***Please email one pdf file of this application including attachments, i.e. application form and all attachments in one pdf document, to*** ***ethics@jcu.edu.au******. If it is not submitted in one pdf file it will not be accepted. A hard copy is not required.***

|  |  |  |
| --- | --- | --- |
|  | HUMAN ETHICS NUMBER*(Office Use ONLY)* | H |
|  |
| 1 | TITLE OF PROJECT |  |
| 2 | CATEGORY OF RESEARCH | You MUST evaluate the potential for harm, discomfort or inconvenience to the participants of your project from the examples below. Please indicate (X) the risk category |
|  |  | 1 | *Negligible risk: Research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience (Low/Negligible Risk* c*hecklist required with application).* |
|  |  | 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 (Low/Negligible Risk* c*hecklist required with application).* |
|  |  | 3 | *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 | *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 | *Research with the potential to cause psychological distress or physical pain. Substantial deception may be involved.* |
|  |  | 6 | *Research involving vulnerable participants; at risk populations; or research that may pose serious ethical considerations.* |
| 3 | PERIOD DURING WHICH ACTIVITIES REQUIRING ETHICS APPROVAL WILL OCCUR (3 year maximum) |
|  | COMMENCEMENT DATE |  | FINISH DATE |  |
|  |
| 4 | PRINCIPAL INVESTIGATOR’S DETAILS |
|  | Last Name  | ESN[[1]](#footnote-1) | ORGU | Discipline/College or Institution (Country) |
|  |  |  |  |  |
|  | First Name and Title |  |  |
|  |  |  |  |
|  | Email | Phone | Fax |
|  |  |  |  |
|  | REASON FOR RESEARCH | No | Yes | If Yes, which degree (i.e. PhD, MSc) |
|  | *Does this research contribute towards a formal qualification?* |  |  |  |
|  | Qualifications |  |
| 4a | DETAILS of CO-INVESTIGATOR 1 (if applicable) |
|  | Last Name, First name and Title | ESN 1 | ORGU | Discipline/ College or Institution (Country) |
|  |  |  |  |  |
|  | Email | Phone | Fax |
|  |  |  |  |
|  | REASON FOR RESEARCH | No | Yes | If Yes, which degree (i.e. PhD, MSc) |
|  | *Does this research contribute towards a formal qualification?* |  |  |  |
|  | Qualifications |  |
|  |
| 4b | DETAILS of CO-INVESTIGATOR 2 (if applicable) |
|  | Last Name, First name and Title | ESN 1 | ORGU | Discipline/College or Institution (Country) |
|  |  |  |  |  |
|  | Email | Phone | Fax |
|  |  |  |  |
|  | REASON FOR RESEARCH | No | Yes | If Yes, which degree (i.e. PhD, MSc) |
|  | *Does this research contribute towards a formal qualification?* |  |  |  |
|  | Qualifications |  |

If there are more than two co-investigators involved in this PROJECT, please copy the previous page and attach the details of these co-investigators at the end of this application (Part 1).

|  |  |
| --- | --- |
| 5 | SUPERVISOR DETAILS (if applicable).There must be at least one JCU Supervisor. |
|  | Last Name, First name and Title | ESN 1 | ORGU | Discipline/College or Institution (Country) |
|  |  |  |  |  |
|  | Email | Phone | Fax |
|  |  |  |  |
|  | Qualifications |  |
| 5a | DETAILS of SUPERVISOR 2 (if applicable) |
|  | Last Name, First name and Title | ESN 1 | ORGU | Discipline/College or Institution (Country) |
|  |  |  |  |  |
|  | Email | Phone | Fax |
|  |  |  |  |
|  | Qualifications |  |

If there are more than two supervisors involved in this PROJECT, please copy this page and attach the details of these supervisors at the end of this application (Part 1).

|  |  |
| --- | --- |
| 6 | FUNDING SOURCE Please explain the source of monetary or in kind support for your project. The National Statement states that research that has merit is ‘conducted using facilities and resources appropriate for the research'. It is expected that adequate resources will be available for this research project. Resources include finances, equipment/ facilities and in-kind support |
| **6.1** | **Project Title** |  |
|  | **Funding Body** |  |
|  | **Funding Scheme** |  | **Value** | **$** |
| **6.2** | **SOURCE OF IN KIND SUPPORT Please explain the source of in kind support for your project. (MUST BE COMPLETED IF NO MONETARY FUNDING IS LISTED ABOVE).**  |
|  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 7 | Has this project been submitted to any other ethics committee? If YES, please attach a copy of the approval notice. | No | Yes | If Yes, which Ethics Committee?  |
|  |  |  |  |
| 8 | Is this project a clinical trial? | No | Yes | If YES – Do NOT proceed with this form – please contact the Human Ethics & Grants Administrator for advice. |
|  |  |  |

|  |  |
| --- | --- |
| 9 | PRIVACY INFORMATION  |
| 9.1 | Does this project involve gaining access to medical information from a COMMONWEALTH AGENCY? | No | Yes | If YES, which Commonwealth Agency? If NO, go to 9.4 |
|  |  |  |  |
| 9.2 | Does this information require the disclosure of personal information, i.e. identifiable information? | No | Yes | If NO, what type of information will you be accessing? |
|  |  |  |
| 9.3 | If you answered YES to 9.2 - Will you obtain informed consent from the individuals to whom the information is related? | No | Yes | If NO, please explain why not? |
|  |  |  |
| 9.4 | Does this project involve the collection, use or disclosure of health information from a PRIVATE SECTOR organisation? | No | Yes | If YES, which Private Sector Organisation? |
|  |  |  |
|  | Is the data from the private sector organisation going to be used for research which is related to: | No | Yes |
|  | * research relevant to public health or safety
 |  |  |
|  | * the compilation or analysis of statistics relevant to public health or safety
 |  |  |
|  | * management, funding or monitoring of a health service
 |  |  |
|  | * Will you obtain informed consent from the individuals to whom the health information is related?
 |  |  |
|  | If, NO, please explain why not? Impracticable? De-identified data? |
|  |  |

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| --- | --- |
| **10** | **BACKGROUND AND SIGNIFICANCE OF THE PROJECT**  |
| **Please supply below a brief description of your project in LAY language. Please explain the purpose of the project and the broad context of the project, i.e. Why should this project be done? Why is it needed? Please explain the potential benefits to the participants and to the general community. (You must provide references for your project outline. These can be attached as an appendix if required) NO MORE THAN HALF A PAGE IN LENGTH**  |
|  |  |

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| --- | --- |
| **11** | **AIMS OF THE PROJECT: Please clearly state the aims of this project and the expected research outcomes? NO MORE THAN HALF A PAGE** |
|  |  |
| **12****12.1** | **ROLE AND EXPERTISE OF INVESTIGATORS IN THIS PROJECT (All sections MUST be completed for each investigator and supervisor on the project.)**Please include details of the **ROLE** of the Principal Investigator, Co-Investigators, Supervisors, students and other collaborators as it pertains to this project. What will each individual do in this project? Please also explain the involvement of cultural brokers, mentors and reference or community groups in the project. |
|  |  |
| **12.2** | Please provide details of the **EXPERTISE** of the Principal Investigator, Co-Investigators, Supervisors, students and other collaborators as it pertains to this project **(No general CVs and no publication lists).** |
|  |  |

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| 13 | VALUES AND ETHICS |
|  | [*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*](https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities) provides guidance to researchers in the conception, design and conduct of research. There are six values at the heart of these guidelines: RECIPROCITY, RESPECT, EQUITY, RESPONSIBILITY, CULTURAL CONTINUITY, SPIRIT AND INTEGRITY. Please outline below how your research demonstrates these values from the National Statement |
|  | RECIPROCITY: *To ensure that research outcomes include equitable benefits of value to Aboriginal and Torres Strait Islander communities or individuals.* Please outline how your project will benefit the community or individual? For example, how does your project contribute to the advancement of participants or communities? How does your project respond to a need in Aboriginal and Torres Strait Islander communities or peoples? Does the community fully support your project? |
|  |  |
|  | RESPECT: *Respectful research relationships acknowledge and affirm the right of people to have different values, norms and aspirations. Those involved in research processes should not be blind to difference. Also essential to a respectful research relationship is the recognition of the contribution of others and the consequences of research.* Please outline how your project recognises the diversity of Aboriginal and Torres Strait Islander peoples  |
|  |  |
|  | EQUITY: *Equity is reflected by a commitment to showing fairness and justice that enables Aboriginal and Torres Strait Islander Peoples’ culture, history and status to be appreciated and respected.* Please demonstrate the ways that participating communities are included in the research processes of your project. |
|  |  |
|  | RESPONSIBILITY: *Recognition of core responsibilities – to do no harm, transparent accountability.* What measures have you undertaken to ensure transparency in the purpose, methodology, conduct and dissemination of results, feedback obligations and arrangements for publications. |
|  |  |
|  | CULTURAL CONTINUITY: *Contributes to a sense of strong, shared and enduring individual and collective identities. Cultural continuity includes maintaining the bonds and relationships between people and between people and their environment. It also includes responsibilities in respect of spiritual domains.* Please explain what safeguards are in place to ensure that the project does not discriminate against or deride Aboriginal and Torres Strait Islander individuals or cultures  |
|  |  |
|  | SPIRIT AND INTEGRITY: *Community decision making based on shared values.* Please explain the relationship between the proposed project and the community’s cultural, spiritual and social cohesion, including workable timeframes. How will you work with the community on this project?  |
|  |  |

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| --- | --- |
| 14 | PARTICIPANT DETAILS |
| 14.1 | How many participants are expected to be involved in the project? | M | # | F | # | Total  | # | Under 18 Years | # |
|  | Of these participants, are any students of JCU? | M | # | F | # | Total | # |  |  |
| 14.2 | How many participants involved in the project are expected to be members of an Aboriginal & Torres Strait Islander community?  | M | # | F | # | Total | # | Under 18 Years | # |
| 14.3 | Does this project involve patients (whether in hospital or in the community) of a [health service district](https://www.jcu.edu.au/research-services/ethics-and-integrity/human-ethics/health-service-districts-and-external-hrec-approvals)? IF YES you may need to follow the External HREC Approval procedures. See link above for further information.  | No | Yes | If YES, please provide details of the health service district ethics committee that granted the ethics approval |
|  |  |  |  |
| 14.4 | Does this project involve children? | No | Yes | Have you obtained a “suitability card” from the Qld Commission for Children & Young People? What is its number and expiry date? Attach a copy. |
|  |  |  |  |
|  |  |
| **15** | **PLEASE DESCRIBE THE TARGET GROUPS INVOLVED IN YOUR PROJECT e.g. farmers in a particular region, Grade 12 female music students, JCU first year students in a certain subject, etc. PLEASE ALSO DETAIL ANY EXCLUSION CRITERIA FOR PARTICIPANTS** (If more than 3 groups, please insert another row.) |
|  | **Groups:** |
|  | **1** |  |
|  | **2** |  |
|  | **3** |  |
|  | **PLEASE LIST THE SITES WHERE THE PROJECT WILL BE CONDUCTED OR SITES WHERE PARTICIPANTS WILL BE RECRUITED** |
|  |  |
|  | **If your project involves any organisations, please list the names of the organisations below:** |
|  | **Name of Organisation** | **Letter Approval/Support** **ATTACHED** | **No** | **Yes** |
|  |  |  |  |
|  | **If letters of support are still to be obtained, please confirm below:****I confirm that when I receive letters of support for my project these will be immediately forwarded to the Research Office.** | **No** | **Yes** |
|  |  |

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| --- | --- |
| **16** | **Please provide a DETAILED METHODOLOGY for the project. Explain clearly and concisely how the project will be carried out. At a minimum you need to describe the design of the study, the specific methods used, the outcome variables of interest, estimate the time required for each protocol to be completed (for example, how long will it take to complete a survey or interview), the data analysis methods used and how results of analyses will relate to the hypotheses of interest. If the study has multiple phases or continues over a considerable time period you may wish to attach a timeline as an appendix. NO MORE THAN ONE PAGE.** |
|  |
|  | **Please indicate the data collection techniques to be used in the project:** |
|  | **Surveys or questionnaires** | **Individually identifiable data** (collection of individual’s name, image DOB or address) |  |
|  |  | **Re-identifiable data** (identifiers removed and replaced by a code – possible to re-identify by linking of code/data sets |  |
|  |  | **Non-identifiable data** (never labelled with individual identifiers or data which identifiers have been permanently removed – no individual can be identified) |  |
|  |  |  |  |
|  | **Interviews** | **Audio taped** |  |
|  |  | **Moving image** |  |
|  |  | **Photographed**  |  |
|  |  | **Included tick boxes for audio/moving image/photograph recording and outlined the ‘limits on use’ consent on informed consent form** |  |
|  |  |
|  | **Focus Groups** | **Audio taped** |  |
|  |  | **Video Taped**  |  |
|  |  | **Photographed**  |  |
|  |  | **Included tick box for permission to record audio/moving images /photographs and limits/use on consent form.**  |  |
|  |  | **Included statement that confidentiality cannot be guaranteed in focus groups on consent form** |  |
|  |  |
|  | **Other****(Please specify)** |  |  |
|  |  |
|  | **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.**  |
|  |  |

|  |  |
| --- | --- |
|  **17** | **RECRUITMENT PROCEDURES: HOW WILL YOU RECRUIT PARTICIPANTS TO THE PROJECT?****Please include STEP BY STEP details of recruitment procedures for each group of participants. How will you select the participants? How will you INVITE them to participate in the project? How will you access the contact details of potential participants – public domain, database, other source? Please advise if you will provide an information sheet for each participant recruited to the study? PLEASE ATTACH THE INFORMATION SHEET/S TO THIS APPLICATION – YOU MUST USE THE JCU SAMPLE INFORMATION SHEET** |
|  |  |
| **18** | **INFORMED CONSENT****Please explain STEP BY STEP how you will obtain informed consent from participants. How will the participants give their consent? If you do not intend to obtain a RECORD of identifiable informed consent, please explain why you believe this is appropriate?****IF APPLICABLE, PLEASE ATTACH THE INFORMED CONSENT FORM TO THIS APPLICATION – YOU MUST USE THE JCU HUMAN ETHICS PRO-FORMA CONSENT FORM** |
|  |
| **Please indicate:** | No | Yes |
| **Does your project have the potential for participants to become distressed? (Category 1 and 2 research should not have the potential to cause participant distress.)** |  |  |
| **If YES, are counselling services available to participants?**  |  |  |
| **If YES, are the details of these counselling services included in the information sheet for participants?** |  |  |

|  |  |
| --- | --- |
| **19** | **DATA RETENTION AND STORAGE. Please ensure you complete all boxes using a (√) to indicate your adherence to these guidelines as applicable to this project or N/A if not applicable. Do not leave any blank boxes.** |
| **Raw data (e.g. signed informed consent forms, completed surveys) must be stored in accordance to the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice.*****Please indicate (√) your adherence to these guidelines as applicable to this project or N/A if not applicable.** | **(√)** **Or****N/A** |
| **Raw data for this study will be retained for at least 5 years. Any data that is stored on computer/CD/DVD will be de-identified.**  |  |
|  | **Signed Informed Consent Forms from this study will be retained for 15 years.** |  |
|  | **Records/copies of suitability cards for interviewing juveniles must be retained for 15 years** |  |
|  | **Raw data from clinical studies (including epidemiological studies) will be retained for 15 years.** |  |
|  | **Upon completion of the study/project raw data will be stored in the Principal Investigator’s School at James Cook University, in a locked box or cupboard.** |  |

|  |  |
| --- | --- |
| **20** | **Dissemination of findings** |
|  | **Please include information pertaining to how findings will be disseminated and to what audience. Consider not only scholarly audiences but also broader audiences. How can participants (organisations and individuals) access information regarding the outcomes of the research in which they participated. If you do not believe that such outcomes are of interest to broader audiences or participants, please give details of your reasoning. (No more than half a page)**  |
|  |  |
| **21** | **COMMENTS** |
| **Please include any additional information that may be of use or interest to the Committee, i.e. alignment with JCU, government, or other strategies, funding body, collaborating organisations, relation to other ethics applications, etc.** |
|  |  |

**22 DECLARATION OF PRINCIPAL INVESTIGATOR – MUST BE SIGNED BY THE PRINCIPAL INVESTIGATOR**

|  |
| --- |
| * I declare that all investigators of this research PROJECT are qualified and authorised to perform procedures described in this document;
* I certify that 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 an annual report 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”.
* The purpose of this PROJECT cannot be achieved by alternatives to the use of human participants.
 |
| Signature *(Principal Investigator)* | Date |

**23. DECLARATION by SUPERVISOR(S) - SUPERVISOR/S MUST SIGN IF THE PRINCIPAL INVESTIGATOR IS A JCU STUDENT (AT LEAST ONE SUPERVISOR MUST BE A JCU SUPERVISOR)**

*(Supervisor(s) must sign this declaration)*

|  |
| --- |
| I/We: * Declare that I/we am/are qualified and authorised to supervise procedures described in this document;
* Certify that the investigators and assistants involved in this PROJECT have been fully briefed on procedures and relevant ethical considerations;
* Am aware of the responsibilities set out in the relevant legislation (see the Human Ethics Guidelines);
* Suitable facilities including contingent facilities are available for this PROJECT;
* Adequate instructions have been given for participant welfare and post-PROJECT care and monitoring;
* The staff members involved are appropriately qualified and competent for the task described.
 |
| Signature *(Supervisor)* | Date | Signature *(Supervisor 2)* | Date |

**24. AUTHORISATION by DEAN OF COLLEGE/DELEGATE – THE PRINCIPAL INVESTIGATOR MUST OBTAIN THE SIGNTURE OF THE DEAN/DELEGATE BEFORE SUBMITTING THE APPLICATION TO THE JCU HREC.**

|  |
| --- |
| I certify that: * Suitable facilities including contingent facilities are available for this PROJECT;
* Adequate instructions have been given for participant welfare and post-PROJECT care and monitoring;
* The staff members involved are appropriately qualified and competent for the task described.
 |
| Signature  | Date |

**25 ABORIGINAL AND TORRES STRAIT ISLANDER ETHICS ADVISOR’S RECOMMENDATIONS – This section must be completed and signed off before the application is submitted to the JCU HREC.**

|  |
| --- |
| **Please indicate your recommendation:** |
|  | **Yes** | **No** |
| This application should be **approved:** |  |  |
| This application should be **approved with the following comments, provisions and/or reservations:** |  |  |
| This application should **not be approved** for the reasons listed below: |  |  |
|  |
| *Aboriginal and Torres Strait Islander Ethics Advisor* | Signature  | Date |

1. Indicate if the Researcher is currently an **E**mployee or a **S**tudent of JCU, or a researcher who is **N**ot affiliated with JCU. If the PROJECT involves international cooperation, please specify the country. [↑](#footnote-ref-1)