**Swinburne**

**Human Research Ethics**

**Application Form**

This form is to be completed in conjunction with the Guide to Completing the Swinburne Human Research Ethics Application Form and the National Statement on Ethical Conduct in Human Research.

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| **Project Title** |  |
| **CI name and title** |  |

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| **Section 1: Level of Risk** |

If a project is of low or negligible risk then ordinarily it can be submitted for sub-committee review. Low risk research is defined in the *National Statement* as: Research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

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|  | **Do any of the below apply to your project?** | **Yes** | **No** |
| 1.1.1 | Research only being conducted for purposes of quality assurance for internal Swinburne purposes only and there will not be any publications, presentations or other such research outcomes. Non-identifiable information only being used or accessed. If yes, then you do not need ethics approval to proceed. Contact the Ethics Office if you need further clarification of this. |  |  |
| 1.1.2 | Has your project already been reviewed and approved by another HREC?  If so, then your project could be eligible for expedited review. Contact the Ethics Office to confirm. You will need to provide:   * a covering letter outlining the Swinburne role in the project: * the approval; * all documentation provided to attain the approval; and * any documentation regarding clarifications etc. |  |  |
| 1.1.3 | Clinical trial or intervention?  If yes, then you will need to contact the Ethics Office as you might need to submit your project for approval at a non-Swinburne HREC such as the Alfred Hospital HREC or Bellberry. If your project can be reviewed by SUHREC then you will need to complete the HREA (Human Research Ethics Application) Form, the Victorian Specific Module and prepare a Study Protocol. |  |  |

Please consult the below list and check any boxes that might apply to your research.

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| **1.2** | **Does your project involve any of the following categories of research requiring HREC review? *NS 5.1.6*** | **Yes** | **No** |
| 1.2.1 | Interventions and therapies, including clinical and non-clinical trials and innovations |  |  |
| 1.2.2 | Human genetics |  |  |
| 1.2.3 | Human stem cells |  |  |
| 1.2.4 | Women who are pregnant and the human foetus |  |  |
| 1.2.5 | People highly dependent on care who may be unable to give consent |  |  |
| 1.2.6 | People with a cognitive impairment, an intellectual disability, or a mental illness |  |  |
| 1.2.7 | Aboriginal or Torres Strait Islander Peoples |  |  |
| 1.2.8 | People involved in illegal activities |  |  |
| 1.2.9 | Planned deception, covert observation, or active concealment of information |  |  |
| 1.2.10 | Collection of identifiable information without permission from person involved |  |  |
| 1.2.11 | People in countries that are politically unstable, where human rights are restricted or where research involves economically disadvantaged, exploited or marginalised participants from such countries |  |  |
| 1.2.12 | Risk of more than discomfort to participants ***NS 2.1.6*** |  |  |
| 1.2.13 | Does your project access information requiring compliance with Section 95 and 95A of the Privacy Act? |  |  |
| **1.3** | **Does your project involve any of the following topics?** | **Yes** | **No** |
| 1.3.1 | Any disease or health problem |  |  |
| 1.3.2 | Sensitive personal issues |  |  |
| 1.3.3 | Sensitive cultural issues |  |  |
| 1.3.4 | Grief, death or serious/traumatic loss |  |  |
| 1.3.5 | Gambling |  |  |
| 1.3.6 | Any psychological disorder, depression, anxiety or mood states? |  |  |
| 1.3.7 | Eating disorders |  |  |
| 1.3.8 | Illicit drug use or substance abuse |  |  |
| 1.3.9 | Self-report of criminal behaviour |  |  |
| 1.3.10 | Parenting behaviour |  |  |
| 1.3.11 | Suicide |  |  |
| 1.3.12 | Minors (except where they are 15-17yrs and project involves no more than anonymous questionnaires of non-sensitive nature) |  |  |
| 1.3.13 | Fertility |  |  |
| 1.3.14 | Termination of pregnancy |  |  |
| 1.3.15 | Race or ethnic identity |  |  |
| 1.3.16 | Sexuality, sexual behaviour or gender identity |  |  |
| **1.4** | **Does your project specifically target participants from any of the following groups?** | **Yes** | **No** |
| 1.4.1 | People highly dependent on medical care |  |  |
| 1.4.2 | People not usually considered vulnerable but who may be thought so in the context of the project |  |  |
| 1.4.3 | People in a dependant or unequal relationship with the researchers (eg lecturer/student, doctor/patient, teacher/pupil, professional/client) |  |  |
| 1.4.4 | People unable to give consent because of difficulties in understanding the Plain Language Statement or Participant Information Statement or the like (eg language  difficulties) |  |  |
| 1.4.6 | People whose ability to give consent is impaired |  |  |
| 1.4.7 | People with a physical disability or vulnerability |  |  |
| 1.4.8 | Residents in a custodial institution |  |  |
| 1.4.9 | Members of a socially identifiable group with a special cultural or religious needs or political vulnerabilities |  |  |

If you answered yes to any of the above questions then your project will probably need to be reviewed by the full human research ethics committee, the Swinburne University Human Research Ethics Committee (SUHREC).

If you answered no to all of the above questions then your project could be reviewed by a sub-committee. Please note that if there is anything in the project details that either the Research Office or the reviewing body considers should be reviewed by the full committee then the project will be referred to SUHREC for review.

If you still believe that your project should be reviewed by a sub-committee because of either the nature of the participants or project then provide a brief justification review below.

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| **Section 2: Administrative Details** |

**2.1 Project Title**

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**2.2 Project time frame for activities that require ethics approval**

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| Commencement date |  | Completion date |  |

**2.3 Chief Investigator details** (CI can’t be a student or a sessional staff member)

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| --- | --- | --- | --- |
| CI’s name and title: |  | | |
| Faculty and/or Research Centre/unit: |  | | |
| Email: |  | Phone: |  |
| Qualifications and research experience relevant to the project. Include # and expiry details of WWCC if one is required. |  | | |
| Role in the project: |  | | |

**2.4 Contact person for communication if different to the above**

|  |  |  |  |
| --- | --- | --- | --- |
| Name and title: |  | | |
| Faculty and/or Research Centre: |  | | |
| Email: |  | Phone: |  |

**2.5 Type of activity** Click on  'check box' to select box. Select as many as applicable

|  |  |
| --- | --- |
| Research by Staff Member | Contract Research (Attach contract) |
| SUT-administered Collaborative Research | Other Collaborative Research |
| Supervised Postgraduate Research | Supervised Honours Research |
| Supervised Class Project (course/unit): | Supervised Undergraduate Research |

**2.6 Category of Research**

|  |  |  |  |
| --- | --- | --- | --- |
| Social/Cultural/Humanities | | Business/Management | Program Evaluation |
| Psych/Brain/Neuro-sciences | | Health/Safety | Design |
| Engineering | | Sciences | Technology |
| Education | Other (please specify) | | |

**2.7 Swinburne Class Projects:**   Not Applicable

This is only for class projects that involve multiple students. Give a summary of the role students will play in the conduct of the project, the training and supervisory arrangements, and indicate where student investigator involvement will be recorded.

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**2.8 Details of non-student Co-investigators** Copy box as many times as required.

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| --- | --- | --- | --- |
| Name, title and position: |  | Faculty and/or Research Centre: |  |
| Email: |  | Phone: |  |
| Qualifications and research experience relevant to the project.  Include # and expiry details of WWCC if one is required. |  | | |
| Role in project: |  | | |

**2.9 Student details (not for class projects)** Copy the below table as many times as required.

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| --- | --- | --- | --- |
| Student’s name, title: |  | Faculty and/or Research Centre/unit: |  |
| Program Level: PhD, Ms by Res/Coursework, Hons etc. |  | Student number: |  |
| Email: |  | Phone: |  |
| Describe any research experience relevant to the project, provide details of training, monitoring and supervisory arrangements. Include # and expiry details of WWCC if one is required. |  | | |
| Role in the project: |  | | |

**2.10 Is this project related to any other previously submitted to SUHREC or a sub-committee?**

Check the box if any of the following applies:

A resubmission

The continuation of a longer-term project

A sub-component of a larger project

If any of these boxes have been checked provide the relevant SUHREC number(s) assigned.

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**2.11 Has your project been peer reviewed?**

NHMRC/ARC Peer Review Panel  Other external funding body peer review

Internal Swinburne peer review  Other external peer review

Student candidature review  Other

Explain briefly the extent to which this project has been subjected to review and the outcome to date:

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**2.12 Has or will this project be submitted for approval to any government departments or institutions or businesses?** Provide details and attach relevant documentation.

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**2.13 Does the project involve research collaboration with non-Swinburne persons or organisations?**

No  Yes

If YES then please clarify the type and degree of collaboration and include the following information:

* Swinburne approval(s) for external ethical and any safety monitoring arrangements;
* reporting arrangements to external parties dissemination of research outcomes;
* management of research materials or data including ownership of IP; and
* insurance or indemnity arrangements

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**2.14 Financial Information**

**2.14.1** How is the project being funded to ensure project viability? (Please select one or more as applicable):

Swinburne/Faculty/Unit  Student Self-funding

Scholarship/Bursary  Student Employer

Australian Competitive Grant  Other Australian Public Sector Grant

Industry Income/Grant  Donations/Bequests/Trusts

Overseas Public Sector  Overseas Private Sector

Other

Briefly clarify funding, materials and other resources being provided or subsidised.

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**2.14.2** For ARC or NHMRC-funded research, please cite ARC or NHMRC-generated ID number(s):

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| ARC Project No:  NHMRC Project No: |

**2.14.3** In the case of resourcing by an external body, other than ARC/NHMRC, clarify to what extent resourcing is covered by a contract or agreement.  Not applicable

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**2.14.4** Outline if any conditions or restrictions have been placed on the receipt of funding including commercial-in-confidence matters, delayed publication of research outcomes, commercial ownership of research data/materials or intellectual property.  Not applicable

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**2.15** Additional or Non-Swinburne Insurance/Indemnity

Check the box if the project involves any one or more of the following:

Medical or Professional Health Assessment or Therapy

Research conducted in a hazardous environment outside of Swinburne

High risk equipment or procedures (not including Swinburne MRI or MEG)

Research conducted overseas in proscribed, hazardous or unsafe areas

Externally supplied substances or devices to use with participants

If any of these boxes have been checked then additional insurance or indemnity may be required. Please check with Swinburne Finance via your faculty. Provide details of any additional arrangements below.

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| **Section 3 Project Details** |

**3.1 What is your project about?** Provide a brief plain language summary (max 200 words). Avoid acronyms.

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**3.2 What is the research background and aims of your project?** Provide a bibliography.

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**3.3 How will you go about your project?** Clearly detail all procedures and methods to be employed specifically those that involve human participants.

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**3.4 What are the benefits of your project?**

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**3.5 Where is the human research component of your project to take place?**

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| Online survey/questionnaire | Swinburne (Australia) |
| Other. State all locations. Specify any external organisations involved, contracts, and status. | |

**3.6 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.** Attach authorising correspondence and/or approval documentation to the application. ***NS 4.8***

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| **Section 4 Participants or their data and Recruitment** |

**4.1 Who will be the participants? ‘**Participants’ includes data about people or human tissue samples. Add rows as required.

Please note: For research involving participants under the age of 18 years old researchers, including HDR students, may be required to hold a current WWCC. (Please see the following more details <http://www.swinburne.edu.au/about/campuses-facilities/safety-security/child-safety/>)

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| --- | --- | --- | --- |
| **Participant/participant group details** | **Number of people/samples** | **Age range** | **Gender** |
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**4.2 What is your justification for targeting these participants?** Where applicable, please include a sample size calculation.

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**4.3 What are the participant selection and exclusion criteria?**

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**4.4 From where will the participants be recruited or sourced?**

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**4.5 What materials will be used to recruit participants and how will they be used?** Attach all material to this application.

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

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**4.7 Will any personal information such as names, contact details or email addresses be accessed for purposes of recruitment?If yes, outline how and by whom this information will be accessed.**

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**4.8 How and when will information about the proposed research activities be provided to participants and any third parties?**

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**4.9 Explain how and when consent will be obtained from participants and any third parties.** This also includes if consent will not be sought due to covert observation or a deliberate decision not to seek consent. Check all boxes that apply.

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| **Type of consent** | | | **Yes** |
| Consent waiver *Please refer to National Statement Section 2.3.10 and, in the box below specifically address how the project meets the nine requirements for a consent waiver* | | |  |
| For those participants who have the capacity to give voluntary and informed consent | | | |
|  | | Written consent |  |
| Oral consent |  |
| Implied consent |  |
| Other |  |
| For those participants who have limited or no capacity or authority to give voluntary and informed consent | | | |
|  | Written consent | |  |
| Oral consent | |  |
| Implied consent | |  |
| Other | |  |

Explain how each consent method will be used, which participants will be involved and why.

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

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**4.11 Will there be any dependant or unequal relationships between the researchers and the participants?**

Yes  No

If Yes then describe the nature of the relationship and how the ethical issues arising are being addressed.

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**4.12 What is the time commitment required?**

**4.12.1** For each of the research activities in your project indicate the approximate time commitment required of participants.

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| **Research activity** | **Estimated time per participant** | | **Research activity** | **Estimated time per participant** | |
| 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 complementary medicines |  |  |
| Body organs, tissues or fluids |  |  | Psychological testing or treatment |  |  |
| Phlebotomy (Blood sampling) |  |  | Other (please specify) |  |  |

**4.12.2 Provide a description of each of the activities checked above:** Attach documents as applicable.

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| **Section 5 Data Collection, Retention, Use and Disposal** |

**5.1 Select the option(s) that reflects the type(s) of data that will be received or handled throughout the research:**

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| **Type of data** | **YES** |
| Non-identifiable: data received or collected about participants, that is, received in a non-identifiable form. This includes data which have 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 Privacy and/or Health Records legislation*:***

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| Does the research involve collection, use or disclosure of health, sensitive or personal information without consent from the individual(s) the information relates to? | **YES** | **NO** |

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| If you answered YES to the above question you will need to provide a proposal to SUHREC 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 statutory or other guidelines. Please see the Guide for more information. |

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

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

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**5.5 Are you taking photographs or recordings including radiology, ionizing or magnetic radiation, and fingerprinting of participants using audio tape, film/video, or other electronic medium? And if so how are these to be used?** Provide the details below.

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

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

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

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**5.9 How will the project outcomes be made publicly accessible at the end of the project and in what forms?**

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**5.10 For all records and materials (written or electronic and including signed consent documents) used or collected during the project, what are the storage methods, location and accessibility to the items both during and after completion of the project?**

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**5.11 What is the minimum time that the records and materials will be retained by the University?**

Enough time for Internal student assessment and requirements only (eg, undergraduate or coursework projects)

5 years after any publication or published outcome

7 years after last health-related interaction with participant(s) or last health service provision

15 years after last interaction with participant(s) (eg, for clinical trials)

Until participant(s) who were minors at the time of research participation attain 25 years of age (eg, identifiable health-related information involving minors)

Indefinite period or archived permanently

Other - clarify below.

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**5.12 Do you plan to use the data in future research projects?**

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| **Section 6 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*.

**6.1 What are the likely benefits to participants in this project?**

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**6.2 What are the likely risks for participants?**

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**6.3 How will the risks will be minimised and mitigated?**

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**6.4 How do the likely benefits of the project justify the burden(s) and/or risk(s) to participants?**

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**6.5 Outline the protocol that will be followed in the event of any reportable adverse events.**

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**6.6 Will participants be reimbursed in any way?**

**6.6.1** Will participants receive any reimbursement of out of pocket expenses, or financial or other rewards as a result of participation?

No  Yes – clarify and justify below  Yes via the REP – Go to Q6.6.2

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**6.6.2** If using the Psychology Research Experience Program (REP), then attach the advertising brief used on the REP site, the debriefing statement, and declare the amount of credit awarded.

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**6.7 Does the research involve limited disclosure including active concealment and explicit deception?** If YES, provide a justification.

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**6.8 Are there any possible risks to the health or safety of the researcher(s) when undertaking this project?** Describe how these risks will be mitigated and managed.

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**6.9 Could there be any possible risks to others not directly involved arising from this project and how will these be mitigated and managed?** This can include relatives of participants, bystanders, the University or sponsor.

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**6.10 Does your project investigate any activity or use a method that is or might be considered to be illegal?** *NS 4.6*

Yes  No

If yes then please answer the following questions:

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| --- | --- | --- | --- |
| **6.10.1** | Are you researching any activity or using a method that is or might be considered illegal? Or could your research uncover illegal activity? Includes researching illegal/illicit substance use, offences, violence, abuse, bullying, etc. | Yes | No |
| **6.10.2** | Could any aspect of your study reasonably be expected to place a participant, a researcher or other party at risk of criminal or civil liability? | Yes | No |

If you answered yes to either one of the above questions, then explain and justify why you should be able to proceed with the project.

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**6.11** **Is there any personal benefit (i.e. financial) for researchers in this study or its outcomes that might represent a perceived, potential or actual conflict of interest?**

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| **Section 7 Declarations and Signatures** |

All persons named in Section 2 are required to sign below. In the case of multiple-student class projects, the CI/Supervisor is responsible for keeping the list of students bound by the above declaration. The CI is responsible for personnel subsequently joining or leaving the project and submitting a modification request to the Research Office.

**7.1 Declaration by Chief Investigator, co-investigators and students**

I/we, the researcher(s) agree that:

* All information is truthful and as complete as possible;
* I/we will conduct the project in accordance with our responsibilities under the *National Statement on Ethical Conduct in Human Research (2007)*, its updates or modifications, and the *Australian Code for the Responsible Conduct of Research;*
* I/we will consult any relevant legislation and regulations in order to conduct the project in accordance with these;
* I/we will conduct the project in accordance with Swinburne requirements and the standard or special ethics clearance conditions including provision of reports as required;
* I/we will only carry out this project with adequate funding and personnel available to enable the project to be conducted according to good research practice and in an ethical manner; and to
* I/we will immediately report in writing to the HREC of any adverse or unforeseen events.

Expand this table or duplicate this page as required.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| CI signature |  | Name |  | Date |  |
| Co-investigator or student signature |  | Name |  | Date |  |
| Co-investigator or student signature |  | Name |  | Date |  |
| Co-investigator or student signature |  | Name |  | Date |  |
| Co-investigator or student signature |  | Name |  | Date |  |

**7.2 Additional declaration for supervisor(s) of student(s)**

I/we agree to:

* Provide appropriate supervision to the student(s) to ensure that the project is undertaken in accordance with the agreement above;
* Ensure that appropriate training is provided necessary to enable the project to be undertaken skilfully and ethically.

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| Supervisor signature |  | Name |  | Date |  |
| Supervisor signature |  | Name |  | Date |  |

**7.3 Endorsement by Academic Unit Head or above**

I declare that:

* I am familiar with this project and endorse its undertaking;
* The resources to undertake this project are available; and that
* The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

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

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| **Section 8: Checklist** |

The following documents are attached to this application:

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| --- | --- | --- | --- |
| Yes | No | N/A\* |  |
|  |  |  | Evidence of approval from Government departments, institutions or businesses, including comments and requested alterations to the application. **Q2.12** |
|  |  |  | Additional Indemnity or insurance **Q2.13 and 2.15** |
|  |  |  | Research with people outside Australia: Evidence of permissions, approvals from overseas authorities etc **Q3.5 and 3.6** |
|  |  |  | Participant Information Statement: either as information sheet, verbal script or survey preamble. **Q4.5** |
|  |  |  | Consent Form for a participant in a research project (written consent is required for the majority of projects). **Q4.5** |
|  |  |  | Consent by a Third Party to Participation Form (required where participants are children under 18 years or a dependent adult). **Q4.5** |
|  |  |  | Other recruitment documentation including advertisements, flyers, recruitment letters, emails of introduction, copy of Facebook event pages and social media event sites. **Q4.5** |
|  |  |  | Procedure/protocol for interviews or focus groups including topics, questions or themes. **Q4.12.2** |
|  |  |  | Survey instrument/Questionnaire (include a printed copy of on-line survey). **Q4.12.2** |
|  |  |  | Proposal to access information protected by the Privacy Act 1988 Sections 95 and 95A **Q5.2** |
|  |  |  | Adverse events procedure. **Q5.2** |
|  |  |  | REP documentation **Q 6.6** |

\*Not applicable

All documents attached should be referred to in the main body of the application and should be clearly labelled using appropriate headings i.e. Attachment 1, Attachment 2 etc. The whole application, including attachments, must be numbered in sequential order.

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| **Section 9: How to Submit this Application** |

1. Convert the completed form to a pdf and, inserting all of the attachments, create a single pdf.
2. Number the pages of the single pdf sequentially.
3. Print the signature pages and obtain all of the required signatures.
4. Scan the signature pages and insert into the single pdf file
5. Email the final pdf to: [resethics@swin.edu.au](mailto:resethics@swin.edu.au). Please ensure that it is a *high quality* pdf file. Hard copies of applications are **not** required.

[Submission deadlines](https://www.swinburne.edu.au/intranet/research/research-integrity--ethics/human-research-ethics/lodgement-instructions-and-deadlines/) apply to all applications requiring main committee (SUHREC) or sub-committee review (SHESC). Research schedules 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.