

SCHOOL OF PSYCHOLOGY

FORMAT FOR APPLICATIONS TO THE SCHOOL'S HUMAN ETHICS SUBCOMMITTEE

TITLE:

INVESTIGATORS, THEIR QUALIFICATIONS AND ROLES:

(e.g. Supervisor, Honours student, Research assistant)

AIM OF STUDY:

BACKGROUND:

(Brief review of major research in the area ($1/2$ - 1 page only is needed))

PARTICIPANTS:

(including source, age-range, selection criteria, and exclusion criteria)

PLAN & DESIGN:

(Outline of methods and procedures)

ETHICAL CONSIDERATIONS:

1. State any possible risks of pain, anxiety or discomfort. The requirement for consent should be considered. If a consent form is to be used, it should be appended with this application. The School's consent form, the University's consent form, or any other appropriate consent form may be proposed. Maintenance of the individual participant's privacy must be addressed. The proposed Information Sheet or letter, or invitation must be appended. Guidelines are overleaf.
2. Studies intending to recruit Psychology I students should provide a description of the educational benefit to those students.

ANALYSIS AND REPORTING OF RESULTS: (In brief)

REFERENCES:

OTHER ETHICS COMMITTEES TO WHICH PROTOCOL HAS BEEN SUBMITTED:

DATE OF PROPOSED COMMENCEMENT:

PROPOSED EXPENDITURES AND PROPOSED FUNDING SOURCE:

(The overall length, apart from references and appendices, should normally not exceed 3 pages.)

Guidelines on Information Sheet Content and Use

An Information Sheet should be given to potential research participants to assist them in their decision about involvement, and to assist if they have any query or complaint. An Information Sheet should accompany each Consent Form; and an Information Sheet or Information Letter is needed even if a Consent Form is not required.

General

1. The Information Sheet is one aspect of providing information so that people may come to informed decisions about their involvement in research. It does not replace personal communication between the investigator and the potential participant.
2. The investigator should ensure that the potential participant is given sufficient time to consider the verbal and written information provided, and to discuss it with other people if desired, before being asked to give consent to involvement.
3. The Information Sheet is to remain the property of the subject and a copy of the signed Consent Form should also be provided if requested.

Style and Content

4. Use simple language with minimal technical terminology or jargon.
5. The sheet must be translated if non-English speaking participants are to be recruited.
6. The following items will usually be included:
 - Purpose of the study.
 - The possible benefits from the study, to the participant or the community, indicating that these benefits are not certain.
 - All procedures that involve the participant including any tasks or types of questions.
 - Foreseeable risks, side effects, discomforts, inconveniences and restrictions, both immediate and later (e.g. travel, absence from work).
 - An explanation if randomisation or placebos may be used.
 - A statement that the participant may withdraw from the study at any time. If a patient, reassurance must be given that future treatment will not be prejudiced.
 - Means of ensuring confidentiality (may be on Consent Form).
 - The name, title and telephone numbers (work numbers, and if appropriate, after-hours numbers) of all members of the research group who can be contacted if any problems arise.
 - The contact details of the Convenor of the Psychology School's Human Ethics Subcommittee.

SCHOOL OF PSYCHOLOGY



TO: Chairman, Department Human Ethics Subcommittee

REQUEST FOR APPROVAL OF HUMAN RESEARCH PROJECT

DECLARATION OF COMPLIANCE WITH GUIDELINES FOR RESEARCH PROJECTS UNDERTAKEN OR SUPERVISED BY RESEARCHERS IN THE SCHOOL OF PSYCHOLOGY.

Title of Project:.....

Responsible investigator/s (staff member/s of Psychology Department.):.....

Other investigators (including external supervisors, research assistants, and Honours, Masters or Research students)

Name	School/Organisation	Role
.....
.....
.....

Notes:

1. Please follow the attached format for the application.
2. Do you propose to seek written consent? YES/NO
If YES, append the Consent Form to the Application.
3. The Subcommittee considers applications in the light of the University's guidelines for human experimentation, and the National Statement on Ethical Conduct in Research Involving Humans. These are available in the Departmental Ethics File, with the application forms. The relevant website address is www.adelaide.edu.au/secretariat/ethics/human/index.htm
4. It is University policy that data gathering may not commence until the Application has been approved.
5. The first named Responsible Investigator will be notified of the Subcommittee's decision, and any recommendations for revision.
6. Complete Applications are normally retained for monitoring by the University Human Ethics Committee.

DECLARATION

We/I conscientiously believe that the proposed questionnaires, interview schedules, psychological tests and procedures comply with the University Council's guidelines for human experimentation and the National Statement on Ethical Conduct in Research Involving Humans.

Responsible Investigator/s: Date:

Other Investigator/s Date:

..... Date:

EXTRACT FROM THE UNIVERSITY OF ADELAIDE HANDBOOK OF ADMINISTRATIVE POLICIES & PROCEDURES - COMMITTEE ON
THE ETHICS OF HUMAN EXPERIMENTATION

9. Consent

9.1 Generally, written consent of subjects to their participation in an experiment is required. Approval for the obtaining of oral consent is given only in special circumstances.

9.2 Consent forms should contain the following minimum requirements:

- (a) The title of the research project.
- (b) Reference to the Information Sheet.
- (c) A statement that the subject has been informed that information provided will be kept confidential.
- (d) A statement that makes it clear that subject is free to withdraw consent at any time.
- (e) Provision for a witness to sign.
- (f) A statement, signed by the person explaining the treatment, that the subject has been informed of and understands the proposed treatment. The person explaining the treatment must be of an appropriate status, and that status must be described on the Consent Form.

9.3 If research is to be undertaken on a child, the mentally ill or those in dependent relationships or comparable situations, it is necessary to obtain the informed consent of the parent/guardian.

9.4 Wherever possible, the Consent Form should be on the reverse side of the Information Sheet or securely affixed to it.

9.5 A standard consent form is included with the Committee's application papers .

9.6 At all times, the subject should be given a copy of the signed Consent Form and, when appropriate, a copy of the Information Sheet.

10. Information Sheet

10.1. The Information Sheet should provide subjects, at their level of comprehension, with sufficient information about the purpose, method, demands, risks, inconveniences and discomfort of the study to enable their consent to be fully informed.

10.2 A contact name and telephone number, for use by the subject, should also be included.

10.3 Whenever possible, the Information Sheet should be on the reverse side of the Consent Form or securely attached to it.

10.4 Guidelines on Information Sheet content and use are included with the Committee's application papers.

11. Experiments on Students

Where exercises are to be performed on students, either as part of a research or a teaching project, written consent must be obtained. It is a matter of judgment for the investigator whether consent is sought from the student or a parent of the student.

12. Experiments on Self

12.1 In general, experiments by a researcher on himself or herself will not be approved, as self-experimentation lacks meaningful informed consent in the manner required.

12.2 However, where the proposed procedure is in no way dangerous or unreasonable, and where objectivity in the observation of results can be maintained, self-experimentation may be approved.

13. Questionnaires

13.1 Straightforward exercises in eliciting information, where the intention is simply to gather true reports of facts (including subjects' perceptions of things) and are unexceptionable do not require clearance from the Committee. Where the information sought is concealed by some form of "trick question" and the information sought is not the ostensible information, the questioning is of ethical concern. Researchers with concerns about the ethical implications of questionnaires should consult the Committee,

13.2 Researchers anticipating questionnaires on publicly controversial issues (for example, AIDS, IVF) should approach the Committee for advice.

14. Guidelines issued by NHMRC

In addition to the NHMRC Statement on Human Experimentation and Supplementary Notes, the Committee will use other Guidelines and information papers published from time to time by the NHMRC, eg.

Guidelines on ethical matters in Aboriginal and Torres Strait Islander Health Research, 1991

Guidelines for the monitoring of research by Institutional Ethics Committees, 1994

Ethical aspects of qualitative methods in health research, 1995

Regulations for the Clinical Trial Notification Scheme 1995

Aspects of Privacy in Medical Research, 1995

Ethical guidelines on assisted reproductive technology, 1996

Copies of such documents may be seen in the Secretary's office.

15. Departmental Subcommittees

Subcommittees are established in the Departments of Psychology and Physiology to deal with straight forward research projects. Subcommittees are subject to annual audit by the Convener of the Human Research Ethics Committee.