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|  | HUMAN ETHICS APPROVAL NUMBER | H      |

Please complete version and date

for each version of this application

|  |  |
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| Version No. and Date\*  |  |

***Submission and completion guide:***

* ***Please complete the checklist, application, supporting documents, Ethics Advisor review and all relevant signatures including the Dean/Delegate. Please send all documents as one PDF file by email to*** ***ethics@jcu.edu.au*** ***when the application is ready for submission.***
* ***You must not start your project until you receive formal approval from the HREC (that includes any advertising or recruitment).***
* ***Applicants should read the instructions for each question and address all of the points identified there.  Use the resources of the National Statement and Human Research Ethics guidance provided at the JCU Human Ethics website.***
* ***Please read the instructions on how to complete a Human Ethics Advisor Review on the last page of this document.***
* ***Please send a final draft only of the application form with supporting documents as appendices to an Ethics Advisor.***
* ***Note*** [***the HREC meeting submission***](https://www.jcu.edu.au/jcu-connect/ethics-and-integrity/human-ethics/closing-dates-for-submission-of-human-ethics-applications) ***dates to ensure you will meet the submission deadline if the project is deemed higher risk research (category 3-6), Aboriginal and Torres Strait Islander research or research that involves any of the areas outlined in Section 4 of the National Statement.***

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| **Ensure you addressed the feedback given by the Human Ethics Advisor and highlighted these changes in yellow? (See instructions on the last page)** |  [ ] Y |  [ ] N |

\***Each time the application and/or supporting documents are updated please change the version number and date of each document.**

**HREC Training**

**To complete the training go to the online** [**‘Human Ethics Research Foundations Training Modules’**](https://open.usq.edu.au/enrol/index.php?id=400)

Before starting your application, please read the National Health and Medical Research Council, [*National Statement on Ethical Conduct in Human Research, 2023.*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

 **A. HUMAN RESEARCH RISK ASSESSMENT CHECKLIST**

This checklist is to help assess potential risks involved in conducting your planned human research project and also be used to decide which level of ethical review your application will require (Refer to the *National Statement* *Chapter 2.1*).

1. Go through the checklist and check ‘YES’ or ‘NO’ for each of the risks listed.
2. Based on this risk assessment, assign a risk category in *Question 7*.
3. For each ‘YES’ you have identified a potential risk, consider how you will:
	1. Gauge the risk – consider the likelihood and severity of any risk.
	2. Remove the risk – can you remove the risk by change your project’s methods?
	3. Minimise the risk – If the risk can’t be removed, can it be minimised by a change to the methods?
	4. Manage the risk/harm – can any remaining risk or harm be managed by putting in place a monitoring program to detect and institute measures to deal with any harm?
4. Outline in your application how you will minimise and manage the risks identified.

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| 1. **Contentious or Controversial Topics: Are any of the following topics covered in part or in whole in your project?**
 |  |  |  |  |
| Research about parenting issues | [ ]  | YES | [ ]  | NO |
| Research investigating sensitive personal issues | [ ]  | YES | [ ]  | NO |
| Research investigating sensitive cultural issues | [ ]  | YES | [ ]  | NO |
| Explorations of grief, death or serious/traumatic loss | [ ]  | YES | [ ]  | NO |
| Depression, mood states, anxiety | [ ]  | YES | [ ]  | NO |
| Gambling  | [ ]  | YES | [ ]  | NO |
| Eating disorders | [ ]  | YES | [ ]  | NO |
| Illicit drug use | [ ]  | YES | [ ]  | NO |
| Substance abuse  | [ ]  | YES | [ ]  | NO |
| Self-reporting of criminal behaviour | [ ]  | YES | [ ]  | NO |
| A psychological disorder  | [ ]  | YES | [ ]  | NO |
| Suicide | [ ]  | YES | [ ]  | NO |
| Gender identity | [ ]  | YES | [ ]  | NO |
| Sexuality | [ ]  | YES | [ ]  | NO |
| Race or ethnic identity | [ ]  | YES | [ ]  | NO |
| Any disease or health problem | [ ]  | YES | [ ]  | NO |
| Fertility | [ ]  | YES | [ ]  | NO |
| Termination of pregnancy | [ ]  | YES | [ ]  | NO |

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| 1. **Research procedures/practices: Are any of the following procedures/practices to be used in your project?**
 |  |  |  |  |
| Use of students’ personal information from a JCU database without specific consent from the students. *If ‘YES’ please submit your application to the JCU Privacy Officer to approve before the HREC* | [ ]  | YES | [ ]  | NO |
| Use of personal data obtained from Commonwealth or State Government Department/Agency  | [ ]  | YES | [ ]  | NO |
| Use of personal data obtained from State Government Department/Agency | [ ]  | YES | [ ]  | NO |
| Use of personal information from a non-government organisation | [ ]  | YES | [ ]  | NO |
| Does your research require a waiver of consent? | [ ]  | YES | [ ]  | NO |
| Deception of participants | [ ]  | YES | [ ]  | NO |
| Concealing the purposes of the research | [ ]  | YES | [ ]  | NO |
| Use of human biospecimens in laboratory-based research | [ ]  | YES | [ ]  | NO |
| Genomic research | [ ]  | YES | [ ]  | NO |
| Covert observation  | [ ]  | YES | [ ]  | NO |
| Audio or visual recording without consent | [ ]  | YES | [ ]  | NO |
| Recruitment of a third party or agency | [ ]  | YES | [ ]  | NO |
| Withholding from one group specific treatments or methods of learning, from which they may “benefit” (e.g. in medicine or teaching) | [ ]  | YES | [ ]  | NO |
| Psychological interventions or treatments | [ ]  | YES | [ ]  | NO |
| Administration of physical stimulation  | [ ]  | YES | [ ]  | NO |
| Physically invasive procedures | [ ]  | YES | [ ]  | NO |
| Potentially painful procedures | [ ]  | YES | [ ]  | NO |
| Administration of drugs  | [ ]  | YES | [ ]  | NO |
| Administration of other substances  | [ ]  | YES | [ ]  | NO |
| Exposure to ionising radiation | [ ]  | YES | [ ]  | NO |
| Tissue sampling or blood taking | [ ]  | YES | [ ]  | NO |
| Collecting body fluid | [ ]  | YES | [ ]  | NO |
| Use of medical records where participants can be identified or linked | [ ]  | YES | [ ]  | NO |
| Genetic testing/DNA Extraction | [ ]  | YES | [ ]  | NO |
| A clinical trial or drug trial | [ ]  | YES | [ ]  | NO |

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| 1. **Participant groups requiring special consideration: Does your project specifically target participants from any of the following groups?**
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| Patients, staff, data, facilities or sites in a Queensland health facility. *Please submit your application to the HREC of that facility* | [ ]  | YES | [ ]  | NO |
| With Aboriginal and Torres Strait Islander Peoples or communities *Please also see the* [*Guidelines for Researcher*](https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples) | [ ]  | YES | [ ]  | NO |
| People suffering from a psychological disorder  | [ ]  | YES | [ ]  | NO |
| People suffering a physical vulnerability  | [ ]  | YES | [ ]  | NO |
| People highly dependent on medical care who may be unable to give consent | [ ]  | YES | [ ]  | NO |
| Children or young people | [ ]  | YES | [ ]  | NO |
| People whose ability to give consent is impaired | [ ]  | YES | [ ]  | NO |
| Resident of a custodial institution | [ ]  | YES | [ ]  | NO |
| People unable to give free informed consent because of difficulties in understanding information provided eg. Language difficulties | [ ]  | YES | [ ]  | NO |
| People with a cognitive impairment, an intellectual disability or mental illness | [ ]  | YES | [ ]  | NO |
| People who may be involved in illegal activities | [ ]  | YES | [ ]  | NO |
| People in dependent or unequal relationships eg. Lecturer/student, doctor/patient, teacher/pupil & professional/client | [ ]  | YES | [ ]  | NO |
| Members of a socially and/or culturally identifiable group with special social/cultural/ethnic or religious beliefs or political vulnerabilities  | [ ]  | YES | [ ]  | NO |
| Women who are pregnant and the human foetus | [ ]  | YES | [ ]  | NO |
| Participants are identifiable in the final report when specific consent for release has not been given | [ ]  | YES | [ ]  | NO |

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| 1. **Risks to researchers: Are there any of the following risks to researchers involved?**
 |  |  |  |  |
| Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots)? | [ ]  | YES | [ ]  | NO |
| Are there any potential risks to non-participants in the research, such as, participant’s family members and social community? e.g. effects of biography on family and friends or infectious disease risk to the community) | [ ]  | YES | [ ]  | NO |

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| 1. **Research overseas: Does your project involve researching in an overseas country?**
 |  |  |  |  |
| Where research is being undertaken in a politically unstable area | [ ]  | YES | [ ]  | NO |
| Where research involves sensitive cultural/social/political/ethnic/economic or religious issues | [ ]  | YES | [ ]  | NO |
| Where criticism of the government and institutions may be a risk to participants and/or researchers | [ ]  | YES | [ ]  | NO |

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| 1. **Researcher conflict of interest: Do any of the following apply to your research?**
 |  |  |  |  |
| Are any of the researchers affiliated with any of the external organisations involved in your research? | [ ]  | YES | [ ]  | NO |
| Are any of the researchers in receipt of any financial benefit from any of the external organisations involved in your research? | [ ]  | YES | [ ]  | NO |

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| 1. **Risk category: Assess your project’s overall risk category (see the HREC’s Application Guide for more information and examples)\***
 |  |  |
| [ ]  **1** | **Negligible risk:** Research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience. |
| [ ]  **2** | **Low risk:** Research in which the only foreseeable risk is one of discomfort. Discomforts include, for example, minor side-effects of medication, the discomfort of measuring blood pressure or the anxiety induced by an interview. |
| [ ]  **3** | **More than low risk:** Research with the potential to cause mild psychological distress or physical stress. Minor deviation from frank disclosure of the true nature of the research may be involved. |
| [ ]  **4** | **More than low risk:** Research with the potential to cause genuine but not severe psychological distress or physical pain with no long-term effects. Deception may be involved regarding the true nature of the research. |
| [ ]  **5** | **More than low risk:** Research with the potential to cause psychological distress or physical pain. Substantial deception may be involved. |
| [ ]  **6** | **More than low risk:** Research involving vulnerable participants; at risk populations; or research that may pose serious ethical considerations. |

\*Please note that if you have said ‘Yes’ to several items in the checklist it is likely that the research is more than low risk (H3-6). Assessing the risk of your research as being lower than it is may lead to a delay in the review of your application, as it will be sent for Executive Review, before being redirected to the HREC meeting.

**HUMAN RESEARCH ETHICS APPLICATION FORM**

1. **PROJECT TITLE**

The project title should be in lay language and understandable by the participant groups being targeted.

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1. **PROJECT DURATION (date range)**

If you are requesting more than 3 years, please justify why you will need more than 3 years and how you will have resources to cover this work.

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1. **RESEARCHER AND SUPERVISOR DETAILS, ROLE AND EXPERIENCE**

|  |  |
| --- | --- |
| **Principal Investigator** |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |  |  |
| **If you are a student, provide the name of the degree being undertaken (and details of your supervisor below)** |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |
|  |
| **Experience** Outline your experience in the role or outline how you will be trained and supervised  |
|  |

|  |  |
| --- | --- |
| **Student Supervisor** (Delete table if not required) |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |  |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |  |
|  |
| **Experience** Outline your experience in your role on the project |
|  |

|  |  |
| --- | --- |
| **Student Supervisor** (Delete table if not required) |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |  |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |  |
|  |
| **Experience** Outline your experience in your role on the project |
|  |

|  |  |
| --- | --- |
| **Student Supervisor** (Delete table if not required) |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |  |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |  |
|  |
| **Experience** Outline your experience in your role on the project |
|  |

|  |  |
| --- | --- |
| **Co-investigator** |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |
| **If you are a student, provide the name of the degree and details of your supervisor below** |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |
|  |
| **Experience** Outline your experience in the role or outline how you will be trained and supervised  |
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| --- | --- |
| **Co-investigator** |  |
| **Email:** |  |
| **Phone:** |  | **Mobile:** |  |
| **Discipline/College/Organisation** |  |
| **Organisation Unit (ORGU) No.** |  |  |  |
| **Relationship to JCU (staff, student, non-JCU)** |  |  |  |
| **If you are a student, provide the name of the degree and details of your supervisor below** |  |
| **Qualifications**  |  |
| **Role in the project** What will be your role in the project? |
|  |
| **Experience** Outline your experience in the role or outline how you will be trained and supervised  |
|  |

**Cut and paste extra tables required for additional researchers.**

**Remove un-used tables**

Please outline below any additional personnel who will be assisting with research, their roles, experience and qualifications.

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1. **FUNDING AND FINANCIAL BENEFITS**

4.1 Researchers should include any source of funding (e.g., departmental, commercial, non-commercial, governmental) The HREC will consider whether there is a conflict of interest *(Refer to National Statement 1.1(f), 2.2.6(h), 5.2.8)*

|  |  |  |
| --- | --- | --- |
| Has this study received research funding or is this submission being made as part of an application for research funding? | [ ]  Yes | [ ]  No |
| What is the status of the funding application? | [ ]  NA | [ ]  Approved | [ ]  Not approved | [ ]  Pending |

4.2 The research is to be funded by:

|  |
| --- |
| [ ]  Government grant or funds |
| [ ]  Not-for profit grant or funds |
| [ ]  JCU grant or funds |
| [ ]  Private sector grant or funds |
| [ ]  Student grant |
| [ ]  Student in-kind funds, e.g. student’s computer, space |
| [ ]  JCU in-kind funds (e.g. JCU computer, space, equipment) Please list:  |
| [ ]  Other – Please explain:  |

4.3 What is the approximate amount of funding?

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4.4 If a grant, what is the project grant title, name of fund and proposed funding duration?

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4.5 How will participants be informed of the source of the funding?

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4.6 If the funding is from the private sector, have any conditions been placed on the research, or are there any possible issues pertaining to conflict of interest, e.g. publication restrictions, intellectual property

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1. **AIMS AND BACKGROUND**

5.1 State the aims and key research questions, any hypotheses to be tested and the significance of the research.

Outline the background and relevance of the project to the field of research, including how the research is justified based on the current literature and its potential to contribute to existing knowledge. Provide references as an attachment to this application to support your answer **(Max 300 words)**

*(Refer to National Statement 1.1(c))*

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1. **PARTICIPANT DETAILS**
	1. Describe the target group(s) who will be recruited into this research. *(Refer to National Statement Section 4 and 1.4(a))*

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6.2 Outline how many participants will be recruited, their sex and age range, experimental/control groups, sampling strategy and any inclusion/exclusion criteria that will be applied. What is the basis for these numbers? *e.g. statistical test, etc.* Please explain the reason behind any proposed or expected imbalances in sex or age and outline what measures will be put in place to prevent bias, or explain how bias is not of concern to the design of the study in the results. *(Refer to National Statement 3.1.14-15)*

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| How many total participants do you need to meet your project aims? |  |
| How many of the total participants will be JCU students? |  |
| Will any participants be Aboriginal or Torres Strait Island peoples? If so, how many of the total sample are expected to identify as Aboriginal and Torres Strait Islander? |  |

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| 6.3 Does the research involve participants under the age of 18 years old? If ‘YES’, please provide details below and attach the document to this application, of an Australian working with children approval (Blue Card if working in Queensland (JCU Australia), or a Singapore Police Certificate of Clearance (JCU Singapore) or other working with children approval if working in another country *(Refer to National Statement Ch.4.2)* | [ ]  Yes | [ ]  No |
|  |

1. **METHODS**

7.1 Provide a brief outline of each step of the proposed methodology, including research design, details of data collection techniques, tasks participants will be asked to complete, the estimated time commitment involved, and how data will be analysed. If the project includes any procedure that is already established and uses accepted techniques please include a description of the procedure. If the study has multiple phases or continues over a considerable time period please consider submitting the phases in separate applications (Max 1 page)

*(Refer to National Statement 1.1(b), 1.3, Section 3)*

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**7.2** **Video/Photography**

If you are recording either a moving image or photographing your participants, please explain why this is necessary in relation to the research aims of the project. If you are recording images which identify individuals please explain how this action adds to your data collection and validation of findings and ask participants also to sign the JCU Marketing Release Form.

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1. **RESEARCH SITES/LOCATIONS**

8.1 Outline the research locations and or sites/locations where the research will be conducted and how they will be appropriate to support the needs of the research, physical and emotional needs and safety of the participants and researchers. *(Refer to National Statement 1.1(f))*

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**Overseas Research**

8.2 If the data is to be collected from a country outside of Australia (JCU-A) or Singapore (JCU-S), which country or countries will be involved? *(Refer to National Statement Ch. 4.8)*

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| --- |
|  |
| Have you received government approval to conduct research in that country? If not, please explain below |
|  |
| * Provide with your application any foreign ethics (or equivalent approvals) and evidence of the foreign government approval for your project to take place in that country
* If no ethics approval needed in that country then attach evidence of this, e.g. an email from a collaborating institution, reference from the country’s government website, etc
 |

1. **RECRUITMENT**

9.1 Describe the process for recruiting participants in detail, including how they will be identified and selected, invited to participate and how you will access their contact details, details of any external organisations assisting, third parties, social media used (include details of groups within social media sites targeted), websites, public documents, details of any personal contacts.

*(Refer to National Statement Ch. 1.4(b), 3.1 Element 2)*

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1. **CONSENT**

10.1 Describe how consent will be obtained from participants (written, verbal, participant & guardian, etc). *(Refer to National Statement Ch 3.1 Element 3)*

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Type of consent (e.g. active, specific, extended, unspecified)

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| --- | --- | --- |
| 10.2 Does the research target participants from any of the groups outlined in *Section C* of the *Risk Assessment Checklist?*  | [ ]  Yes | [ ]  No |
| If ‘YES’, outline for each of those groups you have identified how you ensure the participants provide informed consent, for example:* Provide translations of information sheets and consent forms
* Use an interpreter
* Seek parental/guardian consent for children
* Ensure your research is undertaken in a culturally sensitive manner
* Ensure participants understand their participation is voluntary
 |
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| 10.3 Will the research be requiring a waiver of consent or use an opt-out consent process? If yes, justify this choice based on the criteria outlined in the *National Statement Ch 2.3 – 2.3.2 (limited disclosure) 2.3.10 (waiver) or 2.3.6 (opt-out)* | [ ]  Yes  | [ ]  No |
|  |

**10.4** **Reimbursement/Incentives**

Note that while participants may, in certain circumstances, be paid or reimbursed for their inconvenience and time, any payments or inducements that are offered must not be disproportionate to the time involved such that it might encourage participants to take risks.

*(Refer to National Statement 2.2.10-11)*

|  |  |  |
| --- | --- | --- |
| Will the participants be offered any reimbursement of costs, incentives or other rewards proposed to be given to participants?  | [ ]  Yes  | [ ]  No |

If ***yes***, describe how much and in what form the payment/incentive will take, i.e. SONA credits, coffee voucher, etc.

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**10.5 Dependent/Unequal Relationships and Coercion**

The consent of a person to participate in research must not be subject to any coercion. Research involving those in dependent or unequal relationships (e.g. teacher/student, manager/employee, parent/child, doctor/patient) may compromise a participant’s ability to give consent that is free from any form of pressure (real or implied) arising from this unequal power relationship.

|  |  |  |
| --- | --- | --- |
| Does a dependent or unequal relationship exist between any participant and researcher, particularly those involved in recruiting? | [ ]  Yes  | [ ]  No |

If ***yes***, please explain the relationship and the steps to be taken by the researchers to ensure that the participant’s participation is purely voluntary and not influenced by the relationship in any way. *(Refer to National Statement Ch. 4.3)*

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**10.6 English as a Second Language or with Low Literacy Level**

Describe how you will ensure that participants, whose first language is not English or who have low literacy level will be able to provide informed consent. *(Refer to National Statement 5.2.17(c))*

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**10.7 Discontinuing Participation/Withdrawing Consent** *(Refer to National Statement 2.2.6(g), 2.2.8, 2.2.19-20)*

Describe how, as part of the informed consent process, participants will be advised that they have the right to withdraw at any time or withdraw any unprocessed data previously supplied.

*Note the implications for anonymous surveys where potential participants need to be aware that if they withdraw, their data cannot be identified to be deleted.*

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1. **RISK MANAGEMENT AND BENEFITS**

11.1 Based on the answers in the Risk Assessment Checklist, outline how any of the identified risks will be addressed according to the *National Statement Chapter 2.1*.

|  |  |
| --- | --- |
| **Potential risk** | **Risk minimisation/management strategy** |
|  |  |
|  |  |
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**Add more rows if required. You will need to ‘Unprotect’ the form before doing this and ‘Protect’ the form again after**

**11.2 Potential Benefits**

Outline the potential benefits of the research for the following: *(Refer to National Statement 1.1(a), 1.6, 1.8, 1.9)*

|  |
| --- |
| The participants |
|  |

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| The community |
|  |

**11.3 Risk-Benefit Statement**

Please give your assessment of how the potential benefits to the participants or contributions to the general body of knowledge would justify any risks. *Even if the risk is negligible, the research must bring some benefit to be ethical. (Refer to National Statement 1.1(a), 1.6-1.9)*

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1. **DATA AND INFORMATION MANAGEMENT**

**Confidentiality of Data and Participant Personal Information**

12.1 Human research data must be managed using the [Research Data JCU platform](https://research.jcu.edu.au/data/default/rdmp/user/login) and according to JCU’s Research Data Management policies and procedures.

Please familiarize yourself with Section 3 Element 4 of the *National Statement*, as well as the *Code for the Responsible Conduct of Research* and the [*Management of Data and Information in Research*](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf) supporting guide. Refer to the [Research Data and Information Management (RDIM)](https://www.jcu.edu.au/rdim) website for further details and local application of the national codes.

Indicate how the data, materials and records will be kept to protect the confidentiality, privacy or identities of participants and their data, including hard copies, electronic files and forms.

(Please note the difference between data being *anonymous* *(no identifying information collected)* and *confidential (identifying information collected, but kept secret)* in your answer.)

|  |  |
| --- | --- |
| [ ]  | Data will be entirely anonymous  |
| [ ]  | Data and records will be coded and non-identifiable |
| [ ]  | Data and records will be coded and re-identifiable |
| [ ]  | Some or all of the retained data and records will include personally identifying information |
| [ ]  | Other, please describe: |

|  |
| --- |
|  |

12.2 In what form(s) will data be collected and stored? e.g. electronic, hard copy, recordings, etc

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12.3 Where will data, materials and records be stored during and after completion of the project and how will it be secured? Provide full details of the location for all types of data.

Refer to the Research Data and Information Management (RDIM) website for advice on [data storage](https://www.jcu.edu.au/rdim/terminology/data-storage) and to view a list of [JCU approved storage and collaboration options](https://www.jcu.edu.au/rdim/terminology/active-storage-and-collaboration-options).

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12.4 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?

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12.5 The following guidance is included in Section 2.3 of the [*Management of Data and Information in Research*](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf) guide and the [Retention Rules](https://www.jcu.edu.au/rdim/terminology/retention-rules-for-specific-data-types) on the RDIM website:

* In general, the minimum retention period for research data is 5 years after the last action e.g. from the end of the year of publication of the last refereed publication based on the data
* Data that results in a patent must be retained for 7 years after expiry of the patent (minimum of 27 years)
* For most clinical trials, data should be retained for a minimum of 15 years, and longer if necessary.
* For research areas such as gene therapy, data (e.g. in the form of patient records) must be retained permanently
* If the work has community or heritage value or the data is otherwise significant (see [Retention Rules](https://www.jcu.edu.au/rdim/terminology/retention-rules-for-specific-data-types)) it should be retained permanently

Indicate the minimum period for which data will be retained.

|  |  |
| --- | --- |
| [ ]  | Indefinitely  |
| [ ]  | 5 years  |
| [ ]  | 7 years  |
| [ ]  | 15 years  |
| [ ]  | Other, please describe:  |

12.6 Many funding bodies and journals require that wherever possible, de-identified data from human research is shared with other researchers.

Is there any reason NOT to publish the de-identified or anonymous data from this project via a research data database such as Research Data Australia for use by other researchers?

(If there is a chance the data will be shared/made publicly available and used by other researchers in their projects in the future, please ensure that there are the appropriate statements on the Participant Information Sheet and Consent Form)

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1. **PRIVACY**

13.1 Please give attention to privacy implications and compliance with legislative requirements including the [Privacy Act](https://www.ag.gov.au/rights-and-protections/privacy) (Australia), Information [Privacy Act](https://www.oic.qld.gov.au/about/privacy) (Queensland) or the [Personal Data Protection Act](https://www.pdpc.gov.sg/Overview-of-PDPA/The-Legislation/Personal-Data-Protection-Act) (Singapore). Please see the [*Guidelines Approved under Section 95A of the Privacy Act 1988*](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988) produced by NHMRC. See Queensland Health for information on applying for access to information held by [Queensland Health](https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info) and submitting a PHA application.

|  |  |  |
| --- | --- | --- |
| a) Does this project involve gaining access to medical information from a Commonwealth agency? If ‘Yes’, which agency? | [ ]  Yes | [ ]  No |
|  |
| b) Does this information require the disclosure of personal information, i.e. identifiable information? If ‘Yes’, what type of information will you be accessing? | [ ]  Yes | [ ]  No |
|  |
| c) If you answered YES to the previous question – Will you obtain informed consent from the individuals to whom the information is related? If you are not obtaining consent, please explain why not? | [ ]  Yes | [ ]  No |
|  |

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| --- | --- | --- |
| d) Does this project involve the collection, use or disclosure of health information from a private sector organisation? If ‘Yes’, which private sector organisation? | [ ]  Yes | [ ]  No |
|  |

13.2 Is the data from the private sector organisation going to be used for research which is related to:

|  |  |  |
| --- | --- | --- |
| * Research relevant to public health or safety?
 | [ ]  Yes | [ ]  No |
| * The compilation or analysis of statistics relevant to public health or safety?
 | [ ]  Yes | [ ]  No |
| * Management, funding or monitoring a health service?
 | [ ]  Yes | [ ]  No |
| * Will you obtain informed consent from the individuals to whom the health information is related? If ‘No’ explain why not?
 | [ ]  Yes | [ ]  No |

1. **DISSEMINATION OF RESULTS**

14.1 Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the project’s findings or outcomes. *(Refer to National Statement Ch. 3, Elements 6 and 7)*

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14.2 How will results be made available to participants?

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| --- |
| [ ]  Written summary of results |
| [ ]  Copy of final manuscript (thesis, paper etc) |
| [ ]  Verbal presentation (info session, debriefing etc) |
| [ ]  Presented to all participants |
| [ ]  Presented if requested |
| [ ]  Presented to representative of participants (CEO, teachers of students) |
| [ ]  Other – Please explain:  |
| [ ]  The results will not be shared with participants – Please explain:  |

1. **Supporting Documentation Checklist**

If the recruitment methods/participants involve any of the following please provide a copy of the corresponding documents with your application:

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Mail-out | [ ]  | Copy of the document to be mailed |
| [ ]   | Email | [ ]  | Copy of the email wording |
| [ ]  | Telephone | [ ]  | Script of the telephone conversation |
| [ ]  | Advertisement | [ ]  | Copy of the advertisement |
| [ ]  | Social media | [ ]  | Permission from social media and wording of post |
| [ ]  | Recruiting through third parties | [ ]  | Letter of support from third party, including details of their participation |

1. **DECLARATIONS**

**16.1 Principal Investigator**

I declare that (indicate by ticking boxes):

[ ]  All investigators of this research project are qualified and authorised to perform procedures described in this document

[ ]  The assistants involved in this project have been fully briefed on procedures and relevant ethical considerations

[ ]  I am aware of the responsibilities set out in the relevant legislation

[ ]  I undertake to inform the Human Research Ethics Committee (HREC) of any changes to the proposed procedures or details given in this form subsequent to its submission (including change of contact details)

[ ]  I agree to assist the Committee to monitor the conduct of research by completing and promptly returning annual reports and provide a final report upon completion of the project as appropriate

[ ]  This project complies with the National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018)*

[ ]  The purpose of this project cannot be achieved by alternatives to the use of human participants

**Research Integrity Training**

Please ensure that you complete the mandatory Research Integrity Training for Researchers in LearnJCU (if you have trouble accessing this training, please contact researchintegrity@jcu.edu.au)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Signature** | **Date** |
| **Principal Investigator** |  |  |  |
| **Student Supervisor** |  |  |  |
| **Student Supervisor** |  |  |  |

**16.2 Dean/Delegate**

I declare that:

* There are adequate resources, facilities and support for this project to proceed to conclusion
* The staff members involved are appropriately qualified and competent for the task described
* Adequate instructions have been given for participant welfare and post-project care and monitoring

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| --- | --- | --- | --- |
| **Position** | **Name** | **Signature** | **Date** |
|  |  |  |  |

**Human Research Ethics Advisor’s Review**

**Instructions for Researchers**

1. Please send the unsigned, word version of your HREC Application to a Human Research Ethics Advisor for review before the meeting.
2. After you have received their review, make any changes to the application suggested by the Advisor, please highlight these changes in yellow so the HREC can see where the feedback has been addressed. Please also provide a response in the PI’s response table provided below.
3. If you do not agree with the feedback, please provide a written response outlining the reasons with your application.
4. Then obtain the appropriate signatures before submitting the final version and a copy of this review as one PDF document to ethics@jcu.edu.au
5. Please don’t send it back to the Ethics Advisor for re-review unless they have specifically asked you to.

**Instructions for Human Ethics Advisors**

1. Please review the application and provide any advice to the researcher that you feel will correct any ethical concerns, improve the application and make it align with the principles of the *National Statement* and other applicable guidelines or legislation*.*
2. Outline your comments, advice and suggestions to the researchers in the first table below, using the following headings and the sections of the *National Statement* cited in the application form as a guide, and return to the researcher as a PDF. If the information in the section is acceptable and no changes need to be made, make a comment to that effect.
3. You are only required to review each application once; you don’t need to review revised versions of the same application.

**Ethics Advisor review**

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| --- |
| **Title** |
|  |
| **General Comments** |
|  |
| **Research Team and Experience** |
|  |
| **Aims and Background and Methods**  |
|  |
| **Facilities/Settings**  |
|  |
| **Participants**  |
|  |
| **Recruitment and Consent**  |
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| **Risk Management and Benefits** |
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| **Data and Information Management and Privacy** |
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| **Advisor’s Name** |  | **Signature** |  | **Date** |  |

**Principal Investigator response to Ethics Advisor review**

|  |
| --- |
| **Title** |
|  |
| **General Comments** |
|  |
| **Research Team and Experience** |
|  |
| **Aims and Background and Methods**  |
|  |
| **Facilities/Settings**  |
|  |
| **Participants**  |
|  |
| **Recruitment and Consent**  |
|  |
| **Risk Management and Benefits** |
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| **Data and Information Management and Privacy** |
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