

## **HREC Member More than Low Risk Research Review Guide**

### **Terms of reference**

- Each UNSW HREC will operate in accordance with the terms of reference outlined in the UNSW Human Research Ethics [Procedure](#).

### **Composition of the HRECs**

The composition of the UNSW HRECs is in accordance with the requirements of the National Statement. As far as possible, men and women will be represented in equal numbers and at least one third of the members are from outside the university. The membership of each HREC comprises at least eight representatives from the following categories (National Statement 5.1.30):

- Chairperson with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- Lay Woman who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- Lay Man who has no affiliation with the institution and does not currently engage in medical, scientific, legal or academic work;
- Health Professional with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- Pastoral Care Person who performs a pastoral care role in the community;
- Lawyer who is not engaged to advise the university; and
- Researchers/Content Specialists (at least two) with current research experience that is relevant to research proposals to be considered for review.

### **Appointment of HREC members**

- HREC members are recruited by direct approach, nomination or advertisement. Prospective members are asked to provide a written expression of interest and current curriculum vitae, along with a letter of support from the Head of School or Institute for academic members or contact details for professional referees for external members.
- Expressions of interests are reviewed, and any potential members will be invited to attend a meeting with the HREC Executive. Following the meeting the HREC Executive will make a written recommendation to the Deputy Vice Chancellor Research on whether or not to appoint a member.
- All HREC members are formally appointed by the DVCR following a recommendation for appointment from the Presiding Member for Human Research Ethics and the Director of RECS. Members are appointed for a term of three years, with the possibility to renew membership for a maximum of one more term as decided by the DVCR.
- Memberships may be terminated by the DVCR at any time by providing not less than 24 hours' notice in writing. Members may voluntarily retire during their appointment by providing not less than 24 hours' notice in writing to the DVCR. Members who are staff of UNSW may need to seek approval from their Head of School or Dean prior to submitting a notice of retirement.
- UNSW offers remuneration for HREC members external to the University and professional development for HREC members in general as determined by the DVCR to allow members to fulfil their duties according to the National Statement and UNSW policies and procedures.

### **Scheduling of HREC Meetings**

- Each HREC will meet as required, normally monthly from February to December, to review more than low risk applications and discuss other agenda items as relevant to their terms of reference. The quorum for these meetings is at least eight representatives from the

above categories as required by the National Statement, with each member representing one membership category only.

- Meetings dates will be made available to HREC members before the end of each calendar year.

### **Processing, compliance and pre-review checks of new submissions**

- A compliance and pre-review check of initial human research submissions will be conducted by the Human Ethics Office.
- Incomplete submissions will have a list of items to be addressed and returned to the research team with a request to submit by the next available closing date.

### **Allocation of new submission to a meeting agenda**

- Complete submissions with sufficient detail to allow the HREC to assess the ethical acceptability of the research against the National Statement will be assigned to a meeting agenda.
- A first and second spokesperson with knowledge or background expertise is assigned to each submission.
- The meeting agenda, meeting location, spokesperson allocations, submissions for review, minutes from previous meetings or minutes of meetings conducted by the HREC Executive and any general business items will be circulated to committee members at least 7-10 days prior to the meeting.

### **Ethical review of new submissions prior to the meeting**

- Committee members must notify the Human Ethics Office of any conflicts (real or perceived) that they may have with the submissions under review.
- Prior to the meeting committee members must review the submissions that they are allocated as first and secondary spokesperson using the HREC review guide to structure their review.
- The first and second spokesperson must review, add or remove any comments included in the shared pre-review comments document before the meeting.

### **HREC Meeting Proceedings**

- Meetings will proceed and decision-making processes will be conducted in line with the requirements set out in the Human Research Ethics [Procedure](#).
- The Chairperson will register attendance, apologies, conflicts of interests received from committee members. The committee will be asked to accept (or comment on) the minutes from previous meetings. The decisions will be recorded by the secretariat within the meeting minutes.
- Any general business items will be tabled for discussion and the outcome of these discussions will be recorded by the secretariat within the meeting minutes.
- The first and second spokesperson will be asked to outline their review of new submissions. In order to ensure that all submissions have equal time allocated for discussion the guide for discussion times should be adhered to.
- A committee discussion and decision about the ethical acceptability of the ethics submission will be made based on the general consensus of all members. All outcomes and decisions will be recorded by the secretariat.

### **Minutes and Dissemination of Outcomes**

- The minutes will be drafted following the meeting and sent to the chairperson for approval within 5 days of the meeting.
- Outcome letters that require further clarification will be disseminated to the research team via email.
- Recommendations to approve new human ethics submissions will be sent to the Deputy Vice Chancellor Research and once approved outcome letters will be disseminated to the research team via email.

## Human Research Ethics Committee Review Guide

Project Description	Ethical Principle(s)
Section 1 & 2	<p><b>Research merit and integrity</b> The research proposal must clearly outline each of the following, if it does not the ethical principle that requires research to have merit has not been met. In the reviewer section outline the areas of the proposal that do not meet this requirement, along with an indication of the revisions to be made that link to a requirement of the National Statement.</p> <ul style="list-style-type: none"> <li>The potential benefits of the research.</li> <li>A review of current literature, as well as previous studies that support the current research</li> </ul>
Section 3	<p><b>Research merit and integrity</b> The research proposal must clearly outline each of the following, if it does not the ethical principle that requires research to have merit has not been met. In the reviewer section outline the areas of the proposal that do not meet this requirement, along with an indication of the revisions to be made that link to a requirement of the National Statement.</p> <ul style="list-style-type: none"> <li>The manner in which research has been designed/ developed using methods appropriate for achieving its aims.</li> <li>The expertise, qualifications or competence of the research team.</li> </ul> <p><b>Respect</b></p> <ul style="list-style-type: none"> <li>The process of engagement and establishment of agreements by the research team with participant populations to ensure respect for their welfare, beliefs, perceptions, customs and cultural heritage.</li> </ul>
Section 7 & 8	<p><b>Justice</b> The research proposal must clearly outline each of the following, if it does not the ethical principle that requires research to be just has not been met. In the reviewer section outline the areas of the proposal that do not meet this requirement, along with an indication of the revisions to be made that link to a requirement of the National Statement.</p> <ul style="list-style-type: none"> <li>A fair and transparent process for selecting, excluding and including research participants.</li> <li>A clear recruitment and consent process that does not have the potential to place an unfair burden of participation in the research on particular groups.</li> <li>A process for ensuring that the benefits of participation in the research are fairly distributed to those that take part.</li> <li>A plan for ensuring that participants are not exploited during the conduct of the research.</li> <li>A strategy for ensuring that the benefits of research and its outcomes are made accessible to research participants in a way that is timely and clear.</li> </ul> <p><b>Respect</b></p> <ul style="list-style-type: none"> <li>A plan for ensuring that participants who are unable to make their own decisions or have diminished capacity to do so are included in the recruitment process and discussions about their involvement in the research.</li> <li>A plan for ensuring that throughout the research process, participants are provided with opportunities to make their own decisions in relation to their involvement in the research.</li> </ul>
Section 10	<p><b>Beneficence</b> The research proposal must clearly outline the following, if it does not the ethical principle that outlines the benefits of the research has not been met. In the reviewer section outline the areas of the proposal that do not meet this requirement, along with an indication of the revisions to be made that link to a requirement of the National Statement.</p> <ul style="list-style-type: none"> <li>An accurate list of harms or discomforts participants may (or have the potential to) experience as a result of the research procedures.</li> <li>The harms or discomforts in the recruitment or consent materials.</li> <li>Appropriate strategies for minimising the risk of a participant experiencing harms or discomforts.</li> <li>Appropriate strategies for providing care or support to participants if an event related to the research occurs.</li> <li>A plan to assess or discontinue the research if the risks of the research are no longer justified by the benefits.</li> </ul>
Section 11	<p><b>Respect</b> The research proposal must clearly outline each of the following, if it does not the ethical principle that outlines the benefits of the research has not been met. In the reviewer section outline the areas of the proposal that do not meet this requirement, along with an indication of the revisions to be made that link to a requirement of the National Statement.</p> <ul style="list-style-type: none"> <li>The plan for ensuring that the privacy, confidentiality and/or cultural sensitivities of the participants (and where applicable their communities) is respected.</li> </ul>
Decision	<b>Outcome of ethical review</b>
	<b>Recommended:</b> The research should be recommended for approval without revision but may include conditions of approval (e.g. provision of letters of support).
1.	<b>2. Subject to:</b> The research can be recommended for approval subject to the following clarifications being addressed and reviewed by the HREC Executive.
3.	<b>4. Deferred:</b> The research team must address the following clarifications and the revised submission must be returned to the HREC for review at its next meeting.
5.	<b>6. Rejected:</b> The research cannot be approved as it has been deemed to be unethical.
7.	<b>8.</b> Have you added and/or removed the comments that you would like returned to the research team to the shared pre-review document?
9.	<b>10.</b> Have you ensured that these comments can be linked to a requirement of the National Statement?