|  |  |
| --- | --- |
| **Project Number** | <<Ethics Advisors to complete>> |
| **Version** |  |
| **Project Title** | Full Title – no acronyms |
| **Principal Investigator Name** | Full Name |
| **Review Decision** | <<Ethics Advisors to complete>> |

**Risk Assessment (National Statement 2.1)**

| **Are any of the following harms foreseeable (even if unlikely) …** | **YES** | **NO** |
| --- | --- | --- |
| Physical harm, including discomfort, injury, illness, pain?*If yes, please explain:* | [ ]   | [ ]   |
| Psychological harm, including feelings of worthlessness, distress, guilt, anger, fear or anxiety related, for example, to disclosure of sensitive information, an experience of re-traumatisation, or learning about a genetic possibility of developing an untreatable disease?*If yes, please explain:* | [ ]   | [ ]   |
| Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly?*If yes, please explain:* | [ ]   | [ ]   |
| Cultural harm: including misunderstanding, misrepresenting or misappropriating cultural beliefs, customs or practices?*If yes, please explain* | [ ]   | [ ]  |
| Social harm: including damage to social networks or relationships with others, discrimination in access to benefits, services, employment or insurance, social stigmatisation, and unauthorised disclosure of personal information?*If yes, please explain* | [ ]   | [ ]   |
| Economic harm: including the imposition of direct or indirect costs on participants?*If yes, please explain* | [ ]  | [ ]   |
| Legal harm: including discovery and prosecution of criminal conduct? *If yes, please explain* | [ ]  | [ ]   |

**I wish to submit this application for consideration under the following pathway (select only one, this will be confirmed by the Ethics, Integrity & Biosafety Team):**

|  |  |
| --- | --- |
| [ ]   | Low Risk: Research in which the only foreseeable risk is one of discomfort. |
| [ ]   | Greater than Low Risk: Research where the risk is more than discomfort. |

**EIB Confirmed:** <<Ethics Advisors to complete>>[ ]  Yes [ ]  No

1. **CORE INFORMATION**
	1. **Project Summary**
		1. Provide a brief summary of the research project (plain language, 250 words).
		2. Provide five key subject matter words to describe or define the field of research.
	2. **Institutional Responsibility**
		1. Is the project single institution or multi-institution?

☐ Single institution (LTU Only) ☐ Multi-Institution (LTU and others)

* + 1. Does La Trobe University have overall responsibility for the project?

[ ]  Yes [ ]  No

* + 1. If LTU does not have overall responsibility, what institution holds that role?
		2. Will separate site authorisations be required?
	1. **Funding**
		1. Are there appropriate resources for the project to be conducted?

[ ]  Yes – Fully supported.

[ ]  Yes – Partially supported.

[ ]  No – Under application/Seeking funding.

[ ]  No – Unfunded/Not Applicable.

* + 1. Source:
		2. Amount:
		3. Will the research proceed without funding?

[ ]  Yes [ ]  No

* + 1. Please describe the implications for the project if funding is not obtained.
		2. If the project is internationally funded, have you completed the LTU [Foreign Engagement Risk Assessment Tool](https://forms.office.com/pages/responsepage.aspx?id=2CbumsKXrU-JAJZzX23HP-TQuxJ7cM5EqfiEp7jKiOFUNEdZRUdUWFpGUEVXWkdIUjFYN0dTSkRDNyQlQCN0PWcu) and acted accordingly based on the results?

[ ]  Yes [ ]  No [ ]  Not applicable.

* 1. **Project Location**
		1. Where will the project be conducted (select all that apply)

☐ Victoria ☐ Online (no specific location)

☐ Other Australian States / Territories ☐ Overseas (Specify):

* + - 1. If overseas, have you confirmed the ethics review requirements:

 [ ]  Yes [ ]  No

Will you be seeking international ethics review: [ ]  Yes [ ]  No

* 1. **Project Timeframes**
		1. Start Date
		2. Duration of the Project
1. **PRIOR REVIEW**
	1. Has the scientific or academic merit of the project been evaluated independently of the researchers?

[ ]  Yes [ ]  No

If yes, please describe:

2.2 Has this research project undergone prior ethics review?

[ ]  Yes [ ]  No

If yes, please describe:

2.3 Will any further or specialised review of the project be sought?

[ ]  Yes [ ]  No

 If yes, please describe:

1. **PROJECT TEAM ROLES & RESPONSIBILITIES**
	1. **Which category of research best describes the project to be conducted? (Select all that apply)**

☐ Staff Research

☐ Student research (Please indicate what type of student research)

☐ Undergraduate research

☐ Honours research

☐ Postgraduate research - Masters

☐ Postgraduate research - Coursework

☐ Postgraduate research - PhD

☐ Contract/Consultancy research

☐ Coursework

* 1. **Principal Investigator**
		1. Title:
		2. Name:
		3. Institution:
		4. School:
		5. Department:
		6. Position:
		7. Staff ID:
		8. Email:
		9. Phone:
		10. Expertise relevant to the conduct of the Project:
		11. Responsibilities on Project:
		12. Formal Qualifications:
		13. Ethics & Integrity Training (details and date):
	2. **Co-Investigator(s)** (copy as needed for complete research team)
		1. Title:
		2. Name:
		3. Institution:
		4. School:
		5. Department:
		6. Position:
		7. Staff ID:
		8. Email:
		9. Phone:
		10. Expertise relevant to the conduct of the Project:
		11. Role on Project:
		12. Responsibilities on Project:
		13. Formal Qualifications:
		14. Ethics & Integrity Training (details and date):
	3. **Student Investigator(s)** (copy as needed for complete research team)
		1. Title:
		2. Name:
		3. Institution:
		4. School:
		5. Department:
		6. Position:
		7. Student ID:
		8. Email:
		9. Phone:
		10. Role on Project:
		11. Responsibilities on Project:
		12. Formal Qualifications including name of current program/degree being pursued:
		13. Ethics & Integrity Training (details and date):
	4. For Student Research, describe supervisory arrangements, support and training (include sufficient detail for overseas supervision).
1. **DISCLOSURES OF INTERESTS**
	1. Does any member of the research team and/or funding body/sponsor have an actual, potential or perceived conflict of interest with the research?

[ ]  Yes [ ]  No

If yes, please describe the nature of the conflict of interest.

4.2 Outline your plan to eliminate, mitigate or manage any known or potential conflicts of interest.

1. **PROJECT DESIGN**
	1. This application is for a research project (projects) involving:

[ ]  Human beings (via active participation) including their associated data, exclusive of biospecimens

[ ]  Existing (previously collected) data associated with human beings only

[ ]  Human biospecimens only (use the HREA)

[ ]  Human beings (via active participation) including their associated data and biospecimens (use the HREA)

* 1. What is the aim/s of the project? This should be a predictive statement about the possible outcomes that is measurable, achievable, realistic and time constrained. (500 words)
	2. State your research question/s, challenge/s, or hypotheses.
	3. Provide a brief literature review, inclusive of references, (500 words) to support your project.
	4. How will the project address any gaps, contribute to the field of research, or contribute to existing/improve current practices. (National Statement 1.1(c))
	5. What is the project’s methodological approach (provide answers to indicate section before proceeding to Section 5.16)

|  |  |
| --- | --- |
| [ ]  Action Research | Sections 5.7 |
|  [ ]  Existing Data Sets | Sections 5.8 |
| [ ]  Data Linkage Research | Sections 5.9 |
| [ ]  Ethnographic Research | Sections 5.10 |
| [ ]  Epidemiological Research | Sections 5.11 |
| [ ]  Interview/Focus Group Research | Sections 5.12 |
| [ ]  Observational Research | Sections 5.13 |
| [ ]  Survey Research | Sections 5.14 |
| [ ]  Textual Analysis Research | Sections 5.15 |
| [ ]  Other | Sections 5.16 |

* 1. **Action research**
		1. What is the challenge, need, phenomenon or question that the research will explore?
		2. What process/es will be used to refine the objectives and design of the research, and how frequently will this be repeated during the project?
	2. **Existing Data**
		1. Identify the source(s) of the data (Please select all that apply).

[ ]  Relative or associates f participants

[ ]  Medical / health / mental health record

[ ]  Electoral roll

[ ]  Held by law enforcement agency or judicial body

[ ]  Publicly held database (commonwealth)

[ ]  Publicly held database (state or local)

[ ]  Privately held database

[ ]  Other (specify)

* + 1. Provide details of the data custodians, as applicable, for each of the sources.
		2. Have the data custodians, if any, agreed to provide access to the data for use in the research (Please upload a copy of the permission)?

[ ]  Yes [ ]  No

* 1. Will the data or information to be used for this research include any of the following types of information?

[ ]  Personal [ ]  Sensitive

[ ]  Health [ ]  Other, please specify

* 1. What is the identifiability of the data used?

[ ]  Individually Identifiable [ ]  Non-Identifiable

[ ]  Re-Identifiable (Coded)

* + 1. Was this information/data previously collected for a purpose other than research?

[ ]  Yes [ ]  No

* + 1. Are you linking different data sets/data bases?

[ ]  Yes [ ]  No

* + 1. Describe ethical considerations for the collection and/or use of this sourced data/information.
		2. Describe ethical considerations for the storage of data, include details of the location, retention period applicable protocol for secure destruction.
		3. Do research intend to ‘bank’ this information / data for re-use or sharing?

[ ]  Yes [ ]  No

* 1. **Data linkage research**
		1. How will your research/findings account for any limitations arising from your choice of data sets/databases or from missing data?
		2. How will you control for confounding factors or other vulnerabilities toward bias in your research?
		3. How will you manage any risk that linking databases of non-identifiable data could subsequently result in the individuals being identified?
	2. **Ethnographic research**
		1. How will you distinguish between participants and non-participants in your research, and how will you manage that distinction?
	3. **Epidemiological research**
		1. What population/s will be studied?
	4. **Interview/Focus Group research**
		1. How will you engage with your participants for data collection?

[ ]  Face to face

[ ]  By telephone, text, email, or online collaboration platform (Specify):

[ ]  Indirectly using an online provider (Specify):

* + 1. Will personal identifiers be retained or removed over the course of your project? If they are to be removed what process will be used?
		2. Will participants be able to review or edit their responses or contributions prior to data analysis or publication? If so, when? If not, why not?
		3. Is it foreseeable that your project will explore topics that may cause distress for participants?
			1. If yes, provide your distress management protocol.
		4. Will interviews or focus groups be recorded, photographed or video recorded? If yes, describe methods.
		5. Attach any relevant research instruments or documents relevant to this methodology including lists of questions that will be used.
	1. **Observational research**
		1. What type of observation will you be conducting?
		2. What sampling strategy will you use?
		3. How will you match and follow up participants?
		4. How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias?
	2. **Survey Research**
		1. Is the data collected in your survey qualitative, quantitative or both?
		2. How will you engage with your participants to conduct the survey?

[ ]  Face to face

[ ]  By telephone, text, email, postal or online collaboration platform (Specify):

[ ]  Indirectly using an online provider (Specify):

* + 1. Will personal information be associated with survey responses, or will the data be anonymous (non-identifiable)?
		2. Will personal identifiers be retained or removed over the course of your project? If they are to be removed what process will be used?
	1. **Textual analysis research**
		1. In what way do you consider your research to be human research?
	2. **Other**
		1. Please describe the methodology.
	3. Rationale for choices of method/s (tied to project aims/objectives)
1. **PARTICIPANT INFORMATION**
	1. **Who is your proposed participant population?**
	2. **What is your proposed sample size from your participant population?**
		1. What is the justification for the sample size?
		2. What is the implication to the project if the sample size is not achieved?
	3. **What are the selection criteria for participants/participant groups that you will include or exclude from this project?**
		1. Will the potential participants be screened in regard to these criteria?

[ ]  Yes [ ]  No

* + 1. If yes, by whom and how will this occur?
	1. **What will participants be requested to do?**
		1. What time commitment is required from participants for this request?
		2. Will participants be offered monetary compensation or other inducement(s) to participate in the research?

[ ]  Yes [ ]  No

If yes, please provide detail and justification.

* + 1. Will there be any follow up with participants?
		2. How will the confidentiality of participants’ identities and their data be maintained?
	1. **Will you be researching with Aboriginal and/or Torres Strait Islander Peoples or Communities? (National Statement 4.7)**

[ ]  Yes [ ]  No, go to Question 6.6

* + 1. List the Aboriginal and Torres Strait Islander peak bodies, community organisations and/or individuals with whom you wish to work and from whom you have obtained support and informed consent.
		2. How have you considered the potential impact of your research on culturally restricted information?
		3. How have you considered the principles of Indigenous self-determination, Indigenous leadership, impact and value, and sustainability and accountability?
		4. What arrangements have you put in place to ensure Indigenous Data Sovereignty is embedded within the lifecycle of your project?
	1. **Does the participant population include children and young people? (National Statement 4.2)**

[ ]  Yes [ ]  No If no, go to Question 6.7

* + 1. What age/s or age group/s are you intending to recruit as participants?
		2. How will you determine a child/young person’s vulnerability and capacity to consent to participate in the project?
		3. Describe the form of any proposed discussions with children and young people about the research, its effects and likely outcomes, taking into consideration their capacity and level of comprehension and their capacity to consent.
		4. What measures will be put into place to ensure the child or young person’s safety, emotional and psychological security, and wellbeing?
		5. Do all members of the research team have a valid Working With Children Certificate? Please provide details for non-La Trobe University employees.
	1. **Does the participant population include people in dependent or unequal relationships? (National Statement 4.3)**

[ ]  Yes [ ]  No If no, go to Question 6.8

* + 1. Specify the nature of any existing relationship or one that is likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research.
		2. What steps, if any, will be taken to ensure that the relationship does not impair participants’ free and voluntary consent and participation in the project?
		3. What steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher/investigator or organisations?
	1. **Does the participant population include the targeted recruitment of people with a cognitive impairment, intellectual disability or mental illness? (National Statement 4.5)**

[ ]  Yes [ ]  No If no, go to Question 6.9

* + 1. What mechanisms will be put into place to determine the person’s capacity to consent?
	1. **Does the participant population include the targeted recruitment of people in other countries? (National Statement 4.8)**

[ ]  Yes [ ]  No If no, go to Section 7.

* + 1. Describe the ethical review processes (including how they function) for research to be conducted in other countries and whether the processes are mandatory or voluntary.
		2. What are the values and principles on which the ethical review processes rely?
		3. Do the processes for ethical review in the other countries require reporting of the Australian review bodies’ approval?
		4. Is there a local, readily accessible contact for participants to receive responses, ask questions or lodge complaints about the research?
		5. Describe how the recruitment processes ensure respectful engagement within the cultural context.
1. **RECRUITMENT AND CONSENT**
	1. Where will you conduct recruitment for potential participants?

[ ]  Public website(s) [ ]  Professional Networks

[ ]  Public Records [ ]  Personal Networks

[ ]  Third Party Recruitment [ ]  Involvement of others

[ ]  Self-Selection [ ]  Other

* 1. Outline any use of third-party recruitment or other assistance you will use in your recruitment plans and how you will manage participant confidentiality in those circumstances.
	2. How will participants be recruited?

[ ]  Advertisement(s) [ ]  Email

[ ]  Face to Face Interactions [ ]  Letter of Invitation

[ ]  Phone Call [ ]  Snowball Sampling

[ ]  Website [ ]  Word of Mouth

[ ]  Other

* 1. Describe the recruitment process including how you will make contact, what information you will provide, and how potential participants may express interest in participating.
	2. How will the recruitment strategy ensure that participants can make an informed decision about their participation?
	3. What are the risks associated with the recruitment strategy for potential participants or for the viability of the project?
	4. What is the timeframe for recruitment?
	5. Will you obtain consent from all participants?

[ ]  Yes [ ]  No, Provide rationale [ ]  Not applicable

* 1. What is the scope of the consent that you will be seeking?

☐ Specific (this project only)

☐ Extended (this project and related future research)

☐ Unspecified (this project and future related or unrelated research)

* 1. How will consent be obtained? (Select all that apply)

☐ Written Consent

☐ Verbal Consent

☐ Implied Consent (i.e., online surveys)

* 1. What type of consent will you seek:

☐ Consent for self

☐ Consent by Parent / Guardian

☐ Consent by Person Responsible

* 1. When working with children/young people, people highly dependent upon medical care or potentially unable to give consent, who will make the determination about capacity to give consent?
	2. Will potential participants be invited to discuss their participation with someone who is able to support them in the decision-making process?

Yes [ ]  No [ ]  Provide rationale

If no, please provide a reason.

* 1. How will you ensure that consent is informed and voluntary?
	2. Will participants be offered the opportunity to withdraw from participation or withdraw any data provided by them after their participation has ended?

[ ]  Yes [ ]  No

Please describe:

* 1. Are there any limitations on when consent can be withdrawn or consequences for participants who withdraw consent?

Yes [ ]  No [ ]

If yes, please describe.

* 1. Will there be an opportunity to confirm or re-negotiate consent during the research project?

Yes [ ]  No [ ]

* + 1. If no, please justify.
		2. If yes, please outline the plan for re-confirming/re-negotiating consent, including who will undertake the discussion and the process.
	1. Does the project involve consent via limited disclosure?

[ ]  Yes [ ]  No

* + 1. If yes, what alternatives to limited disclosure have been considered to achieve the aims of the research?
		2. When using consent with only limited disclosure, please describe the extent of the limited disclosure.
		3. Will participants be debriefed after the research and provided with information regarding the aims of the research and an explanation of why the omission/alteration was necessary?

[ ]  Yes [ ]  No

Please explain.

* + 1. Is there any known or likely reason that participants would not have consented if they had been fully aware of what the research involved?

[ ]  Yes [ ]  No

Please describe:

* 1. Are you using an opt-out consent approach?

[ ]  Yes [ ]  No

* + 1. If yes, provide justification.
	1. Are you requesting a waiver of the requirement for consent for some or all participants?

[ ]  Yes [ ]  No

* + 1. If yes, provide justification.
		2. From which agency/agencies will the records or information to be used be sought?
1. **PRIVACY AND CONFIDENTIALITY**
	1. What type of information are you going to collect?

[ ]  Personal [ ]  Sensitive

[ ]  Health [ ]  Other, please specify

* 1. What is the identifiability of the data that will be collected?

[ ]  Individually Identifiable [ ]  Non-Identifiable

[ ]  Re-Identifiable (Coded)

* 1. What type of information will be used in the project (as part of the research or as part of the output)?

[ ]  Personal [ ]  Sensitive

[ ]  Health [ ]  Other, please specify

* 1. What is the identifiability of the of the data that will be used?

[ ]  Individually Identifiable [ ]  Non-Identifiable

[ ]  Re-Identifiable (Coded)

* 1. Describe the ethical considerations for the collection and use of the data from the participants.
1. **RISK AND BENEFIT**
	1. Describe the risks, actual or potential, of the project and consider the likelihood and severity of impact of such risks.
	2. How will these risks be mitigated and managed?
	3. Describe the benefits of the project, including whether these benefits are actual or potential benefits. Include benefits to the participants, the community or others.
	4. Provide an overall justification (risk-benefit analysis) for the project considering the National Statement criteria in Chapters 1.1 and 2.1.
2. **DATA MANAGEMENT**
	1. Describe the ethical considerations for the storage of data, include details of the location, retention period and, where applicable, protocol for secure destruction.
	2. In what form will your data collection be?

☐ Digital Data: For example, PDFs, MS Office files, audio, visual, etc.

☐ Non-digital Data: For example, models, notebooks, biospecimens, etc.

* 1. During your research project, where will you store the digital and non-digital data?

☐ LTU network drive. Details:
☐ LTU approved cloud application. Details:
☐ Building/Level/Room/Cabinet. Details:

* 1. If any data are not stored at LTU, where will you store the data and why?
	2. How is the data protected? Consider physical, network, system security and other technological security measures.
	3. Who is the custodian of the data?
	4. Who will have access to the data during the project?
	5. Have all relevant team members been appropriately trained to fulfil this data management plan?
	6. Data must be kept for at least the minimum retention period from date of publication. For research involving young people (<18 years of age), the data must be kept for the required period from the time they become adults. Please specify the project data storage period:

☐ 1 year (undergraduate assessment)

☐ 5 years (most research)

☐ 7 years ([health data](https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/chapter-b-key-concepts/#health-information) including individual’s physical or mental health)

☐ 15 years (clinical trials)

☐ Indefinitely, following the expiration of the applicable minimum retention period

☐ Permanently (gene therapy or research that has community or heritage value that warrants retention for longer than the minimum required time or in perpetuity)

* 1. Are the arrangements regarding intellectual property and copyright related to the outputs of the research clearly understood and communicated?

Yes [ ]  No [ ]

Please describe:

* 1. For student research, at the conclusion of their educational program, the data will be:

☐ Banked for use in future research.

☐ Permanently [de-identified](https://ovic.vic.gov.au/resource/de-identification-and-privacy-considerations-for-the-victorian-public-sector/) and retained.

☐ Permanently de-identified and published through open-source platforms like OPAL or FigShare.

☐ Deleted or destroyed in keeping with ethics approval, or contractual or other legal requirement.

☐ The data or the metadata will be available for use by other researchers at the end of the project.

☐ Other

1. **DISSEMINATION OF FINDINGS**
	1. Could the research generate findings or results of interest to the participants?

Yes [ ]  No [ ]

If yes, please describe:

* 1. What is the plan for reporting, publishing or otherwise disseminating outputs/ outcomes of the research?
	2. Are there any restrictions on the dissemination of project outputs and outcomes?

Yes [ ]  No [ ]

If yes, please describe:

* 1. How will the privacy of participants be assured in any research outputs/outcomes?
1. **SUPPORTING DOCUMENTATION**
	1. Upload relevant documentation with appropriate naming protocols including clear titles, versions and dates:
		1. Participant Information and Consent Forms
		2. Recruitment materials including but not limited to:
			1. Email invitations
			2. Flyers
			3. Advertisements
		3. Research instruments including but not limited to:
			1. Interview/focus group guides
			2. Questionnaires
			3. Surveys
		4. Research Data Materials including but not limited to:
			1. Observational Logs
			2. Reporting Forms
			3. Data Management Plan

**PRINCIPAL INVESTIGATOR DECLARATION**

By submitting this application, I certify the following:

☐ All information in this application and supporting documentation is correct and as complete as possible.

☐ I have read and addressed the requirements of the National Statement and other relevant guidelines within this application and supporting documentation.

☐ I have familiarised myself with, considered and addressed relevant legislation, regulations, research guidelines and organisational policies.

☐ I have disclosed all relevant financial and non-financial interests for myself and on behalf of the project team.

☐ In my capacity as supervisor, where applicable, I have reviewed this application and will provide appropriate supervision to the student investigator(s) in accordance with the relevant guidelines and policies as specified in this application.

☐ I agree that the research will not commence until and acknowledge my understanding that this research project is not to start until the express approval of the ethics committee has been provided.