# Before you submit the application form

1. Download and complete the [Project Description/Clinical Trials Protocol](https://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics) (mandatory)
2. If recruiting participants, download and complete [Recruitment Materials](https://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics) & [Participant Information Statement & Consent Form/s](https://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics) (PICFs)
3. Complete all required study tools, including data collection tools such as questionnaires, interview schedules, focus group guides, etc.
4. Email by the relevant closing date all completed forms and documents to humanethics@latrobe.edu.au.

# General project details

* 1. **Project Details & Attachments**

|  |  |
| --- | --- |
| **Project Number** | <<Ethics Advisors to complete>> |
| **Project Title** | Insert Ethics Application Tile |
| **Principal Investigator Name** | Insert Principal Investigator name |
| **Review Decision** | <<Ethics Advisors to complete>> |
| **Summary of Comments** | <<Ethics Advisors to complete>> |

|  |  |  |
| --- | --- | --- |
|  | Document | Version date |
| Mandatory Document | Project Description/Protocol | DD MMM YYYY e.g., 10 Dec 2019 |
| Recruitment Materials(e.g., flyers, advertisements, social media ad, letters of invitation) | List all recruitment materials here | DD MMM YYYY |
| Participant Information Statement & Consent Form/s (PICFs)(PICFs for written, verbal, opt-out consent types and/or original PICFs if accessing existing data and/or biospecimens) | List all PICFs to be used here | DD MMM YYYY |
| Study Procedure Materials(e.g., Interview guides, questionnaires/surveys, data points, Case Report Form/s (CRFs), diaries) | List all study procedure materials here | DD MMM YYYY |
| Relevant Approvals/Letters of Support | Insert the names of all documents here | DD MMM YYYY |
| Miscellaneous  | Insert the names of all documents here | DD MMM YYYY |

* 1. **Risk level assessment**

[ ]  Negligible/low risk

[ ]  Above low risk

* 1. **Category of research project to be conducted (select all applicable boxes)**

[ ]  Research by academic staff member (researcher initiated)

[ ]  Undergraduate research (including honours)

If selected - Describe how the student will be supervised, and outline any strategies to support the student in risk activities (e.g., support while in remote locations after hours; learning how to conduct sensitive interviews; collecting biospecimens etc..) Insert text here

[ ]  Postgraduate research – PhD

If selected - Describe how the student will be supervised, and outline any strategies to support the student in risk activities (e.g., support while in remote locations after hours; learning how to conduct sensitive interviews; collecting biospecimens etc..) Insert text here

[ ]  Postgraduate research- Masters

If selected - Describe how the student will be supervised, and outline any strategies to support the student in risk activities (e.g., support while in remote locations after hours; learning how to conduct sensitive interviews; collecting biospecimens etc..) Insert text here

[ ]  Postgraduate research- coursework

If selected - Describe how the student will be supervised, and outline any strategies to support the student in risk activities (e.g., support while in remote locations after hours; learning how to conduct sensitive interviews; collecting biospecimens etc..) Insert text here

[ ]  Contract research

* 1. **Fields of research codes and multi methods\*\*** [https://www.abs.gov.au/ausstats/abs@.nsf/0/0A7442069B0BE879CA2574180004AC0D?opendocument](https://www.abs.gov.au/ausstats/abs%40.nsf/0/0A7442069B0BE879CA2574180004AC0D?opendocument) **Please indicate the research methods that your project is planned to involve:**

Insert text here

* 1. **Investigators**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Full name | Staff/Student ID (if La Trobe) | Institution/school | Email  | Best contact number | Positions/other affiliations relevant to this application | Qualifications/Relevant experience to this project | List Role/s in Project | WWCC number + expiry date | Completed GCP Training (mandatory for Clinical Trial) |
| Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | [ ]  Co-ordinating Principal Investigator (multi-site only)[ ]  Principal Investigator at La Trobe site/s[ ]  Co- Investigator[ ]  Student Investigator  | Insert text here | [ ]  Yes[ ]  Not Applicable  |
| Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | [ ]  Co-ordinating Principal Investigator (multi-site only)[ ]  Principal Investigator at La Trobe site/s[ ]  Co- Investigator[ ]  Student Investigator  | Insert text here | [ ]  Yes[ ]  Not Applicable  |
| Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | Insert text here | [ ]  Co-ordinating Principal Investigator (multi-site only)[ ]  Principal Investigator at La Trobe site/s[ ]  Co- Investigator[ ]  Student Investigator  | Insert text here | [ ]  Yes[ ]  Not Applicable  |

*\*\*copy and paste additional row(s) if needed*

* 1. **Is the research a collaborative project with another organisation?**

[ ]  No

[ ]  Yes \*
\* Please list all collaborative organisations, and indicate if approval is required OR attach relevant approval letter/s

* 1. **Will any part of the project be conducted at another organisation? E.g., schools, hospitals, other universities, private business, government agencies etc..** *Please note for online studies OR studies interviewing in public places e.g., cafes, libraries please answer ‘NO’ to this question.*

[ ]  No

[ ]  Yes \*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Site Name | Address | ABN | Site Principal Investigator Contact details | HREC/Governance Approval |
| insert site name | insert site address | insert site ABN | Name: Insert text hereEmail: Insert text herePhone:Insert text here | [ ]  Not required[ ]  Required, insert HREC/Governance number |
| insert site name | insert site address | insert site ABN | Name: Insert text hereEmail: Insert text herePhone:Insert text here | [ ]  Not required[ ]  Required, insert HREC/Governance number |

*\*\*copy and paste additional row(s) if needed*

* 1. **Select where this project will be conducted in Australia (select all applicable boxes)**

 [ ]  New South Wales

 [ ]  Victoria

[ ]  Queensland

[ ]  Western Australia

[ ]  South Australia

[ ]  Tasmania

[ ]  Australian Capital Territory

[ ]  Northern Territory

[ ]  Not Applicable *(select for international research see Section 6 or online research not directly targeting a state or territory)*

* 1. **Has this project received funding and/or is a funding application under consideration?**

[ ]  No

[ ]  Yes \* insert ALL sources of funding

* 1. **Do any of the researchers or others involved in this project have any perceived, potential or actual conflicts of interest?** **For example:**
* Investigators are treating doctor/clinical and on research team
* Any perceived imbalance of power (e.g., student/teacher)
* Funding provided for the research, expectation of obtaining any direct or indirect financial or other benefits from conducting this research
* Any other perceived or potential conflict of interest you think is important to describe

[ ]  No

[ ]  Yes \*
\* Please describe the perceived, potential or actual conflicts of interest and how they will be managed

#  Participants

* 1. **Will the research directly target any of the following:**

**2.1.1** [ ]  Human gametes (eggs or sperm) or excess Assisted Reproductive Technology (ART) embryos ([NS 3.2](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.2** [ ]  Women who are pregnant and/or the human foetus ([NS 4.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))
*\*\*If ticked, complete question 2.1.2.a*

**2.1.2.a** Who of the following will the research involve:

[ ]  Women who are pregnant and the foetus *in utero* ([NS 4.1.1-4.1.10](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

[ ]  The separated human foetus or foetal tissue ([NS 4.1.11-4.1.23](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.3** [ ]  Children and young people ([NS 4.2](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

*\*\*If ticked, complete 2.1.3.a*

 **2.1.3.a** **Will parent/guardian consent be obtained for all persons under the age of 18 years?**

[ ]  Yes

[ ]  No\* *\*\*If no, complete2.1.3.b and 2.1.3.c*

**2.1.3.b** **Detail the age range where parent/guardian consent will NOT be obtained and the reasons why**

Insert text here

**2.1.3.c** **Describe how the research team will determine a young person’s capacity to provide their own consent**

Insert text here

**2.1.4** [ ]  People in dependent or unequal relationships ([NS 4.3](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.5** [ ]  People highly dependent on medical care who may be unable to give consent ([NS 4.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.6** [ ]  People with a cognitive impairment, intellectual disability or mental illness ([NS 4.5](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.7** [ ]  People who may be involved in illegal activities ([NS 4.6](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.8** [ ]  Aboriginal and Torres Strait Islander peoples ([NS 4.7](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

*\*\*If ticked, answer questions 2.1.8a-b*

**2.1.8.a** **Describe what cultural competence training members of the research team have**.

Cultural competence may include training and/or otherwise appropriate experience gained through for example an Indigenous Reference Group, a mentor or knowledge holders such as elders.

Describe cultural competence

**2.1.8.b ACTION** attach a copy of your negotiated research agreement with Aboriginal and Torres Strait Islander organisations and communities (Guidelines for Ethical Research in Australian Indigenous Studies ([GERAIS](https://aiatsis.gov.au/sites/default/files/docs/research-and-guides/ethics/gerais.pdf)), Principle 9). When developing Project Description, your answers should reflect your understanding of the 14 Principles set out by the [GERAIS](https://aiatsis.gov.au/sites/default/files/docs/research-and-guides/ethics/gerais.pdf).

**2.1.9** [ ]  People in other countries ([NS 4.8](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

**2.1.10** [ ]  None of the above are applicable (select this option is you are NOT directly targeting the groups above in your inclusion criteria).

* 1. **Will you be seeking any of the following types of consent (multi-select tick box)**

[ ]  Waiver of consent \*([NS 2.3.9-2.3.12](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) \* Please provide a justification

[ ]  Opt-out ([NS 2.3.5](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) \* Please provide a justification

[ ]  Limited disclosure ([NS 2.3.1](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) \* Please provide a justification

[ ]  None of the above are applicable

# Data and privacy

* 1. **Will you be directly targeting or asking participants if they are European Union Citizens?**

*This question is needed for two* *reasons (1) so the Ethics Committee can determine if your project complies with EU Privacy Legislation and (2) in the unlikely event of a Privacy Breach we can report this to the EU privacy commissioner as required by law*

[ ]  No

[ ]  Yes

* 1. **Will the research involve the use of personal, sensitive or health information?**

[ ]  No

[ ]  Yes \*\*

*\*\*If yes, compete questions 3.2.1 – 3.3*

**3.2.1 Indicate the type of information/data you will be collecting for this project:**

[ ]  **Personal information** (name, mobile, email and address, and any other data that can be used to identify a living person, directly or indirectly (Privacy Act, s6(1)).

[ ]  **Sensitive information** (*defined as information or an opinion about an individual’s: racial or ethnic origin; political opinions; membership of a political association; religious beliefs or affiliations; philosophical beliefs* *(belief genuinely held, this does not include opinions or viewpoints on available information); membership of a professional or trade association; membership of a trade union; sexual preferences or practices; or criminal record.)*

[ ]  **Health information** *(information about a person’s health status or opinion of a medical professional, genetic information, or predictive health information.)*

**3.3 Identify the source/s of the information/data that you will be collecting and/or using in this project.**
*If information will be obtained from records, government agencies or databases, the details of these sources of information should be provided in the* ***Project Description/Protocol****. This (and other details such as the number of records involved) is a requirement of information to which Commonwealth privacy legislation applies. Details of the specific information source/s should be included in the* ***Project Description/Protocol.***

**3.3.1** [ ]  Participants will give the information directly to the researcher

**3.3.2** [ ]  Relatives or associates of participants will give the information directly to the researcher

**3.3.3** [ ]  Medical/health/mental health datapoints will be given directly to the research

**3.3.4** [ ]  Electoral roll

**3.3.5** [ ]  Held by law enforcement agency of judicial body

**3.3.6** [ ]  **Publicly held database (Commonwealth) (e.g., Medicare, Bureau of Statistics)**
*\*\*If ticked, complete questions 3.3.6a-d*

**3.3.6.a** Please list the name of the Commonwealth agency/agencies from which the personal information will be sought:
Insert text here

**3.3.6.b** Please list or ATTACH the items/datapoints that will be sought from the Commonwealth agency/agencies:
Insert text here

**3.3.6.c** Please provide the number or range of Commonwealth records involved:
Insert text here

**3.3.6.d** Please ATTACH approval to access the records from the Commonwealth custodian.
Insert text here

**3.3.7** [ ]  **Publicly held database (State or Local)**
*\*\*If ticked, complete questions 3.3.7a-d*

**3.3.7.a** Please list the name of the State or Local agency/agencies from which the personal information will be sought:
Insert text here

**3.3.7.b** Please list or ATTACH the items/datapoints that will be sought from the State or Local agency/agencies:
Insert text here

**3.3.7.c** Please provide the number or range of State or Local records involved:
Insert text here

**3.3.7.d** Please ATTACH approval to access the records from the Publicly held custodian.
Insert text here

**3.3.8** [ ]  **Privately held database (including any subscription databases La Trobe subscribes to e.g., Roy Morgan, Business Sources Complete, ProQuest etc…)**
*\*\*If ticked, complete questions 3.3.8a-d*

**3.3.8.a** Please list the name of Private Organisation/s from which the personal information will be sought:
Insert text here

**3.3.8.b** Please list or ATTACH the items/datapoints that will be sought from the Private Organisation/s:
Insert text here

**3.3.8.c** Please provide the number or range of Private Organisation/s records involved:
Insert text here

**3.3.8.d** Please ATTACH approval to access the records from the Privately held database custodian.
Insert text here

**3.3.9** [ ]  **Other**

Insert text here

# Databanks and/or Biobanks and/or Publicly Accessible Data (NS 3.1.55-3.1.62)

## **Will your research establish a databank and/or biobank and/or make data publicly accessible?** [ ]  No [ ]  Yes

*\*\*If yes, complete questions 4.1-4.6*

**4.1 How will you obtain consent from participants in order to store their data within the databank and/or biobank and/or make their data publicly accessible?**

Insert text here

**4.2 What is the name of the databank and/or biobank and how is it proposed to the make the data publicly accessible?**

Insert text here

**4.3 Who is the custodian of the databank and/or biobank and/or the publicly accessible data?**

Insert text here

**4.4 What is the location of the databank and/or biobank and/or the publicly accessible data?**

Insert text here

**4.5** **For future research, what is the process for gaining access to the databank and/or biobank?**

Insert text here

## **4.6 Will you be accessing an existing databank or biobank?**[ ]  No [ ]  Yes

*\*\*If yes, complete questions 4.6.1-2*

**4.6.1 Was consent obtained for ‘future use’ from the participant at the time of data/biospecimen collection?**

[ ]  No\* Select waiver of consent in Section 2.2

[ ]  Yes\*\* attach the generic consent form/s, which is representative of the forms that would have been signed by the participants at the time their data or biospecimens were collected

**4.6.2 How will you gain access to existing records, contact list or biospecimen samples in a way that will not infringe privacy requirements? (**[**NS 3.2**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)**)**

Insert text here

# Language and communication

## **Will the research involve participants whose primary language is not the same as the researchers?**

## [ ]  No [ ]  Yes\*\*

*\*\*If yes, complete questions 5.1-5.2*

**5.1 Describe how you will identify and communicate with these participants**

Insert text here

**5.2 Is there a need to translate study materials (e.g., recruitment advertisements, PICFs etc). If so, please attach a copy of the translated materials and state who was responsible for translating them.**

Insert text here

# Research conducted in other countries

## **Will your research be conducted in countries other than Australia (this does NOT include online research which may recruit participants from countries other than Australia)?** [ ]  No [ ]  Yes\*\*

*\*\*If yes, complete questions 6.1-6.6*

**6.1 Which country/countries will this research be conducted in?**

Insert text here

**6.2 Which region/s will this research be conducted in?** *This question is important as research permit and ethics requirements can change between regions in the same country. It is also important to ensure there are no travel alerts to that region.*

Insert text here

**6.3 Will ethics approval be sought from an Institutional Review Board (IRB) or Ethics Committee within the country/countries where the research is to be conducted (**[**NS 4.8.4**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)**)?**

[ ]  No \* **State reason/s for not seeking approval** Insert text here

[ ]  Yes \* **List the name of the IRB or Ethics Committee.** ([NS 4.8.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)). Insert text here

**6.4 Is a research permit required for any of the countries you intend to conduct your project within?**

[ ]  No

[ ]  Yes \* If yes, please ensure a copy of the permits is attached or provided once received.

**6.5 Will the project be conducted by a student Investigator?**

[ ]  No

[ ]  Yes \* **Describe how the student will be supervised while overseas** Insert text here

**6.6 Have you nominated a local person who will be responsible for receiving complaints about the research? (**[**NS 4.8.16**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)**)**

[ ]  No \* **Explain why not** Insert text here

[ ]  Yes \*\* **Describe how and to whom in-country complaints will be made** Insert text here

# Drug/device clinical trials

## **Will your research involve the use of a drug and/or device in a clinical trial setting?**[ ]  No [ ]  Yes\*\*

*\*\*If yes, complete questions 7.1-7.6*

**7.1 Sponsor Name:** Insert text here

**7.2 Protocol Number**: Insert text here

**7.3 Select Notification Scheme:**

[ ]  Clinical Trial Notification (CTN)

[ ]  Clinical Trial Exemption (CTX)

**7.4 Clinical trials registry number (register at** [**http://www.anzctr.org.au/**](http://www.anzctr.org.au/)**):** Insert text here

**7.5 Please indicate by completing the checklist below, the documents that you have attached to your submission**:

[ ]  International Conference Harmonisation-Good Clinical Practice (ICH-GCP) protocol

[ ]  Indemnity (if sponsored by another organisation)

[ ]  Data Safety Monitoring Board (DSMB) Plan

**7.6 Complete the following information for each investigational drug or device involved in the project.** N.B. Some of the items below do not apply to devices.

|  |  |
| --- | --- |
| Approved Name |  |
| Trade Name (if applicable) | Insert text here |
| Supplier of drug/device (e.g., manufacturer/pharmacy) | Insert text here |
| TGA/ARTG Registration Number (if registered in Australia) | Insert text here |
| Approved therapeutic indication, dosage/duration in Australia (if applicable) | Insert text here |
| Believed mode of action | Insert text here |
| Dosage regimen | Insert text here |
| Mode of excretion (if applicable) | Insert text here |
| Known adverse events | Insert text here |
| Known contra-indications and/or warnings | Insert text here |

\*\**insert additional row(s) if using multiple drugs/devices by right clicking the last row and selecting “Insert- Insert Rows Below” in the dropdown menu.*

# Ionising radiation

## **Will your research expose participants to ionising radiation?** [ ]  No [ ]  Yes\*\*

*\*\*If yes, complete question 8.1*

**8.1 Are the ionising radiation procedures deemed to be part of standard/routine care?**

[ ]  No \* Attach a copy of the Medical Physicist Report

[ ]  Yes – no further action is required

# Collection of biospecimen samples

##  **Will your research involve the collection of human biospecimens?** [ ]  No [ ]  Yes\*\*

*\*\*If yes, complete questions 9.1-9.7*

**9.1 Please complete the table below detailing the biospecimens to be collected.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| List biospecimens you plan to collect | List person/s responsible for collection | What qualifications does this person/s have? | What procedures are in place to minimise the risks? | Attached a letter of support from the relevant person/s |
| Insert text here | Insert text here | Insert text here | Insert text here | [ ]  No[ ]  Yes \* please attach letter |
| Insert text here | Insert text here | Insert text here | Insert text here | [ ]  No[ ]  Yes \* please attach letter |

\*\**insert additional row(s) if needed by right clicking the last row and selecting “Insert- Insert Rows Below” in the dropdown menu.*

**9.2 Describe how human biospecimens will be collected:**

Insert text here

**9.3 Describe how human biospecimens will be stored:**

Insert text here

**9.4 Describe how human biospecimens will be disposed of:**

Insert text here

**9.5 Will genetic testing be conducted on biospecimen samples?**
[ ]  No
[ ]  Yes\*\*

*\*\*If yes, complete questions 9.5.1*

**9.5.1 What genetic tests will you conduct?** Insert text here

**9.6 Please indicate if you will contact participants about information pertaining to the following and describe how they will be contacted, counselled and supported**:

**9.6.1** [ ]  A risk of an inherited condition

Insert text here

**9.6.2** [ ]  Information that may reveal non-paternity, non-maternity, or non-relationship to siblings

Insert text here

**9.6.3** [ ]  Information that might influence a decision to have children

Insert text here

**9.6.4** [ ]  Information that might affect the ability to obtain insurance or employment

Insert text here

**9.6.5** [ ]  Information that might influence a decision to seek medical advice

 Insert text here

**9.6.6** [ ]  None of the above are applicable

 Insert text here

**9.7 Will the biospecimens be used for future genetic research?**
[ ]  No
[ ]  Yes\*\*

*\*\*If yes, complete questions 9.7.1*

 **9.7.1** How will you contact, counsel and support participants about information pertaining to future genetic results?

Insert text here

# **Declaration & Submission**

By submitting this application, we, the Principal Investigator, Co-Investigators and Student Investigators, declare the following:

* All information in this application and supporting documentation is correct and as complete as possible;
* I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
* I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
* All relevant financial and non-financial interests of the project team have been disclosed; and

understand that we cannot commence data collection until we receive a formal approval letter from La Trobe University Human Research Ethics Committee or one of its Low-Risk Committee;

* I will abide by the terms and conditions set by the La Trobe University Human Research Ethics Committee or on of its Low-Risk Committee;
* I will ensure that the qualifications and/or experience of all La Trobe University personnel involved in the project are appropriate to their role and/or to the procedures performed;
* I will ensure that appropriate approvals and/or approvals from external organisations or agencies will be obtained and that any imposed conditions will be observed;
* In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student’s educational program.

**SUBMIT**

1. Principal Investigator to send email with all investigators cc’d
2. Attach this form, Project Description/Clinical Trials Protocol and ALL study materials
3. Email all documents to **humanethics@latrobe.edu.au**