HUMAN RESEARCH ETHICS COMMITTEE WORKING PROCEDURES

Approved by HREC: April 2012
Revised by HREC: March 2014

These working procedures support the University of Divinity in its compliance with Regulation 2.3, the National Statement on Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research (2007).

1. Related documents


2. Primary role of Human Research Ethics Committees

   To ensure that any human research carried out by researchers working in the name or under the auspices of the University, or for which in any other way the University is responsible is: (a) designed and conducted in accordance with the Australian Code for the Responsible Conduct of Research; and (b) ethically reviewed and monitored in accordance with the National Statement.

3. Governance

   The Committee is responsible to the Council of the University under Regulation 2.3.

4. Terms of Reference

   See Human Research Ethics Committee Terms of Reference document. These Terms include details of Committee membership.

5. Appointment of members to the Committee

   The composition of the Committee is determined by the National Statement, and must include at least the minimum membership required by the National Statement.

   5.1 Committee members are appointed on the basis of their expertise within the category to which they are appointed, and not as representatives of any organisation, group or opinion.

   5.2 In the event of a vacancy on the Committee, members may supply names of suitable nominees, along with a brief CV for each nominee, to the Chair. The Chair will forward the nomination(s) to the Vice Chancellor who will present the nomination(s) to the Council for approval and appointment.
5.3 When the Council appoints a member to the Committee, the Vice Chancellor must arrange for a letter of appointment and an induction package to be sent to the new member, which must include the following:

a) confirmation of the membership classification
b) date of the first meeting to which the new member is invited
c) term of appointment
d) provision for Indemnity Insurance for all Committee members
e) Regulation 2
f) HREC Working Procedures
g) contact list of current Committee members and Research Office staff
h) meeting dates for the year

5.4 When a member is granted leave of absence for an extended period, the Council must appoint an acting member in his or her place for the period of the leave of absence, and in the appropriate category of membership.

5.5 The Research Office must ensure that a current membership register is maintained within the Office of the Vice Chancellor.

5.6 The Committee does not have alternate members. However, the Committee maintains a suitable pool of inducted members, who may attend meetings as needed, in the event of the inability of particular members to consider particular projects, or in the event of potential conflict of interest.

6. **Responsibilities of Committee members**

6.1 The Chair is responsible for all decisions of the Committee, and works in close consultation with the Director of Research (the Director) and the Research Services Officer (the Officer).

6.2 The Director is responsible for ensuring that the decisions of the Committee are made and reported to the Council. The Director is responsible for ensuring accurate and timely administration of the Committee’s business, in particular:

a) the accurate and timely distribution of agenda papers
b) the accurate recording of the minutes of each meeting
c) the secure maintenance of Committee files
d) ensuring that the HREC Application Form and Guidelines are current
e) the secure maintenance of an up-to-date applications register
f) ensuring that annual and final reports from researchers are received on time, and that appropriate follow-up is undertaken when a report is not submitted.

g) a regular review of the Working Procedures
The Officer assists the Director in these matters.

The Director is also responsible for liaising between the Committee and the Research Committee.

6.3 Members are responsible for providing impartial advice on applications presented to the Committee, according to their expertise, and for maintaining the confidentiality of material supplied for meetings.

7. **Member Support**

Members are encouraged to identify opportunities for regular education, e.g., by attending relevant ethics conferences and seminars, with the University bearing reasonable costs, upon application.

Members’ voluntary contribution to the Committee is regularly monitored in order to identify excessive workload.

8. **Administrative Oversight**

8.1 The Officer has primary administrative responsibility for the Committee, and is overseen in this work by the Director.

8.2 The Officer forwards all agenda papers to members *no less than one week* in advance of each meeting.

8.3 The Officer is responsible, in consultation with the Director and/or the Chair, for communication with members between meetings.

9. **Procedures for ethical review**

9.1 Normal application

9.1.1 Applications that require ethical clearance must be forwarded to the Research Office by the due date specified in the University’s calendar, in order to be considered at the next available HREC meeting. Applications submitted after the advertised date will not be accepted, unless prior arrangement has been made with the Director.

9.1.2 Incomplete applications, and applications submitted on out-of-date forms will not be considered. In such cases, the Officer informs the researcher and invites them to provide the missing details or re-submit the application on the appropriate form.

9.1.3 Researchers will be notified of the outcome of the application within seven days of the HREC meeting at which their application is considered.

9.2 Applications not requiring ethical clearance

9.2.1 The Director is empowered, in consultation with the HREC Chair when necessary, to determine that an application does not require ethical clearance. When the determination is unclear, the matter may be referred to the full committee.

9.2.2 All such decisions must be noted in the agenda and minutes of the next Committee meeting.
9.3 Expedited review

In exceptional circumstances, an expedited review of minimal risk applications may be undertaken, at the Chair’s discretion, by a small number of HREC members, such decisions being notified to the full Committee. Such a procedure would normally be confined to ‘low risk’ or ‘negligible risk’ research. (For definitions of low and minimal risk, see National Statement 2.1.)

10. Review process

No member of the Committee may adjudicate on any research in which the member has any conflict of interest, personal or financial involvement. Any conflict of interest is to be stated at the beginning of each meeting.

10.1 Primary reviewer

10.1.1 The Director identifies a primary reviewer from the committee members, for each application to be reviewed. The primary reviewer is selected on the basis of particular knowledge, experience and/or expertise in relation to the subject matter of the application. It is expected that members will share this role, so that no member is unnecessarily overburdened. Where appropriate, another committee member may be paired with a primary reviewer.

10.1.2 The primary reviewer reads the application, giving particular attention to ensuring that there is consistency between the applicant’s responses to questions and the summary table.

10.1.3 The primary reviewer introduces the application to the Committee and submits carefully prepared comments to assist the Committee’s deliberations. Reviewers are strongly encouraged to prepare notes that can assist the applicant if substantial changes are needed, or if a re-submission is warranted. Comments may include draft recommendations.

10.1.4 The reviewer should email their comments to the Research Office prior to the meeting, for distribution to members, or to bring sufficient copies to the meeting.

10.1.5 The primary reviewer’s role does not replace the responsibility of each member to read each application prior to the meeting and to ‘decide, independently, whether, in his or her opinion, the conduct of each research proposal . . . will protect participants’ (National Statement, p.15, 2.1)

10.1.6 Neither the Chair nor Director normally act as primary reviewers.

10.2 Resubmissions

10.2.1 Where the Committee requires an application to be rewritten and resubmitted, it must be treated as a new application.

10.2.2 In the case of a resubmission, the Committee may determine which member will be the primary reviewer.
11. **Participation of researchers in meetings**

The *National Statement* (2007) advocates good communication between review bodies and researchers (5.2.13 p.84), ready accessibility of review bodies and their staff to researchers (5.2.14), and a non-adversarial approach towards applications for ethical review. Misunderstandings can often arise when only written communication is used; meeting face-to-face can facilitate clearer communication. Therefore, the Committee invites researchers to attend and speak with the Committee about their application.

11.1 **Procedures for researcher participation**

11.1.1 On receiving an application, the Research Office will invite the researcher to attend the meeting at which their application will be considered. The invitation must include details of time and venue of the meeting.

11.1.2 The researcher should be accompanied by his or her supervisor if applicable.

11.1.3 Prior to the researcher joining the meeting, the members will have received and discussed briefly the primary reviewer’s report, and identified relevant questions to be asked of researcher and/or supervisor.

11.1.4 Each researcher is invited to speak for no more than 5 minutes about their research project. The supervisor may offer any relevant supporting information.

11.1.5 The Committee will discuss the project and application with the researcher for approximately 15 minutes, giving particular attention to matters highlighted by the primary reviewer.

11.1.6 At the conclusion of the discussion, the Chair will advise the researcher when and how they will be notified of the decision.

12. **Procedures for Multi-Centre Research, including transfer of applications from other HRECs**

The *National Statement* allows for multi-centre research, including a research project being conducted by a researcher who changes affiliation from one institution or organisation to another. HRECs are therefore encouraged to develop procedures that will minimise unnecessary duplication and that will ensure timely consideration and review of research protocols.

12.1 **Responsibilities of the Committee**

The HREC must establish to its satisfaction that the assessment and decision of the other committee are scientifically and ethically sound and conform to any principles of operation of their own institution(s). To this end, the Committee has an obligation to

a) communicate with, and give advice to or receive advice from, any other HREC

b) accept assessment of the research by another institution or organisation in order to eliminate any unnecessary duplication of ethical review

c) review and, where the same research project is conducted at two or more institutions or organisations, adopt the reasons for ethical approval or disapproval of another HREC in reaching its own decisions.
12.2 Responsibilities of the researcher

The researcher has an obligation to:

a) disclose to the Committee any previous decisions regarding the research made by another HREC

b) inform the Committee whether the application is currently before another HREC

c) submit annual progress reports, and a final report to the HREC.