## Prior to completing this form, applicants should review the [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) and apply its principles to their project plan and application for ethical approval. Where applicable, National Statement references are provided throughout this form.

## About this Form

This application form should be used by researchers seeking ethical approval for human research projects.

## Sharepoint

Information to assist in preparing a successful application is available on Sharepoint, [Ethics.](https://federation.edu.au/research/internal/ethics/human-ethics) Student researchers must discuss their application with their supervisor. The Coordinator Research Ethics, Mt Helen also welcomes enquiries in the preparation of an application.

## Completing the Form

This form can be completed on your computer using the tab key to move through the template. The response area will expand to fit the content. Click inside a checkbox to record a Yes/No response.

Please do not alter any part of the form, and answer all questions.

## Attachments

Before submitting your application, please check that you have attached copies of all required supplementary documentation. These should be separate unnumbered attachments.

## Submitting the Application

Complete the application and any attachments and submit via email to the Coordinator, Research Ethics research.ethics@federation.edu.au, **cc’ing all co-investigators.** The application submitted should be complete and final.

## Deadlines

Refer to the meeting dates on our [website](https://federation.edu.au/research/internal/ethics/human-ethics) and note the due date for agenda items. Deadlines are strictly adhered to. Late applications will be held over until the next available meeting.

**Caution:** Responsibility lies with the Chief Investigator to ensure the application has been received and scheduled for review. If you have not been advised by the Ethics office that your application has been accepted, please follow-up with an email or phone call **prior to the application deadline** to obtain the Project Number & Meeting Date**.** Contact details are available on our [website.](https://federation.edu.au/research/internal/ethics/human-ethics)

## Notification of Outcome

The nominated Chief Investigator will receive notification of outcome as soon as possible after the meeting date.

**Research must not commence prior to receipt of written approval.**

**Please delete this instruction page before submission.**

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| PROJECT DETAILS |

## Project title: (Avoid acronyms without explanation)

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| Click or tap here to enter text. |

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| What type of project is this? (Tick as many as apply) |
| [ ]  Funded Consultancy | [ ]  Masters by Research | [ ]  Undergraduate Research |
| [ ]  Clinical Trial | [ ]  Masters by Coursework | [ ]  Class Research Project |
| [ ]  Staff Research  | [ ]  Postgraduate Diploma | [ ]  Other - provide details: Click or tap here to enter text. |
| [ ]  PhD | [ ]  Honours Research |

## Risk Assessment (Refer to the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023), Chapter 2.1)

Human research may lead to harms, discomforts or inconveniences for participants or others. The review pathway for your application depends on the identified level of risk associated with your project.

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| [ ]  | Low risk | Low and negligible risk research describes research in which the only foreseeable risk is **discomfort** or **inconvenience**. Research in which the risk for participants is more serious than discomfort is not low risk.If risks associated with your research may be more than discomfort and become **distress**, you should select ‘higher risk.’  |
| [ ]  | Higher risk | Please also select this option if your research is with one or more of the following participant groups (and please select those that apply): |
| [ ]   | Women who are pregnant and the human foetus (N.S. 4.1) |
| [ ]   | People highly dependent on medical care who may be unable to give consent (N.S. 4.4) |
| [ ]   | People with a cognitive impairment, an intellectual disability, or a mental illness (N.S. 4.5) |
| [ ]   | People who may be involved in illegal activities (N.S. 4.6) |
| [ ]   | Aboriginal and Torres Strait Islander Peoples (N.S 4.7)See also the [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research](https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf) |
| [ ]  | People in countries other than Australia, (N.S. 4.8)*Excluding projects which do not specifically target participants abroad, such and studies conducted online.*  |
| Please also select ‘higher risk’ if your research involves/requires any of the following (and please select those that apply): |
| [ ]  | Active concealment or planned deception or aims to expose illegal activity (N.S. 2.3.4); |
| [ ]   | A waiver of consent for use of personal information in medical research, or personal health information (N.S. 2.3.9); or |
| [ ]   | The collection of human biospecimens for research purposes (including biobanks) (N.S. 3.2.1). |

## Through which Research Centre is the research to be conducted?

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| Click or tap here to enter text. |

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| RESEARCHERS |

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| Chief Investigator (must be a Federation University STAFF MEMBER)*Note, for student projects, the Principal Supervisor should be listed as the Chief Investigator* |
| Title & Name: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Institute and Discipline: | Click or tap here to enter text. |
| Phone number: | Click or tap here to enter text. |
| Email address: | Click or tap here to enter text. |
| Academic qualifications: | Click or tap here to enter text. |
| Describe what this researcher will do in the context of this project: | Click or tap here to enter text. |
| Include a brief summary of relevant experience for this project (N.S 5.1.45(a)): | Click or tap here to enter text. |

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| Co-Investigator/s \*\*Copy and paste this table for each person involved in the project. |
| Title & Name: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Institute and Discipline / Organisation: | Click or tap here to enter text. |
| Phone number: | Click or tap here to enter text. |
| Email address: | Click or tap here to enter text. |
| Student ID number if applicable: | Click or tap here to enter text. |
| Academic qualifications: | Click or tap here to enter text. |
| Describe what this researcher will do in the context of this project: | Click or tap here to enter text. |
| Include a brief summary of relevant experience for this project (N.S 5.1.45(a)): | Click or tap here to enter text. |

\*\* Copy additional co-investigator blocks here, as needed.

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| RESEARCHER TRAINING |

All researchers at Federation University are required to undertake training in responsible research conduct (see [*Australian Code for the Responsible Conduct of Research*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)*, R16*).

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| Have all of the above named Federation University researchers completed the online training module provided by the University (Research Integrity, Second Edition)?Every researcher must complete all of the modules assigned to them via Workday, as well as the supplementary module ‘Responsible conduct of human participants research.’ For clarification of training requirements, or more information, contact research.integrity@federation.edu.au.  | [ ]  Yes | [ ]  No |
| If ***no***, please list those still to complete the training below and confirm that the relevant researchers will complete the training within 3 months of the date of approval of this application (evidence will be required).Click or tap here to enter text.[ ]  Confirm |

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| LAY DESCRIPTION |

State the research question/challenge addressed by this project. Provide a brief description of the project including key aspects of the research design (e.g., who will be participating, what information will be collected and by what means, what participants will be required to do, etc.). The lay description must be in **everyday, jargon-free language that is comprehensible by the average educated layperson**. This may be the same or similar to the project description given in your Plain Language Information Statement (PLIS). Define any technical terms or discipline-specific phrases and use the full form of all acronyms the first time they are used. (N.S. 3.1.1-3.1.11) (**300 words max**.)

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| Click or tap here to enter text. |

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| RESEARCH AIMS & SIGNIFICANCE |

State the aims, and significance of the project referencing current literature and any peer review of the research design where appropriate. If relevant, state the specific hypothesis to be tested. Provide justification as to why your research should proceed, including an explanation of any expected benefits to the community and its potential to contribute to existing knowledge.

Refer to section 1 of the [National Statement on Ethical Conduct in Human Research](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) for discussion of the values and principles of research merit and integrity, justice, beneficence and respect. (N.S. pp.9-11 and 3.1.1-3.1.11) **(600 words max.)**

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| Click or tap here to enter text. |

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| FUNDING & FINANCIAL BENEFITS |

Researchers should include any source of funding (e.g., departmental, commercial, non-commercial, governmental). The Ethics Committee will consider whether there is a conflict of interest. (N.S. 3.1.10; 5.1.7)

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| Are any of the researchers affiliated with or in receipt of any financial benefit from any of the external organisations involved in your research? | [ ]  Yes | [ ]  No |
| If ***yes***, explain how, how much and for what purpose:Click or tap here to enter text. |

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| Has this protocol received research funding or is this submission being made as part of an application for research funding? | [ ]  Yes | [ ]  No |
| If ***yes***, what is the source of the funding?Click or tap here to enter text. |
| What is the project grant title and proposed grant duration?Click or tap here to enter text. |
| What is the status of the funding application? | [ ]  Approved | [ ]  Pending |
| What is the registration number of the grant/funding application?GClick or tap here to enter text. |
| How will participants be informed of the source of the funding?***Note:*** *the amount and sources or potential sources of funding should be disclosed to participants when appropriate. This may include financial support, in-kind support, per capita payments or other payments or incentives provided by any entity supporting the research. (National Statement 5.3.7)*Click or tap here to enter text. |

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| ADDITIONAL APPROVALS |

Please complete this section if your research requires additional approvals prior to data collection. Examples include internal public facing organisations such as the *Federation University Psychology Clinic* as well as external organisations such as other HRECs, the *Department of Education and Training,* *School Principals*, *School Councils* (for research involving Government schools); *Catholic Education Office* (Catholic schools); *School Boards* (Independent schools); *Senior Officers* (Commercial or Government entities); *Elders* (Aboriginal communities); or *Representative bodies* (Collectives).

Copies of approval letters must be attached to this application or, if pending at the time of submission, forwarded to the Ethics Team when available. Some authorities may decline to provide permission letters until ethics approval has been granted. In such cases, you should submit your application for provisional approval pending receipt of the documentation.

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| Does research involve or impact on participants from additional agencies or organisations? | [ ]  Yes  | [ ]  No  |
| If ***yes***, has required permission been obtained from relevant agencies? | [ ]  Yes | [ ]  No |

If ***yes*,** please specify from whom and attach a copy.

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| Click or tap here to enter text. |

If ***no***, specify from whom, and advise when/how this will be obtained.

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| Click or tap here to enter text. |

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| RESEARCH METHODOLOGY |

Provide an outline of each step of the proposed methodology, including details of data collection techniques, tasks participants will be asked to complete, the estimated time commitment involved, and how data will be analysed. If the project includes any procedure that is already established and uses accepted techniques, please include a description of the procedure. (**500 words max**)

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| Click or tap here to enter text. |

## Research Activities

Which of the following activities will the research involve? (Tick as many as apply)

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| --- | --- |
| [ ]   | Use of a questionnaire (*attach copy*) |
| [ ]  | Interviews (*attach interview guide*) |
| [ ]  | Focus groups |
| [ ]  | Observation of participants without their knowledge |
| [ ]  | Participant observation |
| [ ]  | Audio- or video-recording of interviewees or events |
| [ ]  | Access to personal and/or confidential data (*including student, patient or client data*) without participants’ specific consent |
| [ ]  | Administration of any stimuli, tasks, investigations or procedures which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process |
| [ ]  | Performance of any acts which may diminish the self-esteem of participants or cause them to experience embarrassment, regret, or depression |
| [ ]  | Investigation of participants involved in illegal activities |
| [ ]  | Procedures that involve deception of participants |
| [ ]  | Administration of any substance or agent |
| [ ]  | Use of non-treatment of placebo control conditions |
| [ ]  | Collection of body tissues or fluid samples |
| [ ]  | Collection and/or testing of DNA samples |
| [ ]  | Participation in a clinical trial[ ]  CTN Trial [ ]  CTA Trial Please *provide Phase number, i.e., either 1, 2, 3 or 4:*Click or tap here to enter text. |
| [ ]  | Testing a medical/diagnostic device |
| [ ]  | Other (please provide details)Click or tap here to enter text. |

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| PARTICIPANT RECRUITMENT  |

## Participant Details

Describe in detail your proposed recruitment strategy to source target participants. Provide the number and age range, giving a justification of your proposed sample size. Include details of statistical power of the sample where appropriate. To ensure the requirements for consent are met, refer to the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) Chapter 2.2 General requirements for consent

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| Click or tap here to enter text. |

## Proposed Recruitment Method

What is the proposed recruitment method? Please select all applicable responses.

*Note: A copy of all recruitment materials used (e.g., emails, printed advertisements, audio transcripts, posters, letters of invitation, etc.) must be attached to this application for review by the committee.*

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| [ ]  | Social media advertisement  | Name platform(s): Click or tap here to enter text.Do you have platform/moderator permission to post this advertisement? Yes [ ]  No [ ]  N/A [ ]  If you answered **‘no**’ or ‘**N/A**’ please provide explanation here:Click or tap here to enter text. |
| [ ]  | Other advertisement (*e.g. for a noticeboard or FedNews*) | Name platform(s)/location(s): Click or tap here to enter text. |
| [ ]  | Recruitment by a third party (*e.g., employer, doctor*) | Have you attached a copy of the letter requesting their assistance, and/or the letter confirming their willingness to assist? Yes [ ]  No [ ]  If ***no,*** please explain: Click or tap here to enter text. |
| [ ]  | Email | How will potential participants’ email addresses be obtained?Click or tap here to enter text.Who will send emails to potential participants?Click or tap here to enter text. |
| [ ]  | Telephone | How will potential participants’ phone numbers be obtained?Click or tap here to enter text.Who will make telephone calls to potential participants?Click or tap here to enter text. |
| [ ]  | Snowball (participants suggest other potential participants) | Please provide additional information about the proposed snowball recruitment method:Click or tap here to enter text.***Note:*** *The research team’s contact details may be given to potential participants, but to avoid any perception of coercion, potential participants’ contact details should* ***not*** *be given to researchers.* |
| [ ]  | Contact details obtained from public documents (*e.g., phone book*) | Provide details:Click or tap here to enter text. |
| [ ]  | Participants from a previous study | Provide details:Click or tap here to enter text. |
| [ ]  | Personal contacts  | Provide details:Click or tap here to enter text.Please explain how perceived coercion to participate will be avoided:Click or tap here to enter text. |
| [ ]  | Other  | Provide details:Click or tap here to enter text. |

## Geographical target

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| **Domestic regions**[ ]  Select for all Australia **or** specify regions: Click or tap here to enter text. | **Global**[ ]  Select for all areas, **or** specify regions: Click or tap here to enter text. |

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| RISK MANAGEMENT PROCEDURES |

This section raises the issue of your duty of care toward research participants.

* To what risks are participants subjected?
* What will you do should an emergency occur, or should a participant experience discomfort (or become upset or distressed, in the case of above low risk projects)?
* What is your risk management strategy?

Any potential risks should be outlined in the Plain Language Information Statement (PLIS) along with contact details of an **appropriately qualified and relevant support organisation** for participant reference, e.g.: Employee Assistance Program, General Practitioner, or other relevant support.

For higher risk projects, if there is the possibility that participants may experience distress, Lifeline, Beyond Blue, etc. may also be appropriate.

Refer [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) Section 2.1 Risk and Benefit

## Risk to Participants

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| Identify as far as possible all potential risks to participants (e.g. physical, psychological, social, legal, economic) associated with the proposed research. **NOTE**: If risks associated with your research may be more than discomfort and become **distress**, your project will be reviewed as ‘above low risk.’Click or tap here to enter text. |
| Will support be provided for participants? Explain what risk management procedures will be put in place. *You may need to consider additional support for participants during or after the study, depending on risks to participants. Consider whether your project would require additional support and what support would be available.*Click or tap here to enter text. |

## Deception

If this research project includes deception what debriefing will participants receive following the study and when? Attach a copy of any written material or statement to be used in such a debriefing. (Participants may need to talk with the researchers about the experience of being involved in the study as well as learn more about the aims of the research.) (N.S. 2.3.1-2.3.8)

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| Click or tap here to enter text. |

## Likely Benefits

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| Are participants and/or the wider community likely to gain direct or indirect benefit from the research? | Yes [ ]  | No [ ]  |
| If *yes*, provide detailsClick or tap here to enter text. |

How will potential benefits to participants or community outweigh the risks?

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| Click or tap here to enter text. |

## Research Location

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| Where will the research be conducted? (*Select all that apply*)  |
| [ ]  Federation University | [ ]  Other location(s) |
| If **other**, please give details (including the URL for web-based studies) Click or tap here to enter text. |

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| Are facilities at the research location appropriate for the scientific needs of the research? | [ ]  Yes | [ ]  No |
| If ***no****,* please elaborateClick or tap here to enter text. |

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| Are the facilities appropriate to meet any physical, emotional or other needs of participants that result from their participation? | [ ]  Yes | [ ]  No |
| If ***no****,* please elaborate:Click or tap here to enter text. |

## Other Risks

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| What plans are in place to deal with adverse outcomes?Click or tap here to enter text. |

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| Will parts of this project be carried out by independent contractors? | [ ]  Yes | [ ]  No |
| If *yes*, please confirm that the independent contractor will receive from the first-named Chief Investigator, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it.Click or tap here to enter text. |

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| If necessary, has the Chief Investigator ensured that the other researchers have undergone a police check and a Working With Children check? | [ ]  Yes | [ ]  No | N/A [ ]   |

How will the conduct of the project be monitored to ensure that it conforms to the procedures set out in this application, the [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023), and the [Australian Code for the responsible Conduct of Research](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018). In the case of student projects please give details of how the supervisor/s will monitor the conduct of the project, e.g., how often student and supervisor will meet; how meetings will be conducted: email/phone/in person; how efforts will be coordinated if a number of researchers are involved.

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| Click or tap here to enter text. |

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| INCENTIVES FOR PARTICIPATION |

Note that while participants may, in certain circumstances, be paid or reimbursed for their inconvenience and time, the payment should not be of an amount that risks inducement to participate, thus potentially biasing the project results. If rewards are to be used, all participants are to have equal opportunity to receive the reward. (N.S. 3.1.21)

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| Are financial or other rewards proposed to be given to participants or their community?  | [ ]  Yes | [ ]  No |
| If ***yes***, describe how much and in what form the payment/incentive will take (e.g., money to reimburse travel costs, vouchers for movie tickets, chocolate frogs).Click or tap here to enter text. |

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| CONSENT |

## Dependent or Unequal Relationships

The consent of a person to participate in research must not be subject to any coercion. Research involving those in dependent or unequal relationships (e.g., teacher/student, manager/employee, parent/child, doctor/patient) may compromise a participant’s ability to give consent that is free from any form of pressure (real or implied) arising from this unequal power relationship. The Committee recommends that, where possible, researchers should choose participant cohorts where no dependent relationship exists. However, if the researcher believes that research involving people in dependent relationships is purposeful and methodologically defensible, the Committee will require additional information explaining why this is so and how any risks inherent in the dependent and unequal relationship will be managed. The Committee will also need evidence to show that participants have been reassured that refusal to participate will not result in any discrimination or penalty. Applicants should note that reasons of convenience will not normally be considered adequate justification for conducting research in situations where dependent relationships exist.

***Note:*** *See*[*National Statement on Ethical Conduct in Human Research 2023*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) *Chapter 4.3 for information on unequal relationships before answering the following question.*

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| Does a dependent or unequal relationship exist between any participant and researcher, particularly those involved in recruiting? | [ ]  Yes | [ ]  No |
| If *yes*, please explain the relationship and the steps to be taken by the researchers to ensure that the participant’s participation is purely voluntary and not influenced by the relationship in any way.Click or tap here to enter text. |

## Informing Participants – Plain Language Information Statement (PLIS)

The potential participant must be provided with information *at their level of comprehension* about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (*including the likelihood and form of publication of research results, and whether their data may be made available for future research projects*) so their consent is fully informed.

***Note:*** *Using the Federation University approved PLIS template will ensure that all required information is provided to participants. Download the current template for the PLIS from the Human Research Ethics* [*website*](https://federation.edu.au/research/internal/ethics/human-ethics) *under the ‘Forms’ heading.*

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| Have you attached a copy of the PLIS for participants? | [ ]  Yes | [ ]  No |
| If **no**, please explain:Click or tap here to enter text. |

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| **Does the PLIS for this project comply with the following guidelines?** | **YES** | **N/A** |
| It has clear identification of the University, Institute(s) or Research Centre(s) involved, the project title, the Chief and Other Researchers (including Federation contact details). | [ ]  | \* |
| It details what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-recording of events), estimated time commitment, any risks involved. | [ ]  | \* |
| It advises how participants’ contact details were obtained and/or how potential participants were selected. | [ ]  | [ ]  |
| It advises that the project has received Federation University ethics approval and provides the ethics reference number. | [ ]  | \* |
| It advises that if the sample size is small this may have implications for privacy/anonymity. | [ ]  | [ ]  |
| It states clearly that if participants are in a dependent relationship with any of the researchers, involvement in the project will not affect ongoing assessment, grades, employment, management or treatment of health (as relevant). | [ ]  | [ ]  |
| It states clearly that involvement in the project is voluntary and outlines whether, how and when consent may be withdrawn for the collection/use of data. | [ ]  | \* |
| It states that arrangements will be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (e.g., subpoena, freedom of information claim, or mandatory reporting in some professions). | [ ]  | [ ]  |
| It advises whether or not data will be destroyed after a minimum period. | [ ]  | [ ]  |
| It advises the de-identified data collected may be used in future research projects | [ ]  | [ ]  |
| It provides any other relevant information.Click or tap here to enter text. | [ ]  | \* |

**\*** Required

## Obtaining and Documenting Consent

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| How will informed consent be obtained/recorded? |
| [ ]  | Signed consent form ***Note:*** *Please ensure the consent form is attached to this application. A template for the consent form can be found on the Forms page of the* [*website*](https://federation.edu.au/research/internal/ethics/human-ethics) |
| Does the consent form comply with the following? |
| [ ]  | It states the title of the project and names of the researchers |
| [ ]  | It confirms that the project is for research |
| [ ]  | It confirms that involvement in the project is voluntary and whether/how participants may withdraw consent for participation or any unprocessed data previously supplied |
| [ ]  | It details specific requirements of participants (e.g., interviews will be audio-/video-recorded) |
| [ ]  | It advises of any legal limitations to data confidentiality |
| [ ]  | It advises that if the sample size is small this may have implications for privacy/anonymity |
| [ ]  | It provides any other information relevant to obtaining participant consent |
| [ ]  | Recorded verbal consent |
| [ ]  | Implied, for example by return of survey *If consent is to be implied by return of survey, all information that would normally be presented on the consent form must be included in the PLIS.* |
| [ ]  | Waiver of consent***Note:*** *If you are seeking a waiver of consent for the use of data, please refer to Chapter 2.3.10 of the* [*National Statement.*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)Please provide justification for waiving the requirement for consent:Click or tap here to enter text. |
| [ ]  | Other (*Please specify*):Click or tap here to enter text. |

***Note:*** *If you are using already collected data, please indicate in the table above how consent was obtained/recorded for the use of that data in this project. You should attach a copy of the PLIS used at the time of data collection to your application as evidence of consent for the use of that data in* ***this*** *project. Please refer to the National Statement, Chapter 3, ‘Secondary use of data or information,’ pp. 36-37*

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| DISCONTINUING PARTICIPATION |

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| Are participants advised as part of the informed consent process that they have the right to withdraw at any time or withdraw any unprocessed data previously supplied? (N.S. 2.2.20) | [ ]  Yes | [ ]  No |
| If ***yes***, please detail how participants are informed of this right.Click or tap here to enter text. |
| If ***no***, please explain why this advice has not been given Click or tap here to enter text. |

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| DATA AND INFORMATION MANAGEMENT PLAN |

Please give attention to implications for compliance with legislative requirements including, for example [Guidelines Approved under Section 95A of the Privacy Act 1988](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988), produced by NHMRC, and [Statutory Guidelines on Research Issued for the Purposes of Health Privacy Principles](https://hcc.vic.gov.au/sites/default/files/2021-04/guidelines_research_vic_gazette.pdf) produced by the Office of the Health Services Commissioner.

**What are Data?** [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023), Chapter 3.1- Element 4, Data are pieces of information, which may include, but not be limited to:

* What people say in interviews, focus groups, questionnaires, personal histories and biographies;
* Images, audio recordings and other audio‑visual materials;
* records generated for administrative purposes (e.g. billing, service provision) or as required by legislation (e.g. disease notification);
* digital information generated directly by the population through their use of mobile devices and the internet;
* physical specimens or artefacts;
* information generated by analysis of existing personal information (from clinical, organizational, social, observational or other sources);
* observations;
* results from experimental testing and investigations; and
* information derived from human biospecimens such as blood, bone, muscle and urine.

## The copyright and other IP in the data is owned by:

*Please refer to the Federation University* [*Intellectual Property Procedure*](https://policy.federation.edu.au/research/procedures/research_ethics/ch04.php) *for guidance.*

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| [ ]   | **Federation University Australia**In general, Federation University Australia owns intellectual property rights, including copyright, in research data originated by all staff including academic staff, except where the data created by academic staff falls within the definition of a ‘scholarly work’, Federation will also own copyright in data generated by students as part of a ‘collaborative research activity’. |
| [ ]  | **Joint ownership: Federation University Australia and another party or parties**Where data is jointly owned by Federation University and another party or parties, data ownership should be clearly articulated in a research agreement.Name of other party/parties: Click or tap here to enter text. |
| [ ]  | **Other/third party**This may be the case in, for example, Indigenous research or contract research. Where data is owned by a third party, this should be clearly articulated in a research agreement. Provide details: Click or tap here to enter text. |
| [ ]   | **The Researcher**Rarely is data generated or accessed by University staff or students owned by the researcher. If this is the case, please provide detail here. Provide details: Click or tap here to enter text. |

## Security and Storage

**Note:** In submitting this ethics application, the Chief Investigator named on this application form takes responsibility for the security of data collected for this project.

Please refer to the Federation University [Research Data Management Procedure](https://policy.federation.edu.au/research/procedures/research_ethics/ch03.php) for guidance.

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| Who will have access to data and information **during** the project? |
| [ ]  Access by named researchers only | [ ]  Access by other(s) than named researcher(s) |

If others have access to data and information, identify who, at which storage site, for what purpose, and their connection to the project.

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| Click or tap here to enter text. |

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| Which of the following methods will be used to ensure data and information security? Please select and describe all applicable responses. |
| [ ]   | Physical, e.g. Hard copy in a locked filing cabinet. | Please describe:Click or tap here to enter text. |
| [ ]  | Network, e.g. Internal University drive, ECM, Sharepoint | Please describe:Click or tap here to enter text. |
| [ ]  | System or other technological security measures e.g. Cloud, etc.  | Please describe:Click or tap here to enter text. |
| [ ]  | Other | Please describe:Click or tap here to enter text. |

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| Does data storage comply with the requirements of the National Statement on Ethical Conduct in Human Research 2023? ([National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023), Chapter 3.1, Element 4) | [ ]  Yes | [ ]  No |
| If ***no*,** please explain:Click or tap here to enter text. |

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| If data and information is to be kept elsewhere during fieldwork, please explain how and where data will be held, including arrangements for data and information security:Click or tap here to enter text. |

## Confidentiality

***Notes:***

* Where the sample size is very small, or information is obtained through a focus group, it may be impossible to guarantee anonymity or confidentiality of participants’ identity, and participants involved in such projects need to be advised of this limitation.
* See National Statement Chapter 3.1, Element 4, ‘Identifiability of information,’ pp. 33-35

| Identifiability of Data | **At collection** | **During analysis** | **Post project** |
| --- | --- | --- | --- |
| **Individually identifiable data**, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual’s name, image, and date of birth or address.If applicable to specific datasets only, please explain here: Click or tap here to enter text. | [ ]  | [ ]  | [ ]  |
| **Re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.If applicable to specific datasets only, please explain here: Click or tap here to enter text. | [ ]  | [ ]  | [ ]  |
| **Non-identifiable (anonymous) data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified.If applicable to specific datasets only, please explain here: Click or tap here to enter text. | [ ]  | [ ]  | [ ]  |

Select all that apply from the boxes below:

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| --- | --- |
| [ ]  | Participants will have the option of being identified in publications arising from the research. |
| [ ]  | Participants will be referred to by pseudonym in publications arising from the research. |
| [ ]  | Personal information will be obtained from a Commonwealth department or agency? ***Note:*** *You may need to comply with the requirements of the* [*Privacy Act 1988*](https://www.legislation.gov.au/Details/C2018C00034). |
| [ ]  | Any other method of protecting the privacy of participants (e.g., use of direct quotes with specific, written permission only; use of real name with specific, written permission only; ethical fabrication of internet data). **Please describe:**Click or tap here to enter text. |

## Future Use of Data

Is it likely / possible that any data or information collected may be used by you, or others, for any research other than that outlined in this application? See NS Chapters 2.2, 3.1.35-36 and 3.1.54-61 when preparing your response.

*Notes:*

* *It is increasingly common for funding agencies to require the sharing of research data either via open access arrangements or via forms of mediated access controlled by licenses. (N.S 3.1)*
* *Please click* [*here*](https://ardc.edu.au/resource/fair-data/) *for information about FAIR data principles (findable, accessible, interoperable and reusable).*

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| [ ]  **Yes** | Ensure participants are informed of this via Plain Language Information Sheets and Consent forms.* Participants should be fully informed of the possibility of any future use of data and information collected and their ‘extended’ or ‘unspecified’ consent gained. Failure to do this may restrict the future use of the data and information.
* Any restrictions on the use of participants’ data and information should be recorded and the record kept with the collected data and information. Restrictions must be accessible to researchers who want to access those data and information for research.

National Statement, Chapter 2.2.15: Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9).National Statement, Chapter 2.2.16: When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.If data may be disclosed or shared with others, please provide information about how and with whom this will occur:Click or tap here to enter text. |
| [ ]  **No** | Justify why you are limiting the use of participants’ data to only one project.Click or tap here to enter text. |

## Post Project

***Notes:***

* *All research data must be kept for a* ***minimum*** *of five (5) years from date of research publication. Some data types must be retained longer than five years. Minimum data retention periods are outlined in the Federation University* [*Research Data Management Procedure*](https://policy.federation.edu.au/research/procedures/research_ethics/ch03.php)*, as per the* [*Public Record Office Victoria Retention & Disposal Authority PROS 16/07*](https://prov.vic.gov.au/recordkeeping-government/document-library/pros-1607-higher-and-further-education-functions)*.*
* *While data or information may be collected, aggregated, and stored for an initial purpose or activity, it is common to ‘bank’ data or information for possible use in future research projects or to otherwise share it with other researchers. It is also increasingly common for funding agencies to require the sharing of research data either via open access arrangements or via forms of mediated access controlled by licenses. (National Statement, p. 37).*
* *If you plan to add data to an open or mediated access repository or make the data or materials available for re-use, any implications of these plans should be provided to participants. The use of ‘extended consent’ or ‘unspecified consent’ (see National Statement 2.2.14 to 2.2.16) may be appropriate for this purpose. (National Statement 3.1.35).*

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| Will data collected for this project be destroyed post project? *Note: Data may be kept indefinitely, but must be appropriately secured.* | [ ]  Yes | [ ]  No |
| If ***yes***, **how, when and by whom** will data be disposed?*Note: Data must be kept for a minimum period of five years. Some data types may have longer minimum retention periods* |
| Click or tap here to enter text. |

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| Where will data be stored, either until the date of destruction or in perpetuity if it is to be retained? |
| Click or tap here to enter text. |

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| DISSEMINATION OF RESULTS |

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| How will results be made available to **participants**? (*Tick as many as apply*) |
| [ ]   | Written summary of results |
| [ ]  | Copy of final manuscript (*thesis, article, etc*.) |
| [ ]  | Verbal presentation (*info session, debriefing, etc*.) |
| [ ]  | Presented to all participants |
| [ ]  | Presented if requested |
| [ ]  | Presented to representative participants (*e.g. CEO, school principal*) |
| [ ]  | Other - *Please explain*:Click or tap here to enter text. |
| [ ]  | None - *Please explain*:Click or tap here to enter text. |

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| Provide any other relevant information about the dissemination of the project’s findings/outcomes **to participants** here. For example, information about when, where, how, and by whom this will be done. |
| Click or tap here to enter text. |

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| How will results be made available to the **research community,** i.e. peers and colleagues? *(Select as many as apply)* |
| [ ]   | Conference papers |
| [ ]   | Thesis |
| [ ]   | Journal article(s) |
| [ ]   | Book |
| [ ]   | Other - *Please explain:*Click or tap here to enter text. |
| [ ]   | None - *Please explain:*Click or tap here to enter text. |

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| LEGAL ISSUES |

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| Does the project involve subject matter or conduct that may give rise to legal vulnerability of participants or researchers?  | [ ]  Yes | [ ]  No |
| If ***yes***, please give details: Click or tap here to enter text. |
| If ***yes*,** please give details of precautions to be taken:Click or tap here to enter text. |

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| Confidentiality of information provided can only be protected within the limitations of the law. Depending on the research proposal, you may need to state these limitations specifically *(subpoena, freedom of information claim, mandated reporting by some professions, etc*.). *Have you included appropriate information on the legal limitations of protecting confidentiality in the PLIS and consent form*? | [ ]  Yes | [ ]  No | [ ]  N/A |
| If***no***, please advise how participants will be advised:Click or tap here to enter text. |

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| CHECKLIST OF ATTACHMENTS |

Please check that the following documents are attached to your application, as relevant.

|  |  |  |
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| **Please indicate which of the following are attached to your application.** | **Yes** | **N/A** |
| Recruitment material (e.g. for noticeboard or FedNews) | [ ]  | [ ]  |
| Plain Language Information Statement  | [ ]  | [ ]  |
| Consent form  | [ ]   | [ ]   |
| Questionnaire  | [ ]   | [ ]   |
| Interviewer script or framework  | [ ]   | [ ]   |
| Debriefing material | [ ]   | [ ]   |
| Evidence of external approvals related to the research  | [ ]  [ ]  Pending | [ ]   |
| Other: Click or tap here to enter text. | [ ]   | [ ]   |

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| DECLARATION |

By submitting this application, the Chief Investigator declares that:

* they have discussed this project with their Centre Director/Dean/Research Advisor or Line Manager;
* all named Researchers and research support staff are aware of, and accept the responsibilities inherent in, their role on this project;
* the methodological/technical aspects of the proposal are appropriate to the tasks proposed;
* the Researcher(s) have the necessary qualifications, experience and facilities to conduct the research proposed and to deal with any emergencies and contingencies that may arise;
* the research team has considered and addressed all ethical concerns related to this project and recommends this application is ready for review by the Human Research Ethics Committee;
* the information contained herein is accurate;
* they accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#download), the [Australian Code for the responsible Conduct of Research](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018) and any other condition laid down by the Federation University’s Human Research Ethics Committee or its sub-committees;
* they have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of the participants;
* they have read the Federation University [Research Ethics and Institutional Biosafety Procedure](https://policy.federation.edu.au/research/procedures/research_ethics/ch11.php); and
* that all investigators and supporting staff have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

## Submitting the Application

This completed application form and all relevant attachments should be submitted via email to the Coordinator, Research Ethics research.ethics@federation.edu.au.

Supporting documents should be included in this email as **separate** and **unnumbered**, but clearly labelled, attachments.

**Co-investigators must be copied in email submission of this application**.