

FORMS AND ADMINISTRATIVE PROCEDURES

Applications for ethical approval of projects involving humans are made to the Human Research Ethics Committee using one of the following forms, as appropriate:

- FORM A** Application for Ethics approval of Research Involving Humans (new project)
- FORM B** Application for Renewal / Progress Report (previously approved project)
- FORM C** Application for Approval of Research with Low Risk (Ethical Requirements) (new project)

For forms please visit the Research and Development website: <http://research.curtin.edu.au/ethics/human.cfm>

Submit copies of FORM A and FORM B to:

Secretary, Human Research Ethics Committee, Office of Research and Development
Level 1, Building 100, Curtin University of Technology, GPO Box U1987, Perth 6845.
(Form B must be submitted if your research changes, finishes or there are problems).

One original and two (2) complete copies of the Form A application is required for submission.

Submit FORM C applications to:

The Ethics Coordinator in the relevant School or Faculty

Queries

If the applicant or reviewer has any uncertainty or doubts in regard to ethical issues the application should be referred to the Human Research Ethics Committee, C/- the Secretary.

Phone (08) 9266 2784, Fax: (08) 9266 3793 or Email: hrec@curtin.edu.au

Approval is granted for one year and is subject to renewal. You must apply to renew your research approval each year or if there are changes to the protocol. Research approvals may be renewed a maximum of three times. To continue beyond four years a new application (Form A or Form C) must be submitted.

Form A

The majority of Form A applications are not referred to the full committee but are reviewed by a small panel of 2-3 people. The sub-committees recommendations are then considered by the full Committee. The review process will ordinarily take an average of one month.

Applications involving physically invasive procedures with a moderate to high degree of risk are considered at HREC meetings. Examples include injections or clinical trials. Applicants should refer to the meeting dates published on the Office of Research and Development website (<http://research.curtin.edu.au/ethics/human.cfm#dates>) for meeting dates. Meetings are held every month.

If an application is deemed to require further information or amendment, the researcher will be contacted in writing and advised accordingly. Applications will be approved only when the Committee is satisfied that all ethical considerations have been addressed and associated documentation provided.

Masters and Doctoral research proposals

In some Schools and Faculties an application for ethics approval at the level of Doctoral or Masters normally will require the completion of a Form A. Students unsure about whether ethics approval is required should refer to the checklist in the *Application for Candidacy for Higher Degrees by Research* (also in Forms A and C).

Attachments

Applications MUST include all relevant attachments where applicable, eg:

- Participant Information Form
- Consent Form
- Advertisements and letters of invitation
- Survey instruments including list of intended questions for interviews (or, if not yet developed, the proposed content of the instrument)
- Details of ethical approval from other Institutional Ethics Committees as applicable
- Description of project.

Form C

Some research, particularly undergraduate research, may be regarded as minimal risk. If this is the case, the applicant should normally complete a Form C "Application for Approval of Research with Minimal Risk (Ethical Requirements)" to be submitted to the ethics coordinator or reviewer in the relevant School or Faculty. In assessing the application the reviewer will decide whether the application can be approved or whether amendment is required. Alternatively, if the reviewer believes the risk associated with the research is not minimal, the applicant may be instructed to complete the more extensive Form A for submission to the Secretary, HREC for assessment by other reviewers. Further information for applicants is contained in the Form C application.

Form B (ethics previously approved)

Investigators who have current ethics approval for a project are required to complete and submit for approval a *Progress Report Form/Application for Renewal* (Form B) at certain times. Primarily, the Form B is used to apply for renewed approval, but is also used to report on progress, provide details of any ethical issues that may have arisen, or advise where the project has been completed or abandoned or if there are changes to the research protocol. The Form B must be completed and submitted to the Ethics Office in the following circumstances:

- Expiry date is reached** – All investigators are required to return this form two weeks before ethics approval for the project expires.
- Changes to the protocol** – If at any time during the study there is a modification to the study design, or if any ethical considerations arise, the researcher must complete and submit for approval a Form B. Modifications may include changes to the methods, information sheet, consent forms, or questionnaires. The application should provide full details of the changes and include copies of any amended documents.

Prior to the expiry date of the project, a Form B will be sent to the researcher. In the case of students this form will be distributed through the project supervisor. This form should be submitted prior to the expiry date of the project wherever possible. It is imperative that the Form B is completed and returned as it is a Commonwealth obligation of human research ethics committees to monitor research projects (at least annually) until completion and to ensure that each project continues to conform with approved ethical standards.

A project may be renewed a maximum of three times. After that a new Form A or Form C application must be submitted for review. Please allow five weeks for the review to be conducted.

NOTES FOR RESEARCHERS

Confidentiality - The applicant must indicate in detail how confidentiality and privacy will be maintained. For example, what procedures and safeguards will be employed. A simple statement of intent to maintain confidentiality is not sufficient.

Anonymity and Identifiable Participants - researchers have a responsibility to take all reasonable steps to protect participants' privacy and to inform participants fully, prior to participation, of any possible risks regarding identification in published material. Researchers should give participants the opportunity to review draft material before it is published, including interview transcripts, to further ensure that the rights and privacy of participants are protected.

Access to Curtin Staff and Students – researchers requiring access to Curtin staff or students to invite them to participate in a research study will require both the approval of (i) the Human Research Ethics Committee and (ii) the Pro Vice-Chancellor, Academic Services, in that order.

Recruitment – The applicant must demonstrate that there is no possibility of undue influence on potential participants through eg power relations such as that between clinician and patient.

Informed Consent - The application must provide details of how consent will be obtained and must include copies of the **Consent Form** and **Information Sheet**.

Risks/Benefits - The proposed benefits of the study must outweigh any potential risk, and any such risks to participants must be minimised and fully communicated to participants before consent is obtained. See Q 3 of Form A.

Adequacy of Method - Applicants should ensure that proposals provide sufficient detail in order to demonstrate to the Committee that the project is justified, relevant and that all methods are clearly outlined.

Invasive Techniques - Any proposals involving invasive techniques should automatically be referred to the Human Research Ethics Committee in order to be vetted by a suitably qualified expert.

External Institutional Approval - Proposals that require external institutional approval, ie approval from institutions outside Curtin University of Technology should be referred by formal submission to the Human Research Ethics Committee.

CONSENT FORM and INFORMATION SHEET

A *Consent Form* and *Information Sheet* must be provided to participants in all but exceptional circumstances. In preparing these documents reference should be made to the *NHMRC National Statement on Ethical Conduct in Human Research* (see paragraph on **Consent 2.2**). Paragraph 2.2 of the *National Statement* says:

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as "the requirement for consent".

This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

Other main points to note from the National Statement are listed below:

- A participant may refuse to participate without giving a reason or justification (paragraph 2.2.19).
- A participant's consent must be clearly established, and the consent of all properly interested parties obtained (paragraph 2.2.12). When appropriate, consent may need to be sought at both an individual and an organisation level.
- Consent must not be the subject of coercion or to any inducement or influence which could impair its voluntary character (paragraph 2.2.9).
- Circumstances in which consent from participants may not be necessary include: the use of non-identifiable data in epidemiological research, observational research in public places, or the use of anonymous surveys (paragraph 2.3).
- A participant must be free at any time to withdraw consent to further involvement in the research.

Consent Form

A consent form would normally include the details listed below:

- title of project
- statements of confirmation, such as -
 - “I have been informed of and understand the purposes of the study.”
 - “I have been given an opportunity to ask questions.”
 - “I understand I can withdraw at any time without prejudice.”
 - “Any information which might potentially identify me will not be used in published material.”
 - “I agree to participate in the study as outlined to me.”
- name of participant, signature and date.

Information Sheet

The main purpose of the *Information Sheet* is to provide participants with a plain language statement that clearly describes the aims of the project and the nature of involvement of participants. Participants should be clearly

informed of their rights and any risks associated with participation. At all times the researcher must observe the welfare of the participants and respect the dignity and personal privacy of the individual.

An Information Sheet must include the following:

- The aims of the project;
- A description of what will be required of the participants (include details of amount of time required of participants);
- A statement which addresses confidentiality and security of information. Details of who will have access to personal information and the purpose(s) for which participant information will be used, including whether participants would be potentially identifiable in any published material;
- A statement that advises participation is completely voluntary; participants are at liberty to withdraw at any time without prejudice or negative consequences; non-participation will not affect an individual's rights/access to other services/care (eg in the case of patients);
- Any risks / benefits to participants;
- The contact details of the investigators (and supervisor where the principal investigator is a student) should the participant require further information;
- The contact details of the Human Research Ethics Committee (Secretary) should participants wish to make a complaint on ethical grounds (phone: 9266 2784 or hrec@curtin.edu.au or in writing C/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth WA 6845);
- Confirmation that the project has been approved by the Curtin University Human Research Ethics Committee, including the approval number.

Use of Sensitive Tests

- Researchers have a duty of care if their research uncovers information about individual subjects that has a bearing on their wellbeing. If the data are valid at the individual level, the researcher has a duty of care to those discovered to be at risk.
- Diagnostic tests and procedures should only be used if they are specific to the research questions asked. Diagnostic tests should only be analysed by persons with the appropriate qualifications and competence to interpret the results.
- If the instrument used in collecting information from the participant is a diagnostic test, and has been collected by someone professionally able to interpret it diagnostically, then the duty of care may require feedback to the individual concerned or to someone responsible for the individual (such as their physician or in the case of school children, the school principal) if the individual is identified as being at risk.
- If the instrument is not diagnostic, but is still indicative or raises concerns about the individual's well-being (eg traits, states, conditions or tendencies), then feedback may still be necessary if a participant's score is extreme.
- If the instrument is non-diagnostic or non-indicative, it is recommended that data should be collected in ways that would not allow an individual's score to be identified, ie, collected anonymously.
- The Information Sheet to participants should clearly state whether the information is to be collected anonymously. If collected anonymously, it should state clearly that individual scores will not be identifiable or made available for any purpose. If not collected anonymously, the researcher should "inform potential subjects of the possibility of diagnosis and the way the results will be handled. In particular, the researcher must outline to whom and how results, which indicate that the subject of the research is 'at risk', will be communicated."
- Where feedback to an individual or carer of the individual is warranted, extreme care is necessary to avoid possible negative consequences such as 'false alarms'.
- The researcher's duty of care to participants pertains only to the information that is central to the purpose of the research.

REFERENCE PUBLICATIONS and WEBSITES

Applicants should refer to the following publications where applicable to assist with their application:

- NHMRC, "National Statement on Ethical Conduct in Human Research"
<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>
- Joint NHMRC/Universities Australia "Australian Code for the Responsible Conduct of Research"
<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>
- Where a researcher would like to use data that has already been collected by a Commonwealth agency, the researcher will need to consult the following publication:
- NHMRC "Guidelines under Section 95 of the Privacy Act 1988"
<http://www.nhmrc.gov.au/publications/synopses/e43syn.htm>

Other resources

- The Australian Privacy Commissioners Website
<http://www.privacy.gov.au/>
- Australian Association for Research in Education (AARE), Code of Ethics (pp1-5)
<http://www.swin.edu.au/aare/>
- NHMRC "Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research"
<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>
- Oral History Association of Australia "Guidelines of Ethical Practice"
<http://www.ohaa.net.au/guidelines.htm>