

## THE UNIVERSITY OF SYDNEY HUMAN RESEARCH ETHICS COMMITTEE(S)

### TERMS OF REFERENCE

The University of Sydney has a strong tradition in research excellence. In relation to research involving human participants, the University has an obligation to ensure research is designed and conducted in accordance with the “Australian code for the responsible conduct of research” and ethically reviewed and monitored in accordance with the “National Statement on Ethical Conduct in Human Research (2007)”. Sydney University established the Human Research Ethics Committee, constituted and functioning in accordance with the National Statement, to ethically review human research conducted by staff, students and affiliates of the University. These Terms of Reference have regard to the National Statement, which in turn is organised around four ethical values: respect, research merit and integrity, justice, and beneficence. Of particular concern is the protection of participants in human research, and taking their perspective in considering research proposals.

#### 1. Objectives

- 1.1. Protect the mental and physical welfare, rights, dignity and safety of participants of research involving humans, their data or human tissue (**‘research’**).
- 1.2. Promote ethical standards of research.
- 1.3. Facilitate ethical research through efficient and effective review processes, in accordance with the National Statement on Ethical Conduct in Human Research (2007) (**‘National Statement’**).
- 1.4. Protecting the University’s reputation as a place of ethical research by reviewing research undertaken by its employees, affiliates and students to promote compliance with the National Statement and associated legislations and guidelines.
- 1.5. Review research applications with the intention of identifying potential safety concerns for University of Sydney staff and student researchers while conducting research.

#### 2. Scope of Responsibility

It is the responsibility of the University of Sydney Human Research Ethics Committee (**‘University HREC’**) to:

- 2.1. Review proposals for research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
- 2.2. Grant approval for research proposals where this review has determined that they are ethically acceptable and in accordance with relevant standards and guidelines.
- 2.3. Withhold ethical approval for research proposals where this review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
- 2.4. Withdraw ethical approval for research proposals where this review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
- 2.5. Monitor the conduct of approved research through the receipt of annual and completion reports.
- 2.6. Review requests from University staff or students or from external researchers proposing to conduct research on University premises, for the University HREC to recognise the ethical approval of a research proposal granted by another HREC.
- 2.7. Provide advice on an ad hoc basis to University researchers on the ethical aspects of their research proposals and projects.
- 2.8. Provide advice to the Deputy Vice Chancellor-Research or their nominee (**‘DVC-R’**) on ethical issues including the ethical aspects of complaints against researchers or research projects and teaching protocols.
- 2.9. Review requests from external organisations or researchers to post advertisements for recruitment of participants for research projects on the University campus or in University publications, or to recruit participants for research projects on campus.
- 2.10. Research proposals from external organisations or researchers with no direct link to the University may be accepted for review at the discretion of the University HREC.

#### 3. Membership

- 3.1. The composition of the University HREC will be in accordance with the National Statement and will include at least the following personnel:
  - A Chair with suitable experience;
  - A Deputy Chair;

- At least two lay people, one man and one woman, who have no affiliation with the University and do not currently engage in medical, scientific, legal or academic work;
  - At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
  - At least one person who performs a pastoral care role in a community;
  - At least one lawyer, where possible one who is not engaged to advise the University;
  - At least two people with current research experience relevant to research proposals considered by the University HREC.
- 3.2. At least one third of the members should be from outside the institution for which the University HREC is reviewing research. As far as possible, there will be an equal balance of male and female HREC members.
- 3.3. To ensure the membership will equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted to the University HREC, some or all of the above categories may be represented by more than one person.
- 3.4. Committee members who are not University staff will receive remuneration to recognise their contribution to the HREC. The details of this remuneration are outlined in the “Guidelines for Committee Payments”.
- 3.5. The Chairs of both HRECs will receive remuneration to compensate for the additional time required to both Chair the meeting and perform executive duties. This remuneration will be extended to the Deputy Chair when they are acting in the capacity of Chair. The details of this remuneration are outlined in the “Guidelines for Committee Payments”.
- 3.6. For the purposes of holding a meeting of the University HREC, a quorum will exist when a minimum number of 7 members including the Chair are present. In circumstances where a member of each category of membership as designated in the National Statement (and specified in item 6.1 above) cannot be present, members may provide written comments for consideration at the meeting. The time of cancellation of the meeting due to lack of sufficient numbers is at the discretion of the Chair.
- 3.7. The University HREC may consult or seek advice from an expert(s) to assist in the review of a research proposal, subject to the disclosure and management of any conflict of interest and to the provision of the same undertaking of confidentiality as required from HREC members.

#### **4. Appointment of Members**

- 4.1. Prospective members of the University HREC may be recruited by direct approach, nomination or by advertisement. Advertisement is mandatory for recruitment of lay members.
- 4.2. Members will be appointed by the DVC-R and will receive a letter including the date of appointment, length of tenure, responsibilities, a confidentiality statement and confirmation that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a University HREC member.
- 4.3. The DVC-R may terminate in writing the appointment of any HREC member if the DVC-R is of the opinion that:
- It is necessary for the proper and effective functioning of the University HREC;
  - The person is no longer qualified or fit to serve on the University HREC; or
  - The person has failed to carry out their duties as a University HREC member.
- 4.4. The Chair(s), Deputy Chairs, lay members and non-institutional members will be offered remuneration, as set out by the University.
- 4.5. Members will be required to sign a statement undertaking:
- That all matters of which he/she becomes aware during the course of his/her work on the University HREC will be kept confidential;
  - That any conflicts of interest that exist or may arise during his/her tenure on the University HREC will be declared.

#### **5. Training for University HREC members**

- 5.1. Newly appointed members will be provided with induction training in accordance with the National Statement.
- 5.2. During their tenure, members will be given the opportunity to attend training that is relevant to the work and responsibilities of the University HREC.

#### **6. University HREC Executive Committee**

- 6.1. The University may establish a sub-committee to conduct activities not required to be performed by a full University HREC, known as the HREC Executive.

- 6.2. Activities that may be reviewed, considered and, where appropriate, approved by the HREC Executive include the following, as well as other activities as approved by the University :
- Low risk research proposals;
  - Requests for recognition of ethical approval by another HREC;
  - Researcher responses to questions/deficiencies identified by the University HREC during review of a research proposal;
  - Requests for modification to approved research proposals;
  - Annual reports;
  - Requests for extension of ethical approval;
  - Requests for advice or queries from researchers;
  - Requests for approval of recruitment advertising on campus;
  - Complaints.
- 6.3. The HREC Executive will meet as often as required. The composition of the HREC Executive will be approved by the University. The HREC Executive may seek advice/input from the University HREC or University HREC members, if required, before reaching a decision. Approvals by the HREC Executive will be reported to/ratified by the University HREC at a subsequent HREC meeting.

## **7. Review of Low Risk Research Proposals**

- 7.1. The University may establish processes for the review of low risk research proposals outside a full HREC setting, in accordance with the National Statement. Such procedures must be approved by the University HREC, and may include review by the HREC Executive, Faculty/School Sub-Committees, and/or Heads of School as appropriate based on the level of risk involved.
- 7.2. Reviews and approvals conducted outside a full University HREC will be reported to the University HREC at a subsequent meeting.

## **8. Meetings**

- 8.1. Each University HREC Committee is expected to meet approximately 12 times per year at monthly intervals, or as required.
- 8.2. Meeting dates and agenda closing dates will be published in a timely manner on the University Human Ethics website.
- 8.3. Any member of the University HREC who has an interest, financial or otherwise, in a proposal or other agenda item considered by the University HREC, should as soon as practicable, declare such interest. If the member is present at the meeting at which the relevant project will be discussed, the member must withdraw from the meeting until the University HREC's consideration of the matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision-making process. All such declarations of interest and absence of the member during discussions will be minuted. The withdrawal of a member from the meeting will be disregarded for quorum purposes.
- 8.4. The University HREC will endeavour to reach a decision by general agreement. This need not involve unanimity.

## **9. Post Approval Responsibilities**

- 9.1. The University HREC will monitor approved projects in terms of compliance with the University HREC's ethical approval. The University HREC requires researchers to provide a report annually, and on completion of the study. The University HREC may additionally request and discuss information on any relevant aspects of the project with the researchers at any time.
- 9.2. The University HREC will, as a condition of approval of each project, require that researchers report as soon as practicable anything which might warrant review of ethical approval of the project, including:
- Proposed changes to the protocol or conduct of the study;
  - Unforeseen events that might affect continued ethical acceptability of the project;
  - Serious or unexpected adverse events (investigators of clinical trials should report these to the HREC within 72 hours);
  - If the project is abandoned for any reason.
- 9.3. The University HREC may adopt any additional appropriate mechanism for monitoring as deemed necessary, including site visits and random audits.

## **10. Records and reporting of the University HREC**

- 10.1. The Ethics Administration Officers will prepare and maintain written records of the University HREC's activities, including agendas and minutes of all meetings of the University HREC.

- 10.2. The Ethics Administration Officers will prepare and maintain a file for each application received including copies of the relevant correspondence between the applicant and the HREC.
- 10.3. Files will be kept securely and confidentially in accordance with the requirements of the Records and Information Privacy Act 2002 and the University's policy on storage and retention of research data.
- 10.4. Records will be securely held for sufficient time to allow for future reference. The minimum period for retention for University proposals is 7 years from the date of completion of a project for general research and 15 years for clinical trials.
- 10.5. The University HREC will provide periodic reports to the DVC-R, which will include information on membership, meetings, the number of research proposals reviewed, complaints received and their outcome along with any other general issues.
- 10.6. The University HREC may, from time to time, bring to the attention of the DVC-R issues of significant concern or on which guidance or policy is required.
- 10.7. The University HREC will provide annual reports to the NHMRC in accordance with its requirements.
- 10.8. The University HREC Terms of Reference will be posted on the Human Ethics website of the University.

## **11. Complaints and Review**

- 11.1. Any concern or complaint about the conduct of a project should be directed to the attention of the Manager of Human Ethics or other person nominated by the University HREC or Director Research Integrity to receive such complaints, whose contact details will be quoted on all approved research project Participant Information Statements. The Manager of Human Ethics or nominee will investigate complaints and consult with the Director Research Integrity, the University HREC, the HREC Executive or other personnel as required. Complaints relating to the ethical approval of a research project will be notified to the University HREC.
- 11.2. Any concern or complaint about the University HREC's review process should be directed to the Director Research Integrity, who will investigate or delegate the investigation of the complaint.
- 11.3. An applicant with a complaint about the University HREC's rejection of their application should bring the complaint to the attention of the Director Research Integrity, who will investigate or delegate the investigation of the complaint.

## **12. Amendments to the Terms of Reference**

- 12.1. These Terms of Reference may be amended in consultation with the University HREC.