HUMAN RESEARCH ETHICS COMMITTEE
AND
FACULTY HUMAN RESEARCH ETHICS SUB-COMMITTEES

The Human Research Ethics Committee at The University of Western Australia conforms to the requirements of the National Health and Medical Research Council (NHMRC) publication National Statement on Ethical Conduct in Research Involving Humans (National Statement). This National Statement identifies the ethical principles and values which should govern research involving humans. The NHMRC requires all institutions or organisations that receive NHMRC funding for research to establish a Human Research Ethics Committee (HREC) and to subject all research involving humans, whether relating to health or not and whether funded by the NHMRC or not, to ethical review by that committee.

Currently the HREC at the UWA reviews applications for ethical approval. The HREC membership complies with the National Statement and has three representatives from the community. Currently, four Schools within the UWA that have large numbers of undergraduate students conducting research projects have sub-committees with delegated authority to grant ethical approval for projects with minimal ethical significance. These approvals are then endorsed by the main HREC.

The number of applications submitted to the HREC has, over the past three years, increased to a level that is unmanageable. Meetings are held monthly and typically, members of the HREC must evaluate approximately 20-25 applications prior to each meeting, and then discuss each application at the meeting. The outcomes of these discussions are then communicated in writing to applicants along with a decision pertaining to the status of the application. This increased workload has resulted in excessive workloads for committee members, lengthy monthly meetings, and in some instances delays for researchers in initiating their research programmes. Hence, following a review of the HREC and the processes it undertakes, a revised and more devolved system is proposed which not only addresses the issues highlighted, but also increases quality control. It is proposed that Faculties assume an increased role in meeting compliance with the National Statement on Ethical Conduct in Research Involving Humans. To this end it is proposed that UWA Faculties establish their own HREC sub-committees and assume responsibility for the decisions reached pertaining to ethics approval. These sub-committees will report directly to the UWA HREC.

It is proposed that if the research involves no more than normal, everyday risk to the participants, it is not necessary to obtain ethical approval. For example, in quality assurance activities or audit, the collection of oral histories and market research studies. Undergraduate students (and Masters by coursework students) conducting education based research projects should not normally require approval by the HREC. These projects should have a training and practical experience focus. Neither the student nor the participants should be exposed to any risk.

FACULTY HUMAN RESEARCH ETHICS SUB-COMMITTEES

The nine Faculties at the UWA will be required to establish Human Research Ethics Sub-Committees (HRESC). These Faculties not conducting large volumes of research involving human participants should consider combining with a Faculty that is more actively engaged in such research.

Membership

HRESCs must consist of at least three members of the academic staff, with members drawn from each school within the Faculty.

(for example):

- a Chair who is the Head of the Faculty or nominee
- the honours programme or graduate programme coordinator
- a member of the Faculty who has recent experience in obtaining ethical approval from the HREC
Where faculties establish a joint FHRESC, staff from each of the faculties will be members (i.e., both postgraduate co-ordinators, two members with recent HREC experience)

(Members of the FHRESC may not review their own research)

Responsibilities

FHRESCs will have the responsibility, on behalf of the HREC, to provide preliminary assessment and to:

- determine if research projects require ethical review
- grant expedited approval if the projects are of academic merit and involve minimal risk to participants and researchers
- refer research projects to the HREC if there are significant ethical implications
- (Consider establishing project-within-program applications)

FHRESCs must:

- meet regularly during the year, or where projects are reviewed by circulation between meetings, a cover sheet for comments should be kept.
- keep appropriate records of meetings and all applications considered and forward minutes of the meetings to the HREC
- ensure that investigators are appropriately qualified
- ensure that proper arrangements are made for secure storage and disposal of confidential data
- monitor all research projects approved at FHRESC level in accordance with the National Statement on Ethical Conduct in Research Involving Humans.

Reporting

The FHRESC must provide an annual report to the HREC of its activities, including

- current membership, including name of Chair
- details of procedures for considering applications, (e.g. frequency of meetings or circulation details)
- list of all minimal risk research proposals approved by expedited review
- procedures for monitoring projects
- maintenance of security of data
- problems which may have arisen (e.g. complaints, adverse events)
- (list of project-within-program applications approved)

It is proposed that FHRESCs invite a member of the UWA HREC to monthly meetings, the purpose being to provide advice when and where necessary and to ensure that research applications meet criteria for approval. This exercise is intended to be a constructive one and to assist FHRESCs in establishing effective procedures. Similarly, members of the FHRESCs will be invited to attend meetings of the UWA HREC.

If a research project is assessed to involve more than “minimal ethical risk”, the application must be referred to the UWA HREC.

In determining whether a project should be referred to the HREC, use should be made of the Expedited Review Checklist:

Research proposals involving the following should always be referred to the UWA HREC:

- Research with Indigenous Australians
- Researching involving persons in correctional institutions
- Research involving personal data obtained without consent
- Research involving use of personal data obtained from a Commonwealth or State Government Department or Agency
- Recruitment via a third party without consent (i.e. breach of Privacy Act)
- Genetic testing
- Research involving personal sensitive issues
- Research involving psychological disorders
- Research involving criminal activities
- Research involving deception or covert observation
- Research involving audio or visual recording without consent
- Clinical trials
- Research involving the administration of a placebo.

The above list serves as a guide and should not be considered comprehensive.
EXPEDITED REVIEW CHECKLIST
FOR
FACULTY HUMAN RESEARCH ETHICS SUB-COMMITTEES

If your planned research project does not present any more than minimal risk to participants, it might be eligible for expedited review by your Faculty Human Research Ethics Sub-Committee (FHRESC).

If however, your project does have more than minimal risk to participants, it should be forwarded to the Human Research Ethics Committee for ethical review.

(NB: It is not acceptable to seek expedited review because of timing constraints.)

HOW TO APPLY FOR EXPEDITED APPROVAL: STEP-BY-STEP GUIDE:

1. Complete the following checklist to determine whether your research project is eligible for expedited review on the basis that it involves minimal ethical risk. Student researchers should complete the checklist with their supervisors.

2. If you answer "NO" to all of the following questions, sign this form and submit it together with a completed Application to Undertake Research Involving Human Subjects to your Faculty Human Research Ethics Sub-Committee for expedited review.

<table>
<thead>
<tr>
<th>Chief Investigator (must be a member of UWA staff):</th>
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<tbody>
<tr>
<td>Student researcher’s name:</td>
</tr>
<tr>
<td>Faculty:</td>
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<tr>
<td>School:</td>
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<tr>
<td>Title of Project:</td>
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SECTION ONE: EXTERNAL REQUIREMENTS

Is the project the subject of a grant application to a large funding body such as NHMRC, ARC, Healthways etc. that requires review by an HREC that has community representation?

Yes ☐ No ☐

If you have answered yes to this question, you are required to submit a full application to the HREC.

SECTION TWO: RISK ASSESSMENT

Does the research involve:

- The intentional recruitment of vulnerable groups who might be particularly put at risk by participation?

  Yes ☐ No ☐

- The recruitment of Aboriginal or Torres Strait Islander peoples or other identifiable cultural/minority groups?

  Yes ☐ No ☐

- Sensitive personal issues? (e.g. suicide, gender identity, sexuality, fertility, abortion, gambling)

  Yes ☐ No ☐

- The recruitment of persons with psychological disorders?

  Yes ☐ No ☐

- Illegal activities, illicit drug taking, substance abuse or self-report of criminal behaviour?

  Yes ☐ No ☐
• Any act that might diminish self-respect or cause shame, embarrassment or regret?  
Yes ☐  No ☐

Does the research involve the following procedures:

• Use of personal data obtained from Commonwealth or State Government Departments?  
Yes ☐  No ☐

• Use of medical records without consent?  
Yes ☐  No ☐

• Use of medical records where participants can be identified or linked?  
Yes ☐  No ☐

• Breaches of the Privacy Act?  
Yes ☐  No ☐

• Deception of participants?  
Yes ☐  No ☐

• The offer of disproportionately large inducements to participate?  
Yes ☐  No ☐

• Audio or visual recording without consent?  
Yes ☐  No ☐

• Withholding of beneficial treatment from a control group or administration of a placebo?  
Yes ☐  No ☐

• Invasive physical interventions or treatments?  
Yes ☐  No ☐

• Administration of drugs or any other substances?  
Yes ☐  No ☐

• Tissue sampling, blood taking or collection of bodily fluid?  
Yes ☐  No ☐

• Genetic testing?  
Yes ☐  No ☐

• Drug trials, clinical trials or ionising radiation?  
Yes ☐  No ☐

SECTION THREE: CONSENT ISSUES

Does the research involve participants whose consent could be compromised by any of the following:

• Physical vulnerability?  
Yes ☐  No ☐

• Psychological disorder?  
Yes ☐  No ☐

• Dependency relationship, e.g. a participant under medical care, in an employer/employee relationship, teacher/student?  
Yes ☐  No ☐

• Minors without parental or guardian's consent?  
Yes ☐  No ☐

• Residency of a custodial institution?  
Yes ☐  No ☐

• Language difficulties?  
Yes ☐  No ☐

• Literacy difficulties?  
Yes ☐  No ☐

SECTION FOUR: RESEARCH IN OVERSEAS SETTINGS

Does the research involve:

• Research into politically sensitive or cultural issues?  
Yes ☐  No ☐

• Research which might put researchers or participants at risk?  
Yes ☐  No ☐
If your answers to all of the above questions are "NO", sign this form and submit it together with a completed Application to Undertake Research Involving Human Subjects to your Faculty Human Research Ethics Sub-Committee for expedited review.

JUSTIFICATION FOR SPECIAL CASE

If, however, some of the answers to the above questions are "YES", you might still be eligible for expedited review. Please provide below particular specific reasons for why your application should be given special consideration for expedited review.

It is not acceptable to expedited review because of timing constraints.

Researcher's Signature:
Date:

Student's Signature:
Date:

Certification of by Chair of FHREC:

The FREC has considered the particulars of the above project and recommends it for expedited review.

Signature of Chair of FHREC:
Date: