Human Research Ethics Committee

Application Companion

Last updated 14 December 2023

Contents

Acknowledgment of Country

We respectfully acknowledge the Kaurna, Boandik and Barngarla First Nations Peoples and their Elders past and present, who are the First Nations' Traditional Owners of the lands that are now home to the University of South Australia's campuses in Adelaide, Mount Gambier, and Whyalla. We are honoured to recognise our connection to the Kaurna, the Boandik and the Barngarla lands, and their history, culture, and spirituality through these locations, and we strive to ensure that we operate in a manner which respects their Elders and ancestors. We also acknowledge the other First Nations of lands across Australia with which we conduct business, their Elders, ancestors, cultures, and heritage.

Introduction, Resources & Support

Scope

This document is intended to help researchers, both staff and students, complete high-quality applications for human research ethics approval. The Application Companion focuses on providing general guidance about key concepts which should be considered and (where applicable to the nature of the specific research project) addressed within the application form to facilitate and streamline the review process. Researchers are required to submit an ethics application that takes into consideration the core values that underpin the National Statement and set out for the review committee how these values have been incorporated throughout the project lifecycle (from the study design, through to project completion and the report of results). The HREC acknowledges that there is not a one size fits all approach to completing an ethics application, and this documentation is designed to prompt considerations on conducting ethically appropriate research.

It is important for all researchers conducting work with or about human participants, their data and/or their tissue, to be familiar with the [National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 ('National Statement').](#) The National Statement sets out nationally agreed upon guidelines and requirements to enable ethically good human research and must be followed when conducting research with human participants. The UniSA human research ethics application form has been created to address considerations set out in the National Statement and the submission of a quality application, with clear information responding to these elements, will allow the Human Ethics Research Committee to promptly review and approve the research project.

Along with the National Statement, UniSA Staff and Students are expected to be familiar with and follow the UniSA Human Ethics Research Policy, as well as the Australian Code for the Responsible Conduct of Research. Additional resources are provided at the end of this document.

All staff and HDR Students are required to complete the UniSA Research Integrity Course. In addition to that, both staff and students are encouraged to complete the UniSA Research Office Human Research Ethics supplementary training module (number 10) which is included as part of the course and is available on UniSA's learnOnline platform. This supplementary module provides an introduction to the area, and to the National Statement on Ethical Conduct in Human Research.

Staff can access this course as follows:

- First log in to learnonline using your regular UniSA credentials, via this link: https://lo.unisa.edu.au/
- Once logged in, you can then access the self-enrolment page for the course by clicking on this link: https://lo.unisa.edu.au/enrol/index.php?id=20824

Students can directly access the course via this link:

- https://lo.unisa.edu.au/enrol/index.php?id=20824

Supervisors

The Australian Code for the Responsible Conduct of Research Code R15, states that supervisors have direct accountability to provide guidance and mentorship on research conduct. Applications that do not meet the ethical review standards can impact on students' completion timeframes. Supervisors are required to ensure that applications made by students are complete and of expected standards before they are submitted for ethical review.

Additional information on the responsibility of Supervisors can be obtained here via the NHMRC Supervision Guide.

New supervisors also have access to the Supervising @UniSA course. Further details on the modules and requirements can be found here: https://i.unisa.edu.au/askresearch/hdr-supervisors/eligibility/.

Research Ethics Advisors

Further support can be obtained by contacting a Research Ethics Advisor. Research Ethics Advisors (REAs) are based in each Academic Unit (AOU) and provide discipline-relevant advice about research ethics, and ethics policy and procedures, at the local level. The REA provides assistance to staff and student researchers, supervisors and other researchers in the Academic Unit, particularly those applying for ethics approval through the University's Human Research Ethics Committee (HREC). In addition to Academic Unit based advisors, there are Aboriginal and Torres Strait Islander (ATSI) REAs to support researchers intending to engage with ATSI people or communities and/or where the research might hold particular significance to ATSI people. In addition to the key support they provide in the promotion of ethical conduct across the Academic Unit in which they are based, REAs also undertake the review of some human research ethics submissions via the University's online ethics application system.

Please reach out to your local REA(s) for individualised advice relating to your specific project and/or for information on upcoming ethics training sessions that may be scheduled in your area. Contact details for current REAs can be found here.

Human Ethics Team in the UniSA Research Office

The Human Ethics Office is available to provide general guidance in relation to ethics applications and troubleshooting any issues with the online form, as well as the key considerations mentioned within this document. The Human Ethics Officers can be reached via email (humanethics@unisa.edu.au) or by telephone (8302 6330).

For any technical issues related to the online ethics application form (MyRM), please contact research.information@unisa.edu.au.

UniSA HREC Approval Processes

UniSA has implemented an online system, My Research Management (MyRM), which is used for submitting and reviewing all Human Research Ethics applications. Information requested in the application form meets the requirements and considerations set out in the National Statement on Ethical Conduct in Human Research.

This system enables applicants to communicate with the Human Research Ethics Officer, the Principal Supervisor (for student applicants) and the [Committee Review Group](#).

MyRM records details of all human research ethics applications and the outcome of the review. Selected data is recorded centrally for administrative and auditing purposes.

There are four pathways for the assessment of your human research ethics application:

- **Exempt** from requiring full ethics review and approval:

  ➢ When commencing a new ethics application form, responses to the initial scoping questions may prompt Research Master to indicate that your study is 'exempt' from requiring full ethical review and approval. On such occasions, your application still needs to be checked by the human ethics team and the Human Research Ethics Committee (HREC) Chair / Deputy Chair to confirm the appropriateness of the 'exempt' outcome in the context of your proposed research. The human ethics team may request further information from you to assist with this confirmation process. Research **cannot commence** until separate confirmation of the exempt status is received from the HREC.

- **Negligible Risk research:**

  ➢ reviewed as an 'E1' application, by the human ethics admin team and the HREC Chair / Deputy Chair.

- **Low Risk research:**
  ➢ reviewed as an 'E2' application, by the human ethics admin team, the HREC Chair / Deputy Chair, and a Research Ethics Advisor.

- **All other research:**
  ➢ reviewed as an 'E3' application by the full Human Research Ethics Committee.
  ➢ applications must be submitted [by the deadline prior to the meeting, as per details provided on the Human Research Ethics website.](#)

Upon submission, an automated risk assessment (made by the MyRM system, based on the researcher's responses to questions within the application form) will assign the application to the

relevant review pathway. This risk assessment (and the associated review requirement) is subject to change upon further assessment made during the ethical review process.
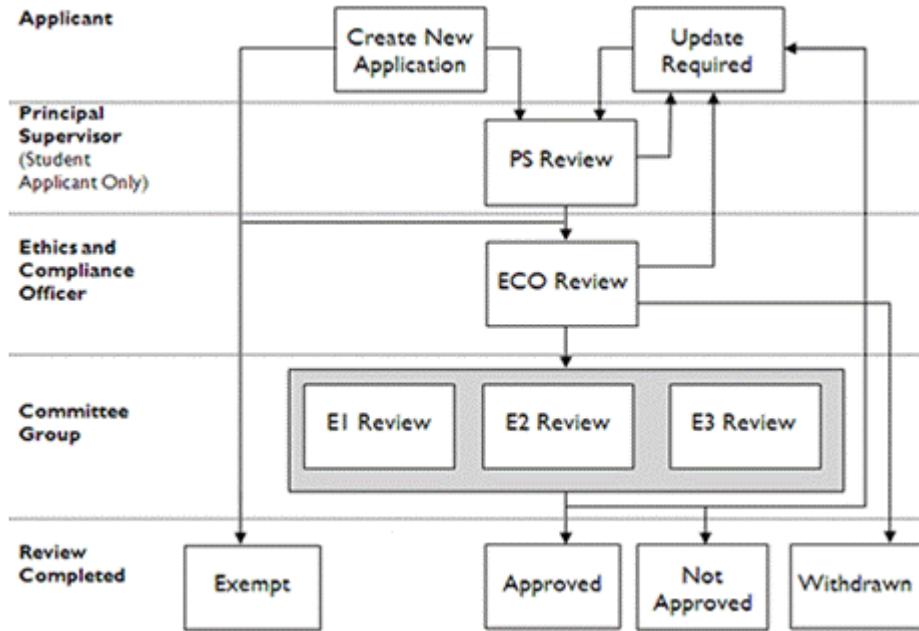
Committee Review Groups:

Risk level	Committee Review Group
Exempt	None
E1	The Chair or Deputy Chair of HREC (E1 Review Group)
E2	A panel comprising the Chair or Deputy Chair of HREC and the Applicant's Research Ethics Advisor (E2 Review Group)
E3	The full Human Research Ethics Committee (E3 Review Group)

Further information on review pathways and risk definitions can be found on the HREC Website.

> *Application Tip:*
>
> **Project Scope Q11-13**
> Pay attention to responses provided at 11.1 and 11.2. If you are conducting research which requires contact with and recruitment of participants, then your work is not archival.

Approval from a Non-UniSA HREC

UniSA HREC seeks to avoid the unnecessary duplication of ethical review. If your ethics application has already been approved by another Australian Human Research Ethics Committee, you can indicate this via your responses/selections within the application form. You will also be required to attach a copy of the full application submitted to the other HREC, a copy of the final approval letter from the external Committee, as well as copies of any relevant supporting documents (e.g.: the relevant research tools and recruitment materials). The remainder of the application form will then be automatically shortened. The UniSA Chair HREC will review these documents, and if satisfied, will ratify the decision made by the other Committee. A full list of NHMRC-registered HRECs can be found here:

https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees#download.

Please note that the approval from the external HREC must be current (i.e.: not expired) and must cover the entire period of the project.

Confirmation of insurance cover is also required from the UniSA Insurance Office for projects that have received prior approval from an external ethics committee. Researchers must apply for this individual insurance assessment through the UniSA Insurance Office website. Once email confirmation of insurance cover has been received, please include a copy of this (as a PDF or Word document) in the 'Attachments' section of your UniSA human ethics application prior to submission. Please see the UniSA Insurance website for requirements.

Please note that final ethics approval cannot be granted until confirmation of insurance cover is provided.

Which HREC should I apply to first?

The decision of which HREC should be considered the 'primary' Committee (i.e.: the HREC which should be responsible for the initial ethical review, approval, and on-going monitoring of the project) is guided by various factors, including considerations of the relevant area of research, the nature of the participant groups involved, and/or the organisational affiliation of the lead researcher. For example:

- If you plan to conduct research with **current Australian defence personnel or veterans, an application will need to be submitted to the** Departments of Defence and Veterans' Affairs HREC.

- If you plan to conduct research about the **health or well-being of Aboriginal people in South Australia, an application will need to be submitted to the** Aboriginal Health Research Ethics Committee.

  Importantly, similar requirements will likely also apply for **research involving Aboriginal and Torres Strait Islander people and/or communities in an interstate setting** (with review and approval required through the local Aboriginal Health HREC). Please note that, in some jurisdictions, this requirement may also extend to <u>any</u> research (i.e.: beyond research about the health or well-being of Aboriginal people).

- If you plan to conduct research in a **hospital or Local Health Network, an application will need to be submitted to the relevant Local Health Network HREC.**

Please also note that Government Departments without a registered HREC will usually still have departmental research approval processes. For example:

- If you plan to conduct research in a South Australian **public school(s),** you will need to apply for approval from the SA Department for Education AFTER you receive ethics approval from UniSA. Similar requirements will likely also apply for research that will be conducted within interstate public school settings.

- Catholic and Independent Schools have separate approval processes. The researcher is responsible for identifying and complying with these requirements.

- Research conducted in a hospital or Local Health Network will likely also require research governance and Site-Specific Assessment approval (separate to ethical review and approval).

Please note that researchers are required to thoroughly investigate (and, where applicable, fulfil) any 'approval' requirements that are relevant to their individual project.

Application Tip:

Non-UniSA HREC Q1.1 and 'Attachments' Section
Select 'yes' at Q1.1 and ensure a copy of the FULL Ethics Application and subsequent confirmation of approval from the external HREC (along with any other relevant supporting documentation) are included in the application 'Attachments' section.

Ethics Approval for Course Wide Projects

The HREC may grant ethics approvals for courses in which a cohort of students undertake short duration research projects. Course approval applications are subject to the same processes (including risk assessment) as other applications, and may be reviewed at E1, E2 or E3 level depending on the degree of risk. However, it is recommended that course coordinators design projects that are low (E2) or negligible (E1) risk for this purpose.

To apply for course approval, the course coordinator should submit an ethics application in the online system prior to the commencement of the course. The application should cover the component of the course requiring ethics approval (e.g.: the research project that students will undertake) according to the curriculum of the course.

In order to gain ethics approval, the course coordinator will need to provide evidence that students have received (or will receive) education in aspects of ethical human research (including informed consent, participant risk identification and management, and data collection, confidentiality, and storage) prior to undertaking their projects. All course coordinators are required to complete the UniSA Research Integrity Course, including the Human Research Ethics supplementary training module (number 10), prior to applying for course approval.

Once ethics approval has been granted, a Course Research Project Parameters Approval form must be submitted to the Human Research Ethics Office each time the course is offered. This report must include a list of all students who will be covered by the course approval, as well as the titles of their individual projects and, when relevant, the names of the organisations where the research/activity is to be undertaken.

The Course Coordinator is responsible for the following:
- assessing the scope and methodologies for all proposed individual student projects to ensure these fall within the parameters of the course approval.
- ensuring that all students have completed the ethical research training.
- conducting appropriate monitoring of the projects and oversight of ethical student conduct, including processes in place to ensure the secure storage and retention of student project data locally.

Confirmation that all students are covered by the course approval must be received before students commence their research.

Responding to Reviewers' Comments:

When researchers receive feedback on their ethics application via the online system, it is important that they not only respond to the reviewers' comments via the 'Action Note' text box (*instructions for 'responding' to comments can be found in the* [MyRM 'Applicant User Guide'](#)), but **that the content of the application itself is also updated based upon the 'Action Note' guidance provided**. The committee cannot review or approve the application if the in-text responses are not amended to reflect the required changes.

Supervisors should review the changes to ensure that they have been actioned accordingly prior to submitting their student's application back to the review group.

When responding to queries raised during the ethics review process, researchers are welcome to provide an explanation / justification where they genuinely believe a comment is not applicable to their research (or where it appears details have been misunderstood by the ethics reviewer). It will

then be at the discretion of the ethics review group to either accept this response or to provide feedback / recommendations otherwise.

Navigating the Online Application

The following guidelines are provided to support researchers in formulating appropriate responses as they work through the ethics application. System focused 'User Guides' and 'FAQs' to assist staff and students with technical issues with MyRM can be found here:

[Human Research Ethics Application Assistance - System Help](#)

[MyRM Human Research Ethics Application - Frequently Answered Questions (FAQ)](#)

The online ethics application 'smart form' expands depending on the responses provided by the researcher and will inform the overall 'risk' category outcome once submitted. It is important that the correct responses are selected when completing the initial application 'draft' to ensure that the automated risk assessment (and subsequent review pathway) is appropriate for your project. Further, providing clear and complete information at the time of submission will enable the reviewers to easily assess the application and finalise approval.

To ensure consistency, responses to in-text questions may be duplicated where applicable within the application by the researcher.

The following 'User Guides' are available for researchers and supervisors to assist with the technical completion of the application, as well as making, reviewing and responding to comments within the smart form:

[Applicant MyRM User Guide](#)

[Principal Supervisor MyRM user guide](#)

For any technical issues related to the online ethics application form (MyRM), please contact [research.information@unisa.edu.au.](mailto:research.information@unisa.edu.au)

Investigators

Researchers must add all co-investigators and/or supervisors to their application, including external members of the research team. If investigator details do not appear in the search function, please email research.information@unisa.edu.au with the investigator's name, staff ID or student ID (if applicable), contact number, organisational affiliation, and email address (if known). Upon receiving these details, the systems team will enter the investigator details into the MyRM database, after which time it will be possible to add the investigators or supervisors to the project.

> ***Application Tip:***
>
> **Q2 – 'Investigators'**
> Ensure that the primary contact has been selected. Only those that are listed as 'Chief Investigator' will be able to 'edit' responses in the application form. Those listed with their 'position' as 'Other Investigator' will be able to 'view' the form, but not make any changes. Please note that there can be multiple 'Chief Investigators' listed – but only one 'Primary Contact' can be nominated.

Purpose of the Project and Ownership of Data

When completing the application, responses in the form should clearly indicate if the project work will be conducted by a student or a staff member – or if this will be both a student and staff project. This information will help to determine if ownership of data and intellectual property (IP) matters have been adequately considered and accurately documented in the ethics application form. Please note that students generally own the intellectual property they develop during their research, unless there is a special agreement in place with the university, a staff member and/or a third party. If the project is a joint staff/student project, then a Student Project Participation Agreement may be required. See the following webpage for additional information on student IP:

https://i.unisa.edu.au/students/research-students/commencing-students/intellectual-property/

If the research includes collaboration with, and/or funding from, external parties (e.g.: with researchers from other institutions / organisations, or with industry partners) a special agreement or contract might be required. It is the researcher's responsibility to ensure that, where necessary, an appropriate written agreement regarding ownership of data and intellectual property is in place.

Should you require any assistance/advice regarding an agreement, researchers should contact the UniSA Research Office Contracts Team (by submitting the ['Request for Research Contract Online Form'](#) -- or by email: research.contracts@unisa.edu.au) or the relevant Academic Unit Partner Engagement Manager: http://www.unisa.edu.au/Research/Industry-partners/Business-Development-Network/.

While this is an important consideration, the ethics review process only seeks to highlight this potential requirement and to prompt researchers to investigate this accordingly. It is then the responsibility of the researchers to consider this for their overall project and put this in to place accordingly, as required. Therefore, once this has been noted/acknowledged via your responses within the application form, you may submit your ethics application in the meantime (i.e.: you do <u>not</u> need to have an agreement finalised to submit). The onus of acquiring and maintaining the records of any requisite agreements, approvals and permissions solely lies with researchers.

> *Application Tip:*
>
> **Project Type Q4.1-4.2**
> Select the primary purpose of the project at 4.1 and include any additional types of research at 4.2 (e.g.: if this is a joint staff/student project – or if there is an external collaborator).
>
> **Ownership of Data Q8.1-8.3**
> If this is a joint staff / student project, select 'UniSA' in addition to 'Student Researcher'. If there is an external collaborator select 'Other'. This should reflect the arrangements as set out in any agreement(s) that are, or will be, in place.

Project Details

Researchers must clearly and succinctly outline the aims, purpose, and proposed data collection methodology within the ethics application form to allow the relevant review group to understand the project in full and to proceed with their assessment of the submission.

Researchers are required to provide in text responses to all questions within the 'Project Details' page. Responses in this section provide key background information and a core overview of the proposed research in its entirety, to support and inform the finer details and specific considerations provided elsewhere in the ethics application. Responses (particularly Q5.5) should include information about

each element of data collection, where that data collection will occur, a specific sample size, what each participant group will be asked to do during data collection, and how long the planned data collection will take. If the research design has more than one phase, with later phases relying on the outcomes of the first phase, consider applying for approval of the first phase only (whilst flagging the intention to conduct later phases), so that the 'known' research elements, as well as the relative risks associated with that work, can be clearly defined, described and assessed for each phase.

> *Application Tip:* **Project Details Q5.4 – Q5.5**
>
> **Q5.4**
> Take care with the response to this question. The answer should incorporate some supporting information and citations sourced from the key references you have included in the 'Attachments' section of your application. Place the aims in the context of existing research or practice AND outline what the study adds to existing literature.
>
> **Q5.5**
> - Only include the information regarding data collection involving human participants.
> - Provide the estimated length of time it will take to complete each phase of data collection / an approximate time commitment required to complete each research activity (e.g.: interviews/focus groups/surveys; etc.
> - Identify how surveys will be delivered and, if applicable, which online survey platform you intend to use.
> - Specify where the data collection will be conducted. For example, will this be conducted in-person (individually or in groups) and, if so, where – e.g.: at the participants' place of work, on UniSA campus, in a neutral public location (such a private meeting room booked in a public library) -- or will data collection be conducted remotely via telephone or videoconference (e.g.: Zoom/Skype of similar) - or will participants be given a number of options?

Project Funding

Chapter 5.2.8 of the National statement advises that it is the researcher's responsibility to disclose to the review body the amount and or potential sources of funding for the research project. If a project is funded either via a monetary amount or through in-kind support, these details must be included in the ethics application (under Section 6). In-kind support could be an organisation providing space for interviews, and/or equipment to support data collection.

Data: Storage, Access, Disposal

As per the [Australian Code for the Responsible Conduct of Research](#) (the Code), researchers (including student researchers and their supervisors) are obligated to ensure that the integrity and security of their Research Data, Primary Materials and Research Records are maintained, and that this material is stored in an recognisable and retrievable way.

As set out in the National Statement, the terms 'data' and 'information' are often used interchangeably. Details relating to the collection, use, storage, retention, disposal and sharing of data and information needs to be clearly outlined within the ethics application for the review committee to consider. According to Chapter 3.1 of the [National Statement](#): *'data' is intended to refer to bits of information in their raw form, whereas 'information' generally refers to data that have been interpreted, analysed or contextualised. Data and information may include, but not be limited to:*

- *what people say in interviews, focus groups, questionnaires/surveys, 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.*

It is good practice for researchers to develop a data management plan that will outline the type of data that will be collected and how it will be stored, used, retained, and disposed of following minimum retention requirements. The Australian Code for the Responsible Conduct in Research has provided a detailed guide to assist with formulation of a data management plan that can be attached to the ethics application:

https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf.

Additional information can be found at the Australian Research Data Commons webpage: https://ardc.edu.au/resource/data-management-plans/.

Please also refer to the Privacy Act: https://www.legislation.gov.au/Details/C2020C00025.

How should I store my data?

Data can be stored in three different forms: 'individually identifiable', 're-identifiable' and/or 'non-identifiable'. Researchers must consider and describe the form in which data will be collected, how data will be stored during the data collection phase of the project, as well as how data will be stored and retained at the end of the research project.

- Information being collected directly from participants or that contains specific identifiers, images, footage or voices of the participant, can be considered 'individually identifiable'.
- Information which utilises a 'coding system' (e.g.: participant ID or pseudonym) that can be linked to individual identifiers can be considered as 're-identifiable'.
- Information collected anonymously (e.g.: online surveys) or data that has had all identifiers removed and destroyed can be considered 'non-identifiable'.

Application Tip:

Q9.1 (and Q67.1.3)
Select 'Individually Identifiable' if you will be collecting and storing video/audio recordings and/or photographs/images (e.g.: recordings of interview or focus group discussions) as voices are considered to be potentially identifiable.

Q9.7 (and Q67.1.3)
If data will be 're-identifiable', include details of how this will be done and what safety measures might be taken to protect this information - for example, by securely storing the information that links participants' personal information to their ID number or pseudonym separately from the research data (i.e.: in a separate and secure computer folder or physically separated).

For example - "After collection of data, identifiers will be removed from interview transcripts and replaced with an ID code. The codification scheme/ linkage key will be held in a separate electronic file to the research data and only the researchers will have access to this information and the 'key' that can link participants' identities to their individual data".

> **Q9.1 and Q9.7**
> Clarify in responses if the data stored on completion of the project will still be 'individually identifiable' or 're-identifiable' ('coded') – or whether you will destroy any information that could link participants' personal information to their data, making this 'non-identifiable'.

Where should I store data?

The University's Ownership and Retention of Data Policy outlines the following requirements for different types of data:

2.1 *Physical data*
1. *Physical data must be stored in accordance with the University's Records Management Policy;*
2. *Wherever possible Research Data, Primary Materials and Research Records should be stored in the Academic Unit in which the Research Data were generated. Where this is not feasible use should be made of the University's off-site storage facilities.*

2.2 *Electronic data*
1. *Wherever possible Research Data, Primary Materials and Research Records should be stored on the local Academic Unit server drive. Research folders can be installed by the University's Information Strategy and Technology Services Unit staff and access granted to each Researcher requiring access to the folder. The data in the folder are backed up nightly. Standard practice should be to store all data on the local server. Working files may be stored on an individual's computer hard drive, USB drive or personal laptop but must be backed up on the server frequently (48-72 hours). Files within the folder should be clearly named so that Researchers/supervisors can find relevant documents, spreadsheets, analysis etc;*
2. *Password protection must be used when Research Data are confidential and restricted to the research team;*
3. *Electronic Research Data should be stored in at least two locations to mitigate complete loss of one copy;*
4. *Electronic Research Data should be stored with appropriate meta-data that is information about each Research Data set describing how, when and where it was generated, instrument settings, software used etc;*
5. *Researchers with large data sets should consult with the University's Information Strategy and Technology Services Unit (ISTS) to determine the appropriate current mechanisms to store such data sets. Large data sets should have data management plans, risk assessments and transition or disengagement plans, the latter particularly necessary where the Research Data are created from data owned by a third party. Large data sets may need risk assessments to include risks associated with long term storage.*

2.3 *Human research data*

1. *Human Research Data should be stored in accordance with the human research ethics application approval requirements (non-identifiable, re-identifiable, individually identifiable). If Research Data are to be accessed and/or used by others, the data must be non-identifiable due to privacy and confidentiality requirements (unless the participants have agreed for their data to be accessed and used for a purpose other than the reason for which it was collected);*

2. *Unless specified otherwise in the approved ethics application, the original data must be retained and stored in a secure location (e.g.: audio tapes of interviews, hand signed consent forms, paper-based questionnaires etc).*

See the University's [Ownership and Retention of Data Policy](#) for further information on data storage and retention.

The HREC recommends <u>avoiding</u> the use of personal devices such as portable hard drives, mobile phones, and USB flash drives as they can be subject to theft, loss, or deterioration over time. Whilst they can be used for data collection purposes, as referenced in the policy, all material should be backed up on a secure UniSA server.

The University offers a range of storage solutions for research data and the most appropriate storage solution will depend on several factors (including the type of data, size, rate of growth, retention, performance, access, etc.).

See the following webpages for further information relating to data storage solutions available:

https://i.unisa.edu.au/askresearch/data-management/data-storage/ and

https://i.unisa.edu.au/askit/staff/hardware/servers/storage-options/.

> *Application Tip:*
>
> **Q9.2**
> Ensure data is stored on secure UniSA Server and accessible (with password protection / restricted access) to all members of the research team, as outlined in the UniSA Ownership and Retention of Data Policy.
>
> **Online video conferencing platforms: Q9.7**
> Consider stipulating that any audio/video recordings will be saved directly to the local computer then transferred to the university server, rather than the Zoom cloud, mitigating the risk of potential unauthorised access by any third parties.

Online Survey Data

For projects utilising a survey tool, if this will be distributed online, clarify which online survey platform you intend to use. The University recommends that researchers use REDCap, Qualtrics or Microsoft Forms if possible as these platforms provide a secure environment to store, manage, and share data. For further information can be found at: https://i.unisa.edu.au/askresearch/tools-services/survey-tools/.

Please also make note in the application form that, until exported, survey data will also be stored on the online survey platform.

> ***Application Tip:***
>
> **Q9.2**
> Ensure a copy of survey data is stored on a secure UniSA Server and accessible (with password protection / restricted access) to all members of the research team, as outlined in the UniSA Ownership and Retention of Data Policy.
>
> **Q9.2 - Online Survey**
> At Q9.2, acknowledge that, until exported, survey data will also be stored on the online survey platform.
>
> **Q9.6**
> Consider selecting 'Yes' if using publicly available online survey software (i.e.: not UniSA-licensed software) as the platform managers (as well as governments in certain countries) reserve the right to access information held in electronic platforms. As such, while data collection is occurring, technically these third parties could potentially have access to this information while it is stored on that platform.
>
> **Q9.7**
> Consider stating that data from the online platform will be exported and deleted as soon as possible after all data has been collected to protect this information from potential unauthorised access.

How Long should I Store Data?

Researchers must ensure that data is stored for an appropriate duration of time depending on the

purpose of the research project and if any external parties are involved (as specified here: https://i.unisa.edu.au/policies-and-procedures/university-policies/research/res-17).

The Code: Retention time requirements for Primary Material, Research Data and Research Records

Type of Primary Material / Research Data / Research Records	Minimum retention time
Short-term research projects for assessment purposes only	12 months
General research	5 years after publication
Research involving an SA Government Department/s (e.g.: Department for Education, etc.)	7 years after publication
Clinical trials (research involving humans)	15 years after publication
Gene therapy (e.g.: patient data / records)	Permanent
Significant heritage value data	Permanent (preferably within a national collection)

In addition to the requirements in the table provided, researchers should also be guided by the specific provisions of the State Records Act 1997 in relation to retention times for specific materials of heritage or archival value.

![University of South Australia logo]

Other Data Storage Considerations and Requirements

To ensure that the University can defend challenged research outcomes (as required under the Australian Code), it is necessary for the University to remain custodian of Research Data and Primary Materials acquired during research (unless other arrangements have been clearly set out and approved in the research ethics application). If a researcher or student researcher moves away from the institution, the University will remain the custodian of Research Data and Primary Materials acquired during their formal association with the University.

Research Data, Primary Material and Research Records should be maintained securely to prevent unauthorised access, destruction, alteration, or removal, accidental or intended damage or destruction.

Researchers are responsible for maintaining records of where their data are stored. If results from research are challenged, all associated Research Data and Research Records must be retained until the matter is resolved. Research Records that may be subject to allegations of research misconduct must not be destroyed.

Research Type

Researchers are required to identify the key research methodologies that will be used throughout the project and the type (or nature) of information that will be provided by participants. Where questionnaires, interviews and/or focus groups will include the disclosure of personal or sensitive information by participants, this must be indicated in responses here (particularly Q14.2) and elsewhere in the ethics application form.

Personal information according to the [Privacy Act 1988](#) and the [Office of the Australian Information Commissioner](#) for example may include;

- an individual's name, signature, address, phone number or date of birth
- [sensitive information](#)
- [credit information](#)
- employee record information
- photographs
- internet protocol (IP) addresses
- voice print and facial recognition biometrics (because they collect characteristics that make an individual's voice or face unique)
- location information from a mobile device (because it can reveal user activity patterns and habits).

Sensitive information is personal information that may include:

- racial or ethnic origin
- political opinions or associations
- personal attitudes or values
- religious or philosophical beliefs
- trade union membership or associations
- sexual orientation or practices
- criminal record
- health or genetic information
- some aspects of biometric information.

Transcripts

Where the research will involve interviews and/or focus group sessions, please specify in the ethics application if participants will be provided with, or offered the opportunity to look over, a copy of the interview/focus group transcript (made from audio or video recording or written/typed notes) for the purposes of 'member checking' the accuracy of the information collected. Alternatively, where

appropriate, a summary of the key points / themes discussed might be provided to the individual or group of participants.

If the researcher does not intend to make transcripts available to participants for review, provide an explanation / justification for why this is the case.

Application Tip:

Q14.2
Select ALL types of methodology to be used as part of the project data collection activities.

Q14.3:
Identify if discussions will be recorded or documented in any way (e.g.: audio or video recorded and/or photographed), making sure that this is clearly outlined for participants in the Participant Information Sheet and Consent form. If you will be recording interviews, focus groups and/or observations, consider that this data will likely be 'individually identifiable' or 're-identifiable'.

Q14.3.1 – External Transcription Services
If applicable, acknowledge here that you will arrange for the transcriber to sign a confidentiality agreement if transcription will be carried out by someone other than the researcher.

If applicable, students should discuss this potential requirement with their supervisor. UniSA staff / supervisors can follow-up within their Academic Unit regarding existing template agreements - or can seek legal advice from UniSA Legal (http://i.unisa.edu.au/staff/chancellery/legal/) and can organise access to legal document templates such as this via Contract Express (further information available at: http://i.unisa.edu.au/staff/chancellery/legal/contract-express-self-service-document-generation/).

Alternatively, where researchers are proposing to use **online / electronic transcription software**, this should be stipulated in the ethics application form.

<u>In all cases</u> the following points should be considered to assess (and justify) the suitable use of these transcription options (particularly where data may include sensitive or personal information):

1) **Sensitivity of data:** considerations about whether the use of an 'external' provider is suitable given the 'nature' of the information

2) **Informed consent**: if the use of an external transcriber has been transparently

> outlined in the Participant Information Sheet and Consent Form, along details of any measures in place to protect confidential information as part of this process.
>
> **5) Confidentiality of data:** considerations / investigations into how this is managed / protected by the external provider
>
> **4) Accuracy:** processes in place for the researcher to check the accuracy of transcriptions (particularly where automated electronic / AI software has been used.

Participant Information

Participants are grouped according to their role in the research data collection process. Researchers must provide details of how many participant groups will be involved, the number of participants in each group, the age range of the participant groups, the relevant characteristics of each group and what each participant group will be required to do (e.g.: pilot study group / main study group; survey group / interview group / focus study group; experimental group / control group; etc.).

If participants are (1) engaged in contributing data over time and (2) require a particular health status (e.g.: not being diagnosed or treated for a medical condition), then specify how you will confirm that initially eligible participants have not changed status at later data collection points.

> *Application Tip:* **Participant Information**
>
> **Q15.1**
> Consider that this number is the number of study groups (e.g.: an 'interview' group and 'survey' group, or 'intervention' group and 'control' group), not organisations or the overall number of participants.
>
> **Q15.3.1**
> Include as much detail as possible via the text box response (and, where necessary, using a supporting document in the 'Attachments' section if required) outlining the characteristics of each participant group that will be recruited.
>
> **Q16.2 and Q16.5 (under 'Section of Participants')**
> Ensure the information provided at Q15.3.1 (and any specific participant group requirements / characteristics) aligns with any participant screening and/or eligibility criteria outlines in the responses at Q16.2 and Q16.5 accordingly.

Selection and Recruitment of Participants

There are a variety of options available for researchers to identify and contact potential participants and invite them to participate in their study. The process(es) that will be used must be outlined within the online form clearly and in full detail.

These may include accessing publicly available details (such as names and contact information via a web search), requesting permission from an organisation to distribute or display information about the study, or to request access to contact details for potential participants (e.g.: to access and utilise an organisation's staff/client/member database, etc.).

Any intention to recruit from known personal or professional contacts should also be outlined in your responses as there is an inherent risk of coercion, intended or not, if a researcher recruits participants with whom they have an existing relationship.

Responses should outline the steps that will be taken by the research team to protect the confidentiality of potential participants, as well as to reduce any possibly risk associated with existing, unequal, or dependent relationships that may be present during the recruitment process.

Additionally, where you are seeking to utilise contacts from a database/registry, it is also important to consider whether those listed have given permission to the relevant organisation (or would likely expect) to be contacted for purposes other than the primary purpose (i.e.: to be contacted for research purposes such as this). This is particularly significant where you are asking for access to contact details from a database (where it must be established that those listed have permitted the referral of their details to thirds parties in this way).

You must obtain final ethics approval, and any other required approvals or permissions, before commencing recruitment for your project. However, prior to applying for, or receiving, ethics approval, you can approach organisations or individuals to:

- develop relationships;
- form collaborative agreements;
- contribute to project design;

- explore potential involvement in your project.

Please note that you <u>cannot</u> ask people to be participants prior to receiving final ethics approval.

Recruiting UniSA Staff & Students

The University strives to preserve the privacy of its staff and students and maintain confidentiality of data and other information held by the University. The University also aims to protect its staff and students from unsolicited emails, and minimise staff and students being over-researched. The University therefore discourages the recruitment of its staff and students, and the collection of data and other information for research purposes, unless the nature of the research is beneficial to the University and/or its staff and students.

Relevant University policies and guidelines:
- [Access to UniSA students, staff and data (A-34)](#)
- [University of South Australia's Privacy Policy (M1)](#)
- [Acceptable Use of Information Technology (IT) Facilities (C-22)](#)
- [Guidelines on Electronic Communications with Students](#)
- [Guidelines for staff on use IT facilities including email and the Internet](#)
- [Guidelines for students on use of IT facilities including email and the Internet](#)

Researchers must seek approval from an appropriate authority to recruit UniSA staff and/or students. Information regarding this requirement can be found at:

https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/recruiting-unisa-students-and-staff/.

Permission to access information held in particular University databases must also be sought from the relevant Unit Director or senior manager.

Permission to recruit via the staff or student portals must also be obtained from the managers / coordinators of those systems.

For recruitment within Administrative Units of the University, permission must be sought from the Unit Director.

Please also contact the Facilities Management Unit and/or the UniSA Students Association (where relevant) for permission to post flyers or posters on campus.

Please be advised that the onus of acquiring and maintaining the records of the requisite approvals and permissions solely lies on researchers.

Recruiting from an External Organisation

Researchers are required to obtain written permission from any organisation to access their employees or clients, data associated with these people or other organisational data for research purposes. This written permission / evidence of support must be granted by an appropriate <u>senior authority</u> within the organisation. Written evidence can include email correspondence.

Written permission from an appropriate senior authority within the relevant organisation(s) must be sought in the following scenarios:

- where you are asking organisations to provide contact details for potential participants or to promote the study (and distribute recruitment information) on the researcher's behalf (for example, through advertisements on websites, social media accounts or by distributing information via email/letter/newsletter, etc.)
- where you plan to recruit participants in their capacity as an employee/representative of that organisation (i.e.: not considered to simply be 'general public' participants)
- where you plan to conduct research activities at participants' places of employment.

Further information relating to this requirement can be found on the following website (under 'Contacting or interacting with Organisations'): https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/getting-started/application-considerations/

This requirement must be acknowledged in responses within the ethics application form. It should also be noted that the onus of acquiring and maintaining the records of any requisite approvals and permissions solely lies on researchers.

Inclusion and Exclusion Criteria for Participants

The inclusion and exclusion criteria for participants must be clearly provided in the response, included what if any mechanisms will be used to determine this eligibility. A copy of any screening tools that will be used to assist with recruitment of participants must be attached to the application for review.

Common types of participant selection criteria include:
- Age range
- English language
- Cultural identity
- Health status
- Access to a smart device and internet connectivity

Application Tip: **Selection of participants**

Q16.1 and Q16.3
Clarify how and from whom the researcher will obtain the contact details of potential participants, including whether this is public information or if you are seeking access to a database/registry of contacts.

Q16.3
Consider if it might be preferable to ask the organisation or someone outside of the research team to distribute the introductory email (with recruitment materials, Participant Information Sheet and survey link, etc.) on your behalf so as to protect the confidentiality of potential participants (and their contact details) and to remove any potential for coercion as a result of dealing directly with the researcher.

Use of Personal Social Media pages
HREC discourages the use of personal Social Media pages for the purposes of recruiting participants. Risks should be identified, and a management plan provided if researchers (particularly students) intend to use their personal social media accounts for recruitment.

> **Private / Closed social media pages**
> Where you will use private/closed social media groups, you will need to investigate and (if applicable) seek approval to post this recruitment material from the relevant senior administrator/moderator for those sites.

Project Dates and Location

If data collection will occur on site at an organisation or school, the researcher will need to provide HREC with the communication seeking approval from an appropriate senior authority within the organisations that they:

- plan to promote your study through (if organisations will be assisting in distributing your recruitment materials); and

- intend to recruit participants from (this includes the recruitment of UniSA staff and/or students – please see section above titled 'Recruiting UniSA Staff and Students' for further details).

These organisational contacts should be provided with a summary of what participants will be required to do as part of the study (potentially including a copy of your research tools), along with a copy of the relevant recruitment materials (Participant Information Sheet and Consent Form) so that they can make an informed decision to permit access.

The researcher must acknowledge that any required permissions will be investigated and obtained prior to commencing data collection.

> *Application Tip:* **Working in Schools**
>
> All research and evaluation activities involving South Australian Department of Education (DE) sites, children, young people, staff, and carers must be submitted to DE for review by their Research and Evaluation unit.

It is the researcher's responsibility to ensure that all necessary DE approvals and permissions are in place before commencing their research.

Further information is available on the DE website: https://www.education.sa.gov.au/department/research-and-data/research-and-evaluation-department/conducting-research-and-evaluation.

Approval is also required if you wish to conduct research in South Australian Catholic Schools. Further information is available on the Catholic Education SA website: https://www.cesa.catholic.edu.au/working-with-us/research.

You must receive final ethics approval from UniSA HREC before finalising approval from the Department for Education or Catholic Education SA.

Research Conducted Overseas

Research conducted in another country is when you are travelling to that country, and not when you are just collecting data from an online survey, or conducting interviews by telephone, Skype or Zoom.

Overseas research might have legal, social, or cultural implications which would not be an issue if the research were carried out in Australia. If you are collecting data in another country, the security of data in that country needs to be managed and specified also.

Researchers are responsible for ensuring that research conducted offshore is culturally appropriate and complies with the legal requirements of the other country, as well as complying with Australian ethical standards.

> *Application Tip:*
>
> **Q21.1 Research conducted overseas (Q 17.2, Q37.3 and Q37.4)**
> It is the responsibility of the researcher (and the research supervisor) to thoroughly investigate any legal, governmental, visa, ethical, cultural or research approval requirements when conducting research in another country.
>
> The researcher (and supervisor) will be responsible for fulfilling those requirements and must acknowledge this in the responses at Q37.3 and Q37.4 accordingly. If applicable, final ethics approval may not be granted until written evidence of having met those

Limited Disclosure/Deception

Section 2.3.1 (a) of the National statement considers limited disclosure or planned deception 'from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants.'

If your project involves any type of limited disclosure or deception, researchers must consider these elements of their project design and provide details within the ethics application on how they will manage these risks. Providing succinct responses to the following as applicable. This can be attached as a separate document or included in responses to the sub-questions that will appear once 'YES' is selected as the response to the question at 18.1.

[Section 2.3.1](#) - *Where limited disclosure does not involve active concealment or planned deception, ethical review bodies may approve research provided researchers can demonstrate that:*

a. *there are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved*

b. *the potential benefits of the research are sufficient to justify both the limited disclosure to participants and any risk to the community's trust in research and researchers*

c. *the research involves no more than low risk to participants (see paragraph 2.1.6, page 18), and the limited disclosure is unlikely to affect participants adversely*

d. *the precise extent of the limited disclosure is defined*

e. *whenever possible and appropriate, after their participation has ended, participants will be:*

   a. *provided with information about the aims of the research and an explanation of why the omission or alteration was necessary*

   b. *offered the opportunity to withdraw any data or tissue provided by them*.

Section 2.3.2 - Where limited disclosure involves active concealment or explicit deception, and the research does not aim to expose illegal activity, researchers should (in addition to the above) demonstrate that:

    a. *participants will not be exposed to an increased risk of harm as a result of the concealment or deception*

    b. *a full explanation, both of the real aims and/or methods of the research, and also of why the concealment or deception was necessary, will subsequently be made available to participants*

    c. *there is no known or likely reason for thinking that participants would not have consented if they had been fully aware of what the research involved.*

With reference to point (e) at section 2.3.1 of the National Statement, researchers should consider that (whenever possible and appropriate) after the participation has ended and participants have been provided with information about the aims of the research and an explanation of why the limited disclosure was necessary, they should be offered the opportunity to withdraw any data provided by them. The committee cannot approve limited disclosure or planned deception without being satisfied that the researchers have considered the risks in context of the National Statement.

Waiver of Consent

As outlined in chapter **2.39 of the National Statement** only a full HREC may grant a waiver of consent for research that intends to use data that is personal information in medical research or personal health information. The HREC must be satisfied that:

    a. *involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants*

    b. *the benefits from the research justify any risks of harm associated with not seeking consent*

    c. *it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)*

    d. *there is no known or likely reason for thinking that participants would not have consented if they had been asked*

    e. *there is sufficient protection of their privacy*

    f. *there is an adequate plan to protect the confidentiality of data*

g. *in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)*

h. *the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled*

i. *the waiver is not prohibited by State, federal, or international law.*

Researchers are required to provide a detailed response to the above points in section 2.3.10 (a) to (i) of the National Statement on Ethical Conduct in Human Research (and provide these responses in text at 18.2.1 or as a document in the 'Attachments' section)

Project Type

Clinical Trials

Chapter 3 of The National Statement - defines a clinical trial as a form of human research designed to find out the effects of an intervention. Health-related interventions can include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, or process-of-care changes.

Please refer to information relating to clinical trials (and the relevant notification forms) on the Therapeutic Goods Administration website: https://www.tga.gov.au/clinical-trials.

It may be helpful to also refer to the following webpage for further information: 'Clinical Trial Exemption (CTX) scheme renamed as Clinical Trial Approval (CTA) scheme': https://www.tga.gov.au/clinical-trials#cta-scheme

Researchers will need to identify in the ethics application form if the project will be conducted under the Clinical Trial Approval (CTA) scheme or Clinical Trial Notification (CTN) scheme. The overall decision as to whether a CTN or CTA is required in relation to the use of an unapproved therapeutic good is the responsibility of the trial sponsor.

Researchers can also contact one of the Allied Health and Human Performance or Clinical and Health Sciences Research Ethics Advisors (REAs) to seek advice with regard to making this decision.

Other items that should be considered when completing the project and ethics application include:

- If there will be a Data and Safety Monitoring Board (DSMB), or similar, for the trial
- If you intend to/have registered this trial in a publicly accessible register (for example, the Australian New Zealand Clinical Trials Registry)
- If an Investigator's Brochure or Product Information will be required
- for relevant health research, researchers should show that the research meets the requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, the World Health Organization International Clinical Trials Registry Platform and the TGA.

If your project is a clinical trial, you are required to register it in a publicly accessible trials registry prior to enrolment of the first participant (for example, the Australian New Zealand Clinical Trials Registry) as a condition of ethics approval.

Clinical drug trials notification forms can be accessed via the Therapeutic Goods Administration website. The person responsible for submitting the application must contact the Human Ethics Office requesting access directly.

Human Samples

If researchers are planning to work with human tissue or fluid samples, it is will very likely they require ethics approval, this also includes bio samples from an existing nonidentifiable repository or archive. Researchers can seek advice from a Research Ethics Advisor or the Ethics Office. Guidance is also available in Chapter 3.2 of the National Statement on Ethical Conduct in Human Research.

If you plan to take tissue or fluid samples from yourself, the following applies:

- Blood and semen do require ethics approval
- Saliva, urine, faeces, sweat, tears and exhaled breath do not require ethics approval

However, if any other person is involved in providing a sample, even a colleague or student, then ethics approval is required.

Researchers must also investigate if biosafety approval is required for your project.

Recruitment

Identify in responses to **Q38** of the application who will be recruited as participants, with multiple selections possible. This will ensure that the smart form populates the subsequent pages to allow for the researchers to identify the key elements of recruitment specific to the participant groups involved, including how they will manage any risks of vulnerable groups during the recruitment processes.

The National Statement sets out key ethical considerations for the following participant groups where specific issues can arise in the recruitment and participation. Noting that currently the statement advises that:

"Ethical review by an HREC is required for any research that involves more than low risk (see paragraph 5.1.6). It is also required for research discussed in several chapters of Section 3, as well as for research discussed in the following chapters of this section: Chapter 4.1: Women who are pregnant and the human foetus, Chapter 4.4: People highly dependent on medical care who may be unable to give consent, Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness, Chapter 4.6: People who may be involved in illegal activities, Chapter 4.7: Aboriginal and Torres Strait Islander Peoples and Chapter 4.8: People in other countries."

See Chapter 4.5 of the National Statement on Ethical Conduct in Human Research for further information.

> *Application Tip:* **Recruitment**
>
> **Q38.1**
> • If the participants are in a dependent / vulnerable relationship – detail your plan within the application questions to manage recruitment to avoid coercion by researchers or those with authority over participants.
>
> • If participants are highly dependent on medical care or have a cognitive impairment, the steps taken by the research team to obtain consent must be thought out and planned in the subsequent sections.
>
> • If English is not participants' first language – give details of interpreter and translation plans, and any necessary confidentiality arrangements with external providers.

Children

There are a number of ethical concerns that researchers need to take into consideration when undertaking research that involves young people. These are considerations are set out by the National Statement section 4.2 as:

- their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation
- their possible coercion by parents, peers, researchers or others to participate in research
- conflicting values and interests of parents and children.

Researcher should become familiar with this chapter to ensure that the risks associated with young people's involvement are considered and the research design incorporates a process to manage this risk.

Whilst children are considered by law under the age of 18, it is difficult to attach an age to all elements of consent involving young people. The individual vulnerabilities and capacities to consent must be recognised and clear information provided to the HREC in section **44.1** of the MyRM application.

Researchers are encouraged to consider ways to include young people in the consent process and ensure that where children are engaged in the discussion around their involvement and potential outputs of the research project.

Verbal scripts in age-appropriate language, for communication with children to obtain agreement to participate, following parental consent, should be provided to HREC as an attachment.

Working with Children Screening

Researchers who intend to undertake research in South Australia with minors or to enter a school, pre-school, childcare centre or other educational facilities in any capacity are required to obtain a criminal history and clearance check.

Clearances can be obtained from the South Australian Department of Human Services Screening Check system. Individuals can only obtain a clearance via their organisation.

Information on how to obtain a clearance via UniSA is as follows:

Staff: https://screening.sa.gov.au/home

Students: Please consult with your Academic Unit regarding local processes.

Further information is available at https://screening.sa.gov.au/home.

First Nations Participants

The HREC will review ethics protocols with significant or targeted participation of First Nations (Aboriginal and Torres Strait Islander) Peoples and communities with the expectation that the researchers have involved First Nations Peoples and/or communities from project inception (research design and methodology) through to the reporting of the research outcomes (to whom and in what form, considering cultural expectations etc).

Researchers are expected to submit a protocol that demonstrates how they have addressed Indigenous inclusivity in the following phases of the research process where relevant:

- Conceptualisation
- Development and approval
- Data collection and management
- Analysis
- Report Writing
- Dissemination of the research results

Researchers need to show how each phase of the research process is ethically defensible, based on the [NHMRC guidelines relating to ethical research with Aboriginal and Torres Strait Islander peoples](#).

Researchers must complete, and provide with their ethics application, the [Aboriginal and Torres Strait Islander Research Ethics Engagement Plan.](#)

Researchers can seek advice from UniSA's Aboriginal Research Ethics Advisor.

Please also refer to the University's [webpage on Aboriginal engagement,](#) including the downloadable guide titled "Yurirka: Proppa Engagement with Aboriginal Peoples".

Application Tip:

Q38.2
Select 'yes' here if the research is likely to be considered significant to Aboriginal peoples.

Q48.1 to Q48.9
Read and consider these questions carefully and attach an Aboriginal Research Ethics Engagement Plan to the application.

English as an additional language

If the research involves participants who have identified English as an additional language, careful consideration must be given to the consent process and how the details of the project will be provided to the participants.

Researchers can utilise translation services for data collection and consider providing participant information sheets and consent forms in the participants' first language. English versions of any document provided to participants in another language must be uploaded for the Ethics Committee to review.

Researchers should also be aware of any cultural differences and understandings when recruiting participants from culturally and linguistically diverse communities. Please identify within the ethics application any areas where these sensitivities need to be managed, and highlight how this will be done throughout both the recruitment and data collection phases.

Risks to Participants

Researchers must show an awareness of the risks involved in their data collection and the ways in which the study has been planned to reduce or manage these risks. Identifying and managing potential risks is regarded as responsible research practice ahead of denying or ignoring potential foreseeable risks and leaving them unmanaged.

Risk management is a core part of human research ethics, and the following guidelines can help shape discussions within the research team or with supervisors as to how particular risks can be identified and managed throughout the lifecycle of the study.

All types of risks must be highlighted to the review committee prior to submission of the ethics application, to allow for a holistic review of the project design and participant involvement.

Chapter 2.1 of the National Statement on Ethical Conduct on Human Research provides the following (non-exhaustive) list of potential harms for research participants:

- physical harms: including injury, illness, pain
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease

- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation
- findings of previously unknown paternity status
- economic harms: including the imposition of direct or indirect costs on participants
- legal harms: including discovery and prosecution of criminal conduct.

Discomfort is less serious than harm. Examples may include minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.

Inconvenience is considered less serious again. Examples may include filling in a form, participating in a street survey, or giving up time to participate in research.

Psychological or Emotional Stress

- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1666

If you are asking people to consider/recall topics which could conceivably relate to adverse or traumatic experiences, or arouse strong feelings, consider ticking 'psychological and emotional distress'.

If your research carries any risk of psychological or emotional stress for participants, your Participant Information Sheet should include:

- Prior warning of this risk (in plain language)

- Information about any measures which may be taken if the participant suffers an adverse event as a result of participating in the research
- Details of relevant mental health support services such as:
  - The participant's GP/doctor
  - Lifeline - 13 11 14 or https://www.lifeline.org.au
  - Beyond Blue - 1300 22 4636 or https://www.beyondblue.org.au

Some participant groups may have specific support services, for example related to cultural identity, health conditions or age, which should be reflected in the specified support sources.

Sensitive or personal information

Personal information according to the Privacy Act 1988 and the Office of the Australian Information Commissioner for example may include;

- an individual's name, signature, address, phone number or date of birth
- sensitive information
- credit information
- employee record information
- photographs
- internet protocol (IP) addresses
- voice print and facial recognition biometrics (because they collect characteristics that make an individual's voice or face unique)
- location information from a mobile device (because it can reveal user activity patterns and habits).

Sensitive information is personal information that may include:

- racial or ethnic origin
- political opinions or associations
- personal attitudes or values
- religious or philosophical beliefs

- trade union membership or associations

- sexual orientation or practices

- criminal record

- health or genetic information

- some aspects of biometric information.

Exposure to ionising and/or non-ionising radiation (Including X-Ray)

If you are using radiation (ionising or non-ionising) for research or technical purposes, you must refer to the University's Radiation web page.

Where participants in human research are exposed to ionising or non-ionising radiation, approval must be sought from the University Radiation Safety Committee (RSC) as a condition of ethics approval. It is advised for such research projects to engage with relevant experts at UniSA and go through the RSC first. Ethics officers will query whether or not this occurred and seek evidence of approval at the time of the ECO review.

A copy of UniSA Radiation Safety Committee approval should be uploaded under the 'Attachments' section of the ethics application or confirm that this will be forwarded to humanethics@unisa.edu.au once finalised.

Please be advised that the onus of acquiring and maintaining records of the requisite approvals and permissions solely lies on researchers.

Application Tip:

> *Application Tip:*
>
> **Q51.1**
> Select all risks to participants that apply.
>
> • If you are asking people about their personal experiences and views, consider ticking 'personal and sensitive information' (Check response is consistent with Q14.2 Research Type).
>
> • If you are asking people to consider/recall topics which could relate to adverse or traumatic experiences, or arouse strong feelings, consider ticking 'psychological and emotional distress'.
>
> •If you are performing any physically invasive or manipulative procedures, or physical movement performance, consider ticking 'risk of physical injury' and/or 'significant pain or discomfort'.

Collection Method

The researchers should provide in-text responses outlining how data that will be collected and stored during the research project. Consider if, at least initially, interview data may be individually identifiable (or coded to be re-identifiable) in order to offer participants, the chance to review their transcript/a summary of their interview notes - and/or to provide them with the opportunity to withdraw their data up until a certain point prior to data analysis and/or publication.

It must be clear to both the ethics reviewers and participants how data generated by the project will be used. Researchers have the following options to consider:

- data will not be used for any other purpose
- data will/may be used for another purpose by the researcher for which ethical approval will be sought
- data will be used to establish a database/collection or register for future use (ethical approval will be sought)
- data will/may be made available to a 3rd party for subsequent use (ethical approval will be sought)
- Other

Comment: Add to the tip box "Consider if the publisher may request data to be made available as part of the publication process" with direction on how to indicate this in the form

> ***Application Tip:***
>
> **Q67.1.3**
> Select 'Individually Identifiable' if you are audio recording interviews/focus group sessions as voices are considered to be potentially identifiable.
>
> **Q67.6**
> If you do intend to use data for another purpose, ensure that the response to Q70.7 is consistent with the response here.
>
> If data will be used for another purpose, consider adding into the Participant Information Sheet a statement such as: "Subject to receiving ethics approval, this data may potentially be used for future research projects".

Participant Relationships

Pre-existing relationships between the research team and potential participants must be highlighted at the ethics review stage, noting that there is an increase in the risk of coercion/exploitation during recruitment.

Researchers should identify any such relationships and consider:

- the potential impact of existing relationships on recruitment (including, but not limited to, hierarchical relationships that may generate an unequal or dependent relationship, such as teacher and student, manager and employee, supervisor and team member or treating health care professional and patient)
- the potential impact of participation on existing relationships.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__461

In addition to acknowledging any pre-existing relationships, the research team must also consider if any of these relationships include people in dependent or unequal relationships. Chapter 4.3 of The National Statement provides the following examples of pre-existing relationships which may compromise the voluntary nature of participation:

- carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation
- health care professionals and their patients or clients
- teachers and their students
- prison authorities and prisoners
- governmental authorities and refugees
- employers or supervisors and their employees (including members of the Police and Defence Forces)
- service-providers (government or private) and especially vulnerable communities to whom the service is provided.

It is up to the research team during the project design process, to identify these relationships and outline the steps they will take to minimise the risks associated with the conduct of the research the participants involved. Considering four key elements; **Research merit and integrity, Justice, Beneficence and Respect.**

Academic staff who are researching their current students therefore need to manage risks of perceived coercion, for example by ensuring communication about the research is sent by someone unconnected to the research or teaching of those students, and/or assuring students that non-participation will have no consequences for their grades or relationships with university staff.

> *Application Tip:*
>
> **Q68.1 (and Q68.1.1 and Q68.1.2)**
> If applicable, describe this potential relationship and what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.

*If staff are recruiting students from their own course, this should be identified within the application.

Q16.3 (under 'Selection of Participants')
Ensure that the recruitment methodology considers any existing relationships that are identified here and outlines the steps that will be taken to avoid coercion (intended or not) during the recruitment stages.

Consent

Chapter 2.2 of the National Statement sets out the general requirements for consent. Consent is a key component of human research and must be taken into consideration throughout the research design and implementation stages, with the focus being on participants providing voluntary and informed consent.

When reviewing applications, UniSA HREC must be confident that consent will be appropriately obtained from participants, with the following information being provided to participants prior to consent being provided:

- the purpose of the research
- any alternatives to participation
- how the research will be monitored
- provision of services to participants adversely affected by the research
- contact details of a person to receive complaints
- contact details of the researchers
- how privacy and confidentiality will be protected
- the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data
- the amounts and sources of funding for the research
- financial or other relevant declarations of interests of researchers, sponsors or institutions
- any payments to participants
- the likelihood and form of dissemination of the research results, including publication

- any expected benefits to the wider community

- any other relevant information, including research-specific information required under other chapters of this National Statement.

Types of Consent:

2.2.14 of the National Statement stipulates that consent may be:

a) Specific: limited to the specific project under consideration

b) Extended: given for the use of data or tissue in future research projects that are:

    i.   (i) an extension of, or closely related to, the original project

    ii.   (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research)

c) Unspecified: given for the use of data or tissue in any future research. The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

Application Tip:

Q70.7
Select here the type of consent that is being sought from participants within the research project. (Cross reference with Q67.6)

Extended Consent or unspecific consent should be considered if the research team want to publish the original data set or make data publicly available via a databank after data collection has been completed.

Whilst unspecific consent may be selected, the implications of this type of consent must be explained to participants and details included in any required consent form and participant information sheet.

Where there is a possibility that research data will be published along with a research publication, this needs to be specified in the consent details provided within the application as well as via the participant information sheet and consent form provided to participants.

Capacity to provide consent

The researchers must take into consideration that not all participants will have the capacity to provide consent for themselves. Participant groups that may not have capacity or legally able to provide consent can include; children, participants with a cognitive impairment and participants highly dependent on medical care. In these instances, consent must be provided from a lawful authority for the potential participant and must be provided in the best interest of the participants.

Children and consent

The capacity of children and young people to take part in a research project must be considered by the researchers at the time of identifying how consent will be obtained. Their individual levels of maturity will impact on the approach to obtaining consent and should be discussed in full with the research team, supervisor and or REA if required.

When providing responses to the Ethics Committee on consent and young people, the researchers must show how the methodology is appropriate for those participating in the research and specify how they will individually determine the child's capacity and identify any particular existing vulnerabilities to providing consent.

Chapter 4.2.7 of the National Statement provides the following guidelines for researchers:

Specific consent to a child's or young person's participation in each research project should be obtained from:

      a. *the child or young person whenever he or she has the capacity to make this decision*

      b. *either*

            i. *one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable*

            ii. *the guardian or other primary care giver, or any organisation or person required by law.*

Whilst participants under the age 18 cannot legally provide consent, it is good ethical practice to include young participants in the consent process and where possible, depending on the individual level of maturity and understanding, their assent or dissent to be involved determined. This may involve providing age appropriate (written, oral or otherwise) information to the child in accordance with their level of maturity. Verbal scripts in age-appropriate language, for attaining assent from children should be provided to HREC.

Application Tip:

Q51.1
If your project involves participants under the age of 18 select 'Involves participation of people who legally cannot provide voluntary & informed consent'.

Process of obtaining consent

Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:

a) the nature, complexity and level of risk of the research; and
b) the participant's personal and cultural circumstances.

Online questionnaires/survey
Consent can be obtained by include a statement such as this within in the Participant Information Sheet:

This is an internet-based survey. Every effort will be made to ensure that responses are confidential, however the researcher cannot guarantee the confidentiality or anonymity of material transferred by email or the internet.

And can include this statement at the beginning of the questionnaires/survey:

"By completing and submitting the questionnaire/survey, you are indicating that you have read and understood the Participant Information Sheet and give your consent to be involved in the research."

Postal questionnaire/survey

The first page of the questionnaire/survey should state something similar to one of these statements:

> **Example 1**: By completing and submitting the questionnaire/survey, you are indicating that you have read and understood the Participant Information Sheet and give your consent to be involved in the research.

> **Example 2**: By beginning the questionnaire/survey, you acknowledge that you have read the information sheet and agree to participate in this research.

Individual consent forms must be completed and provided for in-person data collection such as interviews, focus groups or experiments. UniSA HREC has a consent form template available to all staff and student to use as a foundation for obtaining consent. The template can be adjusted to reflect the project and participant groups as needed.

Refer to the waiver of consent section for details on when it is not possible to obtain consent from participants.

Application Tip:

Q69.1.2.1
If recruiting participants, applicants must provide a response to this question. You may wish to include the following points:

• Each participant's qualifications and current position of employment will be sufficient evidence that they have capacity to decide whether or not to participate in the study.
• Participants are required to read the participant information and sign a consent form, and their signed consent is indicative of their capacity to decide whether or not to participate.
• Participants will be 18 years of age or older.

Q69.1.3
If participants are children this response needs to be 'Yes', as children and young people under the age of 18 years do not legally have the capacity to consent for themselves. Respond to any additional questions which are generated.

> **Q70.1**
> Expand the response here to identify how participants are going to be informed of the key elements of consent. For example; potential participants will be provided with a Participant Information Sheet early on in the recruitment process (i.e. - before the time of data collection) so that they are well informed about the project and what their involvement entails, have sufficient time to consider participation without being in the presence of the researcher and have adequate opportunity to ask any questions. They will then be asked to sign a Consent Form prior to completing the interview/focus group/activity.

Opt-Out Consent

Some researchers may choose to follow an opt-out approach to consent. Chapter 2.3.5 – 2.3.8 of the [National Statement on Ethical Conduct in Human Research](#) details the circumstances in which an opt-out approach to participant recruitment may be approved:

> *An opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible.*

It is the researcher's responsibility to identify this in their application and provide responses to allow the HREC to be satisfied that the risks to participants have been considered how they will be managed throughout the consent process.

> *Application Tip:*
>
> **Opt-out Consent**
> If you wish to seek approval to use an opt-out approach, attach a document to your Ethics Application which addresses each of these points. A separate attachment can be included.
>
> a. involvement in the research carries no more than low risk to participants
> b. the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy

c. the research activity is likely to be compromised if the participation rate is not near complete, and the requirement for explicit consent would compromise the necessary level of participation

d. reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining the nature of the information to be collected, the purpose of collecting it, and the procedure to decline participation or withdraw from the research

e. a reasonable time period is allowed between the provision of information to prospective participants and the use of their data so that an opportunity for them to decline to participate is provided before the research begins

f. a mechanism is provided for prospective participants to obtain further information and decline to participate

g. the data collected will be managed and maintained in accordance with relevant security standards

h. there is a governance process in place that delineates specific responsibility for the project and for the appropriate management of the data

i. the opt-out approach is not prohibited by State, federal, or international law.

Risk and Benefits

Researchers must select yes in response to Q**71.1** if there are **any** risks to participants as a result of participation in this research project (e.g., physical, psychological, spiritual, emotional, legal, social, financial well-being, employability or professional relationships). For example, whether there is any possibility that responding to the survey/interview questions may cause participants to experience emotional or psychological distress. If you have selected identified risks in 51.1 this should be reflected also in 71.1.

If applicable, please address this potential risk in response to this question, and also consider including information in your Participant Information Sheet about any measures which may be taken if the participant suffers adverse events as a result of participating in the research. These risks need to be identified and responses provided to allow the HREC to understand how they will be minimised, monitored and reported. The benefits for the research must also be identified here and the personal risk of the researchers must be considered in response to **71.4.** The risks need to be assessed at a participant, researcher, and community-wide level as relevant to the research design.

Application Tip:

Q71.3
If a reimbursement will be offered to participants, clarify what this is, so that the ethics reviewers know exactly what will be provided and can be confident that the value of the payment will be appropriate and that this will be consistent for ALL participants (i.e. - if a voucher will be provided, provide a specific value and include this information in your Participant Information Sheet). Where possible, HREC recommends providing a generic voucher which does not compel participants to spend money at a particular outlet (such as a VISA, EFTPOS or AusPost gift card), or a provider such as 'Prezzee' that allows participants to redeem the value of their gift with a large number of Australian retailers.

Q71.4
If researchers will be collecting data in the field or away from the University, consider amending this response to 'Yes' to acknowledge the potential risks to the researcher associated with interviewing participants one-on-one in a private space. Answer the additional questions which are generated and explain how you will manage these risks. For example, you may wish to note that you will carry a mobile phone, travel in a university car, and check in with [your supervisor/another member of the Research Team] or another trusted person before and after each interview.

Q72.3
Consider adding here that research project team meetings will have a standing agenda item asking if there have been any adverse events which need to be reported to the human ethics office and/or occupational health and safety (OHS) team - or any need to seek a variation to the approved protocol.

Distress Protocol

If you have identified risks, you need to attach a Distress Protocol detailing the strategies you will use to manage and/or minimise the risks: what will trigger action, what actions will be taken by researchers, and what resources you will provide to participants (e.g., counselling / medical services, including contact details). Please take into account such factors as:

- Consider and identify potential risk to experience distress (physical, psychological / emotional distress)
- Identify any key stages during the project when participants could be more likely to experience distress (e.g., during recruitment, during data collection, following data collection)

- Identify what occurrences/signs will trigger action, including what the researcher will actively monitor / look for

- what initial actions will be taken

- what follow-up, if any, might take place should a participant suffer adverse events as a result of participating in the research

- identifying any support resources that might be referred to / made available, and at what points during the project this information will be provided / reiterated. Contact details for sources of support should ideally be tailored to participant groups – e.g., migrant services for migrant participants, child resources for children, etc. Consider if there are any local services that might be most suitable / accessible for the relevant participant group.

- identify/acknowledge that any adverse effects on research participants or reportable events will be reported within 72 hours to the Human Research Ethics Office (humanethics@unisa.edu.au) using the Adverse or Reportable Event Form (as per details found here:

  https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/adverse-reportable-events/)

- identify any potential for participants to disclose reportable events during the study / mandatory reporting requirements for the researcher and, if applicable, clarify how this will be managed and whether (and under what circumstances) information may be reported to relevant authorities.

The publication linked here may be useful in your development of a distress protocol

Mandatory Reporting

The ethics application assists in identifying situations where sensitive information is shared with researchers which requires mandatory reporting. In some circumstance it is mandatory for researchers to report suspected cases of child abuse/neglect, domestic violence, bullying, illegal activities, use of illicit substances, abuse of elderly persons, professional negligence etc. This may depend on the researcher's status, for example as a registered health professional or educator.

At **Q72.4.1** researchers should select 'yes' if there is any possibility that any of the above could be disclosed during the course of the project and at **Q72.4.1.1** acknowledge mandatory reporting requirements and details of what steps will be taken by the researchers to report any disclosures.

For example, it is mandatory for researchers to report in the case of child abuse/neglect (or reasonable suspicion of harm relating to children and young people). For further information, see - https://i.unisa.edu.au/policies-and-procedures/university-policies/corporate/c-29/

Reporting of Results

HREC considers that it is the researcher's responsibility to proactively offer to provide participants with a summary of their findings wherever possible. This should be clear to the reviewers in the application by selecting 'yes' in response to **74.5.**

To enable this, the following statement can be included in the Participant Information Sheet: "A summary of the research study findings will be available to all participants upon request. Should you wish to receive a summary of the study findings, please contact the chief investigator via the contact details provided."

Alternatively, if conducting an anonymous online survey, the researcher can set up an optional additional survey (separate to the main survey) in which participants can indicate their interest in receiving a summary of findings and provide their email or postal address. It should be made clear to participants that this is not compulsory and that their personal details will not be linked to their survey responses.

Application Attachments

The ethics application has a number of compulsory attachments. This documentation is required to allow the review committee to consider the application in full and understand what information will be provided to participants directly throughout the course of the project.

The following section should be read in conjunction with the examples and templates provided on the human ethics webpages here.

If all the appropriate attachments **are not** provided when the application is submitted, the Ethics Compliance Officer will be unable to complete the review and the application will be reverted back to the research team to update prior to a full review being undertaken.

> *Application Tip:*
>
> **Reference List**
> Attach a list of up to ten key references in support of your response to Q5.4, 'Project Details'.

Research Tools

A separate copy of **all research tools** that will be used in the project must be attached. These can include interview questions, survey templates, focus group scripts, statistical procedures and images of equipment that participants will be required to use during an experiment.

If the research tools are still in development or are reliant on pilot testing or discussions, a draft outlining the types of questions that will be asked in an interview, survey or a focus group guide should be attached. Researchers will be asked to also acknowledge that they will submit the finalised questions for approval by the HREC Chair before commencing that stage of data collection. See the following webpage for further information on this process:

https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/project-variation/.

Participant Information Sheet

The participant information sheet is used to explain the purpose of the research and what participants will be required to do /how participants will be involved. It should be in plain English, using language appropriate to the target audience. In some cases, it will be appropriate to have the information sheet translated into a language other than English, or to provide an interpreter.

All participants should be given a copy of the participant information sheet, even if they are completing an online questionnaire. If there are multiple elements to data collection or multiple participant groups with different requirements, separate participant information sheets may be

required. This will allow the participants to clearly identify what is being asked of them as well as understanding their rights as a participant.

The information provided below outlines what should be included in the participant information sheet. Full details are available on the UniSA Human Ethics webpage [here](#).

[Heading](#)

[Introduction – What does my participation involve?](#)

[What is the purpose of this research?](#)

[What does participation in this research involve?](#)

[What are the possible benefits of taking part?](#)

[What are the possible risks and disadvantages of taking part?](#)

[Do I have to take part in this research project?](#)

[What will happen to information about me?](#)

[What if something goes wrong?](#)

[What happens when the research project ends?](#)

[Who is organising and funding the research?](#)

[Who has reviewed the research project?](#)

[Further information and who to contact](#)

The information within your application must be consistent with what is in the participant information sheet.

All participant information sheets should include:
- An invitation to potential participants to participate in the research study, stating that **participation is voluntary**
- A clear explanation of the purpose of the study.
- A summary of what the participant will be expected to do, or have done to them, during the research

- A statement that the participant may withdraw from the research at any time without affecting their position (or, if appropriate, their treatment or care) now or in the future.

- A statement detailing whether data may be excluded from the study if a participant withdraws, and/or the point up until which data may be withdrawn (e.g., up until a specified date or a particular stage of data collection).

- The possible benefits or risks to the participant in participating in the research.

- If there are no risks beyond those encountered during everyday life, the following statement should be used: "It is not anticipated that there are any risks to participation in this study beyond those encountered during everyday life."

- If some risk has been identified, a description of measures which will be taken if the participant suffers adverse events as a result of participating in the research

- A statement informing participants how long all information collected as part of the study will be retained (for example, five years or seven years), and details of where the information will be stored and the form in which it will be stored. Also, whether data will be individually identifiable, re-identifiable (coded) or non-identifiable.

- A statement that all records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law OR if individuals will be able to be identified, a statement should be included making them aware of this.

- The following statement: This project has been approved by the University of South Australia's Human Research Ethics Committee (Ethics Protocol #####). If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, please contact the Executive Officer of this Committee – humanethics@unisa.edu.au / Tel: +61 8 8302 6330'.

- Details about how and when participants will be provided with either a copy of the final research report or summary of the research findings.

- If you are conducting focus groups, your participant information sheet should include the following statement: "All participants will be asked to maintain the confidentiality of focus group discussions and preserve the anonymity of other focus group participants. Given the public nature of focus groups, however, please be aware that this cannot be guaranteed".

> *Application Tip:*
>
> **Potential Risks**
> If it has been identified in Q51.1 that the project has additional risks, these must be identified in the participant information sheet. If there is a risk of psychological or emotional stress a list of appropriate support services must be provided in the participant information sheet.

Consent Form

Consent forms are used to gain formal, written consent from research participants. When signed consent is required, the Consent Form template should be used. A copy of the Participant Information Sheet must be given to each participant who signs a Consent Form. A separate consent form is required for participants or a person providing consent for another participants. A template can be downloaded from the Human Ethics webpages here.

> *Application Tip:*
>
> **Future use of data and/or participant details**
> If you intend to use data for future research or make available on a data bank or publish along side any research publications, ensure that this is included in the consent form. For example, a dot point stating "I understand that my de-identified data may be used for future research for which ethics approval will be sought".
>
> If you would like to add participants' details to a register for future studies this should also be given as an option within the consent form. For example, "I agree for my details to put on a register to be contacted for participating in future projects".

Recruitment Materials

The application should include all templates for the recruitment materials that will be used to promote the project (including recruitment emails social media posts/advertisements). Where possible (i.e.: if there is not a character limitation, for social media platforms, etc.) the following points should be included:

- the title of the project and a brief description/summary of the purpose of the study

- a brief description/summary of what participants will be required to do, or have done to them, during the research (including an approximate time commitment required to take part)
- any key inclusion/exclusion criteria for participants (if applicable)
- include the statement - "This project has been approved by the University of South Australia's Human Research Ethics Committee (Ethics Protocol *****)".

Other

Any additional supporting documentation should be attached to the application. The fields on the online form cannot be adjusted to alter the order of the attachments. Clear document titles should be included so the reviewer can identify what documents have been provided.

Details on how to attach documents to the online form can be found in the MyRM 'Applicant User Guide'.

Resources

- UniSA Ethics Webpage: https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/
- MyRM 'Applicant User Guide' (under 'Application Assistance': https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/human-ethics-help-and-training/
- UniSA Online Ethics Training Course- (in particular Module 10): https://lo.unisa.edu.au/course/view.php?id=20824
- HREC Conditions of Approval: https://i.unisa.edu.au/siteassets/staff/unisa-ro/docs/unisa-hrec-standard-conditions-of-approval-28-march-2023.pdf
- National Statement on Ethical Conduct in Human Research: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1
- Australian Code for the Responsible Conduct of Research, 2018: https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#download
- Privacy Principles and the Privacy Act: https://www.oaic.gov.au/privacy/privacy-legislation/the-privacy-act
- NHMRC Guidelines approved under Section 95 of the Privacy Act 1988: https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities
- Keeping research on track II (a companion document to 'Ethical conduct in research with ATSI Peoples and communities - Guidelines for researchers and stakeholders): https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii
- UniSA Aboriginal Research Strategy and Yurirka: Proppa Engagement with Aboriginal Peoples: https://www.unisa.edu.au/about-unisa/aboriginal-engagement/resources/