

# Joondalup Health Campus

## HUMAN RESEARCH ETHICS COMMITTEE APPLICATION TO UNDERTAKE RESEARCH INVOLVING HUMAN SUBJECTS

### PRELIMINARY NOTES

1. All applications must be typed in the form provided. Page breaks within the document may be altered depending on text length of responses.
2. The original of this form and 12 copies of the full proposal (**excluding this page**) should be submitted along with related documentation, questionnaires, consent forms, and other relevant materials. (**NB** Four copies only of pharmaceutical sponsor-provided protocols are required for multicentre drug trials.) All correspondence is to be addressed to The Executive Officer, Human Research Ethics Committee, Joondalup Health Campus, PO Box 242, Joondalup WA 6919.
3. Upon receipt, applications are processed by circulation to all members of the Human Research Ethics Committee (HREC), which meets five times a year. Applications will be reviewed at the next HREC meeting (if approval is not achieved sooner) and outcomes from this will be relayed to applicants.
4. Applications must comply with the NHMRC *Statement on Human Experimentation* and its *Supplementary notes, 1992* (located at [www.health.gov.au/nhmrc/publicat/polf/e35.pdf](http://www.health.gov.au/nhmrc/publicat/polf/e35.pdf)) and to *Guidelines under Section 95 of the Privacy Act 1988*.
5. Research must not be undertaken or publicised prior to receipt of written approval from the Ethics Committee
6. Reports on the progress of approved research must be submitted to the HREC annually, or by request, and at completion of the study. ***Any adverse or unforeseen events occurring during the study which effect in any way the ethical dimensions of the work should be reported immediately to the HREC.***
7. The Committee must receive copies of any reports or publications arising from the research.
8. Evidence of professional indemnity insurance for the principal researchers must be submitted with the application.
9. Approval is initially for four years, and researchers must re-apply to continue after that period.

***This form sets out a number of questions which are intended to raise some of the ethical issues which commonly arise in medical and other research. It is not intended to create a system which might inhibit research, but rather to ensure that ethical considerations are being taken seriously before the project begins. The ethical evaluation of research is not, therefore, to be regarded as an obstacle to be overcome but rather as a fundamental part of the research process.***

v05/07

## ETHICS REVIEW COMMITTEE (HUMAN RESEARCH)

This is an initial Application for approval to undertake research with human subjects.

### IN COMPLETING THIS FORM ENTRIES **MUST BE TYPEWRITTEN OR WORD PROCESSED**

Please indicate your answer to NO/YES questions by **CIRCLING** the appropriate response to the question or **deleting** the incorrect response. If you consider a question to be irrelevant to your study please indicate by **writing 'N/A'** on the form next to (or in place of) the 'NO/YES' option on the relevant question. Written answers are to commence for each question ON the "x" so responses appear in a different font and are easier to read. Take as much space as you need and adjust pagination as required.

#### SECTION 1: TITLE and SUMMARY OF PROJECT

1.1 Title of project

x

1.2 Lay description of project (not more than one page in length)

x

1.3 Please provide a literature review, providing theoretical background for the study, previous research, and references. This may be a summary or synopsis.

#### SECTION 2: INVESTIGATORS

2.1 List the following details of the Chief Investigator(s) and any Co-Investigator(s)

**Chief Investigator**

Name: \_\_\_\_\_

Title (Dr/Ms/etc): \_\_\_\_\_

Qualifications: \_\_\_\_\_

Position held: \_\_\_\_\_

Full mailing address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Mobile number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**2.2 Co-Investigator(s)**

Name: \_\_\_\_\_

Title (Dr/Ms/etc): \_\_\_\_\_

Full mailing address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Mobile number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Name: \_\_\_\_\_

Title (Dr/Ms/etc): \_\_\_\_\_

Full mailing address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Mobile number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**2.3 Supervisor(s) (if student/graduate project)**

Name: \_\_\_\_\_

Title (Dr/Ms/etc): \_\_\_\_\_

Full mailing address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Mobile number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**Please attach details of any other co-investigators or supervisors.**

<b>SECTION 3: PROJECT</b>
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- 3.1 Indicate the proposed date of commencement of the project. Researchers are reminded that ***projects may not commence before receiving the written approval of the Ethics Committee.***

x

- 3.2 Indicate the proposed duration of the project. (You are reminded that initial approval is for 4 years, and another application may be required to continue beyond this period.)

x

- 3.3 Please specify all sites (external to JHC) and departments (within JHC) in which the project is to be carried out.

x

3.4 Describe the aims and objectives of the project and the methods to be used. Include a description of all tasks, measures, and procedures. Headings must include aims, hypotheses, materials and methods, recruitment of subjects, data collection and statistical analysis.

x

3.5 Describe the possible benefits of this research to the participant(s)..

x

3.6 Describe the possible benefits of this research to the wider community.

x

3.7 Describe in your view the potential hazards of this research to the participants.

x

3.8 Who will have access to data derived from the research?

x

3.9 Please give details as to how the data will be stored and how participant confidentiality will be protected.

x

3.10 How do you intend for the results of the research to be published or presented? Specify whether and how you will provide feedback to participants.

x

<b>SECTION 4: NATURE OF RESEARCH INCLUDING RISKS</b>
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**NB:** If your study does not include the use of diagnostic tests, pharmaceutical treatment, procedures, or other clinical interventions, tick here  and go directly to 4.7.

4.1 Will this study be conducted under the CTN or CTX scheme under the *Therapeutic Goods Act 1989*?

**NO / YES**

If you answered YES, have you provided all the required documents with your application?

**NO / YES**

4.2 If the above does not apply, will any medication/drugs/invasive devices/procedures/treatments be used?

**NO / YES**

If you answered YES, give details.

x

4.3 Does the research require any physically invasive, or potentially harmful procedures?

**NO / YES**

If you answered YES, state the nature of the procedures, all the risks involved and, if possible, at what rate these risks are expected to occur. All this information must also be included in the Information and Consent Form.

x

4.4 Does the project involve the administration of any radioactive substances?

**NO / YES**

If you answered YES, give details of types of substances used and what precautions are planned for the handling of radioactive substances.

x

4.5 Does the project involve human embryos and/or gametes?

**NO/YES**

If you answered YES, give details of use and the sections of the NHMRC *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research* that apply.

**X**

4.6 Does the project involve genetic testing and/or genetic research?

**NO/YES**

If you answered YES, give details of precautions and protection afforded to participants and their families with regard to findings and implications.

**X**

4.7 Does the project involve deception, concealment and/or covert observation?

**NO/YES**

If you answered YES, give details of precautions/debriefing provided to deal with any potential distress arising.

**X**

4.8 Could the research induce any psychological or physical stress or in any other way adversely affect participants?

**NO / YES**

If you answered YES, state what form these adverse effects could take and what facilities/trained personnel are available to deal with such problems.

**X**

4.9 Are Aboriginal and Torres Strait Islander peoples likely to be significantly represented in the participants recruited?

**NO / YES**

If you answered YES, please indicate in what way indigenous sensitivities have been recognised and which indigenous groups or organisations have been consulted. Please also refer to the NHMRC's *Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.

**X**

<b>SECTION 5: ABOUT PARTICIPANTS</b>
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- 5.1 ***Please note that members of the following groups may fall naturally into the population from which you intend to recruit, and inclusion of members of any of the named groups will not automatically preclude approval of your study.***

Are the participants:

Members of the general public under 18 years of age?	<b>NO / YES</b>
Mentally ill?	<b>NO / YES</b>
Intellectually disabled?	<b>NO / YES</b>
Elderly/infirm?	<b>NO / YES</b>
Members of the armed services?	<b>NO / YES</b>
Prisoners?	<b>NO / YES</b>
Wards of State?	<b>NO / YES</b>
In a carer-client relationship with the researchers or their associates?	<b>NO / YES</b>
In any other dependent relationship with the researchers or their associates?	<b>NO / YES</b>

- 5.2 How will the participants be recruited?

x

- 5.3 Does recruitment involve a direct personal approach from the researchers to the potential participants?

**NO / YES**

If you answered YES, is there any pressure from researchers or others that might influence the potential participant to enrol?

**NO / YES**

If you answered YES, please explain.

x

<b>SECTION 6: PARTICIPANT INFORMATION AND CONSENT/PRIVACY PRINCIPLES</b>
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- 6.1 Will written consent be obtained? **NO / YES**

Attach a copy of the Information and Consent Form.

If you answered NO, give reasons.

x

- 6.2 In the case of participants for whom English is a second language, will arrangements be made to ensure comprehension of the Participant Information and Consent Form, utilising an independent and professional translation service.

**NO / YES**

If you answered YES, what arrangements have been made?

x

If you answered NO, give reasons.

x

- 6.3 Does the Participant Information and Consent Form include the following information:

A short title for the project? **NO / YES**

A brief statement of the aims of the research? **NO / YES**

The names of the researchers, their affiliations and contact telephone numbers? **NO / YES**

An explanation what each participant is expected to do? **NO / YES**

An acknowledgment of any recording using audio tapes, Video tapes, or photographs etc? **NO / YES**

A clear statement of any risks or discomforts? **NO / YES**

Any payment of money or other remuneration? **NO / YES**

Information about how confidentiality of the data will be maintained - how privacy will be maintained, who will have access to the data, - will the data be published? **NO / YES**

A statement guaranteeing participants the right to withdraw at any time, with no effect on their continuing medical care? **NO / YES**

A signed statement of agreement to participate in the research, eg "I agree to participate in this research", with the consent form signed and dated by the participant and signed and dated by an investigator and both witnessed on the same occasion. **NO / YES**

- 6.4 A footnote regarding complaint procedures as follows:

"The ethical aspects of this study have been approved by the Joondalup Health Campus Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Executive Office – phone 9400 9404. Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome."

**NO / YES**

6.5 Have you provided two complete copies of the consent form for the participant to sign – with one to be kept by the investigator and one to be retained by the participant?

**NO / YES**

6.6 If consent from participants is not being sought, which Privacy Principles apply to your research? (Refer to Guidelines approved under Section 95A of the Privacy Act 1988)

x

6.7 Will you require access to information from patient files held in the JHC Health Records Department?

**NO / YES**

<b>SECTION 7: RESOURCES/INTERESTS</b>
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7.1 Is this a funded project or do you intend to apply for funding?

**NO / YES**

If you answered YES, list the funding bodies which support this project or to which submission is planned.

x

7.2 Will this research be undertaken on behalf of (or at the request of) a commercial entity, or any other sponsor?

**NO / YES**

If you answered Yes, who is the sponsor?

x

7.3 Do the researchers have an affiliation with or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research?

**NO / YES**

If you answered YES, provide details.

x

7.4 Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this project?

**NO / YES**

If you answered YES, give details.

x

7.5 Are there any further ethical considerations that you wish to raise? For example, have conditions been imposed upon the use, publication or ownership of the results?

**NO / YES**

If you answered YES, detail what these considerations are.

x

<b>SECTION 8: APPROVALS</b>
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8.1 Has this project been submitted for approval to any other ethics committee?

**NO / YES**

If you answered YES, state which institution or ethics committee.

x

Indicate the status of the application at each other institution or ethics committee.

Submitted	<b>NO / YES</b>
Approved	<b>NO / YES</b>
Deferred	<b>NO / YES</b>
Rejected	<b>NO / YES</b>

<b>SECTION 9: CHECKLIST</b>
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9.1 Have you included the following support documents with your application?

Copies of Information and Consent Forms	<b>NO / YES</b>
Copies of any interviews, questionnaires, or surveys to be used	<b>NO / YES</b>
Copies of any participant recruitment advertisements	<b>NO / YES</b>

<b>SECTION 10: REGISTRATION</b>
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10.1 Has the trial been registered in a publicly accessible trials registry? **NO / YES**

If you answered YES, please state the name of the Registry and the registration number

x

If you answered NO, please state the reasons why trial registration has not been undertaken.

x

<b>SECTION 11: CERTIFICATION</b>
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## 11.1 Title:

Principal and associate investigators (including students)

I/we certify that:

- ♦ all information is truthful and as complete as possible;
- ♦ I/we have had access to and read *the National Statement on Ethical Conduct in Research Involving Humans*;
- ♦ the research will be conducted in accordance with the National Statement;
- ♦ the research will be conducted in accordance with the ethical and research arrangements of the institution involved
- ♦ I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these
- ♦ I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 2.37), including
  - ♦ serious or unexpected adverse effects on participants;
  - ♦ proposed changes in the protocol; and
  - ♦ unforeseen events that might affect continued ethical acceptability of the project.
- ♦ I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 2.38);
- ♦ I/we will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC (NS 2.45);
- ♦ I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

**Principal Investigator**

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Name (block letters): \_\_\_\_\_

**Associate Investigator(s)**

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Name (block letters): \_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Name (block letters): \_\_\_\_\_

**Supervisors of students**

I/we certify that

- ♦ I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- ♦ I/we will ensure that training is provided necessary to enable the project to be undertaken skillfully and ethically

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Name (block letters): \_\_\_\_\_

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Name (block letters): \_\_\_\_\_