|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Office use only | Received: | | |  | | |
| **Human Research Ethics Committee (HREC)** | RM No. | | |  | | |
| **2015 Application for ethics approval** | Ethics Approval No: | | |  | | |
|  | HREC | EXEC | A/P | | HSc | Psych |

|  |
| --- |
| **LEVEL OF ETHICAL REVIEW:** |

Indicate the [level of ethical review](http://www.adelaide.edu.au/ethics/human/guidelines/levels/) that is being sought for this application:

|  |  |
| --- | --- |
|  | **Full HREC review**  Applies to all research involving more than “low risk research” as defined in the [National Statement on Ethical Conduct in Human Research](http://www.nhmrc.gov.au/guidelines/publications/e72)) |
|  | **Low risk review**  Applies to "low risk research” as defined in the [National Statement on Ethical Conduct in Human Research (2007)](http://www.nhmrc.gov.au/guidelines/publications/e72) (referred to hereafter as *National Statement)*. Research timetables should allow for the possibility that a project submitted as a low risk application may be deemed to involve more than low risk, or to raise other issues, therefore requiring full review. Researchers may be requested to provide additional information. |

|  |
| --- |
| **SECTION 1: PROJECT AND RESEARCHERS’ DETAILS** |

**1.1 Project title:**

|  |
| --- |
|  |

**1.2 Project timeframe:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Proposed commencement date of activities that require human ethics approval**: |  | **Estimated completion date of the project:** |  |

Research must not commence without the prior written approval of the HREC. Retrospective approval cannot be provided.

**1.3 If this application is to extend a currently approved project, provide the HREC approval number:**

|  |  |
| --- | --- |
| **HREC approval number:** |  |

An ‘Annual Report on Project Status Form’ should also be completed <http://www.adelaide.edu.au/ethics/human/guidelines/reporting/>

**1.4 Applicant:**

If the project is to be undertaken by a research student, the student’s primary or other supervisor at the University of Adelaide is the ‘applicant’.

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicant’s name, title:** |  | **EMPLID:** |  |
| **School or Department:** |  | | |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

**1.5 Student projects:**

If the project is to be undertaken by a research student as part of their studies, please indicate below. **Section 7** must also be completed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name:** |  | **Student ID:** |  | **Program Level:** | If other please describe |
| **Name:** |  | **Student ID:** |  | **Program Level:** | If other please describe |
| **Name:** |  | **Student ID:** |  | **Program Level:** | If other please describe |
| **Name:** |  | **Student ID:** |  | **Program Level:** | If other please describe |

**1.6 Other researchers:**

List all researchers (other than the applicant and students) in the table below and if applicable their University of Adelaide EMPLID. Include all co-supervisors and researchers internal and external to the University of Adelaide. **Section 7** must also be completed.

| **Names: EMPLID:** | |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**1.7 Has or will this project be submitted for approval to other HRECs?**

Include the HREC’s name, current status of the application (i.e. submitted, approved, deferred or rejected) and attach this documentation.

|  |
| --- |
|  |

**1.8 Has or will this project be submitted for approval to any departments or institutions?**

E.g. Department of Education, prisons, government institutions, or businesses.

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 2: NATURE OF THE PROJECT** |

**2.1 Aims of the project:**

Discuss in standard English the research hypothesis to be investigated and the values and benefits to participants.

|  |
| --- |
|  |

**2.2 Rationale of the project:**

Explain in standard English the appropriateness of the research methodology in achieving the research aims. Provide evidence of an adequate sample size to establish a valid result.

|  |
| --- |
|  |

**2.3 Background to the project:**

Briefly discuss any previous research of relevance and cite no more than 4 key references.

|  |
| --- |
|  |

**2.4 Have there been any preliminary studies? If YES, provide the project title and HREC approval number(s):**

|  |
| --- |
|  |

**2.5 Research methodology:**

Describe how the study will be undertaken and explain what interactions will occur between researchers and participants.

|  |
| --- |
|  |

**2.6 Location/s of the research:**

Include details of all sites where the project will be undertaken.

|  |
| --- |
|  |

**2.7 If research is to be conducted with or about participants living outside Australia outline any local legislation, regulations, permissions or customs that need to be addressed before the research can commence. Outline the steps taken to ensure that this has been adequately considered and addressed.**

Attachauthorising correspondence and/or approval documentation to the application. See *National Statement Chapter 4.8*

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 3: PARTICIPANTS AND RECRUITMENT** |

**3.1 Who will be the participants in this project?**

Participants also includes data about people or human tissue samples.

|  |
| --- |
|  |

**3.2 What is the number of participants?**

|  |
| --- |
|  |

**3.3 What is the age range of participants?**

|  |
| --- |
|  |

**3.4 If this research involves children under 18 years of age, describe how the researcher/s comply with the** [**University’s Child-Safe Environment Policy**](http://www.adelaide.edu.au/policies/3883/)**:**

Specific requirements for research activities involving children are highlighted in Section 2.4 of the [University’s Child-Safe Environment Policy](http://www.adelaide.edu.au/policies/3883/).

|  |
| --- |
|  |

**3.5 What is the participant selection and exclusion criteria?**

|  |
| --- |
|  |

**3.6 Where will participants be recruited or sourced from?**

|  |
| --- |
|  |

**3.7 What materials will be used to recruit participants and how will they be used?**

Provide details of any posters, flyers, participant information sheets, consent forms, advertisements, emails and letters that will be used. Include a listing of any online or physical sites the advertisements will be posted.

|  |
| --- |
|  |

**3.8 How and by whom will initial contact with participants be made?**

If recruitment is to be conducted by a third party, please describe how this will take place.

|  |
| --- |
|  |

**3.9 Will any personal information including names, contact details, email addresses of participants etc. be accessed for purposes of recruitment?If yes, outline how and by whom this information will be accessed:**

Researchers must ensure that personal information is not accessed without the consent of the individual.

|  |
| --- |
|  |

**3.10 Describe how and when information about the proposed research activities will be provided to participants and any third parties:**

A person’s decision to participate in research must be based on sufficient information, an understanding of research and the implications of participation. A template participant information sheet covering the information required by the NS can be used <http://www.adelaide.edu.au/ethics/human/guidelines/applications/>. For online surveys, the information sheet may be incorporated into the survey preamble. These documents are to be attached to the application. See *National Statement Chapter 2.2*.

|  |
| --- |
|  |

**3.11 How and when will consent be obtained from participants and any third parties?**

See *National Statement 2.2.* Templates for consent forms are available at: <http://www.adelaide.edu.au/ethics/human/guidelines/applications/>

|  |
| --- |
|  |

**3.12 How and when will contacts for the project and independent complaints information be provided to participants?**

This information can be provided through a participant information sheet. A sample paragraph is available on the University’s participant information sheet template. Alternatively a separate ‘Contacts for the Project and Independent Complaints Procedure Sheet’ can be used. <http://www.adelaide.edu.au/ethics/human/guidelines/applications/>. See *National Statement 2.2.6 and Chapter 5.6.*

|  |
| --- |
|  |

**3.13 For participants not fluent in English or who have difficulty understanding English, what arrangements will be made to ensure comprehension of the research information?**

|  |
| --- |
|  |

**3.14 In reference to Question 2.5, indicate all research activities in the study and where applicable outline the approximate time commitment required of participants.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Research Activity** | | **Participant Time** | **Research Activity** | | **Participant Time** |
| **Interviews** |  |  | **Focus groups** |  |  |
| **Survey/Questionnaire** |  |  | **Social media analysis** |  |  |
| **Data sets** |  |  | **Observation** |  |  |
| **Academic records** |  |  | **Medical records** |  |  |
| **Personal documents, records or other materials** (other than academic or medical records) |  |  | **Case studies** |  |  |
| **Medical, Biomedical or Physiological test, treatment or interventions** |  |  | **Drugs or isotopes**  If this is selected, a [Drugs to be Administered Form](http://www.adelaide.edu.au/ethics/human/guidelines/applications/#drugs) is to be completed. |  |  |
| **Body organs, tissues or fluids** |  |  | **Psychological testing or treatment** |  |  |
| **Phlebotomy (Blood sampling)** |  |  | **Other (please specify)** |  | |

**3.15 Provide a description of each of the activities selected above:**

Attach surveys, interview or focus group schedules, questions or topics to be covered to the application.

|  |
| --- |
|  |

Information provided in **Question 3.15** should be incorporated into information provided to participants, either through a participant information sheet or other methods as described in **Question 3.10**. University templates for participant information sheets, consent forms, an independent contacts and complaints procedures form and a drugs to be administered form are available at <http://www.adelaide.edu.au/ethics/human/guidelines/applications/>.

Copies of surveys, interview or focus group schedules, questions and topics to be covered should be attached to the application. All attachments should be clearly labelled with appropriate headings and referred to within the body of the application.

|  |
| --- |
| **SECTION 4: ETHICAL CONSIDERATIONS** |

In addition to the ethical considerations pertaining to all research participants, researchers should be aware of the specific issues that arise in terms of the design, conduct and ethical review of research involving various categories of participants as outlined in the *National Statement Section 4*.

**4.1 Describe the likely burden/s of participation and any risks to participants when undertaking the research:**

Burdens include impacts on participants such as inconvenience e.g. filling in a form, participating in a street survey, or giving up time to participate in research and discomfort e.g. minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Risks can be emotional, social, legal, medical or physical and can include distress and harm. See *National Statement Chapter 2.1*.

|  |
| --- |
|  |

**4.2 Describe how the risks will be minimised or mitigated. Outline any relevant protocols for management of risks including distress protocols, occupational health and safety practices, first aid procedures etc.**

See *National Statement 1.7 and Chapter 2.1.*

|  |
| --- |
|  |

**4.3 Describe how the likely benefits of the research will justify the burden/s and/or risk/s to participants:**

See *National Statement 1.6 and Chapter 2.1*

|  |
| --- |
|  |

**4.4 Outline the protocol that will be followed in the event of any adverse events:**

It is a condition of approval that researchers **immediately** report to the [HREC Secretariat](http://www.adelaide.edu.au/ethics/contacts/) any adverse events that might warrant review of ethical approval. See *National Statement 5.1 and 5.5.*

|  |
| --- |
|  |

**4.5 Will participants receive any reimbursement of out of pocket expenses, or financial or other rewards as a result of participation? What is the amount or nature of the reimbursement/reward and the justification for this?**

See *National Statement 2.2.10 and 3.3.18.*

|  |
| --- |
|  |

**4.6 Does the research involve limited disclosure of the research aims? If YES, provide a justification.** See *National Statement Chapter 2.3.*

|  |
| --- |
|  |

**4.7 Describe any possible risks to the health or safety of the researcher(s) when undertaking the research?**

Where interviews are to be held in participants’ homes as opposed to public places provide a rationale other than convenience for why this is necessary (and outline the personal safety protocol for the researchers involved). See the *Australian Code of Responsible Conduct in Research 1.2.*

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 5: DATA – CONFIDENTIALITY, ANALYSIS, REPORTING, STORAGE AND FUTURE USE** |

**5.1 Select the option that reflects the type of data that will be received or collected throughout the research:**

|  |  |
| --- | --- |
| **Type of data** |  |
| **Non-identifiable:** data received or collected about participants that is received in a non-identifiable form. This includes data which has never had personal identifiers e.g. an anonymous survey, or from which identifiers have been permanently removed before you received it. It is not possible for you to identify a specific individual. |  |
| **Re-identifiable:** data from which personal identifiers have been removed and replaced by a code. The data is either received with a code already attached and personal identifiers have been removed or you remove identifiers and replace with code. It remains possible for you or others to re-identify a specific individual by, for example, using the code or linking different data sets. |  |
| **Individually Identifiable:** data where the identity of an individual could be reasonably ascertained. Examples of identifiers include the individual’s name, image, date of birth or address, or in some cases their position in an organisation. |  |

**5.2 Compliance with the *Guidelines under Section 95 and 95A of the Privacy Act 1988:***

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| **5.2.1** Is this research relevant to public health or public safety, or to the management, funding or monitoring of a health service?  This includes collecting, using or disclosing health information for the purposes of research or compiling statistics relevant to public health or public safety. |  |  |
| **5.2.2** Does the research involve collection, use or disclosure of health information held by an organisation **without** consent from the individual(s) the information relates to? |  |  |
| **5.2.3** Will this information be individually identifiable? i.e. the individual’s identity can be reasonably ascertained. |  |  |

If you answer **YES** to all three questions in **5.2**, you will need to provide a proposal to the HREC as to why the public interest value of your research out-weighs the public interest in the protection of privacy. The proposal must address the appropriate sections of the G*uidelines under Section 95 and 95A of the Privacy Act 1988*. The guidelines are available at: <https://www.nhmrc.gov.au/guidelines/publications/pr1> and <https://www.nhmrc.gov.au/guidelines/publications/pr2>.

In the questions below, outline how the privacy and confidentiality of participant data and samples will be protected throughout the different stages of the research, making reference to the type of data (non-identifiable, re-identifiable or individually identifiable) that will be accessed by the researcher(s).

**5.3 How will researcher(s) protect the privacy and confidentiality of participant data and samples during the collection and/or recruitment phase?**

|  |
| --- |
|  |

**5.4 How will researcher(s) protect the privacy and confidentiality of participant data and samples during the data analysis phase?**

|  |
| --- |
|  |

**5.5 Will researchers be taking photographs or recordings of participants using audio tape, film/video, or other electronic medium and how are these to be used?**

This information should be provided to participants.

|  |
| --- |
|  |

**5.6 How will the information or data be analysed and who will have access?**

|  |
| --- |
|  |

**5.7 Will participants receive feedback of findings prior to any publication (including access to transcripts of interviews or drafts of reports)?**

|  |
| --- |
|  |

**5.8 How will researcher(s) protect the privacy and confidentiality of participant data and samples during the reporting of research results?**

Outline if participants will have the option of being identified or referred to by a pseudonym. Where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the information provided to participants. See *National Statement 3.1.10.*

|  |
| --- |
|  |

**5.9 How will the project outcomes be made publicly accessible at the end of the project and in what forms (e.g. journal article, book, conference paper, in the media, presentations)? If not, explain why.**

|  |
| --- |
|  |

**5.10 For all records and materials (written or electronic) used or collected during the project, outline the storage methods, storage location and details of access to the items both during and after completion of the project.**

Refer to Section 2 of the *Australian Code for the Responsible Conduct of Research* at <http://www.nhmrc.gov.au/guidelines/publications/r39>

|  |
| --- |
|  |

**5.11 Outline the length of time that the records and materials will be retained by the University.**

Note that the minimum period for retention of research data is 5 years from the date of any publication and varies depending on the specific type of research. For more information refer to Section 2 of the *Australian Code for the Responsible Conduct of Research* at <http://www.nhmrc.gov.au/guidelines/publications/r39>

|  |
| --- |
|  |

**5.12 If you intend to use the data collected in this project in future research projects, or make it available for use by other researchers describe how the data may be used in future (i.e. for what other purpose).**

How will you inform participants in this research project of how their data will be used in the future? If future use of the data is intended, you must ensure participants are fully informed of this in the Participant Information Sheet and Consent Form.

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 6: CONFLICT OF INTEREST OR OTHER ETHICAL ISSUES** |

**6.1 Outline the source of any project funding:**

See *National Statement 5.2.7*

|  |
| --- |
|  |

**6.2 Outline any ‘conflict of interest’ issues that may arise during the project:**

See *National Statement 5.2.10 and Chapter 5.4*

|  |
| --- |
|  |

**6.3 Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this research?**

Benefits must be declared to the HREC and included in the information provided to participants. See *National Statement Chapter 5.4.*

|  |
| --- |
|  |

**6.4 Outline any other ethical or relevant issues not yet discussed in this application:**

|  |
| --- |
|  |

|  |
| --- |
| **SECTION 7: RESEARCHER(S)’ QUALIFICATIONS AND EXPERIENCE** |

**7.1 Student Researcher(s):**

This section should be completed for all students listed in Question 1.5. If there will be direct contact with participants by the research student/s, outline their experience and training to conduct this research.

|  |  |  |  |
| --- | --- | --- | --- |
| **Student’s name, title:** |  | **School or Department:** |  |
| **Program Level:**  PhD, Masters by Research/Coursework, Bachelor, Honours etc. | | If other please describe | |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Student’s name, title:** |  | **School or Department:** |  |
| **Program Level:**  PhD, Masters by Research/Coursework, Bachelor, Honours etc. | | If other please describe | |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Student’s name, title:** |  | **School or Department:** |  |
| **Program Level:**  PhD, Masters by Research/Coursework, Bachelor, Honours etc. | | If other please describe | |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

**7.2 Other Researcher(s):**

This section should be completed for all researchers listed in Question 1.6.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name, title and position:** |  | **School/Department or other institution:** |  |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name, title and position:** |  | **School/Department or other institution:** |  |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name, title and position:** |  | **School/Department or other institution:** |  |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name, title and position:** |  | **School/Department or other institution:** |  |
| **Email:** |  | **Phone:** |  |
| **Qualifications and research experience relevant to the project:** | (No more than 100 words) | | |
| **Role in the research:** |  | | |

|  |
| --- |
| **SECTION 8: DECLARATION BY THE RESEARCHER(S)** |

**8.1 Readability Review:**

Readability is the ease with which text can be read and understood. Applications are sometimes delayed when corrections due to issues with readability, especially to the participant documents (Information Sheets, Consent Forms, surveys etc.) are needed. Grammar, technical terms and language not tailored to the participant can impact on participants’ understanding of the research and being able to give fully informed consent. A review for readability involves asking someone (other than the author) such as a peer outside the research team to review the application and participant documents for feedback on the ease to which the application was read and understood.

|  |  |  |
| --- | --- | --- |
| Has the application, including the participant documents, undergone a readability review? | Yes | No |

**8.2 Declaration by the Researcher(s):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **I/we have read the** [***National Statement on Ethical Conduct in Human Research (2007)***](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm) and the [***Australian Code for the Responsible Conduct of Research***](https://www.nhmrc.gov.au/guidelines/publications/r39)**.**  **I/we, the researcher(s) agree to**:   * conduct the project in accordance with our responsibilities under the *National Statement on Ethical Conduct in Human Research (2007)* and the *Australian Code for the Responsible Conduct of Research* * start this research project only after obtaining final approval from the Human Research Ethics Committee (HREC) * only carry out this research project where adequate funding and personnel is available to enable the project to be carried out according to good research practice and in an ethical manner * notify the HREC in writing in the event of any adverse or unforeseen events; requesting amendments for approval prior to commencement; completion; discontinuation of the project or changes to research personnel * provide an annual progress report to the HREC for the duration of the research project * provide the HREC with a final report * agree to participate in an audit if requested by the HREC.   **In addition, as the applicant, I**:   * accept responsibility for the conduct of this research project in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* and the *Australian Code for the Responsible Conduct of Research.* * certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfil their role in this project * will take responsibility for the confidential maintenance of the research materials as per the [University’s Responsible Conduct of Research Policy](http://www.adelaide.edu.au/policies/96), the [University’s Records Policy](http://www.adelaide.edu.au/policies/606/) and as required by legislation.   All persons named in **Section 1** are required to sign below: | | | | | |
| Applicant’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |
| Researcher’s signature: |  | Name: |  | Date: |  |

|  |
| --- |
| **SECTION 9: CHECKLIST** |

**The following documents are attached to this application:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A\*** |  |
|  |  |  | Participant information: either as information sheet, verbal script or survey preamble |
|  |  |  | Standard Consent Form for a participant in a research project (written consent is required for the majority of projects) |
|  |  |  | Consent by a Third Party to Participation Form (required where participants are children under 18 years or a dependent adult) |
|  |  |  | Contacts and Independent Complaints Procedure information sheet or statement (required for all projects, including on-line surveys) |
|  |  |  | Other recruitment documentation including advertisements, flyers, recruitment letters, emails of introduction, copy of Facebook event pages and social media event sites. |
|  |  |  | Procedure/protocol for interviews or focus groups including topics, questions or themes |
|  |  |  | Survey instrument/Questionnaire (include a printed copy of on-line survey) |
|  |  |  | Adverse events procedure |
|  |  |  | Evidence of approval/rejection by other HRECs, including comments and requested alterations to the application |
|  |  |  | Research with people outside Australia: Evidence of permissions, approvals from overseas authorities etc |
|  |  |  | Administration of Drugs Form |
|  |  |  | Annual Report on Project Status |

\*Not applicable

**All documents attached should be referred to in the main body of the application and clearly labelled using appropriate headings i.e. Attachment 1, Attachment 2 etc.**

**T**

|  |
| --- |
| **SECTION 10: HOW TO SUBMIT THIS APPLICATION** |

1. Print the completed form and get all signatures.
2. Scan the signed form including all labelled attachments as **one pdf file** and email to: [hrec@adelaide.edu.au](mailto:hrec@adelaide.edu.au).
3. [Submission deadlines](http://www.adelaide.edu.au/ethics/human/deadlines/) apply to applications requiring full HREC review. Applications submitted for low risk review can be submitted at any time. Research timetables should allow for the possibility that a project submitted as a low risk application may be deemed to involve more than low risk, or to raise other issues, therefore requiring full review. Researchers may be requested to provide additional information.

NB References to the *National Statement* throughout the application form are not meant to be exhaustive but rather they aim to provide a starting point for researchers to consider. Researchers should be familiar with the *National Statement* and other relevant guidelines.