

These Guidelines are the basis for the operation of a two tier system for approving research involving human participants at Curtin University of Technology. The Guidelines have been developed in accordance with the provisions of the National Health and Medical Research Council's publication *National Statement on Ethical Conduct in Human Research*.

### **Background**

The Human Research Ethics Committee (HREC) of Curtin University of Technology is responsible for the review of research proposals involving human participants. The *National Statement on Ethical Conduct in Human Research*, to which Curtin is bound, states that

*The purpose of the National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.*

Research involving human participants occurs at all levels of endeavour at Curtin. Whilst the University has a responsibility to ensure that research involving humans is adequately reviewed for ethical aspects, the volume of research is large. This situation requires the establishment of processes that can ensure all research involving humans is appropriately reviewed for ethical considerations.

The section of the *National Statement* most relevant to these Guidelines are Sections 2 "Themes in Research Ethics: Risk and Benefit, Consent" and 5 "Processes of Research Governance and Ethical Review": (refer to the following sub-sections):

- Institutional Responsibilities (5.1)
- Low Risk (Section 2)
- Responsibilities (5.2)

Section 5.1 specifically allows for the establishment of "procedures for expedited review of research involving low risks to participants".

These Guidelines provide a means for the approval of 'low risk' research, operated within the schools or faculties as appropriate and monitored by the Human Research Ethics Committee. This level of ethics approval is referred to hereafter as the second tier. The first tier, the Human Research Ethics Committee, reviews ethics applications for research that is considered to be more than low risk.

### **Structure of Second Tier**

A research ethics coordinator is to be appointed in each School where there is a significant volume of research involving human participants. In addition to the coordinator, each school or faculty should appoint trained staff to help with the review of research projects. Training is coordinated by the Office of Research and Development.

The second tier (i.e. research ethics coordinator in each area) is required to report to the first tier (Human Research Ethics Committee) with details of all approved projects two weeks before each meeting of the Human Research Ethics Committee. ([Meeting Dates](#))

The Human Research Ethics Committee will also conduct periodic audits of applications that have been approved by the second tier as a means of monitoring the quality of the system.

### **Responsibilities of the Second Tier**

The main responsibilities of the second tier are to:

- *approve low risk projects* as defined by the National Health and Medical Research Council "National Statement on Ethical Conduct in Human Research"
- *refer other projects to the Human Research Ethics Committee*
- *communicate approvals to the applicants* (e.g. copy of signed application form)
- *keep records of all approvals* (using a standard spreadsheet format)
- *store copies of applications in the School* and
- *report approvals to the Human Research Ethics Committee, in time for each meeting of the Human Research Ethics Committee, which ratifies each approval or reviews it in detail.*

1. **Approve low risk projects.** Subject to the final agreement by the Human Research Ethics Committee at its regular meetings. The second tier may grant ethics approval to research involving humans in cases where a project is deemed to be low risk and raises no significant ethical issues. The term low risk is defined in the *National Statement on Ethical Conduct in Human Research* as:

*research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.*

In all cases where the research is deemed to be more than low risk, the researcher will be required to submit a Form A. Schools however may develop their own criteria to determine further the kinds of research that can be approved by the second tier, which may or may not be related to levels of academic type. For example, a school may decide that for its discipline(s), all research conducted at a particular level (e.g. Master's by Coursework or higher) will require that the applicant complete a Form A for consideration by the Human Research Ethics Committee (the first tier).

An application may not be approved through the second tier where the research project is to be conducted in a hospital or other health care provider, or involves persons highly dependent on medical care, or involves epidemiological research.

2. **Refer other projects to the Human Research Ethics Committee.** The research ethics coordinator (or reviewer) in the second tier must first assess whether the application is for low risk research, and whether the research is free from potentially complex ethical issues. If the coordinator considers there is potential for risk to participants then the applicant should be instructed to fill out Application Form A, and submit to the Human Research Ethics Committee for consideration (See [Form A Guidelines](#)).
3. **Communicate approvals to the applicants.** Applicants must receive written notification of approval prior to project commencement. A copy of the approved application form (Form C) is appropriate, which should clearly show the period of approval, any conditions, and the approval number.
4. **Keep records of all approvals.** All approved projects must receive a unique ethics approval number that is recorded on the application form. Approval details must then be entered into the standard spreadsheet.

The minimum information needed for entry to the spreadsheet is that which is recorded in the Human Research Ethics Committee agenda documentation:

- approval number
- title of project
- investigator
- School
- supervisor (if applicable)
- approval date
- expiry date of approval
- type of project (eg honours)
- reviewer name.

5. **Store copies of applications in the School.** A copy of Application Form C, including the attachments, must be stored in the school, in accordance with University policy issued by the Records and Archives Office.
6. **Reporting of approvals to Human Research Ethics Committee.** All projects granted ethics approval by the second tier must be reported to the Human Research Ethics Committee.

Reporting by the second tier to the Human Research Ethics Committee should be done prior to each Human Research Ethics Committee meeting ([Meeting Dates](#)). Any ethical issues arising from projects should also be reported.

Second tier approvals are subject to random audit and to further review by the HREC.

#### **Application Forms and Documentation Required of Applicants**

Applicants applying for ethics approval at the second tier level must submit the following:

- Form C – Application for Approval of Research with Low Risk (Ethical Requirements)

- Checklist for Research Involving Humans or Information About Humans (front page to Form C)
- description of the methods and ethical issues
- instruments (if applicable)
- consent form (if applicable)
- information sheet (if applicable).

### **Responsibilities of Research Ethics Coordinators and Reviewers**

Coordinators and reviewers in the second tier are required to observe the following guidelines:

1. A coordinator/reviewer in the second tier may not consider for approval an application from an applicant of a research project for which he/she is a supervisor or a unit coordinator, or is otherwise involved in the research project. Therefore a second or third person will need to be trained as a reviewer to assess those applications where there may otherwise be a conflict of interest and in so doing maintain the integrity of the approval process.
2. A coordinator/reviewer in the second tier may not consider for approval an application Form C where the research project is to be conducted in a hospital or other health care provider, or involves persons highly dependent on medical care, or involves epidemiological research. The applicant will be required to complete a Form A.
3. A coordinator/reviewer in the second tier may not consider for approval an application Form C for a research proposal: (a) where an application for funding is being made or has been made to an agency external to Curtin, and (b) where that funding body requires evidence of ethics approval. An application Form A will need to be submitted to the Secretary, HREC, for consideration.
4. Where a school has introduced a more stringent policy regarding application procedures for research involving humans above that which is contained in these Guidelines, coordinators and reviewers must ensure that the school policy is followed. For example, a school may rule that research undertaken at a certain level (such as master's degree by coursework or higher), regardless of topic or discipline, cannot be approved using the low risk Form C application and that a Form A is required at these specified levels.
5. Prior to reviewing applications, coordinators and reviewers will be required to attend a training seminar provided by the Human Research Ethics Committee, which will provide essential resource materials such as *the National Statement on Ethical Conduct in Human Research*.
6. In assessing applications, coordinators and reviewers are required to apply the provisions of the *National Statement on Ethical Conduct in Human Research* and any Guidelines approved under Commonwealth/State legislation or University policy which have relevance to the ethics of research involving humans.
7. Coordinators and reviewers have a responsibility to stay informed of any changes to guidelines/legislation at a National and University level which have relevance to the ethics of research involving humans, as communicated by the Human Research Ethics Committee.

### **Administrative Support**

Support for the second tier is provided by the Human Research Ethics Committee in the following capacity:

- all forms and procedures to be housed on the ethics web page of the Office of Research and Development website (<http://research.curtin.edu.au/ethics/human.cfm>)
- electronic copies of the standard spreadsheet to be provided to the ethics coordinators
- training in research ethical requirements to be provided to coordinators and reviewers as required
- updated or new information to be provided to ethics coordinators and reviewers as necessary.