Application for Ethical Review of Research Involving Human Participants

Application ID : 0000022430
Application Title : New Application
Date of Submission : N/A
Primary Investigator : N/A
Important Information

Important Information for all applicants:

- Applicants are advised to follow the guidelines provided on the Human Research Ethics website prior to submitting this application.
- Ensure all questions are appropriately answered in plain language with correct spelling and grammar.
- All applications must be sighted and approved by all relevant parties. Applications will not be reviewed without appropriate authorisation.
- Ethical approval will only be finalised once electronic applications including copies of all required documentation and the Declaration Form are submitted to the Secretary for the Human Research Ethics Committee, Office for Research.
- To avoid unnecessary delays, please ensure application is submitted in full to the Ethics Secretary by the submission deadline for the relevant HREC.

YOU ARE REMINDED THAT YOUR PROJECT MAY NOT COMMENCE WITHOUT FORMAL WRITTEN APPROVAL FROM THE APPROPRIATE HUMAN RESEARCH ETHICS COMMITTEE.

Contact:
For help and further information regarding ethical conduct, refer to the Human Research Ethics website: http://research.vu.edu.au/hrec.php or contact the Secretary for the Human Research Ethics Committee, Office for Research.

Ethics Secretary
Phone: 9919 4781 or 9919 4461
Email: researchethics@vu.edu.au

For technical help, refer to the QUEST website: http://research.vu.edu.au/ or contact a member of the QUEST team.

QUEST Administrator
Phone: 9919 4906
Email: Quest.Admin@vu.edu.au

External Resources:

- NHMRC: National Statement on Ethical Conduct in Human Research
- NHMRC: Human Research Ethics Handbook
- NHMRC: Australian Code for the Responsible Conduct of Research

General Details

1.1. Ethics Category*

This question is not answered.

1.2. Project Title*
New Application

1.3. Project Summary (Include brief details of aims, methods and significance of the project in plain language. Maximum of 2000 characters)*

This question is not answered.

1.4. Primary School/Institute for Application*
AEHD-SCHOOL OF EDUCATION

Timeline and Funding

1.5. Period for which ethical approval is sought. Note: ethical approval is automatically granted for a period of 2 years from the project commencement date.

- Immediately upon receiving ethical approval
- Other date

This question is not answered.

1.6. Date the data collection is expected to be completed:*
1.7. **How will the research be funded?**
- External grant
- VU grant or funding (e.g., School, Faculty)
- Sponsor
- Other
- Unfunded

This question is not answered.

1.8. **Is the research a collaborative effort with another organisation?**
- Yes
- No

This question is not answered.

**SECTION 2 - PROJECT INVESTIGATORS**

**Investigators**

2.1. Please list all investigators associated with this project.
Include details of the Primary Chief Investigator (primary contact for application), as well as all other Chief Investigators and Associate Investigators. Student details will be requested separately.

This question is not answered.

**Note:** If you are unable to find a personnel record in this system which must be added to your application, please use the [Request to Add Personnel to Research Database form](#) found on the QUEST website.

**Student Investigators**

2.2. Will any students be involved in the conduct of this project?
- Yes
- No

This question is not answered.

**Involvement of Other Individuals/Organisations**

2.3. Will any individuals who are not members of the research team be involved in the conduct of this project? (e.g., medical personnel involved in procedures, research contractors, teachers)
- Yes
- No

This question is not answered.

**SECTION 3 - NATURE OF THE PROJECT**

**Type of Project**

3.1.a. **Is the project a pilot study?**
- Yes
- No

This question is not answered.

3.1.b. **Is the project a part of a larger study?**
- Yes
- No

This question is not answered.

3.1.c. **Is the project a quality assurance or evaluation project (e.g., related to teaching, health-care provision)?**
- Yes
- No

This question is not answered.

3.1.d. **Does the research involve a clinical trial (of a substance, device, psychological or physical intervention)?**
- Yes
- No

This question is not answered.
3.1.e. **Does the research involve the use of therapeutic/intervention techniques or procedures (non-clinical trial)?**

- Yes
- No

This question is not answered.

**Target Population**

3.2.a. **Does the research focus on Australian Indigenous (Aboriginal and/or Torres Strait Islander) populations?**

- Yes
- No

This question is not answered.

3.2.b. **Does the research involve participants under the age of 18 years?**

- Yes
- No

This question is not answered.

3.2.c. **Does the research involve participants who are highly dependent on medical care?**

- Yes
- No

This question is not answered.

3.2.d. **Does the research involve participants who have a cognitive impairment, intellectual disability or mental illness?**

- Yes
- No

This question is not answered.

3.2.e. **Does the research involve participants in other countries?**

- Yes
- No

This question is not answered.

3.2.f. **Does the research involve pregnant women (with a research focus on the pregnancy) and/or the foetus (in utero or ex utero) or foetal tissue?**

- Yes
- No

This question is not answered.

3.2.g. **Does the research involve participants who are likely to be highly vulnerable due to any other reasons?**

- Yes
- No

This question is not answered.

**Intrusiveness of Project**

3.3.a. **Does the research use physically intrusive techniques?**

- Yes
- No

This question is not answered.

3.3.b. **Does the research cause discomfort in participants beyond normal levels of inconvenience?**

- Yes
- No

This question is not answered.

3.3.c. **Does the research collect potentially sensitive data? (e.g., related to a sensitive topic or vulnerable group; personal health/medical information; sensitive organisational strategies)**

- Yes
- No

This question is not answered.

3.3.d. **Does the research involve deception of participants?**

- Yes
- No

This question is not answered.

3.3.e. **Does the research involve limited disclosure of information to participants?**
3.3.f. Does the research involve covert observation of participants?*
- Yes
- No
This question is not answered.

3.3.g. Does the research involve disclosure of information which may be prejudicial to participants?*
- Yes
- No
This question is not answered.

3.3.h. Does the research involve accessing student academic records?*
- Yes
- No
This question is not answered.

3.3.i. Does the research involve human genetic or stem cell research?
- Yes
- No
This question is not answered.

3.3.j. Does the research involve the use of ionising radiation?*
- Yes
- No
This question is not answered.

3.3.k. Does the research involve the collection of human tissue or fluids?*
- Yes
- No
This question is not answered.

3.3.l. Does the research involve any uploading, downloading or publishing on the internet?*
- Yes
- No
This question is not answered.

3.3.m. Does the research seek disclosure of information relating to illegal activities or is the research likely to lead to disclosure of information relating to illegal activities?*
- Yes
- No
This question is not answered.

3.3.n. Does the research involve procedures that may expose participants to civil, criminal or other legal proceedings?*
- Yes
- No
This question is not answered.

3.3.o. Does the research involve gaining access to medical/health related personal information from records of a Commonwealth or State department/agency or private health service provider?*
- Yes
- No
This question is not answered.

3.3.p. Does the research involve gaining access to personal information (not medical/health) from the records of a Commonwealth or State department/agency or private organisation?*
- Yes
- No
This question is not answered.

SECTION 4 - PROJECT DESCRIPTION

General Information

Note: All fields have a maximum of 4000 characters (unless otherwise specified) in plain text only. If supporting documentation needs to be provided for the following questions (images, graphs etc), please upload as referenced appendices in Section 11.
4.1. **Aims of the project.** Provide a concise statement of the aims of the project (maximum 2000 characters in plain language).* 

This question is not answered.

4.2. **Briefly describe the relevant background and rationale for the project in plain language.*** 

This question is not answered.

4.3. **Methodology and procedures**
Include specific details relating to any measures, interventions, techniques, and/or equipment used in the research.
Provide step-by-step details of the procedures with particular reference to what participants will be asked to do.
Provide details separately for different phases or conditions of the research or, where appropriate, different participant groups.* 

This question is not answered.

Use this textbox if additional room is required for Question 4.3.

This question is not answered.

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**Data Collection**

4.4. **Indicate all types of data to be collected.*** 

- □ Questionnaire / survey responses*
- □ Individual interview responses*
- □ Other data
- □ Group interview or focus group responses*
- □ Participant observations
- □ Blood or tissue samples
- □ Physiological measures
- □ Biomechanical measures
- □ Accessed health / medical records or data
- □ Accessed student academic records or data
- □ Archival data

This question is not answered.

4.5. **Does the research only include the collection of anonymous and non-sensitive survey/questionnaire or observational data that poses no foreseeable risks or discomfort to participants AND any foreseeable risk is no more than inconvenience?**

- □ Yes
- □ No

This question is not answered.

4.6. **Does the research only include the use of non-identifiable and non-sensitive data from an existing database that poses no foreseeable risks or discomfort to individuals whose information is contained in the database, or to individuals/organisations responsible for the database?**

- □ Yes
- □ No

This question is not answered.

4.7. **Does the research involve photographing or video recording of participants?**

- □ Yes
- □ No

This question is not answered.

4.8. **Who will be collecting the data?** (give details for all types of data collected and all persons involved)*

This question is not answered.

4.9. **Where will the data be collected?** (give details for all types of data collected and all locations)*

This question is not answered.
4.10. **How will the data be analysed?** (give details for all types of data collected)*

This question is not answered.

4.11. **Who will have access to the data collected?** (give details of all persons who will have access to the data)*

This question is not answered.

4.12. **Will individuals or organisations external to the research team have access to any data collected?**

- Yes
- No

This question is not answered.

**SECTION 5 - PARTICIPANTS**

**Participant Group Details**

5.1. **Provide details of all distinct participant groups below.**
Please be as precise as possible, if specific details have not been determined you must indicate that they are approximate.

**Group 1**
Details of specific participant population:* 

This question is not answered.

Number of participants: *

This question is not answered.

Age range of participants: *

This question is not answered.

Source of participants: *

This question is not answered.

Record details for additional group? (Group 2)*

- Yes
- No

This question is not answered.

**Participant Selection**

5.2. **Provide a rationale for the sample size.** *

This question is not answered.

5.3. **Does the project include any specific participant selection and/ or exclusion criteria beyond those described above in Question 5.1?** *

- Yes
- No

This question is not answered.

5.4. **Will there be a formal screening process for participants in the project?** (e.g. medical/mental/health screening) *

- Yes
- No

This question is not answered.
5.5. Does the research involve participants who have specific cultural needs or sensitivities? (e.g., in relation to the provision of informed consent, language, procedural details)*
    - Yes
    - No
    This question is not answered.

5.6.a. Does the research involve a participant population whose principal language is not English?*
    - Yes
    - No
    This question is not answered.

5.6.b. Will documentation about the research (e.g., Information to Participants form and Consent form, questionnaires) be translated into a language other than English?*
    - Yes
    - No
    This question is not answered.

SECTION 6 - RECRUITMENT OF PARTICIPANTS

Recruitment and Informed Consent

6.1. Will individuals other than members of the research team be involved in the recruitment of participants?*
    - Yes
    - No
    This question is not answered.

6.2. How will potential participants be approached and informed about the research and how will they notify the investigators of their interest in participating?*
    *Attach copies of the "Information to Participants Involved in Research" form and any flyers or other advertising material to be used in the research in Section 11 - "Required Attachments" below.*
    This question is not answered.

6.3. Will potential participants be given time to consider and discuss their involvement in the project with others (e.g. family) before being requested to provide consent?*
    - Yes
    - No
    This question is not answered.

6.4. How will informed consent be obtained from participants?*
    - Participants be required to sign an informed consent form
    - Consent will be implied e.g. by return of completed questionnaire
    - Verbal consent will be obtained and recorded (audio, visual or electronic)
    - Other
    This question is not answered.

6.5. Provide procedural details for obtaining informed consent:*
    This question is not answered.

6.6. Will you be seeking consent in order to contact participants in the future for related research participation and/ or use participants’ data for related research purposes?*
    - Yes
    - No
    This question is not answered.

Competing Interests

6.7. Will any dual relationship or conflict of interest exist between any researcher and potential or actual participants? (e.g., a member of the research team is also a colleague or friend of potential participants)*
    - Yes
    - No
    This question is not answered.

6.8. Does the research involve participants who are in dependent or unequal relationships with any member(s) of the research team or recruiting organisation/ agency (e.g. counselor/ client, teacher/ student, employer/ employee)?*
    This question is not answered.
6.9. **Will you be offering reimbursement or any form of incentive to participants (e.g., payment, voucher, free treatment) which are not part of the research procedures?**

- Yes
- No

This question is not answered.

6.10. **Is approval required from an external organisation?** (e.g., for recruitment of participants, data collection, use of premises)

- Yes
- No

This question is not answered.

SECTION 7 - RISKS ASSOCIATED WITH THE RESEARCH

**Physical Risks**

7.1.a. **Are there any physical risks beyond the normal experience of everyday life, in either the short or long term, from participation in the research?**

- Yes
- No

This question is not answered.

**Psychological Risks**

7.1.b. **Are there any psychological risks beyond the normal experience of everyday life, in either the short or long term, from participation in the research?**

- Yes
- No

This question is not answered.

**Social Risks**

7.1.c. **Are there any social risks beyond the normal experience of everyday life, in either the short or long term, from participation in the research?**

- Yes
- No

This question is not answered.

**Other Risks**

7.2. **Does the research involve any risks to the researchers?**

- Yes
- No

This question is not answered.

7.3. **Does the research involve any risks to individuals who are not part of the research, such as a participant’s family member(s) or social community (e.g., effects of biographical or autobiographical research)?**

- Yes
- No

This question is not answered.

7.4. **Are there any legal issues or legal risks associated with any aspect of the research that require specific consideration (i.e., are significant or out of the ordinary), including those related to:**

- participation in the research,
- the aims and nature of the research,
- research methodology and procedures, and/or
- the outcomes of the research?

- Yes
- No

This question is not answered.

7.5. **Risk-Benefit Statement:**

10/10/2012
If you consider the participants to be “at risk”, give your assessment of how the potential benefits to the participants or contributions to the general body of knowledge would outweigh the risks.*

This question is not answered.

SECTION 8 - DATA PROTECTION AND ACCESS

Data Protection

8.1. Indicate how the data will be kept to protect the confidentiality/privacy of the identities of participants and their data, including all hardcopies and electronic forms: See help for definitions.*

☐ Data will be entirely anonymous
☐ Data will be coded and non-identifiable
☐ Data will be coded and re-identifiable
☐ Some or all of the retained data will include personally identifying information
☐ Other

This question is not answered.

8.2. Who will be responsible for the security of confidential data, including consent forms, collected in the course of the research?*

This question is not answered.

8.3. Where will data be stored during and after completion of the project? Provide full details of the location for all types of data.

During the project:*

This question is not answered.

Upon completion:*

This question is not answered.

8.4. Indicate the minimum period for which data will be held.*

☐ 5 years post publication
☐ 7 years post publication (data from participants < 18 years of age)
☐ 15 years post publication (clinical trials data)
☐ Other

This question is not answered.

8.5. How will the data be disposed of?*

This question is not answered.

SECTION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS

Publication Details

9.1. Indicate how the results of this research will be reported or published.*

☐ Thesis
☐ Journal article(s)
☐ Book
☐ Research report to collaborating organisations
☐ Conference presentation(s)
☐ Recorded performance
☐ Other

This question is not answered.

9.2. Will any contractual agreement exist between the researchers and a third party that will restrict publication of the research findings?*

☐ Yes
☐ No

This question is not answered.

9.3. Are there any other restrictions on publications or reports resulting from this project?*

This question is not answered.
SECTION 10 - OTHER DETAILS

Comments

10.1. In your opinion, are there any other ethical issues involved in the research?*

☐ Yes
☐ No

This question is not answered.

10.2. Additional information and comments to support this application:

This question is not answered.

SECTION 11 - DOCUMENTS, ATTACHMENTS AND SUPPLEMENTARY FORMS

Required Attachments

The following documentation must be attached to your application:

- Scanned copy of the Declaration Form.
- Copy of the 'Information to Participants Involved in Research' form
- Any flyers or other advertising material to be used in the research

11. Please attach each of the items specifically listed above as well as any other supporting documentation.

NOTE: All documentation must be accurately titled and referenced to within the body of your application where appropriate (i.e. “Appendix A - Declaration Form”, “Appendix F - Risk Factor Assessment Questionnaire”, etc.).

Please limit file types to .doc, .docx, .xls, .xlsx, .pdf, or small-medium images (ie, .gif, .jpg).*

This question is not answered.

SECTION 12 - SUBMISSION DETAILS

Finalise Application

Please ensure you have attached a completed Declaration Form in Section 11 above.

All applications must be signed and authorised by all relevant parties. Applications will not be reviewed without appropriate authorisation.

Note: Only a Chief Investigator is able to submit an application for ethical approval.

The Chief Investigator who is marked as the primary contact for this application is displayed below.

This question is not answered.

To submit, click on the ACTION tab above the left-hand form navigation column.

Click “Submit Application” to forward the application to the Ethics Secretary to be reviewed and assigned to a Committee meeting.

It is strongly recommended that you save a PDF version of your application before submitting as you will lose access to the electronic record while it undergoes formal review.