|  |  |
| --- | --- |
|  | **HUMAN RESEARCH ETHICS**PROJECT APPLICATION FORM |

|  |
| --- |
| How To Use This Form**1. Consider and refer to relevant guidelines and regulations.**References to specific guidelines are provided, with hyperlinks, throughout this form. The primary guide for human research ethics in Australia is the[***National Statement on Ethical Conduct in Human Research (2007) - Updated 2018***](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018). Human research ethics applications at the University of Melbourne are reviewed and approved under the warrant of the *National Statement*. References to the *National Statement* are abbreviated (e.g. [***NS* §2.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_1__risk_and_benefit).)**2. Use plain English.**Use clear, non-technical language in your application. Be concise. Spell out the first instances of acronyms and abbreviations. Avoid jargon. Do not repeat information. Following these directions ensures effective review of your application. It will avoid unnecessary delays which result if applications are not clear and concise.**3. Consider ethical principles.**Your application will be reviewed according to the principles of ethical research outlined in the *National Statement*, namely:* **Research Merit and Integrity** ([***NS* §1.1 - §1.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#research_merit_and_integrity))
* **Justice** ([***NS* §1.4 - §1.5**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#justice))
* **Beneficence** ([***NS* §1.6 - §1.9**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#justice))
* **Respect** ([***NS* §1.10 - §1.13**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#respect))

**4. Use the current version of the application form.**Ensure that you are using the current version by downloading [**this form**](http://research.unimelb.edu.au/__data/assets/word_doc/0009/1977534/HRE-ProjectApplicationForm.docx) each time you prepare a new application.**5. Detailed instructions for specific questions are available online.**If you are unsure about how best to answer a particular question, consult the Human Research Ethics [**Guidance Document**](http://research.unimelb.edu.au/__data/assets/pdf_file/0009/1977543/HRE-Application-Guidance-V-1.1.pdf). That document provides detailed guidance on how to answer specific questions in this form. **6. Where possible, avoid printing this form.**Consult your HEAG to find out if they still require hard copies of your application. If you must print this form, consider printing double-sided and in grayscale (black and white).**7. Save your completed application as a PDF and upload it to** [**Themis**](http://themis.unimelb.edu.au)**.**Refer to your local Human Ethics Advisory Group ([**HEAG**](https://staff.unimelb.edu.au/research/ethics-integrity/human-ethics/contacts)) for detailed instructions on how and when to submit your application. |

**ANSWER ALL OF THE QUESTIONS IN THIS FORM**

|  |  |
| --- | --- |
| **Ethics ID number:** *(assigned by Themis)* |   |
| **Project Title:** *(as recorded in Themis)* |   |
| **Responsible Researcher:** *(as recorded in Themis)* |   |
| **Application Type:***(mark with an “X”)* |  | **Minimal Risk** |
|  | **Standard Project** |

1. Project Details

|  |  |
| --- | --- |
| 1.1 Project Summary | Summarise your research project in plain language. **[Limit: 300 words]** |
| **A) Aims and Objectives**[Briefly describe the broad aims and objectives of this project.]**B) Key Question(s)**[What question, or questions, does the project intend to examine? Where relevant, state the specific hypothesis to be tested.]**C) Research Design**[Outline the research design/approach. In particular, note the type(s) of participants, and type(s) of data collection.] |

|  |
| --- |
| **Specific Guidelines Checklist** |
| **Type an “X” in the left-hand column beside all items that apply to your research project.** Linked sections of the National Statement contain relevant guidelines and requirements that you need to address when completing your application.  |
|  | **Children and/or young people (< 18 years old)** will be recruited as participants. | **🡪 Refer to** [***NS* §4.2**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_2__children_and_young_people)**.** |
|  | **People in dependent or unequal relationships** will be recruited as participants.(There are pre-existing relationships between participants and researchers, or between participants and others involved in facilitating or implementing the research. E.g. student/teacher, patient/doctor, employee/employer.) | **🡪 Refer to** [***NS* §4.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_3__people_in_dependent_or_unequal_relationships)**.** |
|  | **People in countries other than Australia** will be recruited as participants. | **🡪 Refer to** [***NS* §4.8**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_8__people_in_other_countries)**.** |
|  | One or more of the following describes the research project:* it will be about **Aboriginal and/or Torres Strait Islander individuals or peoples**, their health, or their culture(s), language(s) or histories;
* it will be about the impact(s) or effect(s) of some phenomenon or phenomena on **Aboriginal and/or Torres Strait Islander individuals or peoples;**
* it will *specifically target* **Aboriginal and/or Torres Strait Islander people** to be recruited as participants;
* it will be conducted in a geographic location where a significant number of the population are likely to be **Aboriginal and/or Torres Strait Islander.**
 | **🡪 Refer to** [***NS* §4.7**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_7__aboriginal_and_torres_strait_islander_peoples)**.****🡪 Refer to** [***Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)***](https://nhmrc.gov.au/about-us/publications/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities)**.****🡪 Refer to** [**Guidelines for Ethical Research in Australian Indigenous Studies**](http://aiatsis.gov.au/research/ethical-research/guidelines-ethical-research-australian-indigenous-studies)**🡪 This application is ineligible for minimal risk review.** |
|  | One or both of the following describes the research project:* it will *specifically target* **women who are pregnant** to be recruited as participants;
* it will be focused on **women who are pregnant and/or the human foetus** (including human foetal tissue or human embryos).
 | **🡪 Refer to** [***NS* §4.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_1__women_who_are_pregnant_and_the_human_fetus)**.** **🡪 This application is ineligible for minimal risk review.** |
|  | **People who may be involved in illegal activities** will be recruited as participants, ***and the research project could potentially expose such activities.*** | **🡪 Refer to** [***NS* §4.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_6__people_who_may_be_involved_in_illegal_activities)**.****🡪 This application is *likely* ineligible for minimal risk review.** |
|  | **People with cognitive impairment, intellectual disability, or mental illness** will be recruited as participants. | **🡪 Refer to** [***NS* §4.5**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_5__people_with_a_cognitive_impairment__an_intellectual_disability__or_a_mental_illness)**.** **🡪 This application is ineligible for minimal risk review.** |
|  | **People who are highly dependent on medical care** will be recruited as participants. | **🡪 Refer to** [***NS* §4.4**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_4__people_highly_dependent_on_medical_care_who_may_be_unable_to_give_consent)**.** **🡪 This application is ineligible for minimal risk review.** |
|  | **None of the above** applies to this research project. |  |

|  |
| --- |
| **Additional Modules Checklist** |
| **Type an “X” in the left-hand column beside all items that apply to your research project.** This checklist will help you determine if you need to complete any other modules in addition to this application form. Linked sections of the *National Statement* contain relevant guidelines and requirements that you need to address when completing this form and any applicable additional modules. |
|  | This research project will involve the **creation of a** **databank** (i.e. your stored data will be made available to other parties for secondary use in future research projects). | **🡪 Refer to** [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__collection__use_and_management_of_data_and_information)**.****🡪 Complete and attach the** [***Privacy and Databanks Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0006/1977540/PrivacyDatabanksModule.docx)***.*** |
|  | This research project will involve the **collection of information for a databank** (i.e. your stored data will be made available to other parties for secondary use in future research projects). | **🡪 Refer to** [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__collection__use_and_management_of_data_and_information)**.****🡪 Complete and attach the** [***Privacy and Databanks Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0006/1977540/PrivacyDatabanksModule.docx)***.*** |
|  | This research project will involve **accessing information from an existing databank** (i.e. you will be accessing and making use of stored data that was previously collected – not for this specific project – by other parties). | **🡪 Refer to** [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__collection__use_and_management_of_data_and_information)**.****🡪 Complete and attach the** [***Privacy and Databanks Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0006/1977540/PrivacyDatabanksModule.docx)***.*** |
|  | This research project will involve obtaining identifiable (or potentially identifiable) **personal information (including health information)** about individuals ***without their consent.*** | **🡪 Complete and attach the** [***Privacy and Databanks Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0006/1977540/PrivacyDatabanksModule.docx)***.*** |
|  | This research project will involve the collection and/or use of **human tissue/biological samples or materials** (e.g. blood, saliva, cheek swabs, hair, human embryonic or foetal tissue). | **🡪Refer to** [***NS* §3.2**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_2__human_biospecimens_in_laboratory_based_research)**.****🡪 Complete and attach the** [***Body Tissue and Genetic Research Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0012/1977537/BodyTissueGeneticResearchModule.docx)***.*** |
|  | This research project will involve **genomic research.** | **🡪 Refer to** [***NS* §3.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_3__genomic_research)**.** **🡪 This application is ineligible for minimal risk review.****🡪 Complete and attach the** [***Body Tissue and Genetic Research Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0012/1977537/BodyTissueGeneticResearchModule.docx)***.*** |
|  | This research project will involve **medical interventions, therapies or trials.** | **🡪 Refer to** [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_1__the_elements_of_research)**.** **🡪 This application is ineligible for minimal risk review.** **🡪 Complete and attach the**[***Interventions, Therapies and Trials Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0004/1977538/InterventionsTherapiesTrialsModule.docx)***.*** |
|  | This research project will involve **administration of ionising radiation.** | **🡪 Complete and attach the** [***Ionising Radiation Module***](https://staff.unimelb.edu.au/__data/assets/word_doc/0005/1977539/IonisingRadiationModule.docx)***.*** |
|  | **None of the above** applies to this research project. |  |

2. Background and Method

|  |  |
| --- | --- |
| 2.1 Background and Significance | Provide a summary of background information. Explain the significance of the proposed research in the context of this background. **Refer to** [***NS* §5.2.5**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_5_2__responsibilities_of_hrecs__other_ethical_review_bodies__and_researchers) and [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_1__research_scope__aims__themes__questions_and_methods) **[Limit: 500 words]** |
| **A) Background:**[What is the current state of research/knowledge/discourse in this area?]**B) Significance of This Research:**[Explain the significance of the proposed research project in light of existing research, knowledge or understanding. How does your research help to fill a gap in the literature? You may include relevant references, within the word limit.] |

|  |  |
| --- | --- |
| 2.2 Research Design and Method | Provide details of your research design and your proposed method. **Refer to** [***NS* §5.2.5 - §5.2.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_5_2__responsibilities_of_hrecs__other_ethical_review_bodies__and_researchers) and [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_1__research_scope__aims__themes__questions_and_methods)**Attach a copy of any measures, scales, questionnaires, survey instruments (including online surveys), interview questions/themes, and/or focus group topics/questions to be used.** |
| **A) Participants (or Recruitment Targets, such as medical records):**[Describe the sample, i.e. the intended participants or recruitment targets. Explain the basis on which this sample was chosen. Include the number and age range and any other relevant demographic characteristics of participants, as well as any eligibility constraints (i.e. inclusion/exclusion criteria). If the project involves using records or previously-collected data/samples, rather than direct contact with human participants, state that.]**B) Recruitment:**[Describe how recruitment will occur. Explain how potential participants will be identified and approached. Who will do this? Refer to [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_2__recruitment). If you will be using records or data only, and you will be completing the Privacy and Databanks Module, state “N/A.” If you will be using records or data only, but you will not be completing the Privacy and Databanks Module, explain how the records/data will be identified, collected and accessed.]**C) Participant Incentives:**[Do you propose to reward and/or reimburse and/or compensate participants in any way? If yes, give details here and comment on the special considerations discussed in [**NS §2.2.10**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)and [**NS §2.2.11**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent). If no, state “N/A.”]**D) Participant Task(s):**[What will participants be asked to do? What is the approximate time commitment required of each participant? If using records or data only, state “N/A.” If your research will be conducted in schools during class time, give details of the alternate activity arranged for students in the class who will not be participating in the research.]**E) Data/Material Collection Technique(s):**[What data/materials will be collected? Where will the data be collected? List/describe all sites.]**F) Data Analysis:** [How will data/materials be analysed? What methods/techniques/theories will be used? If qualitative methods will be used, refer to [**NS §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__data_collection_and_management).] |

3. Risks, Benefits and Monitoring

|  |  |
| --- | --- |
| 3.1 Potential Risks to Participants | Does your research project pose any potential risks to participants? What are those risks? How will they be negated, minimised or managed?**Refer to** [***NS* §2.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_1__risk_and_benefit)**.****Note that the risks you identify here should also be described in your Plain Language Statement (PLS). Attach a copy of any distress protocol or adverse event protocol (if applicable).** |
| **A) Potential Risks**[Identify, as far as possible, any potential risks to participants associated with the research project. Risks may arise from the nature of questions that participants are asked (such as discussing sensitive or distressing topics), or the tasks that participants will do, or the procedures that they will undergo. Potential risks might be physical, psychological, emotional, social, legal or economic in nature (this list is not exhaustive). Risks also may be associated with the research setting (e.g. outdoors, in unsecure housing, or in countries other than Australia). If you believe that any potential risks are minimal, please state this and explain why.]**B) Risk Management Strategy**[Describe what measures you have in place to negate, minimise or manage the potential risks you have identified. Depending on the type(s) of risks involved, participants may also need additional support (e.g. external counselling) during or after the study. Attach or include a copy of any distress protocol or adverse event protocol which you have developed.]  |

|  |  |
| --- | --- |
| **3.2 Potential Risks to Non-Participants** | Does your research project pose any potential risks to non-participants? (This could possibly include risks to researchers or independent contractors.) If so, how will these risks be minimised?**Refer to** [***NS* §2.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_1__risk_and_benefit)**.** |
| [Describe any potential risks and your risk management strategy for non-participants, if applicable. Risks to non-participants might include things such as potential breach of privacy, stigmatisation of a particular group, or knowledge about familial genetics. If you believe that any potential risks to non-participants are minimal, please state this and explain why.] |

|  |  |
| --- | --- |
| 3.3 Risks, Benefits and Justification | In light of the risks and expected benefits of the research project, explain how the expected benefits of the research justify any risks it may pose. **Refer to** [***NS* §1.6 - §1.7**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#justice) **and** [***NS* §2.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_1__risk_and_benefit)**.** |
| **A) Expected Benefits**[Describe any expected benefits of this research. Include potential benefits to the community or society, and any specific potential benefits to participants, beyond general positive feelings that may arise from participating in research and having one’s voice heard. Note that it is generally not necessary to demonstrate specific benefit to participants in order to show that research is ethically justifiable.]**B) Justification of Risks by Expected Benefits**[Explain how the expected benefits of the research justify the risk(s) which you identified in questions 3.1 and 3.2. Pay particular attention to any risk(s) to participants that are greater than inconvenience.] |

|  |  |
| --- | --- |
| **3.4 Management and Monitoring** | How will researchers manage and monitor conduct of the research project? **Refer to** [***NS* §5.5**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_5_5__monitoring_approved_research)**.** |
| **A) Management**[Provide details of how and by whom the research project will be managed, throughout the life of the project, to ensure that it complies with the protocols set out in this application, and with all relevant legislation and regulations. Address cases where several people are or may be involved in recruiting, interviewing, obtaining data or data analysis.]**B) Monitoring**[If the research will be carried out at some distance from the responsible researcher (i.e. interstate or in countries other than Australia), describe the systems in place to ensure compliance with the research protocols you have outlined in this application. If the research will be undertaken by a student, describe how the student will be supervised to ensure compliance with the protocols, including details of any local supervision to be organised for research conducted overseas or interstate. **C) Independent Contractors** [If any independent contractors (i.e. persons not listed in Themis as researchers on this project) will be carrying out any part of the research, provide details of the contractors involved, explaining their role and their qualifications/experience to fulfil this role. Include details of any training that will be provided to the contractors. Confirm that the contractors will be provided with a copy of the approved ethics protocol and advised of their responsibilities in relation to the research. If no independent contractors will be involved, state “N/A”.]  |

4. Consent

|  |  |
| --- | --- |
| **4.1 Obtaining Informed Consent** | **Type an “X” in the left-hand column beside as many of the following options as apply** to your research project. **Use the space provided below** to explain how you will obtain informed consent from participants. If you seek a waiver of consent, or the use of opt-out consent, use the space provided to justify your request. **Refer to** [***NS* §2.2**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)**,** [***NS* §2.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_3__qualifying_or_waiving_conditions_for_consent)**.** |
|  | **Written consent** will be sought from (or on behalf of) participants. | **🡪 Refer to** [***NS* §2.2.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)**.** **🡪 Attach a copy of your consent form(s).** |
|  | **Verbal consent** will be sought from (or on behalf of) participants. | **🡪 Refer to** [***NS* §2.2.5 - §2.2.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)**.** **🡪 Explain why you have chosen this form of consent, and how an individual’s consent to participate will be recorded.****🡪 Attach a copy of your consent script(s).** |
|  | **Consent will be implied,** rather than explicitly obtained. | **🡪 Refer to** [***NS* §2.2.5 - §2.2.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)**.** **🡪 Explain why you have chosen this form of consent.** |
|  | **Third parties (e.g. parents/guardians of minors) will provide consent** on behalf of participants. | **🡪 Refer to** [***NS* §2.2.12.**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#where_others_need_to_be_involved_in_participation_decisions)**🡪 Explain who will be providing consent on behalf of participants and why.** |
|  | **Third parties (e.g. community elders, school boards) will be involved** in whole of community participation decisions. | **🡪 Refer to** [***NS* §2.2.13**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#where_others_need_to_be_involved_in_participation_decisions)**.****🡪 Provide details of which third parties will be involved, why they will be involved, and how this will be accomplished.** |
|  | This application seeks a **waiver of consent.**  | **🡪 Explain why you are seeking this option. Justify your request by referring to the conditions described in** [***NS* §2.3.10 - §2.3.11**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#waiver)**.** |
|  | This application proposes to use **opt-out consent.** | **🡪 Explain why you are seeking this option. Justify your request by referring to the conditions described in** [***NS* §2.3.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#opt_out_approach)**.** |
| [Write your responses here. If you will be obtaining consent from participants, describe who will obtain consent. Explain how it will be established that potential participants are competent to understand the research and to participate voluntarily, particularly if they are in a dependent relationship with the researcher(s). If you will not be obtaining consent from individual participants, justify your request for a waiver of consent, or for use of opt-out consent.] |

|  |  |
| --- | --- |
| **4.2 Limited Disclosure**  | Do you propose to use limited disclosure, concealment or deception for this research project? (Answer Yes or No. If Yes, use the space below to explain.) **Refer to** [***NS* §2.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_3__qualifying_or_waiving_conditions_for_consent)**.**  |
| **YES or NO:** |  |
| [If NO, you may leave this space blank. If YES, provide a justification for the limited disclosure, concealment or deception. Comment on the special considerations discussed in [**NS §2.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_3__qualifying_or_waiving_conditions_for_consent). Indicate whether you intend to debrief participants and justify that position. If you are seeking a waiver of consent for all participants, select NO.] |

|  |  |
| --- | --- |
| **4.3 Future Use of Data, Materials, or Tissues** | Do you intend for the data and/or materials and/or tissues collected for this research project to be reused in future research? **Type an “X” in the left-hand column beside** **as many of the following options as apply** to your research. **Use the space provided** to specify which data/materials/tissues will be reused, if any. **Refer to** [***NS* §2.2.14**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#consent_to_future_use_of_data_and_tissue_in_research) and [***NS* §3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__data_collection_and_management) |
|  | Consent will be **specific.** | 🡪 Data/materials/tissues will be used *only* for this research project (i.e. **no future use**). |
|  | Consent will be **extended.**  | 🡪 Data/materials/tissues used in this research project may also be used in future projects that are *closely related* to this project, *or in the same general area* of research as this project. Make this clear in PLS |
|  | Consent will be **unspecified.**  | 🡪 Data/materials/tissues used in this project may also be used in *any* future research. Make this clear in PLS |
| [If data/materials/tissues from this research project will not be reused, select “specific” above and state “N/A” here. If data/materials/tissues will be reused, describe which of them will be reused explain and how such future use will occur. If different conditions of consent apply to different data/materials/tissues, explain which conditions apply to which data/materials/tissues. If you will also be completing the Privacy and Databanks Module, you may simply write “Refer to Privacy and Databanks Module” here.] |

|  |  |
| --- | --- |
| 4.4 Conflict of Interest | Does your research present or involve any conflict of interest, whether potential, real, or perceived; or will the researcher(s) have dual roles in relation to the participants? (Answer Yes or No. If Yes, use the space below to explain.) **Refer to** [***NS* §5.4**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_5_4__conflicts_of_interest)**,** [**University of Melbourne Research Integrity and Misconduct Policy (MPF1318)**](https://policy.unimelb.edu.au/MPF1318)**, and** [***Australian Code for the Responsible Conduct of Research* §7.2**](http://www.nhmrc.gov.au/guidelines-publications/r39)**.** |
| **YES or NO:** |  |
| [If YES, explain what the potential conflict of interest is and how it will be managed. If applicable, you may also need to include a comment on the Plain Language Statement and Consent form declaring that potential conflict of interest. If NO, you may leave this space blank.] |

|  |  |
| --- | --- |
| 4.5 Information for Participants | How will relevant information about the research project be provided to potential participants? **Attach a copy of any advertisement (print or online), Plain Language Statement (PLS), consent form, letter, email, telephone script, and/or debriefing statement** to be used. **Refer to** [**NS §5.2.25**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#documents_and_records) and [**NS 3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_1__the_elements_of_research) |
| [Explain how participants will be informed about the research project. If applicable, explain what arrangements will be made for informing participants with low literacy skills, and/or for translation/interpreting of these materials for participants who are speakers of languages other than English. If you are seeking a waiver of consent for all participants, state “N/A.”] |

***Plain Language Statement (PLS):*** Your PLS must satisfy the requirements set out in the *National Statement* ([***NS* §2.2.1 - §2.2.3, §2.2.6**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)). The Research Ethics and Integrity’s website has [**guidance on composing your plain language statement**](https://staff.unimelb.edu.au/research/ethics-integrity/human-ethics/faq/how-do-i-write-a-plain-language-statement), as well as an [**example PLS template**](https://staff.unimelb.edu.au/__data/assets/word_doc/0004/1977574/PLS-Template-.docx). A list of PLS requirements is also provided at the end of this form. ***Ensure that your PLS is written in plain language. Ensure that the information contained in your PLS is consistent with the information in your application.***

***Consent Form:*** Your consent form must satisfy the requirements set out in the *National Statement* ([***NS* §2.2**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent)). The Research Ethics and Integrity’s website has [**guidance on composing your consent form**](https://staff.unimelb.edu.au/research/ethics-integrity/human-ethics/faq/how-do-i-write-a-consent-form), as well as an [**example consent form**](https://staff.unimelb.edu.au/__data/assets/word_doc/0011/1977572/Consent_Template.docx). A list of consent form requirements is also provided at the end of this form. ***Ensure that your consent form is written in plain language. Ensure that the information contained in your consent form is consistent with the information in your application.***

5. Dissemination and Data Management

|  |  |
| --- | --- |
| 5.1 Providing Results to Participants | How will the results of the research project be provided to participants in an accessible format? **Refer to** [***NS* §1.5**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#justice) **and** [**NS 3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_5__communication_of_research_findings_or_results_to_participants) |
| [Describe how participants will be given access to the results of the research. If you will only be using pre-collected data and/or tissue, state “N/A”. If you are seeking a waiver of consent, state “N/A”.] |

|  |  |
| --- | --- |
| **5.2 Reporting Project Outcomes** | How will outcomes of the research project be made public? **Refer to** [***NS* §1.3**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#research_merit_and_integrity) **and** [**NS 3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_6__dissemination_of_project_outputs_and_outcomes) |
| [Describe the format and means by which you intend to make the project’s results public.] |

|  |  |
| --- | --- |
| 5.3 Data Management | How do you propose to manage the data collected in this research project? Specify what types of data will be collected, how they will be stored and in what format. How will access to the data be controlled and by whom? Discuss retention, security, and data sharing plans. What measures will be taken to protect participants’ privacy, and their data? **Refer to** [***NS* §1.11**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#respect)**,** [**NS 3.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#element_4__collection__use_and_management_of_data_and_information)**, the** [***Australian Code for Responsible Conduct of Research* §2**](http://www.nhmrc.gov.au/guidelines-publications/r39)**, and the** [**University of Melbourne Research Integrity and Misconduct Policy (MPF1318)**](https://policy.unimelb.edu.au/MPF1318)**.** |
| **A) Privacy and Confidentiality**[What measures will be taken to protect participants’ privacy and the confidentiality of participants’ data? Describe the format in which the data will be stored (e.g. digital video file, database of survey responses, paper forms.) Describe whether the data will be identifiable. That is, will it be possible for researchers or others to match data to specific participants? If so, how will this be possible? If not, how will such matching be prevented?]**B) Security and Storage of Data**[What short-term storage will you use during the data collection phase? Whose responsibility will it be to manage this? What long-term storage will you use after the data collection phase? Whose responsibility will it be to manage this? Who will have access to unprocessed (raw) data? What security measures will be in place to control access to data? NOTE: If your research will generate digital and non-digital data, separate this section into two parts: “Security and Storage of Non-Digital Data” and “Security and Storage of Digital Data.”]**C) Retention**[For how long will you keep the data generated by this research project? How will you ensure that data is retained if/when the researcher(s) leave the University? For data that are not intended to be kept indefinitely, how will you eventually dispose of the data? NOTE: the minimum retention period for research data and primary materials is five years after the last publication, or public release, arising from the research ([**University Policy**](https://policy.unimelb.edu.au/MPF1318)). Longer minimum retention periods apply for certain types of research – refer to the requirements of relevant regulations.] |

6. Other Issues

|  |  |
| --- | --- |
| **6.1 Other Ethical Issues** | Are there any other issues, not addressed above or in additional modules, which are relevant to the ethical review of your research project? **Refer to the relevant sections of the *National Statement* identified in the Specific Guidelines Checklist, if applicable.** |
| [Use this space to address any relevant ethical issues that are not addressed elsewhere in this application. If there are no other issues relevant to the ethical review of your research project, state “N/A.”] |

|  |
| --- |
| **Attachments Checklist** |
| Review your answers above to determine which attachments (if any) are required for your application. **Type an “X” in the left-hand column beside all items that apply to your research project.** Attach a copy of the items you have selected. |
|  | **Plain Language Statement (PLS) for Participants** |
|  | **Consent Form for Participants** |
|  | **Additional PLS(s)** (e.g. for parents, teachers, schools) |
|  | **Additional Consent Form(s)** (e.g. for parents, teachers, schools; or assent forms for children) |
|  | **Recruitment Materials** (e.g. advertisement(s), posters, letter(s) or email(s) of invitation) |
|  | **Questionnaire(s) and/or Survey Instrument(s)** |
|  | **Measure(s) and/or Scale(s)** |
|  | **List of Interview Questions and/or Themes** |
|  | **List of Focus Group Questions and/or Themes** |
|  | **Participant Distress Protocol** |
|  | **Adverse Event Protocol** |
|  | **Debriefing Statement** |
|  | **Approval(s) of research by an HREC external to the University of Melbourne** |
|  | **Other External Approval(s)** (e.g. schools, communities) |
|  | **Full Protocol** (for Medical Research) |
|  | **Translations and/or Back-Translations** (where languages other than English used) |
|  | **Privacy and Databanks Module** |
|  | **Body Tissue and Genetic Research Module** |
|  | **Ionising Radiation Module** |
|  | **Interventions, Therapies and Trials Module** |
|  | **Other Documents** (e.g. contracts, agreements) – specify which: |
|  |

Plain Language Statement (PLS) Requirements:

1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University’s logo) and the department(s)/ school(s)/faculty(-ies) involved. If printed, the PLS should be on University of Melbourne letterhead.
2. Clearly identify the title of the project, and the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student’s level of study.
3. Clearly explain the purpose of the research project.
4. Clearly explain what participants will be asked to do, and provide an estimated time commitment.
5. If participants will be photographed, audio- or video-recorded, clearly state as much.
6. Clearly explain any risks arising from participation, as well as any procedures or measures in place to minimise such risks.
7. Describe any expected benefits to the wider community. If applicable, also describe any expected benefits to participants.
8. List any payments, incentives or reimbursements to be made to participants.
9. State that involvement in the project is voluntary and that participants are free to withdraw from participation at any time. Explain any implications of withdrawal, including whether it will be possible for participants to withdraw any data already collected from or about them.
10. Describe the likelihood and form of dissemination of the research results, including publication.
11. Describe the arrangements in place to protect the confidentiality of participants’ data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.
12. The project HREC number (which is the ethics ID number assigned by Themis) and the date and version number of the PLS must appear on the PLS. If the PLS is printed, put this information in the footer.
13. Explain what will happen to participants’ data after the research project ends (i.e. how long it will be retained, whether it might be used again for future research and if so who would have access.)
14. Include the following statement: “This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: humanethics-complaints@unimelb.edu.au All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.”
15. If the research is externally funded, state the amount(s) and source(s) of funding for the research.
16. If there are any potential conflicts of interest for any of the researchers, sponsors (if applicable) or institutions, disclose these potential conflicts of interest.
17. If any participants will be in a dependent relationship with any of the researchers, state that decisions about participation will not affect the dependent relationship. (E.g. students’ grades will not be affected if they decline to participate or withdraw from the project at any stage).

Consent Form Requirements:

1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University’s logo) and the department(s)/ school(s)/faculty(-ies) involved. If printed, the consent form should be on University of Melbourne letterhead.
2. Clearly identify the title of the project, the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student’s level of study.
3. If participants will be photographed, audio- or video-recorded, clearly state as much.
4. State that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied. Also state that the purpose of the project is research.
5. Describe the arrangements in place to protect the confidentiality of participants’ data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.

Declaration by the Responsible Researcher

The information contained in this application is, to the best of my knowledge and belief, accurate.

I have read the University’s current human ethics guidelines. I accept responsibility for the conduct of the procedures set out in the attached application in accordance with: those guidelines, with the [***University’s Research Integrity and Misconduct Policy (MPF1318)***](https://policy.unimelb.edu.au/MPF1318), and with any other condition laid down by the University of Melbourne’s Central Human Research Ethics Committee (CHREC), its Human Ethics Sub-Committees (HESCs), or by the Human Ethics Advisory Group (HEAG) which will review this application. I have attempted to identify all risks related to the research that may arise in conducting this research. I acknowledge our obligations as researchers and the rights of the participants stipulated in the [***National Statement on Ethical Conduct in Human Research (2007) - Updated 2018***](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018). I certify that the research team has the appropriate qualifications, experience and facilities to conduct the research described in the attached application, and to deal with any emergencies and contingencies related to research that may arise throughout the life of the project.

If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

I, the Responsible Researcher, agree to:

* start this research project only after obtaining final approval from the HESC (if this is a standard project), or the HEAG (if this is a minimal risk project);
* carry out this research only where adequate funding is available to enable the research to be carried out according to good research practice and in an ethical manner;
* provide additional information as requested by the CHREC, HESC, or HEAG;
* provide progress reports to the CHREC, HESC, or HEAG as requested, including annual and final reports;
* maintain the confidentiality of all data collected from, or about, research participants and maintain security procedures for the protection of their privacy;
* submit an amendment if any modification to the research design or protocol is proposed (including any change of researchers) and to proceed with the research only after the amendment has been approved by the HESC (if this is a standard project) or by the HEAG (if this is a minimal risk project);
* notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any adverse event occurs during the course of the research;
* notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any complaints are received about the research;
* comply with an audit of the research undertaken, if requested by the CHREC, HESC, or HEAG;
* use only the data/tissue samples collected for this research, and for which HESC/HEAG approval has been given.

I certify that all members of the research team have read this application and the [***National Statement on Ethical Conduct in Human Research (2007) - Updated 2018***](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) and that they have agreed to comply with the provisions of the latter.

|  |  |  |
| --- | --- | --- |
| **Responsible Researcher Name** | **Signature** | **Date** |
|  |  |  |

Declaration by Human Ethics Advisory Group (HEAG)

|  |
| --- |
| **For HEAG use only.** **Enter the date the application was received, then type an “X” in the left-hand column beside each item as applicable.** |
| **Date Application Received:**  |
|  | **Technical review** has been completed by the HEAG. | The merit of the proposed research project set out in this application has been reviewed on technical grounds. **Refer to** [***NS* §1.1**](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#research_merit_and_integrity)**.** |
|  | **Ethical review** has been completed by the HEAG. | The HEAG has reviewed the proposed research project set out in this application for compliance with the principles of Human Research Ethics. |
|  | The **Minimal Risk** review process is appropriate for the proposed research project set out in this application. | **🡪 Complete Declaration A (below)** |
|  | The **Standard Project** review process is appropriate for the proposed research project set out in this application | **🡪 Complete Declaration B (below)** |

|  |  |
| --- | --- |
| **Declaration A****(Minimal Risk):** | The HEAG has reviewed this project. The HEAG considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. **The HEAG grants approval for this research project to commence.** The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University’s policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. *[Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]* |
| **Name of HEAG Chair/Authorised Member** | **Signature** | **Date** |
|  |  |  |

|  |  |
| --- | --- |
| **Declaration B****(Standard Project):** | The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. **The HEAG regards this project as ready to submit to the HESC.** The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University’s policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. *[Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]* |
| **Name of HEAG Chair/Authorised Member** | **Signature** | **Date** |
|  |  |  |