case of small departments or centres it may be helpful if two or more combine to form a multi-department HEAG for review of research ethics proposals. Alternatively a faculty-based Human Ethics Advisory Group may also be formed.

**2. Functions and responsibilities**

2.1 To examine proposals which involve the use of humans as participants in the research of staff and students of the department, school or faculty; and to advise the CHREC and its Sub-Committees on whether the proposals comply with the ethical guidelines adopted by the University and the Human Research  Ethics Committee.

2.2 To make an assessment of the ethical implications and the academic value including methodology and technical aspects of proposals to be conducted by staff and students of the department, school or faculty prior to submission of the proposal to the appropriate Human Ethics Sub-Committee, in accordance  with the policy and procedures adopted by the CHREC.

2.3 To consider, approve and keep appropriate records of Project-within-Program proposals, which are derived from Program applications of research previously approved by the Human Ethics Sub-Committees. To report Project-within-Program approvals and forward a signed copy to the CHREC.

2.4 To consider, approve and keep appropriate records of Minimal Risk proposals. To report Minimal Risk approvals and forward a signed copy to the CHREC.

2.5 To assist and advise the CHREC and its Sub-Committees as follows:

(a) to ensure that investigators are appropriately qualified to conduct the research including any specific procedures proposed by them in a project;

(b) to ensure that proper arrangements are made in accordance with University and CHREC policy for security and disposal of confidential data collected in the course of research;

(c) to monitor research projects conducted by staff and students of the department in accordance with the National Statement on Ethical Conduct in Human Research and University procedures;

2.6 To keep appropriate records for audit and compliance purposes.

2.7 To provide ethics training for department researchers, supervisors, post-graduate students and HEAG members, including information on the policy and procedures of the University’s ethics committees.

2.8 Representatives of HEAGs are to attend information sessions and other training seminars provided by the CHREC.

**3. Method of operation**

3.1 The HEAG is to meet regularly during the year to review projects and to discuss general issues relating to the ethical review of research. Minutes, including decisions regarding project approvals made at the meetings, must be recorded, in particular those regarding Minimal Risk or Project-within-Program proposals.

3.2 Where projects are reviewed by circulation between meetings a cover sheet with some record for comments and signatures must be kept. Minimal risk projects which are submitted for approval by the department must be discussed at a meeting of the HEAG and cannot be approved by circulation. Details of discussions at the meeting are to be recorded.

3.3 Members of the HEAG may not review and approve their own research. In such cases another person must review the project and sign HEAG approval.

**3.4 Proposal types**

(a) Individual research projects. Proposals for research involving human participants forwarded by students or staff in the department should be assessed by the HEAG and forwarded to the appropriate Sub-Committee for consideration, together with the Advisory Group’s recommendations or comments,  where relevant.

(b) Program applications. In the case of applications for ethics approval of a program of research, researchers are to complete the program application form and forward it to the HEAG for consideration. HEAG members are to make an assessment of the program with regard to academic merit and ethical implications and then forward to the Sub-Committee the Advisory Group’s recommendations any other comments, where relevant.

(c) Project-within-program applications. In the case of project-within-program applications HEAG members are to make an assessment of the project with regard to academic merit and ethical implications and then, if appropriate, approve the project.

(d) Minimal Risk projects. In the case of Minimal Risk applications considered eligible for approval by the HEAG, Advisory Group members are to make an assessment of the project with regard to academic merit and ethical implications and then, if appropriate, approve the project. The HEAG may decide that a Minimal Risk application requires a full review by the CHREC.

3.5 The HEAG must provide an annual report to the CHREC on its activities, including:

* + current membership including name of Chair and contact details
  + procedures for consideration of proposals, including details and frequency of meetings
  + procedures for monitoring of projects, including projects being undertaken overseas
  + security of data, conditions of storage, development of protocol for storage, access, disposal
  + ethical problems which may have arisen in relation to conduct of projects, complaints
  + list details of all Project-within-Program applications approved by the HEAG,
  + list details of all Minimal Risk applications approved by the HEAG.

3.6 The Chair and/or other HEAG members are to attend at least one meeting of the relevant Human Ethics Sub-Committee to discuss the HEAG annual report and other issues of common interest.

* **Human Ethics Sub Committees**

Human Ethics Sub Committees (HESCs) have the responsibility, on behalf of the Central Human Research Ethics Committee (CHREC), to ensure that ethical standards are maintained in research projects and to protect the interests of the research subjects, the investigator and the institution.

**Terms of Reference**

**1. Membership**

1.1 Membership of HESCs shall comprise:

(a) a chairperson, with suitable experience, whose other responsibilities will not impair the HESC’s capacity to carry out its obligations under the National Statement on Ethical Conduct in Human Research (NHMRC, 2007);

(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, a nurse or allied health professional;

(d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;

(e) at least one lawyer, where possible one who is not engaged to advise the institution; and

(f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

From time to time a HESC may co-opt a person with particular expertise for a specified period.

1.2 Membership and composition shall be in accordance with the requirements of the National Statement on Ethical Conduct in Human Research.

1.3 Membership must be reported to, and approved by, the CHREC.

**2. Functions and responsibilities**

2.1 HESCs have the duty to:

(a) consider the ethical implications of proposed research projects involving humans as participants in the research, and to certify with respect to those projects whether they satisfy accepted ethical standards and codes. In assessing projects HESCs shall have regard to the principles set out in the National Statement on Ethical Conduct in Human Research, and other guidelines published from time to time by the NHMRC, and those adopted by the University;

(b) to ensure, after consultation with departments and Human Ethics Advisory Groups (HEAGs), that researchers are appropriately qualified to conduct the studies, including any procedures proposed by them for a research project;

(c) to ensure, in consultation with departments and HEAGs, that proper arrangements are made in accordance with University and HREC policy, for security and disposal of confidential data collected in the course of research;

(d) to monitor research projects conducted by staff and students of the department in accordance with NHMRC and University guidelines;

(e) to discuss and make recommendations to the CHREC on all aspects of human research ethics and procedures for ethical review of projects.

**3. Method of operation**

3.1 In carrying out its functions the HESC shall conform to the current National Statement on Ethical Conduct in Human Research.

3.2 HESCs should have formal regular meetings, usually monthly, and at least six times a year.

3.3 Minutes of meetings must be maintained and provided to the CHREC for information.

3.4 Records of all decisions must be maintained.

3.5 Certification of approval may apply both to individual projects and broad areas of investigation within HREC guidelines.

3.6 An Executive comprising the Chairperson and two other members of a HESC, at least one of whom must be the member described in 1.1(b) above may be appointed to approve minor modifications to projects. Appointment of the Executive must be approved by the CHREC.

3.7 The Executive may not approve projects. Any decisions taken by the Executive must be reviewed by the HESC at its next meeting.

3.8 In discharging its responsibilities, HESCs may seek the assistance of such experts as it chooses.

* **Central Human Research Ethics Committee**

The Central Human Research Ethics Committee (CHREC) has oversight of all matters pertaining to ethics review of human research at the University of Melbourne. It is constituted in accordance with the National Statement on Ethical Conduct in Human Research, and is chaired by the Pro Vice-Chancellor (Research). Its terms of reference are to:

* + Formulate policy, procedures and guidelines for research involving humans.
  + Monitor and review human research ethics activities.
  + Provide advice to the Academic Board and Council on human research ethics.
  + Establish and determine the composition, responsibilities and membership of the Human Ethics Sub-Committees and Human Ethics Advisory Groups.
  + Receive regular reports from the Human Ethics Sub-Committees and the Human Ethics Advisory Groups on the review and approval of research projects and other issues relating to human ethics.
  + Ensure that all projects and approval procedures conform to the requirements of the National Statement on Ethical Conduct in Human Research and the ethical guidelines adopted by the University.
  + Receive complaints, on a confidential basis, from research participants, research workers or others on the conduct of projects and deal with these in accordance with University procedures.
  + Act as a committee of appeal where necessary.