## **Project Description**

Confidential

This document is confidential and is the property of La Trobe University. No part of it may be transmitted, reproduced, published or used without prior written authorisation from La Trobe University.

Statement of Compliance

This project will be conducted in compliance with all stipulations of this project description, the conditions of the ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007, and all updates) and if applicable, the International Conference of Harmonisation Guidelines for Good Clinical Practice.

Authorship

List Author/s

Version Control

| **Version Date** | **Summary of changes** |
| --- | --- |
| DD MM YYYY | INSERT a simple reason for why the change was made, for example "updated study methodology" |

|  |
| --- |
| Element 1: Scope, Aims, Themes, Questions and Methods (National Statement [Section 3.1.1.-3.1.5](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1)). |
| 1.1 Research question/s and/or challenges  Examples   * Do students perform the same when they attend face-to-face lectures compared to online study? * What is the impact on the environment if Australia uses more solar energy compared to coal energy? * Do subsequent generations of settlers exhibit the same characteristics of the first-generation settlers? |
| Insert text here |
| 1.2 Aims  Examples   * To measure the difference in student results between groups from 2016-2019 * To determine if Australia should invest in solar energy to reduce Australian’s carbon footprint * To determine if characteristics of settlers change with each generation |
| Insert text here |
| 1.3 Background Literature Review: Cite current literature to support your aims and key research questions and how the project fills a gap in the current knowledge (500 words) |
| Insert text here |
| 1.4 Describe the potential benefits of this research to one or more/each of the following: society, individuals including the participants or groups and/or the skill and expertise of the researchers (200 words) |
| Insert text here |
| 1.5 Research design and methodology: Provide an outline of the project timeline, research design (e.g., cross-over, observational, randomized control trial, interventional, cross-sectional, qualitative, Parallel group, randomized crossover, cohort study, cross section, case study etc.), and data collection methods (e.g. interviews, scales, questionnaires, interventions – everything you will ask your participants to do) and time commitment from participants (if applicable).  This section requires a level of detail so that anyone can read this section and know exactly what is being done, where, when and the time commitment. You are encouraged to include timeline and/or flow diagrams*.* |
| Insert text here |

|  |
| --- |
| Element 2: Sample Size and Recruitment (National Statement [Section 3.1.2.-3.1.22](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1)).  [Download recruitment template here](https://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics) |
| 2.1 Participant Groups & Recruitment |
| *\*\*copy and paste headings below for each participant group*   1. Participant/Sample Population Group Name   Insert text here   1. Inclusion/Exclusion Criteria   Insert text here   1. Sample Size: Justify the intended sample size to meet the aims of the project  * [http://powerandsamplesize.com/Calculators/](http://powerandsamplesize.com/Calculators/%20) (quantitative sample size calculator) * <http://stat.ubc.ca/~rollin/stats/ssize/index.html> (quantitative sample size calculator)   Insert text here   1. Describe how participants are identified and recruited (including initial contact). If you are using previously collected data/samples rather than seeking to collect new data from participants, please state this.   Insert text here |
| 2.2 Describe the potential impact of any relationship on recruitment between researchers, others involved in the project e.g. recruiters, and potential participants. If there is no impact write N/A. |
| Insert text here |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Element 3: Consent and Risk Management (National Statement [Sections 2.2, 2.3, 3.1.23-3.1.39](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1))  [Download Participant Information Statement and Consent Form template here](https://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics) | | | | | |
| 3.1 Complete the table below when a project involves obtaining consent from a person and/OR attach original participant information statement and consent forms for previously collected data (e.g., data obtained from another researcher, databank and/or biobank).  *\*\*copy and paste additional row(s) if needed* | | | | | |
| Participant Group | **Consent Type** | **Consent for future use of data** | **How and when will you provide consent materials to potential participants** | **When and to whom will participants indicate their consent?**  **How will researcher monitor competence to give consent?**  **For complex or long projects describe how consent will be renegotiated or confirmed from time to time** ([NS 2.2.8](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)). | **How will any real or perceived coercion be managed** | |
| Insert text here | 1. **Prospective**   Written  Verbal (e.g. phone)  Implied (e.g., completed via survey)  Third party consent (e.g., parents/guardians of minors or persons responsible)  Opt-out   1. **Existing**   ATTACH Original PICF/s  Waiver of Consent requested in application form | Insert text here | Insert text here | Insert text here | Insert text here | |
| Insert text here | 1. **Prospective**   Written  Verbal  Implied  Third party consent (e.g., parents/guardians of minors or persons responsible)  Opt-out   1. **Existing**   ATTACH Original PICF/s  Waiver of Consent requested in application form | Insert text here | Insert text here | Insert text here | Insert text here | |
| 3.2 Reimbursement of expenses or incentives to participate: Justify any proposed reimbursement of out-of-pocket expenses, financial incentive or other ‘reward’ for participation in the project | | | | | | |
| Insert text here | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| 3.3 Risks to participants/sample population: Describe the anticipated risks to participants and strategies to minimise risk  *\*\*insert additional row(s) if needed*  Examples:   * Risk of surveys and/or interviews causing distress * Risks of study procedures (e.g., collecting blood, saliva, genetic testing etc..) * Risks of potentially being identified in an interview on sensitive information * Risks of recruitment (e.g., the potential for coercion/exploitation, any privacy matters relating to the recruitment of participants etc) (NS 3.1.18) | | | |
| What is the risk? | **How will you minimise risks to participants?** | **How will health and wellbeing be monitored?** | **Do the benefits outweigh the risks?** |
| Insert text here | Insert text here | Insert text here | Insert text here |
| Insert text here | Insert text here | Insert text here | Insert text here |

|  |  |  |  |
| --- | --- | --- | --- |
| 3.4 Risks to researchers: Describe the anticipated risks to researchers and strategies to minimise risk.  *\*\*insert additional row(s) if needed*  Examples:   * Risks when visiting a private home * Risks when performing study procedures e.g., blood collection, x-rays * Risks when interviewing about sensitive topics about cultures/organisations etc… | | | |
| What is the risk? | **How will you minimise risks to researchers?** | **How will health and wellbeing be monitored?** | **Do the benefits outweigh the risks?** |
| Insert text here | Insert text here | Insert text here | Insert text here |
| Insert text here | Insert text here | Insert text here | Insert text here |

|  |  |  |
| --- | --- | --- |
| 3.5 Risks to the University: Describe any anticipated risks to University and strategies to minimise risk.  *\*\*insert additional row(s) if needed*  Examples:   * Risks of failure to comply with relevant law where the project is conducted * Risks of claims by participants or researchers who suffer harm in the conduct of the project * Reputational risk | | |
| What is the risk? | **How will you minimise risks to the University?** | **How will health and wellbeing be monitored?** |
| Insert text here | Insert text here | Insert text here |
| Insert text here | Insert text here | Insert text here |

|  |
| --- |
| Element 4: Research Data Management ([National Statement Section 3.1.40-3.1.62](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) |

|  |  |  |  |
| --- | --- | --- | --- |
| 4.1 Data Identification and Collection | | | |
| Data Types | **Please specify what data you will collect and how** | **Source Data Classification** | **Consent for future use of data (as outlined in PICF) (**[**NS 3.1.45i**](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)**)** |
| Physical  paper + pen  including observational field notes | Insert text here | Identifiable  Re-identifiable  Non-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |
| Digital  online tools e.g., RedCaps, social media posts, websites, digital databases, online newspapers | Insert text here | Identifiable  Re-identifiable  Non-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |
| Audio  Smart phone (cloud storage turned off), recording devices, video cameras, cameras, zoom, etc. | Insert text here | Identifiable  Re-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |
| Visual  Smart phone (cloud storage turned off), recording devices, video cameras, cameras, zoom, etc. | Insert text here | Identifiable  Re-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |
| Biospecimens  Refers to any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person | Insert text here | Identifiable  Re-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |
| Physical specimens or artefacts or archival material | Insert text here | Identifiable  Re-identifiable | **Specific**: limited to the specific project under consideration  **Extended**: given for the use of data or tissue in future closely related research projects  **Unspecified**: given for the use of data or biospecimens in any future research |

|  |
| --- |
| 4.2 Data Analysis, Ownership and Licencing |
| 4.2.1 Describe the procedures or plans for verifying, confirming, linking and/or cleaning data |
| Insert text here |
| 4.2.2 Describe how data/materials will be analysed |
| Insert text here |
| 4.2.3 What descriptive record (metadata) will be created for the data to aid discovery and retrieval? |
| Insert text here |
| 4.2.4 Where will data be published? |
| No record published  Research Online, La Trobe’s institutional repository  Figshare (Researchdata.latrobe), La Trobe’s collaborative digital repository  Other archive or repository Insert text here |
| 4.2.5 Intellectual property, copyright and ownership ([National Statement Chapter 3.1.45c](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))  Intellectual property refers to various rights including copyright and moral rights, patents, trademarks, and trade secrets and confidential material. Copyright refers specifically to the exclusive right to use work by copying, publishing or transforming it into another format. Please refer to the [La Trobe Intellectual Property Policy](https://policies.latrobe.edu.au/document/view.php?id=101).  In general, for all research carried out during a researcher’s employment with La Trobe, the IP and copyright owner is La Trobe. For research involving multiple institutions/parties, La Trobe may be an IP and copyright owner.  For Aboriginal and Torres Strait Islander Peoples’ right to assert and retain ownership of the cultural and intellectual property related to the information that is provided to the research project and control over the use of that data in publications and other copyrighted works. Please refer to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders |

|  |  |
| --- | --- |
| **Owner** | **Date copyright was implemented** |
| La Trobe University | Insert text here |
| Other | Insert text here |
| Not applicable |  |

|  |
| --- |
| 4.2.6 Is the data owned by a third party? If yes, complete table below |

|  |  |  |  |
| --- | --- | --- | --- |
| No (go to Element 4.3)  Yes \*\*please complete section below | | | |
| Data ownership type (section 3.1.45c) | What are the legal requirements for pre-existing data? (section 3.1.45c) | Where are the pre-existing data located? | Are there additional requirements for the data? (section 3.1.45g) |
| Purchase  Commercial licence  Open licence  Other (e.g., market research)– include details: | **Detail**: Insert text here | **Detail** (e.g., archive or URL): Insert text here | No  Yes - please provide detail (e.g., permissions need to be obtained from Insert text here parties before publication of data; data must be made publicly available): |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 4.3 Data Storage and Destruction (NS 3.1.4a & 3.1.45e) | | | | |  |  |
| Data Source | **In what format will data be stored?** | **How is data stored securely?** | **Who will have access to the data? Are there any conditions/restriction to access? (NS 3.1.45g)** | **Location**  **(campus/building/online/location)** | **Storage period** | **How will data be securely destroyed?** |
| Physical  paper + pen  including observational field notes | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |
| Digital  online tools e.g., RedCaps, social media posts, websites, digital databases, online newspapers | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |
| Audio  Smart phone (cloud storage turned off), recording devices, video cameras, cameras, zoom, etc. | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |
| Visual  Smart phone (cloud storage turned off), recording devices, video cameras, cameras, zoom, etc. | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |
| Biospecimens  Refers to any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |
| Physical specimens or artefacts or archival material | Identifiable  Re-identifiable  Non-identifiable | Insert text here | Insert text here | Insert text here | **Research:** 5-years post publication date  **Research with Health information:** 7 years post-publication  **Drug/Device clinical trials participants 18+ years:** 15 years post publication date  **Drug/Device clinical trials from participants under 18 years of age**: When the last participant turns 25 or 15 years post publication date, whichever is longest.  **Indefinitely**  **Reason** | Insert text here |

|  |
| --- |
| Element 5: Communication of Research Findings or Results to Participants ([National Statement Section 3.1.63-3.1.68](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) & 3.1.71) |
| 5.1 Describe the timeframe PARTICIPANTS will receive each type of result, the format it will be received (e.g., email, face-to-face, phone call, letter, social media post) and how participants will securely receive research results. For example:   * Checking of data with participants (if applicable): Outline the research team’s processes for checking the accuracy of their results with participants (e.g., checking interview transcripts) * Personal results (if applicable): Outline processes for sending personal results to participants * Lay summary of overall results from the study: Outline processes for sending lay summary results to all participants * A copy of research outputs: Outline processes for sending research outcomes (e.g., thesis, journal articles, abstracts) to research participants |
| Insert text here |

|  |
| --- |
| Element 6: Dissemination of Research Outputs and Outcomes to Research Community ([National Statement Section 3.1.69-3.1.72](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) |
| 6.1 Describe how results will be disseminated to the RESEARCH COMMUNITY.   * Where research outputs will be published (e.g., published paper, conference abstract, conference presentation, reports, student thesis) * How participant confidentiality will be maintained in your reports and/or publications. |
| Insert text here |
| 6.2 Using the table below, describe under what circumstances will you grant access to data or information if requested by another researcher and/or journal)? |

|  |  |
| --- | --- |
| Repository Type | Procedures for consent type (e.g., specific, extended or unspecified), how access to data will be granted, and the security arrangements in place |
| Open Access and Open Data – freely available to use, reuse and redistribute | Insert text here |
| Researcher-mediated access – researchers access the data after approval from the data custodian (i.e., researcher who collected it) | Insert text here |
| Metadata Sharing – online publication of research datasets | Insert text here |
| Restricted Access - data stored in a repository, which password protections, but allowing discoverability and global awareness of research data, but not access. Suitable for:   * Data with commercial potential * Medical research data containing confidential patient information * Research data containing culturally sensitive information * Third party data which have contractual agreements | Insert text here |

|  |
| --- |
| Element 7: After the Project ([National Statement Section 3.1.73-3.1.74](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) |
| 7.1 Does the data or information have cultural, historical or other significance that could warrant retention for longer than the minimum required time or in perpetuity? If so, please explain how this will be managed. |
| Insert text here |