



**APPLICATION TO UNDERTAKE RESEARCH
INVOLVING HUMAN SUBJECTS**

(RESPONSES MUST BE TYPED)

NB: Please answer all questions fully in terms which can be readily understood by an informed layperson. This form is designed to ensure compliance with the National Statement on Ethical Conduct in Research Involving Humans. <http://www.health.gov.au/nhmrc/publications/humans/contents.htm>

1. TITLE OF PROJECT (In lay terms):

**2. CHIEF INVESTIGATOR:
(Must be a member of Staff of The University of Western Australia.)**

Name

Position:

School:

Contact
Address:
UWA Mail Box
Number

Telephone
(Business Hrs):

Specify Adjunct or Clinical
position if held

Email Address:

If this is a student project please include the name, degree course and departmental address of the student. Telephone and email address should be provided if possible. **NB: If this is a Masters by Research or PhD project, students must indicate this and provide student number.**

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3. EXPECTED DURATION OF PROJECT:

Please note that the research or recruitment of participants must not commence until a date after final approval has been obtained from the HREC.

From Date of Initial Recruitment:	Date of Expected Completion:

4. FUNDING: Is this protocol the subject of a grant application? Yes [] No []

If 'Yes', what is the Agency?

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Provide details of any affiliation or financial interest in funding source and/or commercialisation of research results

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5. OTHER ETHICAL APPROVALS:

Has the protocol previously been submitted to the Human Research Ethics Committee?

Yes [] No []

Has the protocol been submitted to another Institutional Ethics Committee?

Yes [] No []

If 'Yes' to which Committee/s has it been submitted?

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What was the outcome of the submission?

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Has the protocol been submitted to the Confidentiality of Health Information Committee (CHIC)? ie: Health Department or Agency Yes [] No []

Does the Project require a “Covenant of Confidentiality”?*? Yes [] No []

(*ie: accessing private practitioner’s medical records – see Human Ethics Office web page: *Code of Practice for the use of Name-Identified Data and Covenant of Confidentiality*)

6 PRIVACY LEGISLATION:

Does this research project involve access to data held by a Commonwealth Department or agency? Yes [] No []

If your proposed research project involves access to data held by a Commonwealth Department or agency, you will have to comply with the privacy principles established under Commonwealth Privacy Legislation. Information and further documentation relating to these issues **must** be obtained from the Secretary to the Committee (Tel: 9380-3703).

Is the data to be collected, used or disclosed from an organisation in the private sector? Yes [] No []

Does the data include information that identifies the individual(s) concerned? Yes [] No []

7 AIMS OF THE PROJECT:

Please give a concise and simple description of the aims of the project. **This must be in lay terms.**

8 PARTICIPANT GROUP:

- (a) Who will be the participants? Please include size of sample(s) and variables such as age, sex and state of health. Please state clearly whether children, mentally ill individuals or persons in dependent relationships such as teacher/student, doctor/patient, staff etc. will be recruited.

- (b) From where and how will participants (including controls if applicable) be recruited? How will the initial contact be made with the participants?

- (c) Does recruitment involve the circulation/publication of an advertisement, circular, letter, email list, bulletin etc?

Yes [] No []

If 'Yes', please provide copies and details of publication

- (d) Does the research specifically target Aboriginal people or is the sample likely to include a significant percentage of Aboriginals?

Yes [] No []

If 'Yes', please refer to the NHMRC publication [*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*](#).

Please provide a statement demonstrating how the study recognises the values outlined in the above publication and which Aboriginal groups or organisations have been consulted. This statement should address the six values that lie at the heart of the Guidelines (Under the headings of items 2.2.1 to 2.2.6).

9 DETAILS OF PROCEDURES:

- (a) Please describe briefly the project methodology. Describe all procedures to which participants will be subjected, highlighting any which may have adverse consequences.

- (b) Will any chemical compounds, drugs or biological agents be administered?

Yes [] No []

If 'Yes', describe names, dosages, routes of administration, frequency of administration, and any known or suspected adverse effects. All suspected adverse events should be listed on the Information Sheet/Consent Form.

- (c) Does the research involve use of unmarketed drugs?

Yes [] No []

If 'Yes', Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) approval must be obtained before the project may proceed.

Investigational brochure enclosed.

Yes [] No []

CTN approval has been requested.

Yes [] No []

CTX approval has been requested.

Yes [] No []

- (d) Will blood or other tissue samples be taken? Yes [] No []

If 'Yes', please state site, frequency and volume of any blood or other tissue sampling.

If 'Yes', list all personnel who will be involved in this procedure.

- (e) Will there be any invasive procedures other than blood or tissue sampling? Yes [] No []

If 'Yes', please provide details of these procedures.

- (f) Will participants be exposed to ionising or non-ionising radiation? Yes [] No []

- (i) If 'Yes', please provide details including the quantitative assessment of the absorbed dose, supported either by dosimetric calculation or other information.

- (ii) If 'Yes', has the radiation Protection Office been asked for approval? Yes [] No []

If 'Yes', please attach copy of approval notification.

10 NHMRC NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS (1999) <http://www.health.gov.au/nhmrc/publications/humans/contents.htm>

- (a) Please indicate whether the protocol conforms to the *National Statement on Ethical Conduct in Research Involving Humans*. Yes [] No []
- (b) Please indicate whether the protocol conforms to the *National Statement on Ethical Conduct in Research Involving Humans* with regard to the following areas of research:
- (i) Research involving children, young people, persons with intellectual or mental impairment, persons highly dependent on medical care or persons in dependent or unequal relationships Yes [] No [] N/A []
 - (ii) Research involving collectivities Yes [] No [] N/A []
 - (iii) Research involving Aboriginal and Torres Strait Islander Peoples Yes [] No [] N/A []
 - (iv) Research involving ionising radiation Yes [] No [] N/A []
 - (v) Research involving assisted reproductive technology Yes [] No [] N/A []
 - (vi) Clinical trials Yes [] No [] N/A []
 - (vii) Innovative therapy or intervention Yes [] No [] N/A []
 - (viii) Epidemiological research Yes [] No [] N/A []
 - (ix) Use of human tissue samples Yes [] No [] N/A []
 - (x) Human genetic research Yes [] No [] N/A []
 - (xi) Research involving deception of participants, concealment or covert observation Yes [] No [] N/A []
- (c) Please address the ethical considerations of the proposed research to satisfy the Committee that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage both individual and collective (Refer Item 2.22 of the *National Statement on Ethical Conduct in Research Involving Humans*)

11 ETHICAL ISSUES

Please indicate which of the following ethical issues are involved in this research.

- (a) Does data collection require access to confidential data without the prior consent of participants? Yes [] No []

- (b) Will visual recordings be made, eg: photo, video, etc? Yes [] No []
- (c) Will audio recordings be made, eg: tape or digital, etc? Yes [] No []
- (d) Will participants be asked to commit any act which might diminish self-respect or cause them to experience shame, embarrassment or regret ? Yes [] No []
- (e) Will any procedure be used which may have an unpleasant or harmful side effect? Yes [] No []
- (f) Does the research use any stimuli, tasks, or procedures, which may be experienced by participants as stressful, noxious, or unpleasant? Yes [] No []
- (g) Will the research use no-treatment or placebo control conditions? Yes [] No []
- (h) Will any samples of body fluid or body tissue be required specifically for the research, which would not be required in the case of the ordinary treatment? Yes [] No []
- (i) Does the research involve a fertilised human ovum? Yes [] No []
- (j) Does the project use embryos beyond a period of fourteen days after fertilisation? Yes [] No []
- (k) Does the project involve the implantation of embryos, which have been the subjects of prior experimentation? Yes [] No []
- (l) Are there in your opinion any other ethical issues involved in the research? Yes [] No []

If the answer to any of the above questions is 'Yes' please amplify below. Details required of secure storage of recordings, preferably within Departmental facilities.

12. INFORMATION SHEET AND INFORMED CONSENT FORM:

Normally, each participant is given an information sheet and is required to sign a consent form.

Do you undertake to obtain written consent for each participant? Yes [] No []

- (a) If 'Yes', please attach a copy of the Information Sheet and the Consent Form to be given to and signed by all participants and/or their responsible signatory. These forms should be on departmental letterhead. The Information Sheet should describe all the procedures proposed in clear, simple terms. It should list any potential short- or long-term side effects and any hazards. **The required standard paragraph must be included at the bottom of all Consent Forms, or Information Sheets where appropriate.** (As the majority of concerns raised by the Human Research Ethics Committee are raised in connection with the Information Sheet and Consent Form, it is strongly recommended that you

consult the *Guidelines for Preparation of Information Sheet and Consent Form*, available on the Human Ethics Office web page.)

- (b) If 'No', please justify this departure from normal procedure.

13. POTENTIAL BENEFITS AND RISKS:

- (a) What are the possible benefits of this research?

- (i) To the participant:

- (ii) To humanity generally;

- (b) What in your view are the possible hazards of this research to the participants?

14. REMUNERATION:

Is any financial remuneration or other reward being offered to participants in the study?

Yes [] No []

If 'Yes', please state how much will be offered and for what purpose, e.g. to cover travelling expenses, time spent etc. Volunteers may be recompensed for inconvenience and time spent, but any such payment or compensation should not be so large as to be an inducement to participate.

15. EXTERNAL AUDITS:

Will individual results of this study be subject to an audit by any agency external to the University?

Yes [] No []

If 'Yes', who will be conducting the audit?

CHECK LIST**To assist with processing this application, I have:**

- | | |
|---|--|
| 1. answered all the questions fully; | Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] |
| 2. signed this application form and obtained the Head of Department's signature; | Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] |
| 3. enclosed the original application form , with a copy of the Information Sheet/Consent Form and any related documentation (questionnaires, letters, etc.) attached; | Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] |
| 4. enclosed eleven, complete, collated copies of the application form including Information Sheet/Consent Form and related documents as per 3 above. (making 11 copies in all including the original). | Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] |
| 5. and enclosed two copies of the full grant/research proposal. | Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] |
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Chief Investigator:

- I certify that I am the Chief Investigator named on the front page of this application form.
- I undertake to conduct this project in accordance with all the applicable legal requirements and ethical responsibilities associated with its carrying out. I also undertake to ensure that all persons under my supervision involved in this project will also conduct the research in accordance with all such applicable legal requirements and ethical responsibilities.
- I certify that adequate indemnity insurance has been obtained to cover the personnel working on this project.
- I have read the Code of Practice for the use of Name-identified Data. I declare that I and all researchers participating in this project will abide by the terms of this Code.
- I make this application on the basis that it and the information it contains are confidential and that the Human Research Ethics Committee of The University of Western Australia will keep all information concerning this application and the matters it deals with in strict confidence.

Name (Please print):

Signed:

Date:

Head of School:

I am aware of the content of this application and approve the conduct of the project within this school.

Name: (Please print):

Signed:

Date:

Last updated 1 July 2002