

Human Research Ethics Committee

Application for Approval

1. ABOUT THE PROJECT

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|---|--------------------------------|--------------------------------|--------------------------------------|------------------|--|
| Project Title: | | | | | |
| Type of Project: | <input type="radio"/> Teaching | <input type="radio"/> Research | <input type="radio"/> Clinical Trial | Is your Project: | <input type="radio"/> New <input type="radio"/> Continuing |
| Proposed Start Date: | | | Anticipated Completion Date: | | |
| Please note: The Committee cannot grant retrospective approval! | | | | | |
| Is this project related to a previous application? | <input type="radio"/> Yes | <input type="radio"/> No | If yes, original project number: | | |
| Does this project repeat a previous study? | <input type="radio"/> Yes | <input type="radio"/> No | | | |
| If yes, please explain why repetition is necessary: | | | | | |

1.1. ABOUT THE CHIEF INVESTIGATOR

| | | |
|---|-------------|-------------|
| Family Name: | Given Name: | Title: |
| Email - Please provide a staff or student email address only: | | |
| Faculty / University Research Centre: | | |
| Staff ID: | and/or | Student ID: |
| Course of study (if a student): | | |

1.2. UNIVERSITY OF CANBERRA SUPERVISOR (if Chief Investigator is a student)

| | | |
|---------------------------------------|-------------|--------|
| Family Name: | Given Name: | Title: |
| Faculty / University Research Centre: | | |
| Phone: | and | Email: |

1.3. QUALIFICATIONS AND EXPERIENCE OF CHIEF INVESTIGATOR

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|--------------------------------------|--|
| Qualifications: | |
| Relevant Research Experience: | |

1.3.1. FOR STUDENTS ONLY

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|---|--|
| Degree and Training in Research: | |
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1.4. CO-INVESTIGATOR 1

| | | | | | |
|--|--|--------------------|---------------|---------------|--|
| Family Name: | | Given Name: | | Title: | |
| Faculty / University Research Centre: | | | | | |
| Name of external organisation: | | | | | |
| Phone: | | and | Email: | | |
| Qualifications: | | | | | |
| Relevant Experience: | | | | | |

1.4. CO-INVESTIGATOR 2

| | | | | | |
|---------------------------------------|----------------------|-------------|----------------------|----------------------|----------------------|
| Family Name: | <input type="text"/> | Given Name: | <input type="text"/> | Title: | <input type="text"/> |
| Faculty / University Research Centre: | <input type="text"/> | | | | |
| Name of external organisation: | <input type="text"/> | | | | |
| Phone: | <input type="text"/> | and | Email: | <input type="text"/> | |
| Qualifications: | <input type="text"/> | | | | |
| Relevant Experience: | <input type="text"/> | | | | |

1.4.1. CO-INVESTIGATOR 3

| | | | | | |
|---------------------------------------|----------------------|-------------|----------------------|----------------------|----------------------|
| Family Name: | <input type="text"/> | Given Name: | <input type="text"/> | Title: | <input type="text"/> |
| Faculty / University Research Centre: | <input type="text"/> | | | | |
| Name of external organisation: | <input type="text"/> | | | | |
| Phone: | <input type="text"/> | and | Email: | <input type="text"/> | |
| Qualifications: | <input type="text"/> | | | | |
| Relevant Experience: | <input type="text"/> | | | | |

1.4.2. CO-INVESTIGATOR 4

| | | | | | |
|---------------------------------------|----------------------|-------------|----------------------|----------------------|----------------------|
| Family Name: | <input type="text"/> | Given Name: | <input type="text"/> | Title: | <input type="text"/> |
| Faculty / University Research Centre: | <input type="text"/> | | | | |
| Name of external organisation: | <input type="text"/> | | | | |
| Phone: | <input type="text"/> | and | Email: | <input type="text"/> | |
| Qualifications: | <input type="text"/> | | | | |
| Relevant Experience: | <input type="text"/> | | | | |

1.5. DETAILS OF ANY OTHERS INVOLVED IN THE RESEARCH (IF KNOWN)

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|----------------------|--|
| Name(s): | |
| Role(s): | |
| Qualifications: | |
| Relevant Experience: | |

1.6. SITE(S) WHERE THE RESEARCH WILL BE CONDUCTED

| | |
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| Address 1: | |
| Address 2: | |
| Address 3: | |
| Address 4: | |

1.7. FUNDING AND REVIEW

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| Source of funds and amount: | |
| RM Number (if applicable): | |

Do the funding and/or commercial and intellectual property arrangements place you in a conflict of interest as a researcher? If so, please provide details below.

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| Details: | |
| Constraints on publication if any: | |
| Describe any peer review of the proposed research: | |

2. RESEARCH DESIGN AND METHODOLOGY

This section is to provide members of the HREC with clear understanding about the need for the research and the approach adopted. Please use language that can be understood by those outside of the discipline or profession.

2.1. RATIONALE AND LITERATURE REVIEW

The purpose here is to understand how the problem being investigated fits with other research in the area (see [NS 1.1\(c\)](#)).

2.2. AIMS OF THE RESEARCH

2.3. RESEARCH APPROACH, METHODS AND INSTRUMENTS

Please note that the National Statement requires additional ethical matters to be considered in particular types of research such as clinical trials, the collection of human samples, genetic testing, cellular therapy, ionising radiation, research on gametes or the creation of embryos (see [NS 3.3-3.6](#)).

2.4. RESEARCH PRODUCTS *(please select)*

| | | | | |
|--------------------------------------|---|--|-------------------------------------|--|
| <input type="radio"/> Book(s) | <input type="radio"/> Commercial Product(s) | <input type="radio"/> Conference Paper(s) | <input type="radio"/> Exhibition(s) | <input type="radio"/> Journal Article(s) |
| <input type="radio"/> Performance(s) | <input type="radio"/> Report(s) | <input type="radio"/> Therapeutic Product(s) | <input type="radio"/> Thesis | <input type="radio"/> Other |

If Other, please explain:

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2.5. BENEFITS AND OTHER IMPACTS OF THE RESEARCH

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3. PARTICIPANTS, RELATIONSHIPS, FEEDBACK AND CONSENT

Please note that the National Statement focuses on the principle of respect for persons. In addition to the participants recruited for the research, there is a need to consider the impact on others who may be affected by the research (see [NS 1.1 \(d\)](#), [1.6-1.9](#), [1.10](#), [Chapter 2.1](#)).

3.1. PLEASE DESCRIBE WHAT PARTICIPANTS WILL BE REQUIRED TO DO OR AGREE TO HAVE DONE TO THEM.

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3.2. PLEASE OUTLINE THE RISK OF ANY POSSIBLE DISCOMFORT OR HARM FOR PARTICIPANTS AND YOUR STRATEGIES FOR MINIMISING THIS RISK.

3.3. PLEASE OUTLINE ANY POSSIBLE RISK TO YOU AS THE RESEARCHER AND YOUR STRATEGIES FOR MINIMISING THIS RISK.

3.4. PLEASE OUTLINE ANY POSSIBLE RISKS TO OTHERS ARISING FROM THIS RESEARCH.

3.5. PLEASE DESCRIBE HOW YOU WILL SELECT, RECRUIT AND CONTACT PARTICIPANTS.

3.6. IF APPLICABLE, PLEASE DESCRIBE HOW YOU WILL OBTAIN APPROVAL TO ACCESS PARTICIPANTS.

3.7. HOW MANY PARTICIPANTS WILL YOU RECRUIT? WHAT IS THE RATIONALE FOR THIS NUMBER?

3.8. WILL YOU TARGET PARTICIPANTS FOR WHOM THERE ARE SPECIFIC ETHICAL CONSIDERATIONS?

☐ Children and young people

☐ People in dependent or unequal relationships

☐ Women who are pregnant and the human foetus

☐ People unable to give consent for health or other reasons

☐ People with a cognitive impairment, intellectual disability or mental illness

☐ Aboriginal and Torres Strait Islanders

☐ People in other countries

☐ People who are incarcerated

☐ People for whom English is a second language

☐ People who may be involved in illegal activities

3.8.1. IF SO, HOW ARE THE SPECIFIC ETHICAL CONSIDERATIONS BEING ADDRESSED?

3.9. ARE ANY CATEGORIES OF PARTICIPANT SPECIFICALLY EXCLUDED? IF SO, PLEASE PROVIDE A RATIONALE.

3.10. PLEASE DESCRIBE ANY PAYMENT OR COMPENSATION TO PARTICIPANTS.

3.11. PLEASE DESCRIBE ANY PRE-EXISTING RELATIONSHIP WITH PARTICIPANTS AND ANY ETHICAL CONSIDERATIONS THAT NEED TO BE ADDRESSED AS A RESULT OF THIS RELATIONSHIP.

3.12. HOW WILL YOU OBTAIN PARTICIPANTS' CONSENT TO PARTICIPATE? HOW WILL YOU ENSURE THAT CONSENT IS VOLUNTARY? HOW WILL YOU ENSURE THEIR RIGHT TO WITHDRAW FROM THE RESEARCH WITHOUT PENALTY AND WITHOUT FEELING DISCOMFORT?

3.13. DO YOU INTEND TO WITHHOLD OR DISGUISE THE PURPOSE OF THE RESEARCH IN ANY WAY? IF SO, PLEASE PROVIDE REASONS.

3.14. WILL YOU PROVIDE ANY FEEDBACK TO PARTICIPANTS ABOUT THE RESULTS OF THE RESEARCH? IF SO, PLEASE ADVISE IN WHAT FORM FEEDBACK WILL BE PROVIDED.

4. DATA

It is important that privacy and respect are the principles underlying the collection, storage and use of data. Data should be reliable, retrievable and replicable if necessary. (See [Section 2 of the Australian Code for the responsible Conduct of research](#))

4.1. HOW WILL YOU PROTECT THE CONFIDENTIALITY AND PRIVACY OF PARTICIPANTS?

4.2. WILL OTHERS BE ABLE TO IDENTIFY RESEARCH PARTICIPANTS FROM PUBLISHED DATA OR OTHER SOURCES (E.G. INTERPRETERS, TRANSLATORS, OBSERVERS)?

4.3. WILL THE DATA BE INDIVIDUALLY IDENTIFIABLE, NON-IDENTIFIABLE (COLLECTED IN A WAY THAT NO ONE KNOWS THE NAME OF THE PARTICIPANTS) OR RE-IDENTIFIABLE (CODED IN SOME WAY SO THAT ONLY THE RESEARCH TEAM CAN CONNECT THE DATA TO SPECIFIC PARTICIPANTS)?

4.4. HOW WILL YOU ENSURE THE SECURITY OF THE DATA?

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4.5. IN WHAT FORM WILL THE DATA BE STORED?

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4.6. WHERE WILL THE DATA BE STORED?

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4.7. WHO WILL HAVE ACCESS TO THE RAW DATA?

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4.8. DO YOU ANTICIPATE USING THE DATA IN A FUTURE PROJECT?

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4.9. WILL THE DATA BE ARCHIVED OR DESTROYED? IF DESTROYED, PLEASE PROVIDE A DATE.

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4.10. IF THE DATA WILL BE ARCHIVED, WHO WILL HAVE ACCESS TO IT AND WHAT CONDITIONS WILL BE ATTACHED?

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5. DECLARATIONS AND SIGNATURES (please print this page and ensure that all researchers, supervisors and the ADR sign it, please do not insert any electronic signatures)

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 Human Research*, and that the research will be conducted in accordance with the national Statement and in accordance with the ethical arrangements of the organizations involved.
- I/we 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 5.5.3).
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 5.5.6, 5.5.8b).
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements, including the provision of annual progress reports and final reports as required.

**Chief Investigator/Co-Investigator(s)/
Supervisor name:**

Signature:

Date:

I certify that:

- I am familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

**Associate Dean Research or nominee
(name):**

Signature:

Date:

6. ATTACHMENTS CHECKLIST

☐ Participant Information Form(s) and Consent Form(s)

☐ Recruitment Material

☐ Questionnaires, surveys, interview questions, test items

☐ Organisational and/or institutional approvals

☐ Relevant agreements or contracts

☐ Other relevant information or documentation

NOTES FOR APPLICANTS

When completing this Application Form, you should always refer to the Human Research Ethics Manual. Please go to <http://www.canberra.edu.au/research/ucresearch/ethics/human-ethics-manual> to download a copy.

INSTRUCTIONS TO APPLICANTS

- Please answer all questions. If a question is not applicable then please state "not applicable" in the relevant box.
- Please save the form when you have finished and, if approved by your supervisor and/or ADR, forward an electronic copy to the Research Ethics & Compliance Officer.
- Please print the signature page only and ensure that all researcher(s), your supervisor (if applicable) and the Associate Dean Research sign it. A scanned copy of the signature page should then be sent to the Research Ethics & Compliance Officer.
- To be considered at a particular meeting, completed application forms must be submitted to the Research Ethics and Compliance officer by the scheduled closing date listed on the [Research Services Office website](#).
- University insurance must be arranged for each project involving clinical trials (definition: <http://www.nhmrc.gov.au/health-ethics/human-research-ethics/clinical-trials>). Complete the [Clinical Trials Insurance Data Collection Form](#) and return to insurance@canberra.edu.au.
- MAC users - Please complete the form using Adobe Reader and please do not use Mac Preview. If you use Mac Preview then your entered form data may disappear.

CHECKLIST FOR SUBMISSION OF APPLICATION

Having completed the application form please check the following:

- Full details of Chief Investigator and Supervisor have been provided.
- All questions have been answered and the language used can be understood by a layperson.
- Attachments are clearly identified, numbered and included with the application.
- Does your Participant Information Form conform to UC Guidelines?
- Letters of approval from cooperating institutions, e.g. schools and government agencies, have been included (if applicable).
- Storage of data has been stated as being at the University of Canberra.
- Private addresses and phone numbers have not been used as means for participants to contact the Researcher.
- Follow-up counselling has been identified if necessary, and the counselling service identified.
- Application has been signed by Researcher/s, Supervisor and Associate Dean Research (or nominee).
- Starting date of the research postdates the meeting at which the application will be considered.
- The relevant closing date for receipt of applications has been noted.