

Application for Ethical Review of Research Involving Human Participants

Application ID: 0000022993
Application Title: New Application

Date of Submission : N/A
Primary Investigator : N/A

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Introduction

Important Information

Application version: V.13-07

IMPORTANT INFORMATION FOR ALL APPLICANTS:

- Applicants are advised to follow the guidelines provided on the <u>Human Research Ethics website</u> 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 members of the research team and any relevant parties.
 Applications will not be reviewed without appropriate authorisation.
- To avoid unnecessary delays, please ensure application is submitted in full 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:

Ethics Secretary

For help and further information regarding ethical conduct, refer to the Human Research Ethics website: https://research.vu.edu.au/hrec.php or contact the Secretary for the Human Research Ethics Committee, Office for Research. Phone: 9919 4781 or 9919 4461

Email: researchethics@vu.edu.au

Quest Service Desk

For technical help, refer to the Quest website: https://research.vu.edu.au/quest.php

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

Quest Guide

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Quick Tips for Using Quest

Need Help? For help and instructions, we strongly recommend that you download the full <u>Quest Online Ethics Guide (.pdf)</u>. Your questions may also be answered in the <u>FAQ page on the Quest Website</u>.

Answer All Questions:

Most questions are mandatory and must be completed before the application can be submitted. These questions are marked with a red asterisk (*)

· Access Help and Tips:

The Phelp icon, found next to questions and at the top of each page, will provide you with detailed advice on ethical content.

· Remember to Save:

Use the \blacksquare floppy disk icon (and the \checkmark green tick in some sections) regularly to avoid losing any answers. Each page will save automatically when you click $Next \Rightarrow$ or $Back \Leftarrow$.

• Print or Save a Copy of Your Application:

You can use the report icon at any stage to generate a printer friendly version of the form. Select HTML to print to screen. To save as a .pdf file to your computer select PDF then save a copy from the pop up screen. (Don't forget to save a copy before you submit!)

• Submit Application:

When you have completed your application, click on the *Action* tab in the left-hand column and click *Submit Application*. The system will then convert the form to read-only and send it to the Ethics Secretary for review. You will receive an email confirmation at submission. Double check that your application has been submitted by viewing the application status in the *My Applications* page.

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Responding to comments (if your application is returned)

There may be stages throughout the application process in which the Ethics Secretary will instruct you to amend your application form. These amendments will be communicated to you via 'Comments' within the eForm.

1. Generate a List of All Comments:

Click the report icon, select *Comments Report* from the Document drop-down field and click *OK*. This list will show all comments created in your application and which page they are applicable to. Click *Cancel* to return to the application form.

2. Revise your Answers:

Open the page which shows a ▶ red flag; these denote an Action Comment which you are required to respond to.

Revise the relevant question(s) in your application form as required. Remember to click 🖫 save!

3. Respond to Action Comments:

AFTER you have revised your answers, you must provide a response to each Action Comment explaining to the Committee how you have addressed their communication. Open the Page Comments window and click New Comment to enter your response into the textbox. Click the Page Comment to save your text.

4. Mark Comments as Responded:

Once you have revised your answers AND finished responding to all comments, reopen Page Comments window, use the checkbox to select the *Action Comments* and click *Mark Selected Comments as Responded*. The colour of the flag will change to yellow and the page will become Read Only.

Important: DO NOT mark the comments as 'Responded' until you are completely satisfied with your revised answers - you will lose access to edit the page and the comments.

5. Submit Revised Application:

Once you have addressed all of the Red Flags, open the *Action* tab and click *Submit Revised Application*. The system will then send the form to the Ethics Secretary for review. Remember to save a copy of your application by clicking the Report icon and generating a PDF or printer-friendly version.

[Office Use Only - Administration]

| Application ID - Assign HRE # using "Manage Applications | 3" |
|----------------------------------------------------------|----|
| 0000022993 | |
| Clearance Purpose | |
| This question is not answered. | |
| | |
| For Review: | |
| Assigned Ethics Committee | |
| This question is not answered. | |
| Risk Level (Enter 'High' or 'Low' or 'Neg') | |
| | |
| This question is not answered. | |

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| | Students involved in conduct of project? (Enter 'Yes' or 'No') | |
|---------------|----------------------------------------------------------------|---|
| 7 | This question is not answered. | |
| | Date Accepted by Ethics Secretary | |
| Г | | |
| 7 | This question is not answered. | |
| _ <u>F</u> | For Finalisation: | |
| C | Date Approved | |
| | | |
| 7 | This question is not answered. | |
| A | Approved Start Date for Project | |
| | | |
| 7 | This question is not answered. | |
| | | |
| | Approved End Date for Project | |
| 7 | This question is not answered. | |
| | Date Rejected | |
| | | |
| | This guaration is not answered | |
| | This question is not answered. | |
| | Date Withdrawn | |
| | | |
| 7 | This question is not answered. | |
| | | |
| Æ | Application Process Comments | _ |
| | | |
| 7 | This question is not answered. | |
| | | |
| е | Use Only - Risk Assessment] | |
| <u>N</u> | NEGLIGIBLE RISK INDICATORS | |
| A | Applicant has responded YES to: | |
| _ | HIGH RISK INDICATORS | |
| | Applicant has responded YES to: | |

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POSSIBLE HIGH RISK INDICATORS
Applicant has responded YES to:

<u>LOW RISK INDICATOR</u>
If no statements appear under the headings above, the applicant has not responded yes to any negligible or high risk indicators.

SECTION 1 - PROJECT OVERVIEW

| Gen | eral 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 College or Institute for Application* |
| | RESEARCH SERVICES |
| 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. Project commencement date:* Immediately upon receiving ethical approval Ofther date This question is not answered. Date the data collection is expected to be completed:* |
| | This question is not answered. |
| 1.7. | How will the research be funded?* External grant VU grant or funding Sponsor Other Unfunded This question is not answered. |
| 1.8. | Is the research a collaborative effort with another organisation?* O Yes O No This question is not answered. |

SECTION 2 - PROJECT INVESTIGATORS

Investigators

23/07/2013 Page 6 / 18 2.1. Please list all investigators associated with this project.

The research team is the group of investigators accountable for the conduct of the 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.* Other staff (e.g. technicians) may perform tasks within the project although they are not necessarily investigators. They should be listed as "Other Staff" if appropriate.*

This question is not answered.

Note: Please click the Question Help icon above for instructions on how to search for personnel and use this table. If you are unable to find a personnel record in this system which must be added to your application, please use the <u>Request to Add Personnel to Research Database form</u> found on the Quest website.

| Stud | lent Investigators |
|------|----------------------------------------------------------------|
| 2.2. | Will any students be involved in the conduct of this project?* |
| | O Yes |
| | O No |
| | This question is not answered. |
| | |

| Involv | vement 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) * |
| | O Yes |
| | O No |
| | This question is not answered. |
| SECT | TION 3 - NATURE OF THE PROJECT |
| Туре | of Project |
| 3.1.a. | Is the project a pilot study?* |
| | O Yes |
| | O No This question is not answered. |
| | inis question is not answered. |
| 3.1.b. | Is the project a part of a larger study?* |
| | O Yes |
| | O 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)?* |
| | O Yes |
| | O No |
| | This question is not answered. |
| 3.1.d. | Does the research involve a clinical trial (of a substance, device, psychological or physical intervention)?* |
| | O 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)?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| Targe | et Population |
| 3.2.a. | Does the research focus on Australian Indigenous (Aboriginal and/or Torres Strait Islander) populations?* |
| | O Yes |

O Yes
O No
This question is not answered.

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| 3.2.b. | Does the research involve participants under the age of 18 years?* |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | O Yes |
| | ○ No |
| | This question is not answered. |
| 3.2.c. | Does the research involve participants who are highly dependent on medical care?* |
| | O Yes |
| | O No |
| | This question is not answered. |
| 3.2.d. | Does the research involve participants who have a cognitive impairment, intellectual disability or mental illness? * |
| | O No |
| | This question is not answered. |
| 3.2.e. | Does the research involve participants in other countries?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| | Does the research use physically intrusive techniques?* |
| 3.3.a. | |
| | ○ Yes ○ No |
| | This question is not answered. |
| 3.3.b. | Does the research cause discomfort in participants beyond normal levels of inconvenience?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| 33e | Does the research involve limited disclosure of information to participants? |
| 0.0.0. | O Yes |
| | O No |
| | This question is not answered. |
| 2 2 f | 4 |
| | Does the research involve covert observation of participants?* |
| 0.0 | Does the research involve covert observation of participants?* |
| 0.0 | ○ Yes |
| 0.0 | ○ Yes ○ No |
| 0.0 | ○ Yes |

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| | O Yes |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | ○ No |
| | This question is not answered. |
| 3.3.h. | Does the research involve accessing student academic records?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| .3.i. | Does the research involve human genetic or stem cell research? |
| | O Yes |
| | O No |
| | This question is not answered. |
| 3.3.j. | Does the research involve the use of ionising radiation?* |
| | O Yes |
| | O No |
| | This question is not answered. |
| 3.3.k. | Does the research involve the collection of human tissue or fluids?* |
| | O Yes |
| | O No |
| | This question is not answered. |
| 3.3.I. | Does the research involve any uploading, downloading or publishing on the internet?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| 3.3.0. | 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?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| ECT | ION 4 - PROJECT DESCRIPTION |
| iene | ral 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 reference |

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Aims of the project. Provide a concise statement of the aims of the project (maximum 2000 characters in plain language).*

4.1.

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| This question is not answered. |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Briefly describe the relevant background and rationale for the project in plain language.* |
| |
| This question is not answered. |
| 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 gr |
| This question is not answered. |
| Use this textbox if additional room is required for Question 4.3. |
| This question is not answered. |
| Collection |
| |
| 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. |
| Does the research <u>only</u> include the collection of anonymous and non-sensitive survey/questionnaire or observat data that poses no foreseeable risks or discomfort to participants AND any foreseeable risk is no more than inconvenience?* |
| O Yes |
| ○ No |
| This question is not answered. |
| Does the research <u>only</u> include the use of non-identifiable and non-sensitive data from an existing database that no foreseeable risks or discomfort to individuals whose information is contained in the database, or to individuals/organisations responsible for the database?* |
| O Yes |
| O No |
| This question is not answered. |
| Does the research involve photographing or video recording of participants?* |
| O Yes |
| ○ No |
| This question is not answered. |
| Who will be collecting the data? (give details for all types of data collected and all persons involved)* |

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

4.9.

| 7 | his question is not answered. |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ۲ | low will the data be analysed? (give details for all types of data collected)* |
| | |
| 7 | his question is not answered. |
| | Who will have access to the data collected? (give details of all persons who will have access to the data)* |
| | |
| | his question is not answered. |
| | Vill individuals or organisations external to the research team have access to any data collected?* |
| | Yes |
| |) No |
| I | his question is not answered. |
| | |
| (| DN 5 - PARTICIPANTS |
| | |
| | pant Group Details |
| | |
| | |
| | rovide 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 appro |
| | reade be as precise as possible, it specific actains have not been actornified you must indicate that they are appre |
| | |
| | Froup 1 |
| | |
| | Froup 1 |
| | iroup 1 letails of specific participant population:* |
| T | Petails of specific participant population:* This question is not answered. |
| T | iroup 1 letails of specific participant population:* |
| T | Petails of specific participant population:* This question is not answered. |
| 7 | Petails of specific participant population:* This question is not answered. |
| 7 | Actails of specific participant population:* This question is not answered. This question is not answered. This question is not answered. |
| 7 | Details of specific participant population:* This question is not answered. Sumber of participants: * |
| 7 | Petails of specific participant population:* This question is not answered. Illumber of participants: * This question is not answered. This question is not answered. This question is not answered. The question is not answered. The question is not answered. |
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| 7 | betails of specific participant population:* this question is not answered. lumber of participants: * this question is not answered. ge range of participants:* this question is not answered. |
| | his question is not answered. Jumber of participants: * Jumber of partici |
| | Interestion is not answered. It is question is not answered. |
| | Pricate the details of specific participant population:* In this question is not answered. It is question is not answered. |
| | Petails of specific participant population:* Initial question is not answered. Itember of participants: * Initial question is not answered. |
| | Petails of specific participant population:* In this question is not answered. It is question is not answered. |
| | Petails of specific participant population:* Initial question is not answered. Itember of participants: * Initial question is not answered. |
| | Pretails of specific participant population:* In this question is not answered. It is question is not answered. |
| | Petails of specific participant population:* In this question is not answered. It is question is not answered. |
| | Pretails of specific participant population:* In this question is not answered. It is 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?*

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| | O Yes |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | O 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)* |
| | O Yes |
| | O 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)* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| 5.6.a | Does the research involve a participant population whose principal language is not English?* |
| | O Yes |
| | O 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?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| | |
| SEC | TION 6 - RECRUITMENT OF PARTICIPANTS |
| | |
| Recr | uitment and Informed Consent |
| | |
| 5.1. | Will individuals other than members of the research team be involved in the recruitment of participants?* |
| | O Yes |
| | ○ No |
| | This question is not answered. |
| 5.2. | 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.* |
| | |
| | |
| | |
| 5.3. | This question is not answered. |
| | This question is not answered. 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?* |
| | Will potential participants be given time to consider and discuss their involvement in the project with others (e.g. family) |
| | 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?* |
| | 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?* O Yes |
| 3.4. | 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?* O Yes No |
| 5.4. | 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?* O Yes O No This question is not answered. How will informed consent be obtained from participants?* |
| 6.4. | 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?* O Yes O No This question is not answered. How will informed consent be obtained from participants?* D Participants be required to sign an informed consent form |
| 6.4. | 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. 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 |
| 6.4. | 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. 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) |
| 6.4. | 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. 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 |
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| 6.4. 6.5. | 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. 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 |
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| | 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. 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. |

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?*

6.6.

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| Comp | peting 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)* O Yes O 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. counsellor/client, teacher/student, employer/employee)?* O Yes O No 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?* O Yes O 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)* O Yes O No This question is not answered. |
| | TION 7 - RISKS ASSOCIATED WITH THE RESEARCH |
| - | Are there any PHYSICAL RISKS beyond the normal experience of everyday life, in either the short or long term, from participation in the research?* O Yes O No This question is not answered. |
| Psych | nological Risks |
| 7.1.b. | Are there any PSYCHOLOGICAL RISKS beyond the normal experience of everyday life, in either the short or long terms from participation in the research?* O Yes O No This question is not answered. |
| Socia | ll 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?* O Yes O No This question is not answered. |
| Other | Risks |
| 7.2. | Does the research involve any risks to the researchers?* |

O Yes O No

This question is not answered.

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| | O 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)?* |
| | O Yes |
| | O 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? |
| | * |
| | O Yes |
| | O No |
| | This question is not answered. |
| 7.5 | Diak Panafit Statement |
| 7.5. | Risk-Benefit Statement: Please give your assessment of how the potential benefits to the participants or contributions to the general body of knowledge would outweigh the risks. Even if the risk is negligible, the research must bring some benefit to be ethical.* |
| | |
| | |
| | This question is not answered. |
| | |
| SEC | TION 8 - DATA PROTECTION AND ACCESS |
| | |
| Data | Protection |
| 8.1. | Indicate how the data, materials and records will be kept to protect the confidentiality/privacy of the identities of |
| | participants and their data, including all hardcopies, electronic files and forms. See help for definitions.* |
| | O Data and records will be entirely anonymous |
| | O Data and records will be coded and non-identifiable |
| | O Data and records will be coded and re-identifiable |
| | O Some or all of the retained data and records will include personally identifying information |
| | O Other This question is not answered. |
| | This question is not answered. |
| 8.2. | Who will be responsible for the security of and access to confidential data and records, including consent forms, collected in the course of the research?* |
| | |
| | |
| 8.3. | This question is not answered. |
| 0.3. | |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the |
| | |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. Note: The VU Research Storage provides secure digital storage and long term retention for research project data including graduate research projects. |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. Note: The VU Research Storage provides secure digital storage and long term retention for research project data including |
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| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. Note: The VU Research Storage provides secure digital storage and long term retention for research project data including graduate research projects. During the project:* This question is not answered. |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. Note: The VU Research Storage provides secure digital storage and long term retention for research project data including graduate research projects. During the project:* |
| | Where will data, materials and records be stored during and after completion of the project? Provide full details of the location for all types of data. Note: The VU Research Storage provides secure digital storage and long term retention for research project data including graduate research projects. During the project:* This question is not answered. |

O Yes

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| | Indicate the minimum period for which data will be retained. See help for definitions.* |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | O Indefinitely |
| | O 5 years post publication |
| | O 7 years post publication |
| | O 15 years post publication |
| | O 25 years after date of birth of participants |
| | O Other |
| | This question is not answered. |
| | Who will be responsible for re-evaluating the data/materials after the retention period and considering a further retention period for some or all of the data/materials?* |
| | This question is not answered. |
| | Will you transfer your data or materials to a managed archive or repository during the project, after the project, or after the retention period? Which discipline specific or institutional archives will be considered? Note: Some funding agencies and publishers may require lodgement with an archive or repository. Retain a copy at VU where possible.* |
| | This question is not answered. |
| | When further retention of data and materials is no longer required, responsible disposal methods should be adopted. Disposal software should also be adopted if digital software, computer hardware, disks or storage media are reused or retired. What methods of appropriate disposal or destruction will be employed? Note: Personal, sensitive or confidential information, both digital and hardcopy, will require secure destruction or disposal. For other materials you may need to refer to the Hazardous Materials Policy, Animal Ethics Standard Operating Procedures, or the |
| | Ethics and Biosafety site found on the VU Office for Research website. * |
| | Ethics and Biosafety site found on the VU Office for Research website. * This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS |
| ΓΙ | This question is not answered. |
| ГІ | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details |
| - C | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* |
| - | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* Thesis |
| יו כ | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* Thesis Journal article(s) |
| ' | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* Thesis Journal article(s) Book |
| - I | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* Thesis Journal article(s) Book Research report to collaborating organisations |
| C | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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) |
| ΓI C | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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 |
| -1 | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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 |
| | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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 |
| TI C | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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. Will any contractual agreement exist between the researchers and a third party that will restrict publication of the |
| | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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. Will any contractual agreement exist between the researchers and a third party that will restrict publication of the research findings?* Yes |
| | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* hesis Journal article(s) Book Research report to collaborating organisations Conference presentation(s) Recorded performance Other This question is not answered. Will any contractual agreement exist between the researchers and a third party that will restrict publication of the research findings?* |
| ГІ | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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. Will any contractual agreement exist between the researchers and a third party that will restrict publication of the research findings?* Yes No |
| ΓΙ | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details Indicate how the results of this research will be reported or published.* Thesis |
| TI CC | This question is not answered. ION 9 - DISSEMINATION/PUBLICATION OF RESEARCH RESULTS cation Details 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. 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. Are there any other restrictions on publications or reports resulting from this project?* |

SECTION 10 - OTHER DETAILS

Comments

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| In your opinion, are there any other ethical issues involved in the research?* |
|--------------------------------------------------------------------------------|
| O Yes |
| O No |
| This question is not answered. |
| 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 <u>must</u> be attached to your application:

- Scanned copy of the **Declaration Form for External Investigators** (if applicable)
- Copy of the 'Information to Participants Involved in Research' form (*Please use the templates provided on the <u>Human</u> <u>Research Ethics website</u>)*
- Copy of Consent Forms to be used in the research (*Please use the templates provided on the <u>Human Research Ethics</u> website)*
- 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. 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.

Note: Please click the Question Help icon above for instructions on how to upload documents and use this table. If you are certain that you do not need to supply a *Consent Form* or *Information to Participants Involved in Research* (both of which are mandatory), please tick *Hard Copy* and type 'N/A' in the *Reference* field.

SECTION 12 - SUBMISSION DETAILS

Declaration

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I / we, the undersigned, declare the following:

- I / we accept responsibility for the conduct of the research project detailed above in accordance with:
 - a. the principles outlined in the National Statement on Ethical Conduct in Human Research (2007);
 - b. the protocols and procedures as approved by the HREC;
 - c. relevant legislation and regulations.
- I / we will ensure that HREC approval is sought using the Changes to the Research Project process outlined on the Human Research Ethics website if:
 - a. proposing to implement change to the research project;
 - b. changes to the research team are required.
- I / we have read the National Statement on Ethical Conduct in Human Research prior to completing this form.
- I / we certify that all members of the research team involved the research project hold the
 appropriate qualifications, experience, skills and training necessary to undertake their
 roles.
- I / we will provide Annual / Final reports to the approving HREC within 12 months of approval or upon completion of the project if earlier than 12 months.
- I / we understand and agree that research documents and/or records and data may be subject to inspection by the VUHREC, Ethics Secretary, or an independent body for audit and monitoring purposes.
- I / we understand that information relating to this research, and about the investigators, will be held by the VU Office for Research. This information will be used for reporting purposes only and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

This question is not answered.

Declaration Instructions and Information

- A digital signature must be supplied by each and every member of the research team using the declaration table above.
- ullet The 'Needs Signature' icon \square shows which records you are responsible for signing.
- Physical signatures are not required for VU staff and students in applications using form version V.07-2013.
- External Investigators do not have access to Quest. The Chief Investigator must supply a completed physical declaration on their behalf by following the steps below:
 - 1. Send the person a copy of the full application form (including any attachments), as well as the <u>Declaration Form for</u> External Investigators document.
 - Once returned, attach the signed External Investigator Declaration Form document in 'Section 11 Required Attachments'.
 - 3. Enter into the External Investigator's record in the above declaration table and mark the checkbox to indicate these steps have been completed, include the date you have done so.
 - The 'sighted by' field will automatically populate with your name. (Only the Chief Investigator will have permission to complete this step.)
- The application cannot be submitted until all members of the research team have logged in and completed this declaration.

Finalise Application

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All applications must be sighted and approved by all members of the research team and any relevant parties.

Please ensure each member of the research team has completed their declaration in 'Section 12 - Declaration' above, including any declaration forms supplied on behalf of External Investigators.

Applications will not be reviewed without appropriate authorisation.

Reminders:

- Once the form is complete and all documents are attached, click on the 'Action' tab above the left-hand form navigation, then 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.
- 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:

| This question is not answered |
|-------------------------------|

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