La Trobe University Human Research Ethics Applications

In deciding if you need to apply for human research ethics approval, the first question you must ask yourself is are you doing human research? The National Statement on Ethical Conduct in Human Research 2023 (National Statement) tells us that research is "widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers" and that human research "is conducted with or about people, or their data or tissue." Ask yourself if your research fits those parameters. If your answer is yes – then you should apply for ethics approval.

If you're still not sure, Research Ethics Advisors are available to help, email humanethics@latrobe.edu.au.

How long will the process take?

It is the applicant's responsibility to allow enough time for the ethics review process. Ethics applications should be early if there are other relevant deadlines such as grant submissions, start dates for education programs, etc. Ethics applications are reviewed in the order in which they are received.

Factors that may have an impact on the timeframe for review include:

- the completeness and quality of the initial ethics application;
- review category, e.g., low risk versus greater than low risk review;
- number of ethics applications currently under active review by the Low-risk Ethics Advisory Panel (LEAP) or Human Research Ethics Committee (HREC);
- the time taken by the applicant to provide requested information; and
- potential wait for external documents or letters of permission associated with the application.

We recommend you start your application **eight (8) weeks in advance** of your anticipated start date. This will allow time for all steps in this process including any governance review, discussions with ethics advisors and any necessary modifications, and then ethics review. This document will help you submit an application that should meet the requirements under the LTU Human Research Ethics Procedure. This is especially important for Honours and HDR students with time critical deadlines.

All Research Ethics Applications must be submitted via PRIME.

1. Save the application document as a PDF document.
2. Save each supplementary document as a separate PDF document.
3. Log in to PRIME Researcher portal.
4. Under Ethics Applications, click "+ New Human Ethics Application"
5. Add all researcher personnel
6. Upload the completed form and study documentation (as separate documents)
7. Click on "Submit to Research Office" by the relevant closing date

National Statement references are contained in this guide as it provides the foundation of the LTU Human Research Ethics Procedure. Using these references to complete your submission will help move the approval process along. This guidance will help you understand what the LTU research governance and ethics reviewers will be looking for in your application and what you can expect in the process. We have designed this guidance to follow the format of the basic application form; it doesn't address every individual question, but it does provide a strong foundation.

Applicants wishing to submit a clinical trial, biospecimen or clinical research ethics application should use the National Health and Medical Research Council Human Research Ethics Application and related forms available for online completion and download. These can then be uploaded to the LTU PRIME system. Additionally, if you have not already done so, you should

consider consulting with the La Trobe University Clinical Trials Platform team via CTP@latrobe.edu.au.

Research Ethics Advisors are available to assist researchers in answering questions on completing the application and about relevant guidelines. Simply email humanethics@latrobe.edu.au and someone will get back to you within two business days. There are also weekly drop-in sessions available from the **Ethics, Integrity and Biosafety (EIB) Team** see the Human Research Ethics Web Page for dates and times.

The Risk Assessment

Everything you want to consider when thinking about your human research ethics application begins with research merit and integrity, justice, beneficence, and respect. The level of potential risk to the research participant determines whether research is classified as low risk or greater than low risk research. You can read more about risk profiles in Chapter 2.1 of the National Statement.

The Risk Assessment section of the application assists the applicant to identify the risks involved in their project. In completing this section, you should consider the likelihood of different risks occurring and the severity or magnitude of any occurrence and their related consequences. Considering this on a matrix will help you assess the level of risk.

Likelihood \ Impact	Negligible	Minor	Moderate	Significant	Severe
Very Likely	Low Med	Medium	Med Hi	High	High
Likely	Low	Low Med	Medium	Med Hi	High
Possible	Low	Low Med	Medium	Med Hi	Med Hi
Unlikely	Low	Low Med	Low Med	Medium	Med Hi
Very Unlikely	Low	Low	Low Med	Medium	Medium

At the end of the assessment, you will select an ethics review pathway based on your assessment of risk. EIB will consider your selected pathway, your completed assessment and will either confirm this or discuss it with you further. However, the EIB or the ethics reviewers may at any time, during the review, amend the risk level and/or transfer the project to another committee at their discretion based on National Statement criteria.

Quick Tip: Writing in PLAIN Language

Ethics applications including associated documents should be written in plain language (National Statement 3.1.1) – Think of it as writing for the average adult population. Avoid technical or professional language such as may be used in grant submissions or with peers.

Use short, clear sentences. Use bullets or timetables for multiple visits or procedures. Select an easy-to-read font size. Use second person (you) statements rather than first person in your application, however, consider using the first person in your Participant Information and Consent Form as you will be 'speaking' directly to your participants. Use correct spelling and grammar. If the consent form is more than one page, use footers: page 1 of 3, page 2 of 3, etc.

Within Microsoft Word you can set your Options to include the tools you need to help you determine if your submission meets these standards. The Proofing options offer lots of options to improve readability statistics as well as correcting grammar and punctuation. You can also add Grammar & Refinement settings to help you limit jargon, wordiness, and complex words.

Click on File from the top menu, then:

- Options
- Proofing
- Writing Style
- Grammar and Refinements

You will be able to select the items you want to watch for within your writing. You will also see a tick box to show you the readability statistics.

Remember to set your spell and grammar check to "English – Australian!"

Open your document and run the "Spelling and Grammar" or "Editor" (depending on your version of Word) check function on the Standard Toolbar.

When Microsoft Word finishes checking spelling and grammar, it will display information about the reading level of the document using the Flesch-Kincaid Reading Ease score, which rates texts on a U.S. grade-school level. This is equivalent to the Australian school levels.

To improve readability, consider using shorter words and shorter sentences. Keeping the scientific and technical jargon to a minimum, ensuring that all documents are proofread, grammar and spell checked, will significantly diminish readability issues and help you avoid rewrites later.

Do not use acronyms without defining them first.

Section 1 Core Information

1.1 Project Summary

Summarise the participants, procedures and aims involved in this research in non-technical language. There are reasons for this – the ethics committee that reviews your application is made up of individuals from a wide range of backgrounds – not all of them will be familiar with the scientific or technical words that are common to your discipline. It also helps to ensure that individuals, participants, and interested individuals will be able to understand what you are doing. The more you get used to writing for a generalised audience, the more straightforward your submission becomes and the more easily it is understood. Keep your summary to 250 words.

1.2 Institutional Responsibility

LTU is committed to the National Statement Chapter 5.5 guidance on minimising duplication of ethics review. To that end, if you are applying for a multi-institution project, consider who has overall responsibility for the project.

Is LTU the lead institution (1.2.2)? If not, you may wish to discuss this with a Research Ethics Advisor to determine if a full application to LTU is necessary or if registering an external HREC approval is an option for you.

1.3 Funding

We often get asked why we ask about research funding. National Statement 5.3.7 states 'The researcher should disclose the amount and sources or potential sources of funding for the research to the review body and, where appropriate, the participants.' By doing this the HREC/LEAP can consider the relationship between the source of the funding and the aims of the project and whether there might be any implications for the ethical conduct of the project. This is particularly important as concerns recruitment, the information/data you are collecting, and freedom to publish.

The LTU HREC/LEAP are also required to ensure that there are appropriate resources available for a project, this ensures that projects won't be abandoned and potentially leave participants in limbo or worse - harmed. Like everything else, the risk of your project is balanced against resources, an absence of funding does not equate to withholding approval – it just means the reviewers will be looking at your other risk mitigation plans.

1.4 Project Location

The geographic location of your research may influence the State and Territory legislation that impacts your research along with the makeup of the population characteristics and related ethical considerations.

Where human research is conducted overseas the National Statement provides:

> 4.8.1 Research conducted overseas by researchers from Australian institutions must comply with the National Statement.
>
> 4.8.5 Where there are no ethics approval processes in an overseas country, the National Statement may provide the only applicable process for ethical approval. In this case, the Australian ethical review body should take account of the available resources and means to conduct the research and avoid imposing unrealistic requirements, providing always that research participants are accorded no less respect and protection than the National Statement requires.

There may be times where more than one review will be required, and you may need to do some searching to find out if countries you are working with have ethical review legislation/ regulations but knowing that will help you in your application process with LTU. A great place to start is the International Compilation of Human Research Standards which is updated regularly by the Office of Human Research Protections in Washington DC.

LTU also considers the impact or potential impact of foreign interference. To that end, we are looking to ensure all research has considered the funding through this lens by completing the requisite steps here at LTU by using the Foreign Engagement Risk Assessment Tool.

1.5 Project Timeframe

The project start date should not be prior to ethics approval unless you have clearly articulated a research component that does not involve human participation that is a precursor to the project that is included as a foundation of the application. Remember, human research ethics approval is not provided retrospectively.

Section 2 Prior Review

National Statement 1.2 provides that where a prior review has judged that a project has research merit, the question of research merit is no longer subject to the judgement of those ethically reviewing the research. This includes prior review by a scientific committee, a peer review committee, prior ethical review, academic review such as confirmation of candidature. Your answers to these questions may impact the depth and breadth of review by the LTU ethics review body.

Section 3 Research Team

3.1 Category of Research

The EIB, HREC and LEAP need to understand the category of research the project falls under. This includes research undertaken by LTU staff, research undertaken as part of an educational program and research undertaken as part of a contract or consultancy with an external organisation. The category of research has governance implications for LTU under LTU policies, the Australian Code for the Responsible Conduct of Research 2018 (the Code) and the National Statement.

3.2 – 3.4 Investigators

The Principal Investigator on an LTU ethics application may be:

- The primary investigator on an LTU project.
- The primary LTU investigator on a multi-institutional application where an external investigator has an overarching primary responsibility.
- The Chief Investigator on a multi-institutional application where they are also the LTU PI.
- The primary supervisor of a student who is conducting a project involving human research.

Primary supervisors must be listed as the principal investigator for all student projects with human participants. Primary supervisors are responsible for ensuring student research is conducted in accordance with LTU policies and national guidelines, including obtaining relevant approvals. Prior to submission of a student project to the LTU HREC, the primary supervisor should review and approve the project and all associated documentation.

National Statement 1.1 requires consideration be given to the ability of a researcher to reasonably conduct or supervise the research involving human participants. To that end, the LTU application asks for details in three areas on all involved investigators, this includes:

- expertise in support of their role on this project: National Statement 4.8.7 requires that investigators have enough experience, or at least the access to that experience, to engage with participants in ways that accord due respect and protection.
- research activities on this project: the activities for each team member as relates to the project are sufficiently detailed so that an ethics reviewer would understand what the individual will be doing.
- qualifications/education and training: qualifications include the educational qualifications earned in the field while education and training addresses specifics such as experimental procedures, research ethics and integrity and good clinical practice. Research ethics and integrity training should be updated at least every three years.

If you have a position identified for your project, but the person has not yet been hired, describe the required qualifications or training the person will receive, as applicable. But don't forget you will have to come back and file a modification to add the individual if they are named after you receive ethical approval.

Examples:

- An undergraduate will be hired to enter the data and will be trained in the described procedures to maintain confidentiality. List their experience to date and identify the training they will receive.
- A person certified to perform venepuncture will do the blood draws. List their certification for the procedure.

3.5 Student Supervision

National Statement 4.8.8 states that when research is to be conducted overseas by a researcher who is subject to academic supervision, researchers should inform the Australian ethical review body of how that supervision is to be effected so that due respect and protection will be accorded to participants.

The Code also requires that researchers provide guidance and mentorship on responsible research conduct to other researchers or research trainees under their supervision and, where appropriate, monitor their conduct. This is further outlined in the supporting guide on Supervision.

The application should provide sufficient detail to meet these requirements.

Section 4 Disclosure of Interests

The LTU Conflict of Interest Policy indicates that a conflict of interest may exist where the following may lead to an unfair advantage or disadvantage when making decisions on behalf of the University:

- our personal relationships and/or
- connections with former employers and former employees and/or
- participation in external activities and/or
- interests in another business
- personal gain in making business or academic decisions

This policy applies in research as it does in other parts of university business.

4.1 Acknowledging Conflicts of Interest

National Statement 5.3.11, 5.3.12 and 5.6.6 require researchers to disclose any interests that may constitute a conflict of interest relating to their research as outlined above and as involved in competing research. The nature and extent of any conflicts as relates to the LTU Conflict of Interest Policy and/or the relevant National Statement sections should be outlined and the linked to the relevant research team member.

4.2 Mitigation Strategy

A plan to eliminate, mitigate or manage the conflict of interest should be included in the application. This should include an awareness of the potential for conflicts to arise during the project and how you will recognise when that occurs and manage them.

Section 5 Project Design

The first questions of this section get to the basics of your project:

- What are you proposing to do?
- Why are you proposing to do this?
- Is the research question useful? Is the research worthwhile?
- Is the research likely to yield new information, enhance understanding, or clarify existing uncertainty?
- Has this, or something similar, been done in the same or similar contexts?
- Can the research proposal be supported by a systematic review of the literature that would demonstrate the importance of the research question?
- Does it build upon the results of previous research?
- Does the value of the project justify the use of human participants?
- Have you engaged in co-design with the relevant community?

How you respond to the initial questions in this section will determine the subsequent questions and your methodology questions then further enhance your project.

Be sure to include your references (parenthetically) within your literature review. If you wish, you can also add a full reference list with your supporting documentation at Section 12 as additional evidence for your project.

Section 6 Participant Information

6.2 Sample Size

What is the total participant population? How many individuals are you hoping to enrol? This includes at all sites if you are doing a multisite project. You will also need to explain why your proposed sample size is suitable to meet your project's goals.

In scientific terms we often think about statistical power and whether your project will lead to statistically significant results. In the ethics arena, we want to ensure that a project's results warrant the engagement of the participants and their time. If your project has been scientifically reviewed prior to your ethics application, this will have been established through

that review. If it has not received that type of review, the ethics committee will want to see justification for the engagement of participants.

6.3 Selection Criteria

What are the specific things that make someone eligible to be in your research and what will definitely keep them out? An easy example of an exclusion criteria is often something like anyone under the age of 18. An easy example of an inclusion criteria is anyone who is fluent in English. You will need to think about how you will confirm these criteria – will a researcher check that participants meet inclusion criteria? Or that they don't fit the exclusion criteria?

6.5 Indigenous research

At LTU we recognise and respect the unique culture and contribution that Aboriginal and Torres Strait Islander peoples and communities bring to our research. There are several resources available to you to help you structure your projects, including:

- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (the AIATSIS Code)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
- Keeping research on track II 2018
- National Statement Chapter 4.7

Targeted populations requiring specific considerations.

The National Statement Section 4 discusses the need to institute additional precautions to protect individuals that may require special considerations as research participants. This might include individuals who may have a diminished capacity to make informed decisions regarding their participation or may be susceptible to coercion due to their circumstances (e.g., inpatient) or to their relationship to the investigator. Identify any circumstances or situations where you might consider additional safeguards that may be necessary when recruiting, obtaining informed consent, or conducting other study procedures.

Section 7 of the LTU Application asks about a number of populations that may require special consideration when conducting your research. Depending on which boxes you select, questions are asked to that will help us better understand your planned research and the benefits and risks it may bring.

Please be sure to consider each one carefully and, as always, contact a Research Ethics Advisor at humanethics@latrobe.edu.au if you have any questions!

Section 7 Recruitment and Consent

'The guiding principle for researchers is that a person's decision to participate in research is to be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.' National Statement Section 2.2.1

7.1 – 7.7 Recruitment

Consent starts at recruitment. How you recruit your participants must be completely free from any coercion including the perception of coercion. Recruitment takes a few steps:

- identification of potential participants;
- the initial contact;
- potential screening for the inclusion and exclusion criteria; and
- the information you share during recruitment.

Populations should not be singled out solely because they may be "easier" to recruit (for example, institutionalised persons), if the PI intends to generalise results to a wider population. If certain people are targeted for participation, state why. If groups are excluded, state why. For example, "only women will be surveyed because we want to learn how women perceive the barriers to advancement in this male-dominated field".

Care must be taken to prevent even the appearance of coercion in recruiting. Coercion is a factor if the participant perceives that they may suffer negative consequences for not participating. For example, an individual may feel they must participate if the researcher is in an authority position, such as teacher/student, care provider/patient, employer/employee, etc. relationships, or if their employer or care giver is involved in recruitment.

The application asks a few questions around recruitment to make sure your project recruitment is equitable, done without coercion, and is done ethically and legally.

7.8 – 7.17 Informed Consent

Obtaining consent is a process, not merely having the person read a statement and sign it. The purpose is to ensure that the potential participant has sufficient understanding of the study and their role in it before agreeing to participate. It is the responsibility of the PI to ensure that the information is presented in a manner that each person can comprehend, that the person understands the risks and benefits, and can ask questions. The PI must also make it completely clear that the potential participant is free to either participate or not without any negative consequences and may quit at any time, although it may not always be possible to withdraw their data. Those details must be made clear, and the differences explained.

For populations that include children and/or those who may be decisionally impaired, the PI must describe the conditions and procedures for obtaining appropriate consent. In some cases, (e.g., people with acute mental illness), a determination must be made whether the person is capable or not. The procedures for this determination must be described. If it is determined that a parent, guardian, or other advocate must provide written consent, describe how this will be obtained. The participant may also be asked to provide consent/assent, if able, in addition to other consents. If this is not possible, explain why.

The consent process and the Participant Information and Consent Forms (PICF) are critically important for the protection of participants in research. Obviously, the risk involved for the participant will determine the appropriate consent process.

The PI must obtain consent under circumstances that provide the potential participant or representative enough opportunity to consider participation and minimise the possibility of coercion or undue influence.

- The information must be written in language that the person, or representative, can easily understand.
- The consent must not include any language that waives or appears to waive any legal rights of the participant.
- The consent must not include any language that releases the PI, LTU, a sponsoring agency, or individuals from liability for negligence.

To ensure that participants understand the nature of the research and their personal involvement, the investigators must provide a thorough oral explanation to prospective participants and answer their questions and, unless otherwise approved by the HREC/LEAP, obtain a signed consent from participants.

In certain circumstances, such as online surveys, a Participant Information Sheet may serve as the standalone mechanism for explanation and the survey commencement will serve as implied consent.

The nature of your research and the level of risk determine the type and amount of information that you need to include to enable a potential participant to understand the project and their role in it. Consider what the person will need to know to make an informed decision to participate. For example, interviews or questionnaires with highly sensitive questions require detailed information about procedures to protect confidentiality or to enable a participant to decide whether they are prepared to divulge the information which will be sought. Research involving therapy or exercise may need more information about physical risks.

Translations of consent information are necessary for people who do not speak English, or who do not speak or write English with sufficient competence to meaningfully participate. Describe how information will be translated and by whom. For greater than low risk applications, the translation must be certified and done by a qualified translator. For low and negligible risk applications, the translation may be done by native speakers or qualified educators. The PI should provide details on how the translations were obtained.

An approved LTU Participant Information and Consent Form is available and its use is encouraged.

For additional help in considering recruitment and consent see the following:

- Understanding consent in research involving children: The ethical issues
- Payment of participants in research

7.12 Consent for another

For a decisionally impaired person, a legally authorised representative (LAR) must provide written permission. Provide signature and date spaces for the LAR and the participant, if the latter is capable of agreeing to participate.

State whether the participants and data are anonymous or confidential. If participants are anonymous, no one, including the researcher, knows the identity of those who participated in the study or which data they provided. If the information is confidential, the identity of participants and the data is known, but is kept in strict confidence within legal limits. Coding identities and storing data in locked files are methods of preventing private information about participants from being revealed. Be aware that confidentiality and anonymity may be limited, for example if participants are involved in group sessions, or if their employer/care provider is involved in recruitment.

A copy of the consent must be given to every participant. The PI retains the original signed statement. The investigator must retain these documents for at least three years past the completion of the research activity.

7.18 Limited Disclosure

Limited disclosure to participants about the aims or the method of your project is sometimes used when the research goal simply could not be achieved if the information were fully disclosed. Disclosure, however, covers a spectrum and where a project sits on that spectrum plays a part in consent and ethical review. National Statement Chapter 2.3 provides information on qualifying or waiving conditions for consent with key requirements listed at 2.3.1 through 2.3.4.

7.19 Opt-out consent

An 'opt-out' approach is used when it is not feasible to contact some or even all the participants in a project. Typically, this is used when the scale of project is so large that consent would be a huge undertaking or if the project is using data previously consented, and the re-consent process would be onerous. The significance of the benefit then would have a direct impact on the approvability of opt-out consent. National Statement 2.3.5 through 2.3.8 will give you more detail on this.

7.20 Waiver of Consent

A request for a waiver of consent may be submitted when neither explicit consent nor opt-out consent are appropriate for the project. This means that ultimately the research participants will likely not know that they (or their tissue or data/information) have been involved in research. It should be noted that only an HREC may grant a waiver of consent for research using personal information in medical research or personal health information and in projects that may expose illegal activities. For more information and to see if your project fits into the requirements see National Statement 2.3.9 through 2.3.11.

Section 8 Privacy and Confidentiality

While there is no agreed definition of, or general right to, 'privacy' in an Australian context there are laws which speak to the 'privacy' of certain types of data or information, and which also regulate the ways in which it may be collected, used, shared, stored, re-used and destroyed. In a human research context, the following types of data or information are protected:

- **Personal information**: Any information or opinion recorded in any form and whether true or not, about an identifiable individual or from which their identity can be reasonably ascertained (for example, name, address, mobile phone number, email address, photo, voice recording, employment record, student record, medical record etc.).
- **Sensitive information**: A subset of personal information (see above) that might be used to discriminate against an individual and therefore requiring more protection (for example, racial or ethnic origin, sexual preferences or practices, political opinions, membership of a political association, religious beliefs or associations, philosophical beliefs, union membership or criminal record).
- **Health information**: Defined broadly as information or opinion about physical, mental or psychological health, disability, expressed wishes about health care provision, a health care service provided, of an identifiable individual (living or dead).

Information is only sensitive information or health information if the information can be linked to an identifiable individual or from which their identity can be reasonable ascertained.

Where the terms identifiable, re-identifiable and non-identifiable are used in relation to the kind of data being collected, used or stored, the meanings are as follows:

- **Identifiable**: The identity of an individual can be reasonably ascertained.
- **Re-identifiable**: It is possible to re-identify an individual. For example, identifiers removed from main dataset and replaced by a code (stored separately) which enables data to be linked back to a particular individual.
- **Non-identifiable**: Any identifiers permanently removed, and no specific individual can be linked to particular data.

Over the lifecycle of a research project or activity the identifiability of data may change. For example, it may be collected in an identifiable format, made re-identifiable (coded) for the purposes of use and analysis and then stored in a non-identifiable format (separate file containing codes destroyed and all identifiers permanently removed).

Depending upon the nature of the information the researcher collects, loss of confidentiality can be a serious research risk for the participant. The level of risk assumed by the participant if the information were to be known by others determines the level of safeguards that the PI should institute to protect the participants. For example:

Are the participants clearly informed that their information will only be used for this project? Or have you clearly requested extended consent? Extended consent may remove barriers in the future if you believe you may build upon this research. An example of PICF language may be included, e.g.: 'Be aware that in participating in this research, your de-identified data may be used to inform future research …'

A survey or interview about individuals' illegal activities or their opinion of their job/employer has more potential for negative consequences for the participant if the information became known, than a survey or interview on frequency of exercise or study habits.

What measures do you propose to protect the confidentiality of information during your project? Are these adequate to give the degree of protection promised to participants? Consider using the least identification possible, starting with anonymity, then coding, and eliminating collection of unnecessary demographics and data. Destroy identifiable data or links to identifiers as soon as possible. Limit the number of people with access to identifiable, confidential data.

Video and audio recordings are identifiable information. The limits of their use must be clear. If information is sensitive, transcription/analysis should be completed, and the recordings destroyed as soon as feasible. If they are to be retained, state why.

Section 9 Risk and Benefit

9.1 – 9.2 Risk and Mitigation

Risks in research are not limited to physical or psychological harm. Consider any possible negative consequences to the individual for participating in your research including social, economic, and legal harm. When identifying the risks, consider the magnitude of the risk as well as the likelihood that it may occur. Assessment and management of risk is dealt with in National Statement 2.1.

Provide information from published literature when possible and appropriate. State the precautions that you will take to minimise the risk, and procedures that you will follow if harm occurs.

For example:

- In similar studies, a few participants have become mildly upset during the interview when discussing the trauma they had witnessed. The interviewer is experienced in counselling trauma victims and will stop the interview and provide immediate support. If the anxiety persists, the following actions will be taken ….
- There is a very small possibility of heart attack during the strenuous exercise in this program. However, it is very unlikely because the participants are healthy, athletic and <35 years old. Monitoring procedures conducted throughout the exercise include ….
- In case of emergency, these personnel and equipment are available … and these procedures will be followed ….

While the National Statement focuses on the risk to the participant, the university considers the risk to the research team as well. In that regard, the ethics committee considers that risk in its review of the project to a limited extent. Is there risk to members of the research team during the project? Will you be in an unfamiliar location? Will you need support? The LTU OHS policy should be considered, and the location of where you have filed your OHS plan in accordance with the policy noted here. Is there a risk to the project if there is a negative outcome and will that have a negative outcome for participants?

If the researcher is a student, the provisions made by the supervisor to maintain a level of connectivity to ensure the student's safety should have been noted previously at Question 3.5, this can be referenced here, and further detail added if needed.

9.3 Benefits

Benefits to the individual or to society should be reasonable in proportion to the risk. A benefit is a positive outcome that a participant can reasonably expect from their involvement in the research procedures. Payment for participation is not considered a benefit.

9.4 Overall Justification

Research is ethically acceptable only when its potential benefits justify any risks involved in the research. This is your opportunity to state how the potential benefits of your project justify the risks that may exist in your research – this is where you really want to think about those core values of merit and integrity, respect, justice, and beneficence. Review National Statement 2.1.

Section 10 Research Data Management

The LTU Research Community must adhere to the Code, the supporting Guide Management of Data and Information in Research, and the LTU Research Data Management Policy. The questions in this part of the ethics application provide your research data management plan in support of your compliance with those requirements and those under the National Statement.

Section 11 Dissemination of Findings

We don't often hear about restrictions placed on dissemination of research outcomes, but there are occasionally some. Sometimes sponsors have restrictions in place for timing issues or commercial in confidence items. Additionally, the Department of Defence places a restriction that anything Defence related must have one star (or equivalent) approval before publication – that includes student theses or dissertations. These types of items should be highlighted at this Section.

Having a plan for your dissemination means that La Trobe may be able to promote your work as well.

Section 12 Supporting Documentation

Not everyone will have the same attachments. Your documentation list will be unique to your research. You will be prompted to upload any supporting documents such as:

- PICF
- recruitment materials including
    - email invitations
    - flyers
    - advertisements
- research instruments including
    - interview/focus group guides
    - questionnaires
    - surveys
- research data materials
    - observational logs
    - reporting forms
    - data management plan

Principal Investigator Declaration

Confirm your agreement to the conditions and submit the form.

What Happens Next?

Governance Review

Within three business days of submitting a completed Ethics Application in PRIME, a Research Ethics Advisor will begin a Research Governance Review. Once your form has undergone a governance review to ensure that it is complete, you may be notified that further information is needed, or some changes are required.

Any required changes should be made using track changes and uploaded to PRIME with a new date and version control number. Do not delete previous versions! If you do not respond to the governance review within 60 days, the Research Ethics Advisor will provide a ten (10) day reminder before withdrawing the application. Once any necessary revisions have been made or additional information provided and the Research Ethics Advisor is satisfied with the application, it will be forwarded for ethics review.

Ethics Review

Once your application has finished governance review it will be forwarded to the relevant LTU ethics review body based on risk level. The ethical review actions can be one of the following:

- approve the proposal as written;
- approved pending modifications;
- modifications and resubmission requested; or
- not approved; resubmission not requested.

The HREC/LEAP actions will be communicated to the PI within one week of the completed review with instructions for any required next steps. This may include updating your online application and providing additional or amended documentation if requested by the Committee.

Acronyms and Terms

AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies
Code	Australian code for the responsible conduct of research
Data	Information that is collected, observed, generated or created to validate original research findings.
EIB	Ethics, Integrity & Biosafety Team
HREA	Human Research Ethics Application Form
HREC	Human Research Ethics Committee
LEAP	Low-risk Ethics Advisory Panel
LTU	La Trobe University
NS	National Statement
PI	Principal Investigator
PICF	Participant Information and Consent Form
PRIME	The La Trobe University online application system