

Table of contents

1.	Human research ethics and responsibilities of UniSC researchers.....	3
2.	Does your project need ethics approval?	6
3.	Review pathways at UniSC.....	9
4.	UniSC HREA user guide and tips.....	13
5.	Regulatory and ethical privacy considerations	18
6.	Research requiring approval by third parties	20
7.	Engaging third parties in the conduct of research.....	21
8.	Risks and benefits in human research	22
9.	Recruiting participants.....	25
10.	Payments to participants	33
11.	Informed consent.....	35
12.	Observation without consent, limited disclosure, opting-out, or waived consent	37
13.	Managing human research data	41
14.	Secondary use of data or information	43
15.	Research involving human biospecimens	46
16.	Genomic research	49
17.	Clinical research and clinical trials	51
18.	Human research involving ionising radiation.....	54
19.	Language issues in human research	56
20.	Ethical issues in survey-based research.....	57
21.	Ethical Issues in focus group research	58
22.	Audio-visual recordings and photographs.....	59
23.	Ethical issues in online research	62
24.	Research involving children and young people	65
25.	Research involving university or other students	68
26.	Human research and unequal relationships	71
27.	Participants with mental impairments or those unable to give consent.....	73
28.	Vulnerable, disadvantaged, or powerless participants.....	74
29.	Research and the discovery of illegal behaviour	76
30.	Research involving Aboriginal and Torres Strait Islander participants, communities, locations or topics....	78
31.	Research conducted in other countries	80

Further information

These guidelines have been developed in line with the [National Statement on Ethical Conduct in Human Research](#), which is the primary guiding document for human research ethics reviewers and researchers in Australia. Researchers submitting an ethics application must have read and applied the values and principles outlined in this document.

The UniSC specific resources referred to throughout these guidelines are available on the [Portal](#) (for both staff and students).

To discuss human research ethics further contact:

- **Research Ethics Officers, Office of Research**

Claire Smith-Moloney: +61 7 5430 2823

Angela Bestard: +61 7 5459 4574

Mic Ashton: +61 7 5456 5904

Email: humanethics@usc.edu.au

- **Student Supervisors**

Student researchers should consult their supervisors throughout the research design and ethics application process.

Acronyms and abbreviations

ARC	Australian Research Council
COI	Conflict of Interest
HREC	Human Research Ethics Committee
National Statement	National Statement on Ethical Conduct in Human Research
NHMRC	National Health and Medical Research Council
REO	Research Ethics Officer
RPIS	Research Project Information Sheet

1. Human research ethics and responsibilities of UniSC researchers

UniSC is committed to the highest ethical standards in human research. UniSC Researchers should refer to, and be familiar with, the following national documents and UniSC policies:

- [Australian Code for the Responsible Conduct of Research](#)
- [National Statement on Ethical Conduct in Human Research \(2023\)](#)
- [UniSC Human Research Ethics - Governing Policy](#)
- [UniSC Human Research Ethics - Procedures](#)
- [UniSC Responsible Research Conduct - Governing Policy](#)

Human research being undertaken by UniSC cannot commence until researchers receive written confirmation of ethics approval from UniSC. UniSC ethics approval may be granted via a number of different review pathways depending on the level of risk associated with a project and whether ethics approval has already been granted by another ethics review body. The duration of ethics approval must cover the recruiting of participants and the collection of data but does not necessarily need to include data analysis or write-up. Ethics approval correspondence will outline the conditions of the ethics approval, which researchers must comply with. As per the standard conditions of approval, researchers must notify the Human Research Ethics Committee (HREC) of the following:

- adverse events (serious or low risk, expected or unexpected)
- complaints received about the conduct of the project
- withdrawal of participants where there may be some ethical concern
- amendments required to project details or protocols.

Procedures and forms associated with this can be found on the 'Managing your Approved Human Research Ethics Project' tab on the [Portal](#).

The National Statement

UniSC's human research ethics arrangements are based on the [National Statement on Ethical Conduct in Human Research](#). The National Statement provides guidance to, and outlines the responsibilities of, researchers, ethics reviewers, and institutions. The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) require that funded research and host institutions comply with the National Statement.

The National Statement defines human research as 'research conducted with or about people, or their data or tissue.' Examples of human research include:

- conducting surveys, interviews, or focus groups
- administering psychological, physiological, or medical testing or treatment
- observing participants
- accessing data (e.g. medical records, previously completed questionnaires, a biobank dataset)
- collecting and/or using body organs, tissues, fluids, or exhaled breath

Participants can include people who are unaware that they are participants or are unaware of the true nature of their participation. This can happen when:

- the need for consent has been waived by an HREC
- participants have previously given consent for their data to be used in future projects
- participants are being observed and/or tested using limited disclosure, which has been approved by an HREC.

The principles of ethical conduct in human research

Section 1 of the National Statement identifies and provides details on the four principles of ethical conduct in human research:

1. **Research merit and integrity:** Research that is justifiable in its contribution to knowledge, is well designed, is conducted by experienced researchers, and is conducted using appropriate facilities.
2. **Justice:** Research that is fair in its recruitment and inclusion of participants, in which no particular groups are overly burdened, the benefits of the research are fairly distributed, and there is no exploitation of participants.
3. **Beneficence:** Research in which risk is justified by benefits and is designed to minimise risk and to care for the welfare of the participants.
4. **Respect for persons:** Research that respects humans and has due regard for the welfare, beliefs, perceptions, customs, and cultural heritage of those involved in the research.

Key features of ethics review

- Researchers must consider ethical requirements (e.g. the welfare of participants) from the earliest stages of planning and during research design.
- Ethics approval is often a condition of research funding, access to potential participants pools (e.g. Education Queensland students), and publication in research journals.
- Ethics review includes an assessment of research merit and integrity.
- Ethics review provides feedback on the ethical considerations relating to the proposed research.
- Ethics review may generate ideas that increase participation rates, improve project design, or safeguard access to participant populations and sites.
- Ethics reviewers are often 'lay' people so technical terms must be explained, and expert knowledge should not be assumed.
- There may be multiple approaches to an ethical issue; reviewers might question an approach or recommend a different approach. In response, applicants may defend or justify their approach based on their expertise and knowledge or by referencing the National Statement.

Other regulatory or legislative requirements

Researchers need to be aware of, and comply with, other UniSC policies and procedures and other regulatory or legislative requirements that apply to their research. Ethics review is not intended to cover all other requirements; while these may be noted in feedback as a reminder, it is the researcher's responsibility to ensure compliance.

See [Guideline 5](#) (Regulatory and ethical privacy considerations) and [Guideline 31](#) (Research conducted in other countries).

The importance of researcher expertise

Ethics reviewers need to be satisfied that the researcher possesses the necessary expertise to conduct the research, especially for research that is higher risk or has ethical sensitivities. When a project is to be conducted by a team, the necessary expertise must be present across the team and during the relevant parts of the project.

Researcher expertise may be assessed based on:

- **methodological expertise:** the researcher must have the experience, knowledge, and training necessary to conduct the data collection, to operate equipment, and/or to analyse the data
- **participant and context expertise:** where the research involves participants of distinct groups (e.g. cultures, religions, sexual orientation) or where the research is conducted in a distinct context (e.g. a refugee camp), the researcher must have the experience, knowledge, and training relevant to that group or setting
- **risk expertise:** where the project involves significant risks (e.g. psychological distress), the researcher must possess the necessary experience, knowledge, and training to address the risk.

When a research team does not possess the necessary expertise, they may seek the input of an external adviser. Researchers should consider how to acknowledge the contribution of the adviser (e.g. in reports or publications) and whether the research presents any risks to the adviser.

Conflicts of interest

UniSC researchers must be familiar with and adhere to the [UniSC Conflict of Interest – Governing Policy](#). Conflicts of interest can now be disclosed through the UniSC [Conflict of Interest Online Disclosure Tool](#), which is accessible on [MyUniSC](#). Conflicts of interest disclosed via this tool should also be referenced in relevant ethics applications.

In the context of human research ethics, a conflict of interest (COI) is a situation in which a researcher's private interests could influence their research, or where a dual relationship exists such as where the researcher is an employee or stakeholder of an organisation where research is being conducted (e.g. a teacher using their students as participants). Dual relationship conflicts are common sources of complaint about the ethical conduct of research and may give rise to the following:

- recruitment and consent issues (e.g. potential participants may feel pressure to participate)
- risks to participants (e.g. researchers having access to information relevant to their other role)
- privacy and/or legal issues (e.g. a researcher having access to participant information in their other role).

COIs may be actual, potential, or perceived, and must be disclosed in an ethics application with an explanation of measures that will be taken to address the COI. If a researcher fails to disclose a COI their application may be delayed or rejected. If a COI is not disclosed but later emerges, researchers may be found to be in breach of UniSC policy and the *Australian Code for the Responsible Conduct of Research*.

COIs must be disclosed to potential participants in the informed consent materials so that participants can decide if the COI is significant to them and if they still wish to participate.

If a third party is involved in the research, COIs must be disclosed to them and by them.

COIs may occur within the operation of the HREC (e.g. where a member of the HREC is a member of the research team on a project under consideration). HREC members are required to disclose such conflicts and are asked to leave the room during discussion of the project.

2. Does your project need ethics approval?

[Publicly available information](#)

[Social media, blogs, online forums and communities](#)

[Quality assurance and evaluation activities](#)

[Teaching and learning activities](#)

[Student research](#)

[Case studies](#)

[Pilot studies](#)

[Research conducted by external researchers](#)

Whether an activity requires ethics approval depends on whether that activity is considered ‘human research.’ As referenced above, the [National Statement](#) defines human research as ‘research conducted with or about people, or their data or tissue.’ If there is uncertainty about whether the use of humans, their data or their tissue is ‘for research purposes’, it should be noted that at UniSC, an activity will be considered human research, if there is an intention to publish any work based on the use of people, their data or their tissue.

The following provides guidance on determining whether human research ethics approval is required for certain types of activities. If human research ethics approval is required, please refer to [Guideline 3](#) for further information on the pathways through which ethics approval can be sought and granted at UniSC.

Regardless of whether human research ethics approval is required, activities that may involve potential risks, harms, or vulnerable people, should be carefully managed in line with UniSC policies and procedures such as The [Enterprise Risk Management – Governing Policy](#) and [Procedures](#) and the [Working with Vulnerable People – Governing Policy](#) and [Procedures](#).

Publicly available information

Prior to 2024, the National Statement and UniSC Human Research Ethics arrangements allowed some publicly available information to be used for human research purposes without human research ethics approval. Due to recent changes to the National Statement, this has been revised to require ethics approval for the use of publicly available information for research purposes.

In line with section 5.1.17 of the National Statement, UniSC has adopted a new exemption pathway with the intention of this approval process being as efficient as possible. Approval can be granted via the exemption pathway if, as per section 5.1.17 of the National Statement, ‘lower risk research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.’

The review pathway for human research involving other publicly available information largely depends on the identifiability of the participants/subject, the degree of risks and/or potential harms involved in the project, the way the data was originally collected, and the credibility and/or reputation of the source of the data. As per Chapter 3.1 of the National Statement: ‘The guiding principle for researchers is that, although data or information may be publicly available, this does not automatically mean that the individuals with whom this data or information is associated have necessarily granted permission for its use in research.’

Social media, blogs, online forums, and communities

Research projects that will collect data from social media pages or groups, blogs, online forums and communities, or similar, will require ethics approval. It should be noted that due to issues associated with identifiability and consent, this type of research is unlikely to be eligible for approval via the exemption pathway. Although the terms and conditions of some online platforms may state that data will be used by third parties and/or researchers, participants rarely read these terms and it would be unethical to use this as a blanket approach to consent because these terms and conditions are not optional and most users would not expect their information to be used for research purposes. Additionally, many users are identifiable on these sites and thus their data and

information must be considered in this context. An ethics application must be submitted and researchers will need to consider how consent will be addressed. See [Guideline 23](#).

Quality assurance and evaluation activities

Data might be collected to inform or improve processes, programs, policies, teaching, or services at UniSC or at external organisations. For example, students might complete a survey to provide feedback on orientation week activities or a UniSC researcher might work with an external organisation to analyse data from a staff survey on health and safety initiatives.

Refer to NHMRC's [Ethical considerations in quality assurance and evaluation activities](#). As per this guideline, ethics approval will be required where data from a quality assurance or evaluation activity will be used for research purposes. If research may be an outcome of the evaluation activity, ethics approval should be sought before the data is collected so that the appropriate consent mechanisms are in place.

If possible, external organisations should be encouraged to add a consent process into their evaluation activities that would allow for future use of the data—this could then be provided with the ethics application to demonstrate that the participants were aware of, and consented to, the potential future use.

Teaching and learning activities

Most activities that involve the collection of data or tissues from humans for teaching and learning purposes do not require human research ethics approval. These might include, but are not limited to, aptitude tests done in class, clinical technique simulations, or practicing interventions such as physical tests or measurements. If any activities are undertaken that may result in data that would be used for research purposes, then ethics approval would be required.

Where an activity or intervention takes place in a classroom, and where that activity would not take place if not for the research, ethics approval is required. For example, tutors might teach a new technique and then be interviewed for feedback—the ethics application should cover the interviews and the in-class activity with all students considered as participants (it may be possible to request a waiver of consent or to use the opt-out approach).

Student research

Ethics approval is required for human research projects conducted by higher degree by research or honours students as such work is for research purposes and is undertaken with the intention of results being published. Prior to 2024 human data collected for the sole purpose of UniSC coursework assessment pieces did not need ethics approval unless there was an intention for this data to be used for research purposes.

As of 2024, the National Statement (5.1.17) specifies that lower risk human research 'conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only' is eligible for (requires) approval via an exemption pathway.

Where 'human research' forms part of a coursework requirement, staff and students need to be aware of this requirement and ensure that ethics approval is sought via the exemption pathway as appropriate. As students are not able to be listed as the Chief Investigator, a staff member will also need to be listed on these applications. As coursework students are not experienced researchers, teaching staff should guide students to design lower risk projects that can be achieved in the required timeframes by avoiding vulnerable participant groups, sensitive subjects and complicated data collection methods.

If staff are concerned about the additional pressures this may put on students and timeframes, consideration should be given to whether equivalent research skills and experience can be developed in a way that does not require the use of humans, their data or their tissue.

Case studies

Case studies often include mixed methods of data collection such as analysis of publicly available or privately held documents, interviews, observations, etc. Some data collection methods will require ethics approval, while others may not. The ethics application only needs to cover the methods that do require ethics approval; however, it may help to contextualise the research by briefly describing those methods that do not require approval. It may be helpful to include approvals from participating organisations to access research materials (e.g. a sporting club may give access to their archives). As per the protocol template, it is helpful for reviewers if multiple points of data collection are presented as a snapshot in a table.

Pilot studies

A pilot study is a small-scale preliminary study that is conducted to assess and improve project design prior to the full project being undertaken. Pilot studies involving humans require ethics approval. In some cases, the pilot study portion of the project can be incorporated into the full ethics application with amendments being made if changes occur following the pilot.

Pilot studies should not be confused with peer review. For example, researchers conducting a survey might send it to subject matter experts (or friends and family) for feedback on wording and relevance. If the feedback will not form part of the data set, then ethics approval would not be required for this component of the work. In the ethics application for the survey, it might be prudent to explain that this process will happen and that this feedback will not be included in the project data.

Research conducted by external researchers

If the research activity originates from an external source (e.g. a researcher from another institution that has ethics approval and wishes to survey UniSC staff) and no UniSC staff or students are listed on the research team, then UniSC ethics approval will not be required.

If the research involves UniSC staff or students as participants, it may require administrative approval (e.g. from the Head of School or department). Anyone wishing to collect information from or about UniSC students must refer to the [Student Survey - Policy](#) and [Procedures](#) and submit an application for approval as required. These approvals occur outside of the HREC and the Office of Research. External parties should contact studentsurvey@usc.edu.au for more information.

3. Review pathways at UniSC

Refer to:

- Section 6 of the [UniSC Human Research Ethics - Procedures](#)
- ‘Applying for Human Research Ethics Approval’ on the [Portal](#), which includes a table that outlines each review pathway and the forms and supporting documents required

As per the [UniSC Human Research Ethics - Governing Policy](#) and [Procedures](#), human research conducted by UniSC staff or students must not commence until UniSC ethics approval has been granted in writing. Applications for UniSC human research ethics approval will be reviewed via one of the following review pathways. Application forms and necessary supporting documents vary for each review pathway. Full application requirements are detailed on the ‘Applying for Human Research Ethics Approval’ on the [Portal](#).

Pathway	Eligibility Criteria	Reviewer
Exemption	See Section 5.1.17 of the National Statement below.	Office of Research
Prior Review	Research that has already been granted ethics approval by another ethical review body.	Office of Research
Expedited Review (E1)	Lower risk research with no significant ethical issues to explore.	HREC Chair
Expedited Review (E2)	Lower risk research with some significant ethical issues that have been adequately addressed by the research design.	HREC Panel (Chair and two HREC Members)
Full Review	Research that does not qualify for any of the above pathways, or where the National Statement specifies that the category of research must be reviewed by a HREC	HREC

Upon receipt of an application, the HREC Chair determines the review pathway based on the risks and ethical issues associated with the research. While these guidelines intend to help applicants accurately identify the pathway that will apply to an application, it is possible that the review pathway determined by the HREC Chair will be different to that anticipated by the research team.

Exemption pathway

As per section 5.1.17 of the National Statement, research may be eligible for approval via the exemption pathway if it carries a lower risk to participants or the community **and** satisfies one or more of the conditions in (a)–(d), below:

- (a) the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree
 - (i) not to attempt to re-identify those with whom the information or data is associated;
 - (ii) to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised; and
 - (iii) that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;

- (b) the research is restricted to observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;
- (c) is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;
- (d) the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

Prior review pathway

This pathway is used where a UniSC researcher is listed on a project that has been approved by another Australian ethics review body, or where it can be demonstrated that an overseas approval was granted within a framework equivalent to the National Statement.

If a UniSC researcher has transferred from another Institution this pathway may be used only if the original ethics review body will remain the lead reviewing body for the research. If no team members remain at the original institution, their ethics approval will likely cease and a new application will need to be submitted at UniSC.

The Prior Ethics Review Cover Sheet should be provided along with the other ethics review body's approval letter and all approved application documents. Where the other HREC has listed documents specifically on their approval letter, those documents must be submitted to UniSC for our records. Where no documents have been listed, we would usually expect to see an application form and/or protocol document, recruiting materials, a research project information sheet (RPIS), the consent mechanism, and data collection tools. If amendments have been approved by the lead HREC, these should also be included.

Notes and considerations for Prior Review projects:

- Many overseas ethics frameworks do not have the same expectations regarding documentation as we do in Australia. If the level of review and documentation provided is not in line with Australian requirements researchers may be asked to submit a full application to UniSC.
- UniSC researchers should be clearly listed in the application documents. Some HRECs will list all researchers on the approval letter, where they don't, the UniSC researchers should be listed on the application form and/or the protocol at minimum.
- The UniSC Prior Ethics review Cover Sheet should list the Chief Investigator (this may be an external researcher) and all UniSC researchers. Other researchers at other institutions do not need to be listed nor do they need to sign the UniSC form.
- Not all institutions require the same format of documents; however, topics of importance (background/aims, participants, recruiting methods, consent methods, methodology, and data collection and storage) must be covered somewhere within their documentation.
- The RPIS should contain the key information as per the UniSC templates—who can participate, what participants will do, how participants will give consent, how data is collected and stored, risks and benefits, and who participants can contact if they have concerns or complaints. Ideally there would be a local contact in Australia if the research is being led overseas. The UniSC logo should be included if possible.
- If there is a UniSC specific document, such as an RPIS, this should be approved by the other HREC. If necessary, researchers may be asked to create UniSC specific documents and submit them as an amendment at the original HREC before UniSC approval is granted.
- Researchers are responsible for ensuring that all other approvals, resources, and agreements, are in place (e.g. risk management, working with children checks, budgets/funding).

- Line managers are asked to sign the Prior Ethics Review Cover Sheet to ensure that they support the application. They may require additional documents, outside of the documents required by ethics, to ensure that the necessary resources and agreements are in place prior to the project commencing.
- Project amendments must be submitted to, and approved by, the lead HREC first. Amendments must then be submitted to UniSC with the UniSC Amendment request Cover Sheet, the amendment approval notice from the lead HREC, and all amended documents.
- Progress reports are required for prior review projects; the report submitted to the lead HREC along with evidence of their approval of the report should be submitted.

Queensland Health: If UniSC research will involve Queensland Health staff, patients, data, or facilities, ethics approval should first be sought from [Queensland Health](#). UniSC ethics approval can then be granted via the prior review pathway. If the project will involve Queensland Health and non-Queensland Health based sites it may be necessary for separate ethics approvals to be granted. It is recommended that the full scope of the project be reflected in the Queensland Health ethics application and the inclusion of non-Queensland Health sites be highlighted when submitting your UniSC prior review application to humanethics@usc.edu.au.

Education Queensland: Researchers need to apply to [Education Queensland](#) to conduct research in Queensland state schools or to access departmental data. Ethics approval can be sought at UniSC at the same time as research approval is being sought from Education Queensland.

Expedited review pathway

Expedited review level 1 (E1) is used for lower risk research with no significant ethical issues to explore. E1 applications are reviewed by the HREC Chair.

Expedited review level 2 (E2) is used for lower risk research with some significant ethical issues that have been adequately addressed by the research design. These applications are reviewed by a panel of HREC members (usually the Chair and two members).

Full review pathway

Full review by the HREC is required for research that has more than a low level of risk, or is identified by the [National Statement](#) as requiring full review. Full review applications are reviewed by the HREC at regularly scheduled meetings. Papers are due two weeks prior—specific dates are published on the [Portal](#).

Research requiring full review may include, but is not limited to:

- risks (physical, psychological, social, economic, or legal) that are more than discomfort
- human genetic research
- stem cell research
- accessing sensitive collections of data (e.g. health care records)
- collecting or accessing biospecimens
- research that requests a waiver of consent
- research that impacts on the pregnancy of a participant and/or a foetus
- participants who are dependent on medical care, unconscious, or are unable to communicate
- participants with a cognitive impairment, intellectual disability, or mental illness
- clinical trials or clinical interventions
- the exposure of illegal activity or where this is likely to be discovered
- the intentional recruitment of Aboriginal or Torres Strait Islander people, or where it is probable that there may be a high proportion of these participants recruited incidentally
- issues of established significant or ethical interest to Aboriginal or Torres Strait Islander people
- exposure to a human toxin, the injection of an agent, the ingestion of a substance for a therapeutic and research purpose, or exposure to a human pathogen

- exposure to ionising radiation, in which the level of radiation is more than that of standard diagnostic x-rays, or more than 20mSv
- limited disclosure in which potential participants will be intentionally deceived or subject to active concealment of important information about the research project
- access to identified personal information prior to the consent of the individuals
- research conducted in other countries or with participants in other countries
- participants or researchers in a highly unstable country and/or research that could be perceived as critical of an oppressive regime
- the possibility of third-party identification of participants
- activities that are illegal, unsafe, or otherwise inappropriate for minors
- research involving children or young people
- research where the unequal relationship between researcher and participant could be viewed as coercive
- research where participants are asked to disclose sensitive personal information
- research where legal, contractual, professional, or moral obligation might compel researchers to disclose information or data to third parties
- research where it is not possible to justify the value of the incentive, or where it could be considered coercive
- research asking participants whether they have considered self-harm or suicide, where there is no-one from the research team with appropriate experience, and/or no effective mechanism for referring participants to an appropriate source of support.

4. UniSC HREA user guide and tips

[HREA technical support](#)

[Project description/protocol](#)

[Q1.9 Project team](#)

[Q1.12 Project evaluation](#)

[Q1.17 Research Methods](#)

[Q1.18 'with whom or with what' the research will be conducted](#)

[Q1.19 Participants](#)

[Q2.2.2.1 Scope of consent](#)

[Upload attachments](#)

[Q4.5 Review pathway](#)

[Q4.6 National Mutual Acceptance Scheme](#)

[Generating the HREA and submitting](#)

[Revising applications and responding to feedback](#)

The Human Research Ethics Application (HREA) is an online application form produced by the NHMRC in line with the National Statement. Users need to create and manage their own account and password—the HREA is not a UniSC website.

HREA Technical Support

The [HREA resources](#) page includes:

- frequently asked questions
- HREA 'how to' guide
- how to download and save your HREA
- HREA troubleshooting
- contact details for the technical support team.

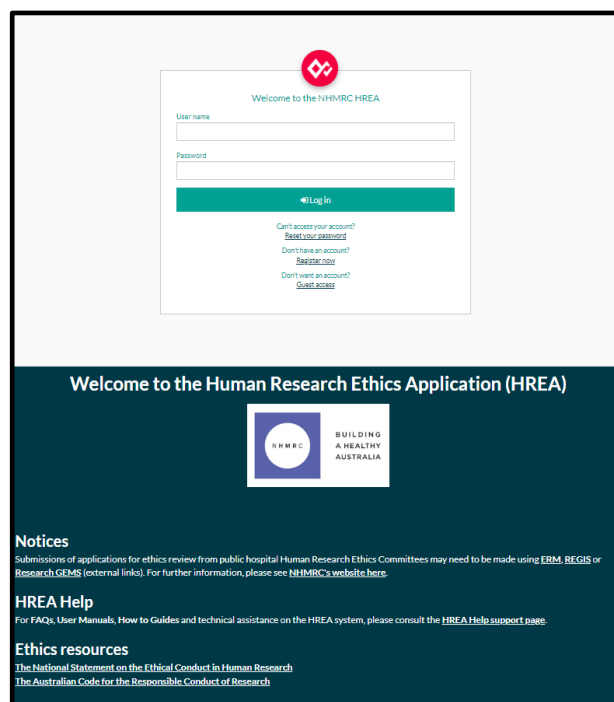
The 'HREA How-to Guide' explains how to create and manage your account and how to create, submit, and revise an application. If you need technical assistance, please contact help@hrea.gov.au or 1800 500 983 (within Australia) or +61 2 6217 9451 (international callers).

Project description/protocol

To assist with completing the HREA form, we recommend that researchers write their [Project Description / Protocol](#) document first. The template can be found on the [Portal](#).

Tips

- Use the template as this contains headers and prompts for information that is specifically required for ethics review (confirmation documents or grant applications often do not have the details required).
- On average, a protocol can be completed in less than 10 pages—dot points are okay and simple language is preferred (many reviewers are not academics).
- If using multiple data collection methods, or participant groups, it is helpful to reviewers if this is presented as a table—see template linked above.
- Rather than duplicating information, you may refer to specific sections or pages of the protocol in your answers in the HREA (e.g. See section 5.3 of protocol)



Q1.9 Project team

As per UniSC policy, the Chief Investigator (CI) must be a UniSC staff member. For student projects this is the primary supervisor. Please only list one CI in Q1.9.10. For Q1.9.5, say yes for the person who is the CI.

Researchers who are involved in the project (recruiting participants, collecting data, analysing data) should be listed on the application form. Where groups of students or volunteers may be used to collect or analyse data (e.g. recruiting participants to do a survey on an iPad in a public place, analysing de-identified data), they do not need to be listed individually in the HREA. The protocol should include a statement to say that these groups will be involved, what they will do and/or access, and that the researchers will ensure that they understand and comply with approved protocols and the National Statement. This also applies to teams of people working on overseas projects (e.g. translators, enumerators, etc.).

Q1.12 Has the scientific or academic merit of the research project been evaluated?

Select 'Yes.' At UniSC, all projects must have some form of peer review prior to submission, which is either via completion of the UniSC [Peer Review Checklist](#).

Q1.17 Research methods

Several options may apply—read the descriptions carefully. Further questions depend on the selections made here. As a rule of thumb, if the additional questions don't relate to your project, consider revising your selections.

Q1.18 'Indicate with whom or with what the research will be conducted'

Select only one option. Further questions depend on the selections made here.

- Select '**human beings**' when participants will be recruited and will provide data or biospecimens for this project. This applies to most projects.
- Select '**human biospecimens**' when the project only involves the use of specimens that have already been collected for another purpose.
- Select '**data associated with human beings only**' when the project only involves the use of data that has already been collected for another purpose.

Q1.19 Participants

Further questions depend on the selections made here. The answers here may also determine the review pathway for the project. Only tick the options where you are directly targeting these groups, or where you would expect large numbers of these participants because of the participant pool you will be targetting.

For example, if you are conducting interviews with village women about food choices, you might capture a few women who are pregnant, but, as they are not the target of the research, you do not need to tick the 'Women who are pregnant and the human fetus' box.

Aboriginal and Torres Strait Islander people should be ticked if the project involves the intentional recruitment of Aboriginal or Torres Strait Islander people, or where it is probable that there may be a high proportion of these participants recruited incidentally.

'People in dependent or unequal relationships' should be ticked where researchers are recruiting their students or tutors as participants.

Q2.2.2.1 Scope of consent

Ensure consistency in the scope of consent listed in the HREA form (including sections that relate to future use of data), protocol, research project information sheet (RPIS) and consent form. The UniSC RPIS and Consent Form template includes a plain language indication of what is meant by specific, extended and unspecified consent as follows:

- **Specific consent:** Consent is sought for this research project only.
- **Extended consent:** Consent is sought for this project and for related, ethics approved, projects that may be undertaken by this research team.
- **Unspecified consent:** Consent is sought for this project and for related, ethics approved, projects that may be undertaken by other research teams.

In determining the scope of consent to be requested consideration needs to be given to whether extended or unspecified consent will increase risk in any way and/or be required to allow for future use of data. If requesting extended or unspecified consent, it is recommended that participants be given the option to choose the scope of consent they wish to grant wherever possible. This choice should be clearly indicated in the consent form by including 'this OR that' type response options or including yes/no check boxes for each consent option.

Upload attachments

All project documents must be uploaded into the HREA, including:

- project description/protocol
- recruiting materials (e.g. flyers, emails, social media posts, etc.)
- Research Project Information Sheets
- consent forms
- data collection tools—surveys, interview questions, observations proformas, etc.
- endorsements or approvals, as required, from third parties (e.g. letter of support from a School)

The zip file is considered the official record of approved documents; as such, it must contain all attachments. The peer review checklist and line manager authorisation forms are the exception—they can be submitted within the HREA or separately.

Where possible, please simplify file names (no project titles, researcher names, etc.) and add the date last modified. For example:

- RPIS 1Jan23
- Survey 1Jan23
- Protocol 1Jan23

Q4.5 Review pathway

Please indicate the review pathway you think can be used for your project but note that the HREC Chair will determine review pathway based on the full application.

Q4.6 National Mutual Acceptance Scheme

Select 'No.'

Generating the HREA and submitting your application

Once your application is complete, 'generate' the HREA document.

A pop-up window will appear prompting you to download and save:

- 'All application forms and attachments' as a zip file, which contains the 'output form', based on the online form, and all the attachments you uploaded
- 'HREA file able to be re-uploaded at a later time': the '.omni' file—save this file but do not try to open it (it is a data file to use in future to upload the application back into the HREA as they are removed after 90 days)

If you miss this window, do not panic! On the HREA home page, your applications will be listed (if they aren't all showing click the applications button). Click on the 'identifier' for the completed application and a menu will appear below with options to 'download data file' and 'download application attachments'.

Submission to UniSC is completed via email. Please send the following to humanethics@usc.edu.au:

- HREA zip file
- .omni file
- peer review checklist
- line manager authorisation form.

The screenshot shows a web form titled "Generate HREA document". At the top right, there are three buttons: "Track Changes", "Preview", and "Save". Below the title is a "Previous" button. The main text asks: "Is your application complete and have you attached the Project Description/Protocol and any relevant supporting documents?" with radio buttons for "Yes" and "No". A note states: "Note: Once you finalise this application (by clicking the below 'Generate HREA document' button) it will be removed from the HREA system after 90 days. Ensure that you retain a copy of the provided .zip and .omni files on your computer." Below the note, it says: "Verify that you are ready to generate your HREA document. When the below 'Generate HREA document' button is clicked your application will be finalised and will no longer be editable. You will still be able to copy this application on the Applications Tab to, for example, make some post-review revisions." There is a checked checkbox for "I understand and would like to proceed." At the bottom, there are "Previous" and "Generate HREA document" buttons.

The screenshot shows a web form titled "Application completion". The main text states: "Application submission is not automatic through this portal. You MUST download and save your application zip file(s) and .omni file to your computer as a first step. Uploaded HREA data is removed from the system 90 days after an application is uploaded." There are two hyperlinks: "[All application forms and attachments \(.zip\)](#)" and "[HREA file able to be re-uploaded at a later time \(.omni\)](#)". Below the second link, it says: "- Click on the hyperlink above to download the .omni file. This is a HREA system data file that contains your application and all associated attachments. It is used to re-upload your application into the HREA system if needed at a later time." At the bottom, there is a checkbox for "I have downloaded and saved all of the available files." and a "Next" button.

Revising applications and responding to feedback

If you need to revise your application in response to feedback or to make an amendment after ethics approval has been granted, you will need to log into the HREA website and create a new version of your application, which is an exact copy of the application that you can edit. The responding to feedback document, that is sent with feedback, and the amendment request coversheet, both have the following instructions to assist with this process.

1. Revise all relevant documents such as the protocol, RPIS etc. Accept any previous changes and show only current changes via track changes or highlights.
2. log into HREA website (hrea.gov.au) with your HREA login (not your UniSC login)
3. under the 'Top 5 in progress applications' click 'View all' to list all applications and then follow one of the following options:

If your application is listed and the status is marked as 'in progress':

- click on the application title

If your application is listed and the status is marked as 'complete':

- click the application identifier
- select 'new version'
- in the pop-up box select 'new version'
- rename (for clarity) and click 'new version'
- click on the application title

If your application is not listed:

- click upload application (top right)
- navigate to the relevant .omni file on your computer and double click
- click 'new application' in the pop-up window
- add an application title
- click save
- click on the application title

4. edit answers in the form if required by navigating the tabs on the left
5. In the 'upload' tab (on the left side)
 - i. Delete old versions of documents that have changed—press the red delete button
 - ii. upload new versions of documents—click 'add another'
 - iii. leave documents that have not changed
6. click through the next two sections (HREC and Declaration)
7. click the green 'Generate HREA document' button
8. from the pop-up window, download and save all available files including:
 - i. 'All application forms and attachments' (.zip)
 - ii. 'Tracked changes' (.docx) (if available)
9. 'HREA file able to be re-uploaded at a later time' (.omni) (DO NOT try to open this file –it is an HREA specific data file—simply save and send
10. Email the amendment request coversheet or your response to feedback document, the zip file, tracked changes form (if available) and the .omni file to humanethics@usc.edu.au.

5. Regulatory and ethical privacy considerations

Resources:

- Commonwealth [Privacy Act 1988](#)
- [Australian Privacy Principles](#)
- [Queensland Information Privacy Act \(2009\)](#)
- [Overview of Information Privacy Principles \(QLD\)](#)
- [National Statement](#)
- Secondary use of data or information (e.g. student grades)—see [Guideline 14](#)

UniSC researchers must design their research to adhere to the National Statement, Queensland Privacy regulations, UniSC policies and procedures, and local ethical and regulatory requirements. Privacy laws apply to personal information that is accessed, collected, generated, or otherwise obtained; such laws apply even when individuals will not be identifiable in publications or reports arising from the research. Identified personal information should only be accessible by authorised officers of the organisation the individuals provided the information to, and should only be used for the purposes for which that information was provided, unless:

- at the time of the collection, or subsequently, the individuals gave consent for their information to be used for other purposes and/or to be given to authorised third parties
- the new use (e.g. for research purposes) is consistent with the purposes for which the information was originally collected
- the individuals will provide specific consent to the original organisation to give their information to the research team.

Exemption--public interest test

A researcher may request an exemption to requiring consent to access data under s95 or s95A of the Commonwealth Privacy Act. This section provides for a public interest test, which permits the use of identified personal information for health research without the consent of the individual where this is approved by a research ethics committee. See [Guidelines approved under Section 95A of the Privacy Act 1988](#).

Confidentiality

Confidentiality is not always an ethical requirement; some research participants will want their information and comments attributed to them. When conducting research in which participants will be identifiable and/or where direct quotes will be ascribed to them, key considerations include:

- the degree to which participants understand how their information will be used and the risks and benefits of their participation—this must be clear in the informed consent materials
- the mechanism and options for consent
- the mechanism by which participants can review and/or edit their contributions or quotes
- the degree to which participants would be considered a vulnerable group
- whether a participant's identification could expose them to risks.

Alternately, protecting the confidentiality of participants may be important—this is especially true when the information collected is sensitive and/or their participation exposes them to risk. Strategies to protect confidentiality should be considered for all stages of a research project (i.e., from identification of participants through to data storage). Researchers must consider not only privacy regulations, but general ethical and privacy considerations (e.g. where interviews will occur and whether participants might be overheard). Care should be taken when reporting case study results if the 'voice' of the participant remains and could allow for identification. Audio-visual recordings or other data that would enable identification must be used and stored carefully.

Providing potential participants with a clear explanation of the intended approach to confidentiality will give them confidence in the research and will improve the chances of them participating.

Anonymity

Anonymity can be further divided to:

- **completely anonymous:** nobody knows who participated and there is no way any data can be directly linked to a participant
- **anonymous responses:** the identity of the participants may be known, but their identity cannot be linked to their responses—it may be important to ensure that third parties (e.g. employers) cannot identify who has participated
- **protected anonymity:** the identity of participants is known and may be linked to specific data, but steps are taken to ensure that third parties cannot determine participatory status and cannot link specific data with specific respondents.

There will be circumstances in which it is preferable and/or ethical for participants to be anonymous (e.g. the presence of unequal relationships, sensitive topics, potential disclosure of illegal activity). Anonymity may be an important factor in determining participation; as such, it should be specifically outlined in the recruitment and/or informed consent materials.

If the anonymity of participants is important, but it is necessary to match data collected from the participants at a number of points, researchers may ask participants to generate a code (e.g. house number plus birth year). The self-coding formula should be such that there is no risk of participants being identifiable.

Researchers should consider the degree to which participants could be identified (e.g. tracing an IP address) and how they could be protected from harm in the event of a breach of privacy and/or where they might receive a subpoena or other lawful directive to disclose research data.

Identification by inference

Even when participants will not be directly identified, they may be identified by inference. This occurs when sufficient information is present to determine the identity of an individual. This is most commonly an issue in qualitative research in which case study descriptions appear in publications. It could also occur in close knit industries with small participant pools, in an organisation's internal research, or within social or professional peer groups.

If identification by inference is possible, this, and any associated risks, should be clear in the ethics application and informed consent materials. Participants might review their quotes/stories/descriptions to check the degree to which they might be identifiable and to assure them that they have been represented fairly and that risks have been minimised.

Duty of disclosure

A duty of disclosure occurs when a researcher is obliged to divulge information to third parties. Examples include:

- evidence of previously unidentified child abuse
- where a crime has been concealed
- an imminent and real threat to life
- a significant public health concern.

The law recognises that a duty of care may override a contract (e.g. a contract of confidentiality). These situations are difficult to handle because the moral responsibility for action is placed on the researcher; they will need to reflect upon which action is more ethically justified (e.g. protecting confidentiality or preventing the spread of an infectious disease). Researchers who are also members of professional associations are often bound by the associations' ethical guidelines. The potential for duty of disclosure should be outlined in ethics applications and informed consent material.

6. Research requiring approval by third parties

In addition to UniSC ethics review, a project may require the approval of a third party who has a responsibility or duty of care for the site and/or the potential participants (e.g. research done at schools with students). Approval may be a matter of courtesy or could be a condition of the conduct of research. Obtaining such approvals may offer legal protection; as such, researchers are encouraged to obtain agreements in writing.

Some research will require ethics approval from the third party (e.g. Queensland Health). Such approval may be in addition to other required agreements or approvals. If the third party is the lead HREC, the project can be approved at UniSC using the prior review pathway.

Managing third party approvals

Where possible, a researcher should attach evidence of third-party approvals to their UniSC ethics application. Some third parties may not give their approval for a project unless the research has received HREC approval; in these cases, researchers should state that such approvals will be obtained and that a copy of the approvals will be provided to UniSC.

Researchers may consult with third parties prior to UniSC ethics approval; however, the project cannot commence until receipt of written confirmation of UniSC ethics approval. Researchers should note that the UniSC review process may result in changes to the protocol; consequently, it may be prudent to seek the approval of the third party after the UniSC review is complete.

If UniSC receives a complaint about the ethical conduct of a project, or there is an adverse event, it is the responsibility of the researcher to notify the third party. Conversely, if the third party receives a complaint, it is the researcher's responsibility to notify UniSC. UniSC will liaise with the third party if necessary.

In addition to following UniSC amendment procedures, researchers must consult with, or notify, third parties regarding project amendments.

7. Engaging third parties in the conduct of research

Researchers may use third parties to assist with recruiting participants, collecting data, or analysing data. Third parties might be an associated organisation (e.g. a sports club), a commercial entity (e.g. a market research company), or a fee-for-service organisation (e.g. an online survey service like Qualtrics). The use of third parties should be clearly articulated in the ethics application. If they are engaged after approval, an amendment must be submitted and approved prior to their involvement.

Researchers must ensure that third parties carry out their work in line with the National Statement, UniSC policies and procedures, and relevant legislation. An effective way of doing this is to document procedures for all tasks undertaken by the third party and to provide all relevant documents such as recruiting materials, informed consent documents, and data collection tools. Third parties should be informed that they must only use or circulate ethics approved documents. It may be important to document procedures that require the third party to deviate from their standard practice (especially those relevant to the concept of voluntary participation and consent).

Researchers are also responsible for monitoring the conduct of the third party. Highly sensitive research involving third parties may require more vigilant monitoring. Some research may involve risks or sensitivities that make it inappropriate to use a third party.

Potential conflicts of interest

Using a third party may introduce real or perceived conflicts of interest. For example, a provider who is paid for every telephone interview they conduct can be seen to have commercial interests that conflict with the ethical imperative of voluntary participation. Researchers must:

- identify any real or perceived conflicts of interest
- consider the potential for the conflict to impact on research design and results
- include the conflicts, and measures taken to address them, in the ethics application
- consider whether to inform participants of the conflicts
- address such conflicts in agreements made with the third party.

If conflicts of interest are not addressed appropriately, they may ethically compromise a project, cause suspicion or dissatisfaction among participants, or create risks for participants and researchers.

Note that the [UniSC Conflict of Interest Governing Policy](#) 'applies to all members of the University community when participating in activities related to the University.'

Managing privacy

All research conducted under the auspices of UniSC is subject to the Queensland Information Privacy Act; this includes any research that involves the use of a third party. Researchers must:

- identify any legal or privacy considerations that may apply before using lists of potential participants or identified data from a third party (e.g. did those people give consent for their details to be used for such purposes?)
- ensure that the third party can store data securely, control access to the data, and train their staff appropriately (especially if they will be handling identifiable and/or sensitive data)
- ensure that the third party clearly understands the timelines, procedures, and requirements for de-identifying data when necessary.

In many cases a formal agreement will need to be established with the third party, which should be submitted with the ethics application.

8. Risks and benefits in human research

Refer to Chapter 2.1 of the [National Statement](#).

Researchers, ethics reviewers, and potential participants must have a clear understanding of the risks and benefits of a project. Potential risks and their management and minimisation must be clear in ethics applications and informed consent materials. Research involving risks may be approved if the risks are addressed and it can be shown that the benefits of the research justify the risks and burdens.

Benefits in human research

Anticipated benefits should be based on a thorough review of theory, literature, and/or prior work. Research benefits may include:

- gains in knowledge, insight and understanding
- improved social welfare and individual wellbeing
- gains in skill or expertise for individual researchers, teams, or institutions
- access to project results or specific information about themselves for participants.

Depending on the nature of the research, benefits might flow to participants, the participant's community, other stakeholders or sponsors, the researchers, or society. Potential participants should be provided with a reasonable assessment of the potential benefits, the likelihood of these benefits being realised, and who will realise these benefits—especially if not the participant since they may be accepting risks or burdens. It may be appropriate to state that if the anticipated benefits are not realised, that the research will still make a useful contribution to disciplinary knowledge.

Risks in human research

Risk is defined as 'a potential for harm or discomfort.' Research must be designed to consider the 'likelihood that harm or discomfort will occur, and the severity or magnitude of the harm, including its consequences.' Risks can impact participants, potential participants, third parties, researchers, the institution, and the environment and may include (but is not limited to):

- physical harm: including injury, illness, pain or death;
- psychological harm: including feelings of worthlessness, distress, guilt, anger, fear or anxiety related, for example, to disclosure of sensitive information, an experience of re-traumatisation, 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;
- cultural harm: including misunderstanding, misrepresenting or misappropriating cultural beliefs, customs or practices;
- social harm: including damage to social networks or relationships with others, discrimination in access to benefits, services, employment or insurance, social stigmatisation, and unauthorised disclosure of personal information;
- economic harm: including the imposition of direct or indirect costs on participants;
- legal harm: including discovery and prosecution of criminal conduct.

Negating, minimising, and managing risks

In some cases, once a risk has been identified, it may be possible to negate the risk (e.g. by making responses anonymous if a survey uncovers illegal action). If risks cannot be negated, it may be possible to minimise the chance of the risk occurring or the seriousness of the harm if it does occur. For example, if during interviews about a potentially distressing topic participants may have an emotional reaction, this risk could be minimised by:

- forewarning the potential participants of the nature of the questioning
- screening the participant pool to exclude persons who are at high risk of experiencing distress
- using experienced interviewers who can identify signs of distress and take appropriate action.

Where risk may remain, strategies to manage the impact of the risk should be considered. In the above example, it may be possible to manage this risk by providing participant with free-to-the-user counselling support.

Risks that are part of normal life

In some cases, participants may experience risks regardless of research participation such as in the following examples:

- a focus group with participants who have experienced a home invasion—discussions may be distressing but may be no different from distressing discussions with family or friends
- blood extraction—while there are associated risks, this is a common procedure
- players conducting batting practice while wearing motion detectors—while there is a risk of injury, this is no greater than what they would experience in competition or training.

Examples of situations where such risks should still be identified and addressed in the ethics application and in recruiting and informed consent materials include:

- where participants are exposed to the risk for UniSC research purposes
- where participants may wish to self-screen to avoid uncomfortable situations
- where not all participants may face the predicted risks as part of their everyday lives.

Separating research risks from other risks

Research projects are often conducted at the same time as other activities. For example:

- surveys are conducted before and after a participant accesses a community service
- data collection occurs alongside an already organised event
- x-rays are analysed after being taken for a medical purpose
- additional exercises are completed alongside athletic training.

The other activities may include risks, but those risks would exist regardless of the research. This can be problematic, because the non-research activities may not be under the control of the researcher and it may not be possible to address the associated risks. The following questions may help researchers to determine whether the research needs to address such risks:

- Would the activity and the associated risks occur regardless of participation in the research?
- To what degree would the other activities be described as having a research purpose?
- Is the likelihood of occurrence and/or the severity of the potential harm compounded by the research element of the activity?

Both the ethics application and the informed consent materials should distinguish between activities with some degree of research purpose and activities that would occur without the research. Where an activity genuinely does not have a research purpose, and would occur irrespective of the research, then the research design does not need to address the associated risks.

When the researchers will also be conducting the non-research activities, it may be prudent to treat the non-research activities as having a degree of research purpose throughout the participant documents. In such cases, researchers should identify and address the risks holistically.

Describing risks in an ethics application

If there are risks associated with a project that are not addressed in the application, reviewers may raise this as a concern. Researchers should include the following in their application:

- risks that were identified and negated through research design
- an explanation as to why an approach was selected to minimise a risk where there may have been other options; this may eliminate reviewer questions, especially if an approach was chosen for cultural or contextual reasons that the reviewers may be unaware of.

Describing risks to potential participants

For a potential participant to make an informed decision about their participation in a project, the project materials should include an explanation of potential risks, the likelihood that the risks may occur, the level of harm possible if the risks occur, and strategies used to address the risks. To assure participants that all risks have been considered, risks that have been negated or that have a very low probability of occurring may also be included. That said, a long list of risks, where the likelihood of harm is low, could take attention from the more serious risks and may cause concern to potential participants. Researchers should consider their target participants and the context of the project when determining how much information to provide.

When preparing participant information, technical language and/or jargon should be avoided unless the terminology is likely to be known to the potential participants. Where such language must be used, it should be defined. Participant documents should use appropriate language for the participant pool, the research, and the context. Rather than using statistical terms, the chance of risks occurring should be described in lay language.

Counselling and support services

Risks are often addressed by providing details for, or offering to arrange, counselling or other support services. The selected support service must be appropriate for the issues and the participant pool. The suggested service must be able to provide timely support, and participants should feel comfortable accessing this service. It may be appropriate to provide the details of an internal service (e.g. UniSC Counselling Service) or a generalist community-based service (e.g. Lifeline). The service should be free-to-the-user; if there were to be a cost to the participant, this must be clear in participant materials.

Burdens on participants

Aside from risks, there may be other burdens on participants that researchers should consider and address. These may include:

- time taken to complete surveys/interviews/testing
- lost income due to time taken to participate
- transport costs
- costs for tests, treatment, or other activities associated with participation.

The ethics application and informed consent materials should disclose these burdens, the degree to which the burdens will be addressed, and the degree to which the burdens are justified by the benefits of the research.

Monitoring benefits and risks

Where risk is uncertain, the HREC may specify extra monitoring requirements. Researchers must also monitor the project and if the benefits and risks change, or become clearer, they may need to amend processes or informed consent documents. Amendments must be submitted to, and approved by, the Office of Research before they are implemented. Where there are already participants, it may be necessary to provide those participants with supplementary information and to seek new and/or continued consent.

9. Recruiting participants

Recruiting involves identifying potential participants, contacting them, and if necessary, screening or excluding them. Recruiting must not occur until the project has received ethics approval. All recruiting material (e.g. emails, flyers, presentations) must be approved. Any changes to wording or recruiting processes must be approved as amendments prior to implementation.

When planning recruitment strategies and writing an ethics application, researchers should consider:

- What individual and/or groups would make the best participants?
- How will potential participants be identified and contacted?
- How will potential participants find out about the research?
- How will potential participants express interest in, or take part in the project?
- How will participants be screened to ensure they meet criteria?

Over-researched populations

Some populations are repeatedly identified as potential participants; this can occur if the population is easily accessible and/or their characteristics make them unique or of interest. Section 1.4 of the [National Statement](#) specifies that research must not place an unfair burden on particular groups and that there should be no exploitation of participants. When planning a project and writing an ethics application, researchers must consider and address:

- whether potential participants have previously been asked to participate in research and what additional burdens this new research will place on them
- the potential benefits that may flow to the population
- how vulnerable the potential participants are
- if they have previously participated in other research, whether it is discriminatory to deny them the chance to participate (particularly if this would prevent them from accessing benefits).

Identifying potential participants

Method	Considerations
Using lists of potential participants - an organisation's mailing, client, or employee list	<ul style="list-style-type: none"> • legal restrictions/privacy laws • where organisations will contact participants on the researcher's behalf they must: <ul style="list-style-type: none"> ○ only use ethics approved materials ○ confirm that the approach is made on the researcher's behalf and that personal information has not been given to the researcher ○ state whether they will know who participates • for researchers to access the lists directly: <ul style="list-style-type: none"> ○ the organisation must provide written approval ○ potential participants must have given the organisation permission to release their details to third parties
Cold face-to-face contact - walking up to people you do not know (e.g. in waiting rooms, outside a shop)	<ul style="list-style-type: none"> • people approached may feel obliged to participate • potential participants may feel threatened or annoyed • there may be risks to researchers depending on the location • approval may be required by third parties (e.g. festival organisers)
Familiar face-to-face contact - approaching people known to the researcher (e.g. colleagues, friends)	<ul style="list-style-type: none"> • people approached may feel obliged to participate, especially if there is an existing relationship • the approach must not be coercive or insistent • whether existing relationships expose either party to risks

Introduced contact - researchers are introduced by someone (e.g. a group facilitator)	<ul style="list-style-type: none"> participants may feel obliged to participate because of their relationship with the intermediary may feel intrusive if introduced during service provision
Snowballing - potential participants are identified by existing participants, often by forwarding or sharing recruiting material	<ul style="list-style-type: none"> researchers should not be given names or contact details without permission—existing participants should provide potential participants with researcher details participants may feel pressured to participate through their existing relationship only ethics approved materials should be forwarded or shared
Self-identification - potential participants identify themselves in response to an advertisement	<ul style="list-style-type: none"> this is often the lowest risk approach to recruiting permission may be required to post flyers on noticeboards or to post materials to social media or other pages (e.g. from group moderators)
Public Sources - identifying participants via publicly available information (e.g. website)	<ul style="list-style-type: none"> during initial contact, researchers should explain how they got their contact details and why they have been targeted
Professional Sources - information not available to the public (e.g. organisation's internal phone directory)	<ul style="list-style-type: none"> organisational approval may be required similar considerations to approaching using organisation lists (see above)
Private sources - personal information (e.g. personal email addresses) of people known to the researcher (e.g. former students or clients)	<ul style="list-style-type: none"> people approached may feel obliged to participate, especially if there is an existing relationship privacy considerations may prevent the use of this information for research purposes this approach often raises ethical issues that are not easily addressed (e.g. blurred relationships between students and teachers)
Mandated or referred participation - an authority directs individuals to do an activity (e.g. prison authorities/ inmates, principals/ students)	<ul style="list-style-type: none"> raises ethical issues regarding voluntary participation if possible, the mandatory activity and the research should be separated (e.g. pre and post activity surveys are optional) further complicated if researchers conduct the mandatory activity

Approaching potential participants

Contacting potential participants before they have consented to participate can expose them to risk. Common methods of approaching participants, along with ethical considerations, are outlined below.

Method	Considerations
Direct correspondence - to individuals or group lists by posting a letter, sending an email, phoning	<ul style="list-style-type: none"> recruiting material must not disclose participant information (e.g. return labels on envelopes that may indicate a disease) correspondence must explain: <ul style="list-style-type: none"> whether personal information has been disclosed to the researcher (e.g. through a company list) who has distributed the correspondence the degree to which third parties (e.g. the organisation distributing the material) will know who participates all recruiting text (including phone scripts) must be approved care must be taken during all forms of contact (e.g. when leaving messages with other people) a third party may need to authorise the distribution
Flyer/notice/ad (indirect) - on noticeboard, website, social media, chat room, etc.	<ul style="list-style-type: none"> a low-risk approach because participants self-identify

	<ul style="list-style-type: none"> • easy to target specific groups (e.g. a banner on a sporting club's website, via posts in specific social media groups) • those assisting with recruitment must be respectful of social media rules and take care not to annoy members by repeatedly approaching the same group • depending on the nature of the project, marketing@usc.edu.au may be able to provide guidance in the design of a recruitment strategy and management of social media (e.g. turning off comments to ensure that potential participants are not unexpectedly identified by being tagged in a post)
Flyer/notice/advertisement (direct) - presenting material directly (e.g. handing out flyers)	<ul style="list-style-type: none"> • may require permission to do so (e.g. shopping mall management) • participants may feel pressured or annoyed
Face-to-face Cold - unknown (e.g. door knocking) Familiar - known to researcher (e.g. co-workers) Introduced - third party (e.g. introduced to support group)	<ul style="list-style-type: none"> • appropriate time and space (especially for riskier research) to consider their participation must be provided • may be perceived as threatening, pressuring, or annoying • consider risks to researchers • consider that existing relationship may influence participation decisions • intrusion should be minimal
Third party - third party contacts potential participants (e.g. employers email employees, survey panels)	<ul style="list-style-type: none"> • potential participants must not feel pressure to participate (e.g. assure that employer won't know who participates) • third parties must understand the importance of circulating only ethics approved recruitment materials

Risks during recruitment phase of project

Recruiting can raise risks for participants, researchers, and/or third parties, which may be difficult to address because they occur before an individual has consented to the research. These potential risks must be identified and addressed during research design and throughout the ethics application.

Participant risk

- **being a potential participant:** meeting the inclusion criteria and/or the decision to participate could expose participants to social, legal, or other risk if third parties knew they were participating (e.g. if it was known that gang members were being interviewed)—confidentiality of participants must be maintained through all phases of the project
- **impact of the initial approach:** for example, if the project relates to domestic violence, sending correspondence to the home could expose participants to risk if the correspondence was intercepted by the abusive partner
- **risks from screening mechanism:** results of screening may put participants at risk (e.g. stigma if identified as having a psychological condition), or the tests themselves might be a source of risk (e.g. physical risks of a test)

Researcher risk

- **aggression from potential participants:** people may respond aggressively to being approached
- **risks of conducting research in homes, or private or secluded locations:** consider risk factors and address these risks (e.g. recruiting in a location where an alarm could easily be raised, checking in with people at agreed upon times, or recruiting with another person)

- **psychological distress:** researchers could be exposed to distressing information or circumstances (e.g. reviewing files related to violence)—incorporate some form of debriefing mechanism or support into the project
- **criminal, civil, or other legal risk:** researchers may be exposed to legal risk (e.g. recruiting in countries with oppressive regimes)—these risks can be serious and difficult to address; researchers should consult widely and implement strategies to mitigate risks

Third party risk

- **risks to relatives/friends/colleagues:** recruiting might indirectly identify other at-risk groups (e.g. recruiting children of abused women could expose the woman to risk)
- **risks to organisations involved in recruiting:** third parties involved in recruiting may be exposed to risk (e.g. losing customers who are offended by recruiting material)

Privacy and regulatory issues

The Queensland Information Privacy Act applies to UniSC researchers even if the originally collected data was not subject to these regulations (e.g. collected in another country). This section introduces the ethical and privacy issues that apply to the recruiting portion of a project. For a more complete discussion of regulatory and privacy issues, please see [Guideline 5](#).

Recruiting can be problematic if identified personal information is required to screen potential participants and/or to identify who to approach (e.g. identifying people with an illness by accessing medical records)—the identified information is required but ethical and legal considerations dictate that the files should not be accessed without the prior consent of the individuals. Even when a researcher has access to these files for another reason (e.g. a UniSC staff member may have access to academic results) this does not mean they can access those records for research.

If accessing personal data from third parties during recruiting, consider the following:

- Does a blanket consent exist that authorises the third party holding the data to release it for research purposes? If yes, separate consent to access the data may not be needed.
- Is the research project consistent with the purpose for which the information was originally collected and do the identified individuals understand that their information might be used for such research? If yes, separate consent to access the data may not be needed.
- Is it practical to obtain consent from individuals to access their data for the purposes of identifying potential participants? Consent may be sought directly by the third party or distributed by the third party on behalf of the researcher.
- Can the third party that holds the identified information contact potential participants and provide them with the researcher's details?
- Could the third party provide a coded version of the information to enable researchers to identify potential participants so that the third party could contact those specific people?
- Does some form of exemption mechanism apply (e.g. Section 95/95A of the Commonwealth Privacy Act for Health research) that allows researchers to seek a waiver for obtaining informed consent?
- Is it possible for the third party to provide de-identified information and for the research to be conducted using only that information?

Screening and exclusion

Screening potential participant pools to exclude or include specific people may be necessary to provide valid and important protections, especially when the research will involve significant risks. Common screening strategies include:

- to include or exclude persons with specific medical conditions

- to include or exclude persons from a specific genomic group
 - to exclude persons to minimise a risk factor (e.g. excluding people with mental health problems that may be exacerbated by the research)
 - to exclude persons because their participation is ethically or legally inappropriate
- to exclude persons who are under 18 years of age.

Ethical considerations of screening

Researchers should address the following:

- Is the screening fair and justifiable based on the data being sought or because it is a mechanism to address risk?
- Could the screening have a distributive justice implication (e.g. denying individuals access to an experimental treatment or other benefits)?
- How will the screening be implemented (e.g. self-screening for an online survey, controlling who can access a website by providing login details, via an in-person questionnaire)?
- How will the rationale for screening be explained to potential participants?
- What will an excluded person be told about the reasons for their exclusion? Who is the appropriate person to offer the explanation? Should the individual be referred to a support service or encouraged to seek assistance and/or treatment?
- What (if any) records will be maintained about exclusions. Why will such records be kept?
- How will the screening process be justified and explained in the reporting of the research?
- Does the screening create any limitations on the validity of results for a wider population (e.g. excluding English as a second language participant could skew data)?
- Does the research unintentionally exclude participants (e.g. online research may exclude lower socio-economic groups or seniors)? If yes, does this affect the validity of the data?

Ensuring that the above issues are addressed in the recruiting and/or informed consent materials allows potential participants to:

- understand why they might be included or excluded
- understand that the risks associated with participation might be greater for some people
- self-identify as to whether they are suitable to participate.

Screening based on demographics

Screening participants on age, gender, language, socio-economic status, and/or a disability can raise justice issues. The ethical principle of justice means that it is not ethically acceptable to exclude people on such grounds, unless there is a valid reason (e.g. to minimise risk, as a control variable, or because the research would not be culturally acceptable to a group). Such screening could:

- unfairly exclude people from the benefits of participation
- distort the results or create a limitation on the validity of the results
- perpetuate social inequalities, prejudice, and/or discrimination.

Negative consequences of screening

Being included or excluded from a research project may expose participants to risk. This could happen where inclusion or exclusion criteria expose a condition and where third parties (e.g. employers) may know who has participated. Researchers must attempt to minimise these risks and should modify recruitment processes to protect the confidentiality of participants. Potential participants may complain about being excluded from research if they believe they are missing out on a benefit of participating or if they feel that they had been unfairly and/or inappropriately excluded.

Screening to minimise risk

Researchers must consider whether the potential participant pool includes people who are susceptible to the identified risks or who will suffer greater consequences if the risks occurs. The recruitment process should include a mechanism to identify these individuals in order to exclude them or to provide them with additional support and/or protections.

Screening prior to consent

When designing a screening or exclusion process, it is important to consider whether consent to participant should be obtained before or after participant screening occurs. In cases where participants self-identifying whether they are eligible to participate, a specific screening process may not be required (beyond information being provided in recruitment and consent materials). Where screening processes do not involve the disclosure of personal or sensitive information, it may be feasible for screening to occur prior to informed consent being obtained. In cases where participants will be asked to disclose personal or sensitive information as part of the screening process, it is preferable for informed consent to be obtained prior to screening. This allows participants to be informed of what the screening process will involve and how this data will be used prior to being asked to disclose personal or sensitive information. Where possible, screening processes should limit the disclosure of personal or sensitive information.

Some research projects may require screening before recruiting and/or before informed consent is sought from potential participants—this is common in medical research. Some research may require a test or other assessment to determine the suitability of a participant. Such an approach is valid if:

- the selection process does not involve any risk of harm
- the selection process does not involve sensitive personal information
- the data of excluded people will not be retained, analysed, or used.

If any of the above conditions are not met, some form of informed consent will be needed for the screening process. If the above conditions are met, potential participants should still be briefed about the testing, including explaining who might be excluded and what will happen to their results.

Self-screening vs researcher screening

Researchers should consider whether it is sufficient to have potential participants self-screen, or whether tests, examinations, and/or consultations with clinicians will be needed to determine whether the participation of an individual is appropriate. This should be informed by:

- the seriousness of potential harm if at-risk individuals are not excluded
- the complexity of the research and/or medical conditions and the degree to which individuals would be able to self-screen in an informed way
- the degree to which potential participants might be living with an unknown condition
- whether there might be an incentive for potential participants to not disclose information (e.g. because of the perceived benefits of participation)
- the method of data collection (e.g. participants would self-screen for an online survey).

Screening by qualified professionals

When screening criteria requires some form of assessment by a qualified professional (e.g. by a psychologist), their expertise and experience must be made clear to potential participants. If a standardised test, or formulaic assessment are used, review and debriefing by a professional may be required to explain the results to the individual and/or to clarify any action to be taken.

Communicating screening results to potential participants

Screening results may be distressing for potential participants (e.g. diagnosis of a disease) or may be disappointing for them (e.g. being excluded from research that offers unaffordable treatments). The following should be considered:

- how to provide an explanation and justification for the screening process
- how the results of the screening will be communicated, by whom, and how disappointing or distressing results will be handled
- whether individuals might be offered information about other treatments or research projects
- whether excluded participants need to be referred to a clinician
- whether any third parties might be affected by results (e.g. siblings knowing genetic results).

Referring screened participants to clinicians or other professionals

If, through screening, a medical condition is identified, it may be necessary to refer individuals to a clinician, or to urge them to consult with their general practitioner. If an immediate and acute risk is identified (e.g. suicidality), there may be a professional obligation to take appropriate action and/or to contact the relevant authorities.

Reducing perceived pressure to participate

Participants feeling pressured to participate is a significant ethical concern. Participants must be able to make a voluntary decision about their participation. Perceived pressures may arise because:

- there is an existing and/or potentially unequal relationship between the researcher and/or third parties (e.g. employers) and potential participants
- an employer or other significant person or organisation is sponsoring the research and/or encouraging participation
- there is an association between the research and a desired service, entitlement, or benefit
- the recruiting methods (e.g. face-to face recruiting)
- timelines regarding decisions about participating.

Strategies to reduce perceived pressures include, but are not limited to:

- giving potential participants time and space to review information and to decide
- using an independent third party (e.g. a market research company) to assist with recruiting
- using language and manners which are courteous, non-threatening, and free from pressure
- approaching people at suitable times and locations (e.g. they are not busy, there is privacy)
- ensuring that research related activities are clearly delineated from other activities (especially where the other activity might be compulsory)
- ensuring that participatory status is unknown (especially to third parties like employers)
- stressing that participation is voluntary and participation will not affect any existing relationships, course grades, treatments, etc.
- analysing participant data after a certain date (e.g. after grades are released).

Culturally appropriate recruiting

Recruiting must be done in a way that respects local cultures and/or Indigenous people, both within Australia and internationally. Examples of key considerations are:

- Is it necessary to consult with community Elders, council, or other leaders prior to recruiting?
- Will it be most appropriate for men to recruit men, and for women to recruit women?
- Are there physical locations where recruiting would be inappropriate?

- Are there days of the week or specific dates on which recruiting would be inappropriate?
- Are there any specific cultural protocols that should be adhered to (e.g. removing shoes)?

Where there are no members of a research team with the appropriate cultural knowledge, language, or experience, it may be necessary to seek the input of an advisor, or a local or Indigenous person to assist with the research. Examples of key considerations are:

- How will they contribute to the design and conduct of the research?
- Will they be a member of the research team or will there be monetary or other recognition?
- If they are translating, will it be necessary to further authenticate the translations?
- Does their involvement create risks for participants? If so, how will these risks be addressed?
- Will they encounter risks? If so, how will these risks be addressed?
- Will their contributions be recognised in publications or other research outputs?
- Will they have access to the data and/or results? Will they be authorised to use the data or results for their own purposes?

10. Payments to participants

Regarding reimbursements, the [National Statement](#) stipulates the following:

- 2.2.10: It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.
- 2.2.11: Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted.

Researchers wishing to reimburse participants should refer to the NHMRC document [Payment of participants in research: information for researchers, HRECs and other review bodies](#) for detailed guidance and ethical considerations.

At UniSC:

- It may be appropriate for some projects to offer participant payments—all payments are assessed on a case-by-case basis.
- Researchers must justify:
 - the payments being offered (including why the payments should not be considered coercive with regard to the circumstances of the participants)
 - the method of payment (see Payment Options below)
- Researchers should ensure cost centre management approval of potential payments prior to submission of an ethics application. (Refer to [FMPM – Expenditure & Commitments](#)).
- Payments may be done via prizes awarded to some participants or as a payment to all participants.
- Payments to reimburse participants for direct costs (e.g. travel or parking) are usually appropriate.
- Payments or prize values should be commensurate with time taken. For example, multiple smaller prizes (5 at \$20 each) for the completion of a survey rather than one large prize (an iPad) would be more appropriate.
- Researchers are responsible for obtaining any required permits for promotions including draws involving an element of chance,
- Any form of payment must be clearly outlined in the RPIS including whether partial payments would be made if a participant withdraws partway through the study.
- Advertised payments must be awarded as per the approved ethics application.
- Where participants are to remain anonymous, payments or prizes must be managed in a way that allows responses to remain anonymous (e.g. in an online survey, a separate survey at the end of the main survey may be used to gather contact details).

Payment options:

- **Direct cash reimbursements to bank accounts:** This is UniSC Finance’s preferred method of payment. Researchers would need to collect the participant’s name, email, BSB, and account number. Contact financial_operations@usc.edu.au for the bulk payment spreadsheet. Participant information should clearly state that these details would be required and that they would be securely stored by UniSC Finance. Consideration would need to be given to how the research team would store these details, or when they would be deleted, to ensure privacy and confidentiality in adherence with the approved ethics protocol.
- **Vouchers:** Vouchers may be used where this can be justified to be the most ethical way to make payments to participants. Researchers should note that: vouchers are a popular payment method for scammers; vouchers can be difficult to buy in bulk; and that, similar to petty cash, vouchers must be registered, stored, and tracked appropriately.

- **Gifts:** Gifts appropriate to the target participant group may be offered. Consideration needs to be given to how gifts would be delivered, what personal details would be required to do so, and how these would be managed to ensure privacy and confidentiality of participants.
- **A donation per participant to a selected charity:** Although this is not a payment to a participant per se, this is an increasingly popular method of providing an incentive that does not require participants to provide any identifiable details. Donations are often made to a charity or organisation that is relevant to the research being undertaken. Researchers should ensure cost centre approval for this funding prior to submitting the ethics application.

11. Informed consent

Informed consent is the process through which potential participants are given information about the research before they decide to participate. As per the [National Statement](#) 'consent should be a voluntary choice and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.' Refer to:

- Chapter 2.2 of the National Statement
- Chapter 2.3 of the National Statement and [Guideline 12](#) for information relating to limited disclosure, deception, and qualified or waived consent
- Section 4 of the National Statement and Guidelines 24-28 for ethical considerations relating to specific participants, some of whom may be unable to make informed consent decisions on their own.

Approaches to consent

The approach to consent must be:

- appropriate for the subject matter
- relevant to the context and methodology of the research
- respectful to, and appropriate for, potential participants (language, delivery, structure)
- suitably detailed in line with project complexity and risk
- free from pressure and coercion.

Approaches to consent include:

- **implied consent**—not used at UniSC (as anonymous surveys must contain a consent question)
- **verbal consent (in response to written information)**—commonly used for interviews that are audio recorded and transcribed and/or where written consent is inappropriate (e.g. could expose participants to risk, is inappropriate for cultural reasons etc.)
- **verbal consent (following verbal briefing)**—this mechanism may be best when literacy levels are unknown or low, or where participants may not trust formal documents
- **written consent**—this may involve signing a paper form, confirming consent via email, or ticking to agree to a consent question on an online survey. Written consent is preferable when:
 - there is a greater than low risk of harm
 - where risk is not increased by seeking written consent
 - it can be conducted in a way that is meaningful and appropriate for the participant pool
 - published results may identify participants
 - it might be necessary to confirm what participants were told and what they consented to.

Required features of an informed consent mechanism

Research Project Information Sheets (RPIS) and Consent form templates are available on the [Portal](#). As much as possible, participants should be provided with written information that they can keep. The following information must be on the RPIS:

- **UniSC logo** (except in cases where the work is mainly being conducted by another institution)
- **ethics approval number**
- **project title** (clear, in language appropriate for participants)
- **researchers** and their roles on the project, with contact details for at least one. (If there are several researchers and/or a researcher has limited involvement, it may not be necessary to list them all)
- **project description and aims** (unless using limited disclosure)
- **selection of participants**—how and/or why participants were selected and/or identified, whether special criteria apply, and, if applicable, how researchers got their contact details

- **participation details** (e.g. what participants will be asked to do, location, duration etc.)
- **voluntary participation**—a statement indicating that participation is voluntary
- **benefits**, including to whom the benefits will flow
- **risks**, including the likelihood of occurrence, impact, strategies used to minimise or negate, and what participants should do if they experience them (e.g. call Lifeline)
- **consent**
 - how consent is given
 - whether anyone will be able to identify if they choose to participate
 - whether data will be identifiable and, if so, by who
 - whether the data might be used in future projects
 - if consent may be withdrawn throughout the project and how
- **privacy, confidentiality, and results**
 - how will data be stored (e.g. identifiable, re-identifiable), where, and for how long
 - how audio or visual recordings will be managed:
 - what kind of recordings will occur?
 - if they will be transcribed and by who
 - if they will be deleted after transcription (if no, why not)
 - who will access recordings?
 - whether they might participate without being recorded
 - how participants can access results
 - whether participants will get to review and approve comments prior to publication
 - whether participants will be able to access individual results and/or be debriefed (e.g. results of a psychological test with analysis by researcher or psychologist)
 - how results will be published (in what format—aggregated, identifiable etc.)
- **questions or concerns**—researcher details and the HREC Chair details.

Optional features of an informed consent mechanism

- why potential participants are being contacted (e.g. they previously agreed to be contacted about further research)
- who has approved the research (e.g. Queensland Health, participant’s employer)
- reimbursement of costs or time
- prize draws
- funding sources for the project
- conflicts of interests—actual or potential, real or perceived
- whether data might be re-used or shared, and in what format
- optional statements where participants can agree to specific uses of their data (e.g. a video clip being played at a conference, a photo being published)
- how the research will be monitored
- information related to the extraction, storage, and data related to human tissue.

Written consent forms

The UniSC *Consent Form* template ([Portal](#)) should be used and modified as required, such as:

- to allow for signature by another person (e.g. a parent or guardian)
- to be witnessed by somebody else (e.g. for an adult with an intellectual disability)
- adding options related to audio or visual recordings or the use of images
- adding options to consent to future contact for other research
- adding statements to reiterate that participants may be identifiable, or identifiability may be inferred.

12. Observation without consent, limited disclosure, opting-out, or waived consent

Refer to Chapter 2.3 of the [National Statement](#): Qualifying or waiving conditions for consent. There can be circumstances where it is ethically justifiable to not seek consent, to not fully disclose project information to participants, or to request waivers of consent. For example:

- **Observation without consent:** observational research where it would not be feasible to get consent from all ‘participants’ (e.g. observing members of the public to see how they interact with a public space) or where consent would change behaviours (e.g. watching hand washing stations in a restaurant)
- **Limited disclosure:** projects that involve a degree of deception where full disclosure could bias the participants (e.g. participants are told that a test assesses memory recall when it actually assesses the impact of performance anxiety on memory related tasks). This approach to consent must be justified in the ethics application against each point in section 2.3.1 and, as required, 2.3.2, of the National Statement.
- **Opting out:** potential participants are notified and advised that if they do not want their data included that they would need to advise the researcher (e.g. researchers may email a cohort to advise that their assessment grades will be analysed—students who want to be omitted would need to let someone know). This approach to consent must be justified in the ethics application against each point in section 2.3.6 of the National Statement. See the [example](#) below.
- **Waivers of consent:** projects in which researchers will not seek consent and this is approved by an HREC or delegate (e.g. accessing a data set, such as student records or clinical data without participant consent to do so) This approach to consent must be justified in the ethics application against each point in section 2.3.10 of the National Statement. See the [example](#) below.

The above categories are not mutually exclusive and some types of research may involve more than one of these approaches to consent. The context of the research may determine the most appropriate strategy. For example, observations of people in a public place may not require specific consent—such projects may be eligible for an exemption (as per Section 5.1.17(b) of the National Statement) or an opt-out strategy or a waiver of consent could be used.

Consider the difference between observing people in a busy city square versus observing local children playing a game in a small village square. In a busy city square, a researcher may not be noticed and seeking consent would be impractical. In a smaller setting, it may still be impractical, and perhaps culturally inappropriate to get specific consent, but it may be useful to seek consent from a village Elder, or to notify villagers of the research and to offer them an opportunity to opt-out (e.g. they may speak to the village Elder to voice their concerns/non-consent).

The ethical justification and level of review of such research rests upon questions and considerations such as:

- Is this the only practical way to pursue the objectives of the research?
- Do the anticipated benefits of the research justify such an approach?
- Will participants be exposed to increased risk?
- Will the full details of the research be provided to participants at a later point?
- Would participants agree to participate if they were aware of the full facts about the project?
- What is the extent of, and the reasons for, the deception or limited disclosure?
- Will data be identifiable or non-identifiable?
- Was the data that was originally collected of a sensitive nature?
- Is it practical to contact potential participants to offer an opt-out, or does the nature of the research mean that a waiver is suitable?
- Is concealment ‘active’ (e.g. the use of a blind or other mechanism to conceal a researcher’s presence and/or data collection activity), and if so, what is the nature of the research and level of risk (e.g. secretly watching a hand washing station vs secretly watching illegal activity)?

Opt-out approach example

When an opt-out approach to consent will be used, answer yes to question 2.2.7 in the HREA and in the question that follows, (and/or in the protocol) justify this approach against each criteria point. The following is provided as an example only—responses can also be provided as ‘a story’ similar to the waiver example below.

a) involvement in the research carries no more than low risk to participants (see Chapter 2.1). b) the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy

The data being requested is de-identified responses to surveys and questionnaires that were done when clients first accessed XYZ’s services, and at the completion of the program. Data will be presented in publications and findings in an aggregated way in which there is no risk of any individuals being identified. As the service being provided by XYZ is designed to assist clients with ABC issue, which is highly prevalent in the community, the benefit of the project outweighs any risks.

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

To ensure statistical validity, the full data set of approximately 1500 clients of XYZ organisation is required. This would represent a span of 10 years and it is important to this research that there be data points across time. As many of the clients use the service only once for a brief period, and there is generally no further contact, gaining explicit consent would be difficult and based on XYZ’s knowledge of their client base, they do not anticipate that many would respond to a request for consent.

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

XYZ organisation will send an email to their client contact list. The email will have a brief description of the project, the details of the investigators, and the instructions, and link, to opt-out of being included. A full version of the RPIS will be provided as a link to the project information website.

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

The clients will have three weeks, from the date of the email above, to ask that their data not be included.

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

Participants will be advised in the initial contact email, and on the RPIS, that they can contact the listed investigators to discuss the project. They will be advised in the contact email that they can email the project email, project@usc.edu.au, or they can click an ‘opt-out’ button in the email, by X date (3 weeks after sending) to ask that their data not be included in the research data set.

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

Data will be collected and stored securely as per UniSC’s data management procedures. While the project is ongoing, the research team will collaborate via a password-protected Sharepoint site and upon project completion data will be stored in R drive.

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

XYZ Organisation and the UniSC researchers have a data management agreement in place and both will follow the required governance procedures in place at their organisations.

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

The team is not aware of any reason why this approach to consent would be prohibited.

Waiver of Consent example

When a waiver of consent is being requested, answer yes to question 2.2.8 in the HREA and in the question that follows, (and/or in the protocol) justify this approach against each criteria point below:

- a) involvement in the research carries no more than low risk to participants (see Chapter 2.1).
- 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.

The following example is presented as a guide only. In the above opt-out example, each criteria was addressed separately; however, it can also be done similar to the example below as long as all criteria are covered.

Specific consent will be obtained for all aspects of the research project with the exception of XYZ's historical evaluative survey data. The researchers request a waiver of consent for the secondary use of XYZ's evaluative survey data, based on the following reasons:

First, the surveys have been modified so that any qualitative question that may yield names or identifying information have been removed and such qualitative data will not be used in any analysis. The researchers accept that it is of utmost importance to protect the identity of these vulnerable individuals. There is negligible risk that a client may be able to identify their individual survey response. However, given the anonymity of the data collection process, the organisation is unable to identify who participated in the survey and who did not participate. The researchers believe that the risks of obtaining consent from every individual who were involved with the organisation since 2013, outweighs the risks of proceeding without consent.

The benefits of this research include, contributing to the limited literature about [topic] in Australia. Specifically, the results from the research may be able to inform the development and expansion of future programs. These programs seek to benefit the community, in particular the safety of the public. [Topic] is a financial burden on the economy so research focussed on lessening the prevalence and related outcomes of [topic] will be of great benefit to the public and society. Furthermore, this research will benefit and improve the services and practises of XYZ. Specifically, this research will assist with program funding which will enable the organisation to continue to support [target population]. Therefore, the researchers believe that the outlined benefits of this research outweigh not gaining consent from all clients for the secondary use of their data. Under privacy legislation we as researchers are not permitted access to participants' contact details. The data dates from 2013, therefore contacting those who participated several years ago could create an unnecessary burden on them. For example, given the sensitive nature of this topic, for some individuals this may have been a highly emotional and traumatic experience. Receiving a letter requesting consent many years after may be triggering for them, and neither the researchers or the organisation would be in a place to be aware or put support in place for such an occurrence.

Given the participants freely and anonymously participated in the surveys initially, it is likely that they would also consent to the secondary use of the data. As stated above, the data was collected anonymously and is non-identifiable and unable to be linked with the person who completed the survey by the organisation or by the researchers. Therefore, the privacy of the people who completed the surveys are sufficiently protected. In addition to the non-identified data, on analysis of the data each survey response will be given a further de-identifying code to protect confidentiality. The data will be treated sensitively and will be stored securely on R drive. At no stage will the organisation be given any information which might enable them to identify individual responses.

As participants and their responses are non-identifiable, it is not possible to make the findings available to individual participants. There is no possibility of commercial exploitation and to the researchers' knowledge, there is no prohibition under State, Federal or International law for use of the data.

13. Managing human research data

Regarding data management, researchers should be familiar with the following:

- Chapter 3.1 of the [National Statement](#)
- UniSC [Research Data Management – Procedures](#)
- UniSC research data management site - [Nexus](#)

The National Statement should be consulted in specific cases for advice—this is particularly relevant where data is stored in databanks or where the data consists of genetic information.

UniSC staff should note that just because they can access certain information for operational or academic reasons (e.g. course results), this does not mean they have the right to access this same information for research purposes. If it is unclear who the relevant UniSC data custodian is, advice should be sought from the Insights and Analytics Unit, who can assist with identifying and obtaining authorisation from the appropriate data custodian. In cases where the data custodian is associated with the research project, authorisation from a higher level custodian will be required.

Principles of managing human data:

- data managements protocols need to consider:
 - the ethical sensitivity of the data (e.g. medical records vs. opinions on music)
 - the identifiability of the information (see the 'Identifiability of information' section in the National Statement)
 - whether the identification of participants would expose them to any risks
 - whether the data are being published, and in what format (e.g. quotes vs aggregated results)
 - whether third parties (e.g. market research companies, other UniSC staff) are collecting, or accessing the data
 - the right of individuals to access personal information about themselves on request
- data should be managed and stored as per the approved ethics application, with amendments sought as required
- data should be managed as per the RPIS, which is provided to participants and includes:
 - the level of identifiability of the data at various stages of the project
 - who can access the data (e.g. members of the research team, third parties)
 - how the data will be used (e.g. publications, conferences)
 - whether the data can be used in related or future research projects
 - whether the participants will have the opportunity to review their data (e.g. quotes)
 - whether participants will be able to access their individual results and how that will be managed
- data must be stored securely and disposed of securely in line with the UniSC's [Research Data Management – Procedures](#)
- data related adverse events or breaches of protocol (e.g. data are accessed by unapproved persons or data are lost) must be reported to the Office of Research

Strategies for managing human data

Data security

- ensure all members of the research team, and any involved third parties, are familiar with the approved protocol
- if it is methodologically sound, as soon as it is feasible, reduce the identifiability of data (e.g. change individually identifiable data into re-identifiable data, and re-identifiable data into non-identifiable data)
- control access to the data to authorised personnel (the research team, or specific members of the research team)

Electronic data

- store electronic data on password protected computers or servers (e.g. UniSC Research Drive)
- refrain from using USBs to store data as they can easily be lost—if you must use a USB or external hard drive, password protect data and store the device securely
- delete audio recordings once transcripts have been produced (except where the recording provides information that would not translate into a transcript, such as in a linguistics project)
- when emailing data, be careful of ‘replying all’ if not all recipients have approval to access data.
- when emailing data, use a secure network, password protect the file, and send the password separately
- ensure that data stored online (e.g. in clouds) is appropriately secured and that only relevant researchers have access

Hard copy data

- store all hard copy / paper based data in locked filing cabinets
- if it is methodologically sound, consider converting hard copy data into electronic data
- ensure disposal is done securely (e.g. document destruction bins, shredded)

Publishing data

- check with participants before publishing quotes (even if the quote is non-identifiable)
- ensure information is presented in a way that minimises the chance of identity being inferred
- when emailing summaries of results to participants, do not “cc” the list of participants, “bcc” is appropriate if done with care

Participant consent

- use the *Research Project Information Sheet* and *Consent Form* templates (available on the [Portal](#)), which contain prompts for all required information/statements
- clearly articulate who can access the data (e.g. to minimise risks not all members of the research team may be able to access individually identifiable data)
- clearly articulate issues relating to inferred identity (i.e. where the data non-identifiable but where certain people may be able to infer the identity of the participant from published results)

Third parties

- inform the liaison person of the confidential nature of the data and of the need to follow approved protocol—ensure that they will communicate this to others in their organisation
- limit the number of third parties
- identify all persons who may come in contact with the data, inform them of the confidential nature of the data and of the need to follow the approved protocol
- send data to the researchers as per an approved schedule
- place information into appropriately marked envelopes (e.g. ‘confidential, do not open’)
- keep materials in secure locked boxes

General

- keep codes used for re-identifiable data separate from the data itself
- keep consent forms separate from the data itself
- do not use identifiable consent forms unless necessary (e.g. use tick based consent for anonymous surveys)
- if storing data at home, ensure if it stored securely
- be careful when transporting data (e.g. take hard copies in carry-on baggage if possible)

14. Secondary use of data or information

Refer to Sections 3.1.50 – 3.1.62 of the [National Statement](#), which states that ‘research may involve access to and use of data or information that was originally generated or collected for previous research or for non-research purposes, including routinely collected data or information’. This may include researchers:

- reusing their own, or their collaborators, previously collected human data or biospecimens to conduct new analysis or to verify earlier results
- being provided with a data set from an external organisation
- using organisational data such as student records
- accessing data through a repository or biobank
- using information that is publicly available
- downloading online content such as social media or other comment threads.

The secondary use of data is subject to the same considerations and regulations (e.g. privacy legislation) as the original collection and an ethics submission is required for all of the above scenarios. The overall context of the project will need to be considered before a review pathway can be determined and this will depend on factors such as:

- the mechanism and scope of consent for the originally collected data and whether documented evidence of this consent can be provided
 - Was consent informed (e.g. via a previous project information sheet)?
 - Did consent allow for future use?
 - Was future use an option or was it given as blanket consent (e.g. on a registration form or by ticking to agree to terms and conditions)
- whether seeking specific consent for the new work would place additional burdens on the participants
- the practicalities, or impracticalities, of obtaining specific consent for the new work
- the identifiability of the data
- the sensitivity of the data
- whether the secondary use is culturally appropriate
- the relationship between the original and the proposed research
- privacy considerations and legislation
- whether the proposed access to or use of the data or information would match the expectations of the individuals from whom this data or information was obtained or to whom it relates
- how results will be used and disseminated

Review Pathways for secondary use of data or information

As noted above, every project involving the secondary use of data or information is different, and there are many factors that can determine which review pathway is more appropriate (see [Guideline 3](#)). While the HREC Chair will determine the final review pathway that is used for a project, the discussion below intends to provide guidance.

Researchers who are **reusing their own, or their collaborators, previously collected human data or biospecimens to conduct new analysis or to verify earlier results** may be able to apply for approval via the exemption pathway if they can satisfy the criteria in section 5.1.17 of the National Statement. For example, the re-use of data collected via an anonymous online survey, which had extended consent for future use, may be eligible for an exemption. The original informed consent mechanism should be provided with the exemption request.

Review via an expedited or full review pathway would be required if the previous consent was specific to that project only, or if the data was originally identifiable to the researcher, or if the subject matter was such that the survey responses may have contained sensitive information (e.g. there were open-ended questions about mental

health issues or illegal activities). Whether a project could be expedited or if it needed full review by the HREC would depend on the factors listed above—most notably, the original consent and the level of risk inherent in the data. When re-using data, if the original consent did not allow for future use, researchers would likely need to request a waiver of consent—for innocuous topics or low-risk participant groups, an expedited review may be possible. A waiver of consent to analyse sensitive health care data, even if it is de-identified, and particularly if the original participant cohort could be considered vulnerable, would require HREC review.

A similar logic applies when researchers are **being provided with a data set from an external organisation**. As always, the main considerations are the original purpose of the data collection, what the participants would have understood regarding the use of their data and information, and what, if any, consent was obtained. Most external organisations collect data with no clear consent process because the data is usually collected for evaluation or internal reporting purposes rather than research. In some cases, a weak consent mechanism exists in the form of a blanket consent statement on a registration form, or terms and conditions that are a take-it-or-leave-it option, which does not meet the criteria of consent for research being ‘informed’.

Although being provided with a de-identified data set may appear to meet the criteria for an exemption, again, the overall context of the project must be considered. It may be difficult to justify research against the criteria that the research ‘carries a lower risk to participants and the community’, particularly where health care records are being provided. Even when de-identified, these can be considered personal information, which is sensitive and therefore carries risk—this combined with the fact that consent for research was not informed (e.g. a blanket statement on a registration form), and therefore a waiver of consent needs to be requested, would mean that full review by the HREC would be required.

If researchers have an ongoing relationship or collaboration with specific external organisations, they should work with the organisation to strengthen their processes to include robust consent mechanisms that provide an option for future use of data for research purposes—such future consent must be an option and not a blanket agreement.

At UniSC it is common for researchers to request approval to **use organisational data such as student records** (e.g. course or assessment grades, attrition rates, demographic data, etc). Organisational data can only be used for authorised purposes. While staff may have access to organisational data or student data as part of their role, ethics approval and authorisation from the data custodian is required to use this data for research purposes. If it is unclear who the relevant UniSC data custodian is, advice should be sought from the Insights and Analytics Unit, who can assist with identifying and obtaining authorisation from the appropriate data custodian. In cases where the data custodian is associated with the research project, authorisation from a higher level custodian will be required.

An exemption may be possible if the research can be justified against the criteria set out in section 5.1.17 of the National Statement. See [Guideline 3](#). In other cases, an opt-out approach or a waiver of consent can be requested via an ethics application. For example, if data collection was recent, such as the last semester’s course grades, it may be appropriate to email the class with project details and to ask them to opt-out of their data being included by a certain date. Where several years of data will be used, requesting a waiver of consent may be a more practical option. Whether this can undergo an expedited review would depend on factors such as the nature of the data (e.g. assessment marks vs disability status), the aims of the project and how results would be disseminated, and the participant cohort (e.g. all students vs Indigenous students).

Sharing of data and open access is increasingly common and is often required by journals as a condition of publication. As such, researchers may wish to **access data through a repository or biobank**. Again, the overall context of the project must be considered. An exemption may be possible where the criteria of section 5.1.17 can be met. Information about the repository or biobank should be provided, including evidence that the data was collected ethically (e.g. a terms and conditions website, their consent proforma).

The use of existing data and information that may be eligible for approval via the exemption pathway where it is lower-risk and where ‘the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law’ (see [Guideline 2](#) and [Guideline 3](#)).

As per [Guideline 2](#) and [Guideline 23](#), downloading online content such as social media or other comment threads will require ethics review via the expedited or full review pathway depending on the overall context of the project.

Submitting an application at UniSC to re-use previously collected data

When submitting an application to UniSC, to re-use previously collected data, consider the following:

- If the research only involves the use of previously collected data and can satisfy the criteria outlined in section 5.1.17 of the National Statement approval may be granted via the exemption pathway.
- If the research does not satisfy the criteria for an exemption and/or the project involves more than the use of previously collected data, ethics review via another pathway will be needed (see [Guideline 3](#)).
- If the HREA form is being used:
 - For Q1.18:
 - select 'data associated with human beings only' if the project will only access existing data
 - select 'human beings' if the project will involve other methods, including active participants
 - For Q1.19: Please select any groups relevant to the research. This will bring up follow up questions which can be answered in the context of the project.
- In the application, clarify why and how data was originally collected, including the consent mechanisms originally use. Where possible, provide a copy of the consent materials provided to the original participants.
- If the original consent mechanism involved specific consent for the planned re-use of data it may be possible to avoid the need for further consent to be obtained. However, as above, blanket registration forms or terms and conditions are not considered informed consent.
- If the original consent mechanism did not involve specific consent for the planned re-use of data, clarify which of the following consent mechanisms will be applied to this project:
 - An informed consent approach where the original participants will be contacted to provide informed consent for the re-use of data. If this approach is to be used the consent materials that will be provided to participants as part of this project will need to be included in the HREA application.
 - An opt-out approach where the original participants will be contacted and given the option to advise if they do not want their data to be re-used in the proposed project (See [Guideline 12](#)). If this approach is to be used, answer yes in Q2.2.7 of the HREA form and answer the associated questions. In doing so, the criteria outlined in section 2.3.6 of the National Statement will need to be satisfied.
 - A waiver of consent to allow consent not to be obtained from the original participants (See [Guideline 12](#)). If this approach is to be used, answer yes in Q2.2.8 of the HREA form and answer the associated questions. In doing so, the criteria outlined in section 2.3.10 of the National Statement will need to be satisfied.
- Provide evidence of approval from the organisation and/or data custodian as relevant.

15. Research involving human biospecimens

Refer to Chapter 3.2 of the [National Statement](#), which defines ‘human biospecimens’ as ‘any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.’

Levels of ethics review

The level of ethics review will depend on:

- level of risk to the donor, and/or their relatives
- identifiability of the specimens and related data
- the process for biospecimen extraction
- the original use of the biospecimens and the original consent.

For example, projects that involve the collection of urine in a non-identifiable format for the current project only would likely be considered via an expedited pathway. Alternately, projects that involve the collection of biospecimens for analysis that could reveal distressing secondary results, or where identifying or medical information would be linked, would need to go to the HREC for full review. The HREC Chair will determine the review path based on the full application.

Consent

The National Statement stipulates that proposed research involving human biospecimens must be submitted for ethics review and that such work is subject to the standard principles of ethical conduct; it also acknowledges that different approaches to consent may be used. For example, researchers may have no direct contact with the original donor if the biospecimens have been sourced from a pathology laboratory or a tissue bank—these donors should still be considered as participants.

If human biospecimens have been previously collected and stored, researchers need to take reasonable steps to determine whether the original consent mechanism would cover their research. If not, they may need to contact the original donors to seek informed consent for their purposes, or consider an alternative approach to consent (e.g. a waiver of consent).

Any wishes expressed by a person about the use of their biospecimens post-mortem should be respected. If this was not stipulated in their records, researchers must obtain consent from the person authorised by relevant legislation.

Project specific consent should be sought where:

- the original consent mechanism stated that the data would not be used for any other purpose or used strictly for limited purposes
- the proposed research might yield a commercial benefit (e.g. a patent)
- the donor pool is likely to have included a significant proportion of persons who may have cultural concerns about the proposed research and use of their biospecimens.

Waivers of consent

Researchers can request a waiver of consent, which they must justify according to Section 2.3.10 of the National Statement. Where identifiable personal medical or health information will be accessed, the application will require review by the HREC. Researchers should provide the HREC with examples of the original consent mechanism and an explanation of the relationship between the proposed research use of the biospecimen and the purposes for which it was initially obtained.

When considering a waiver of consent, the HREC will also need to consider privacy issues such as:

- whether biospecimens are identifiable, or re-identifiable, by the research team
- whether results will be reported or communicated to other parties who will be able to associate the reported results with individuals
- whether the research team will have access to any other associated and identifiable personal information (e.g. medical records)
- the degree to which the identification of donors exposes them to a potential harm.

If there are privacy concerns, it is unlikely that the HREC will authorise the waiver of consent. Where there is identifiable information associated with the biospecimens there may be legislation that requires that specific consent is obtained.

Future research

If a project will involve the direct collection of biospecimens, researchers should consider whether allowing for the future use of these biospecimens may facilitate future research. This may be important if the biospecimens are rare or hard to obtain. This can be done by including options in the consent materials where participants can select how their biospecimens may be used in subsequent research. For example:

- consent to use for highly related tests or procedures
- consent to use for research in the same area and/or by the same research team
- consent to use for any research purposes and/or by any research team
- consent to share data in an identifiable or non-identifiable format with other researchers.

Results

Research involving the use of biospecimens has the potential to identify health or other information (e.g. paternity) of potential significance to donors and/or their relatives. In cases where the researcher or collecting laboratory can identify the donors, researchers must consider:

- whether the informed consent materials acknowledged that such information might result and how that would be managed
- whether donors could indicate if they wished to be provided with such information
- who would communicate the results (e.g. an appropriately experienced medical practitioner)
- whether the results could impact relatives (e.g. the identification of a genetic condition) and whether consent should be obtained from those relatives.

Where it is likely that these situations may occur, project specific consent will likely be required. A researcher might conclude that data should be collected and analysed in a non-identifiable way; however, a duty of care may exist and this may not be the most ethical solution. These issues need to be addressed in the ethics application.

Third party approvals

In the case where biospecimens are supplied by a third party and where the researcher will not have direct access to the donors, formal approvals may be required to confirm that:

- the original consent permitted future research use of the biospecimens
- the supply of the biospecimens for research purposes is not contrary to the *Transplantation and Anatomy Act*.

If these requirements are not clearly met, the HREC may request specific assurances. The absence of such assurances may result in the researcher needing to get project specific consent.

Commercially sourced cell lines

In cases where commercially available cell lines will be sourced from a reputable supplier who has relevant consent processes in place, the exemption pathway may be used at the discretion of the HREC Chair. Refer to [Guideline 3](#) for further information about the exemption pathway.

16. Genomic research

Genomic Research is defined in the [National Statement](#) as ‘research with the potential for hereditary implications which may range from single gene genetic research to whole genome sequencing and any other ‘omic’ research (e.g. exomic, proteomic, etc) with potential heredity implications. Genomic research includes the full scope of ‘genetic’ research.’ Genomic research is constantly evolving and may have implications not just for participants, but also for their relatives and communities; as such, genomic research creates unique ethical challenges.

Regulatory considerations

Researchers must be familiar with:

- Chapter 3.3 of the National Statement
- NHMRC’s [Principles for the translation of ‘omics’- based tests from discovery to health care](#)
- [Essentially Yours: The Protection of Human Genetic Information in Australia \(ALRC Report 96\)](#)

There is a growing body of regulation in genomic research and, as relevant, researchers must be familiar with legislation surrounding the use of human embryos, xeno-transplantation, genetically modified organisms, somatic gene therapy, stem cell work, and cloning. Different regulations may apply across different jurisdictions.

Resources are also available via the World Health Organization at [Human genomics in global health](#).

Level of ethics review

As per the National Statement, ‘as a general principle, research including genomics will require review by an HREC; however, if no information that can identify an individual is used and no linkage of data is planned, the research may be determined to carry low risk.’ Some applications may be considered via one of UniSC’s expedited pathways; the HREC Chair will determine the review path.

Consent

Ethical issues and requirements for consent specific to genomic research are outlined in sections 3.3.10 - 3.3.17 of the National Statement. Specific information must be given to participants and in some instances, participants must be able to select their preferences (e.g. whether results can be shared with relatives). Researchers should consider whether consent may be required from relatives or community members. There may be instances where a waiver of consent may be appropriate; researchers must justify a request for a waiver as per section 3.3.14 of the National Statement.

Returning findings and results

If a project will obtain results likely to be of significance to participants and/or their relatives, and the results are in an identified or coded form, researchers will need a protocol to manage the disclosure or non-disclosure of genomic information. Requirements and considerations are outlined in detail in Sections 3.3.26 - 3.3.61 of the National Statement, which includes the *Decision tree for the management of finding in genomic research and health care*. The ethical principles of integrity and beneficence mean that participants should have the option to receive these results; this may be done by including a separate ‘tick box’ option on the consent form.

Privacy, databanks and data management

Issues around privacy specific to genomic research are discussed in Sections 3.3.58 - 3.3.61 of the National Statement. The storage and sharing of data, including genomic data, is discussed throughout the National Statement. In general, where a researcher anticipates the sharing, banking, and/or future use of genetic material, the informed consent material should clearly articulate such details and seek the relevant consent from the participants.

Risks and harm in genomic research

Genomic research gives rise to the possibility of unique risks and harms such as:

- impact on familial relationships (e.g. unexpected paternity results)
- impact on relatives or communities
- personal distress (e.g. revealing likelihood of genetic conditions and/or future health issues)
- social risks due to stigmatisation
- discrimination (e.g. employers or insurance companies)
- impact on perceptions of self
- impact on perceived quality of life.

When considering an ethics application for genomic research, the HREC will expect that all relevant risks and harms have been identified and addressed, and that the informed consent materials explain to participants how their privacy will be protected and how results will be communicated to them (if they wish to receive them).

Genomic research and insurance

The potential impact on future insurance coverage could be a significant risk, which may not be immediately obvious to potential participants. This issue may need to be discussed in the informed consent materials to allow participants to make a fully informed decision about participating and/or receiving their individual results.

Please refer to information at:

- <http://www.genetics.edu.au/genomic/Recruitment-and-samples/insurance>
- <https://www.hgsa.org.au/documents/item/20>
- <https://www.australiangenomics.org.au/news-events/news/2018/parliamentary-committee-releases-recommendations-from-inquiry-into-australias-life-insurance-industry/>

17. Clinical research and clinical trials

Clinical research refers to a subset of human research activity that, in addition to medicine, can include psychology, nursing, physiotherapy, pharmacology, and allied health. The work can be undertaken within clinical institutions, private practice, university facilities, private residences, and elsewhere in the community. At times it may be difficult to distinguish clinical and related research from quality improvement and clinical audit. In such situations, guidance is available from the NHMRC publication [Ethical Considerations in Quality Assurance and Evaluation Activities](#).

Clinical trials fall under the umbrella of clinical research. A clinical trial is a form of human research designed to find out the effects of an intervention. Interventions may include a drug, diagnostic procedure, surgical procedure, therapeutic procedure or treatment, or the testing of any related devices.

When a clinical trial will involve work with a pharmacological agent, medical device, or complementary medicine that has not been approved for use in Australia the Therapeutic Goods Administration's (TGA) clinical trial arrangements apply. Not all clinical research are clinical trials, and not all clinical trials fall within the scope of the TGA's arrangements.

National and international guidance

Ethical guidance for clinical research at UniSC is underpinned by the following resources:

- NHMRC
 - [National Statement on Ethical Conduct in Human Research](#)
 - [Australian Clinical Trials \(ACT\)](#)
- [Therapeutic Goods Administration](#)
 - [Clinical Trials](#)
 - [Australian Clinical Trial Handbook](#)
 - [Clinical efficacy and safety guidelines](#)
 - [ICH Guidelines for Good Clinical Practice](#)
- World Health Organization – [Clinical Trials](#)
- World Medical Association – [Declaration of Helsinki](#)

Ethics review at UniSC

At UniSC many clinical research projects are reviewed by external ethics committees (e.g. Queensland Health or Bellberry) and the UniSC Office of Research processes these projects through the prior review pathway—see [Guideline 3](#). Clinical trials or health related interventions involving the use of a substance or device that has not been approved for use in Australia must undergo full review by the HREC, unless already reviewed and approved by an external review body.

Dissemination of clinical research results

The dissemination of results is an important component of the ethical conduct of research and, as per the [Australian Code for the Responsible Conduct of Research](#), is a key responsibility of researchers and institutions. In clinical research, there are often contractual constraints that impact what results can be released and when. Researchers must comply with these contractual agreements and must act responsibly with regards to commercial interests and privacy issues. When negotiating contracts, researchers should ensure that findings can be widely disseminated regardless of the results.

Sponsored clinical research

The fact that a clinical research project is sponsored does not automatically render the project ethically compromised—much clinical research would not be possible without sponsorship.

The important ethical consideration is the degree to which the sponsor is exerting undue influence over the design, conduct, analysis, and dissemination of results. In commercial research, researchers will need to find a balance between what the sponsor wants and the integrity of the research.

When there is some sort of sponsorship arrangement for research, researchers must:

- during negotiations, carefully consider if conditions requested by the sponsor could alter or compromise the research in any way (e.g. research design and methods, data analysis, dissemination of results)
- disclose sponsorship in the ethics application
- disclose sponsorship to potential participants
- ensure that analysis and reporting of results are accurate and honest
- disclose sponsorship in reports or publications
- ensure that sponsors lodge trials in an established and public clinical trial register.

Even when the research is conducted to the highest scientific and ethical standards, the failure to do the above could undermine the research and could constitute research misconduct.

Common issues in clinical research

Risks (after participation): In some cases, a risk may manifest after participation in the research. As such, the risk management strategy needs to allow for situations where the researchers cannot directly respond (e.g. giving participants details of what to do and who to contact). When the risks are serious and/or highly likely, a follow-up consultation between the participants and the researchers may be appropriate. It may also be appropriate to ask participants to remain in a rest area after participation or to arrange travel for them.

Risks (declaring participant status to clinicians): Treatment in a clinical research project may be incompatible with other treatments, and/or may be contraindicated or cause significant harm. If a participant is unable to communicate their involvement in a research project to a clinician (e.g. unconscious, unable to describe complexities) and/or the potential for harm is serious enough to warrant extra precautions, the participant may be given an information card to carry that would have an emergency contact number for the researchers.

Costs: Clinical research can involve costly tests, procedures, consultations, drugs, or equipment. Research costs cannot be charged to Medicare and are unlikely to be covered by private health insurance. If participants face any costs, this must be clear in the informed consent materials. If a sponsor is meeting the costs, this must also be declared to avoid conflict of interest issues.

Access to treatment after the research: An important consideration for clinical research is whether interventions will be available to participants after the conclusion of the research (including control group participants)—this must be made clear to participants. Making the intervention available is desirable and may be an important benefit to participants but consideration must be given to costs and other resource implications. This is of particular concern for research conducted in developing nations and/or with participants who would not be able to afford the treatment after participation.

Feedback and debriefing: It is expected that participants will be provided with a summary of the results of the research; in the case of clinical research, an individual's own results can be significant to them. Researchers must consider the following in their research design:

- whether participants will be offered their individual results
- how participants can request the results
- who will communicate the results and their significance to the participant?

- what counselling or other services will be made available if required
- whether the results might have significance for other people (e.g. siblings or offspring) and how will that be managed.

Using a third party in the informed consent process: In some cases, a person not involved in the treatment and/or care of a potential participant may be involved in the informed consent process. Such a strategy may reduce feelings of pressure that a participant may experience (e.g. they may not want to disappoint their carer/clinician). Researchers should consider whether the potential participant might feel uncomfortable with a third party accessing their information, and whether people involved in the participants care or treatment should also be involved as they know the participant and their condition.

18. Human research involving ionising radiation

Research that exposes participants to ionizing radiation must adhere to the [National Statement](#) and to the [Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes \(2005\)](#) (the Code). The Code is designed to assist researchers to provide sufficient information to potential participants and to allow the HREC to properly consider risks. As per s1.4 of the Code, the scope of these arrangements is limited to human research where participants are exposed to ionising radiation that is 'additional to that received as part of their normal clinical management'.

In many cases UniSC will not be the host or lead HREC (e.g. where the exposure is conducted at a QLD Health facility) and the prior review pathway will be used. The application to UniSC must include an assurance that the 'lead' ethics committee considered the application in line with the Code and that the required report from a medical physicist was included. Section 2.2 of the Code prescribes the role of an appropriately qualified medical physicist. Where UniSC is the lead HREC, the ethics application must include the medical physicist's report.

Selecting and screening participants

Where participants are to be exposed to ionising radiation, the risks for some categories of participants are higher than for the general population. The Code identifies these groups and sets out standard screening technique, and precautions and risk management strategies.

Consent

Section 2.1.3 of the Code sets out additional requirements for obtaining informed consent and stipulates that participants must be provided with specific information about the purpose of the research and the ionising radiation exposure, the method of exposure, the radiation dose, and associated risks and discomforts.

Annex 2 of the Code provides text to be included in the informed consent materials, which depends on the radiation dose. Section 2.1.8 outlines how long participants must keep the informed consent materials. Section 2.1.4 discusses additional requirements for substituted consent. In Queensland, additional legal considerations may apply to substituted consent.

Using the UniSC dual energy X-ray absorptiometry (DEXA) scanner

UniSC researchers using the DEXA scanner for research must do so as per the Code. If the scanner is used for medical reasons in addition to the research purposes, this should be made clear in the application. The scanner must be operated according to the approved standard operating procedures.

In addition to the project consent form, participants need to sign a consent form for the scan; it may be amended to suit the project or group of participants. This should be sent to the participants ahead of time for their review and to ensure that they do not have any conditions that would exclude them from participation (e.g. pregnancy). On the day of the scan the licensed DEXA scanner will present the consent form, ask participants to review and sign it, and the licensed scanner will witness it.

All participants need to be informed before going for a DEXA scan that previous exposure to radiation may mean that it is not wise to be exposed again. Detailed information should be collected from the participants well before the DEXA scan regarding:

- X-Ray imaging scans (ultrasound, CT scan, MRI, DEXA, mammography, bone density scan, radiology scan, or nuclear medicine) in the previous 12 months
- whether they have worked with a source of radiation as part of their occupation
- whether they have worked in a mine site that produces radioactive ores.

Three days before the DEXA scan, participants should be told to prepare in the previous 24 hours by:

- wearing casual, figure hugging clothes that have no metal items (e.g. zips, metal jewellery)
- increasing their fluid intake the previous day
- eating no food or fluid on the testing day
- avoiding vigorous physical activity in the evening prior to the testing day.

19. Language issues in human research

It is not ethical to screen participants based on language unless there is a valid scientific reason.

Researchers must identify and address language issues during the design and conduct of their research including:

- recruitment methods
- informed consent materials and mechanisms
- how data is collected
- how participants might access feedback/debriefing/results.

Depending on the potential participant pool, all, some, or no potential participants could have language issues. Where all, or a high proportion of, potential participants are likely to have language issues the research design must explicitly address how the identified language issue will be addressed. Where only some or very few participants might have language issues but where there are significant risks or ethical issues, or the potential participants are vulnerable (e.g. in a dependent relationship), the research design must explicitly explain how language issues would be addressed.

Translators and advocates

Where language issues may be present, a translator or advocate may translate and/or clarify meaning to potential participants. If the research is low risk and participants are not vulnerable, this could be done by a member of the research team. An independent translator or advocate is necessary when research has significant risks and/or the participants are vulnerable. These third parties may be required during the consent process and following the research in case of questions or complaints.

Special needs and communication

When participants have sight, hearing, or other conditions that impede their ability to communicate with the research team, strategies must be implemented to facilitate their understanding (e.g. third parties reading them the material, braille translations, sign language, etc.). As much as possible, these participants must not be excluded from the research. If they will be excluded, the justification for such exclusion is especially important where participation may generate real benefits to participants.

Translated materials for participants

Participants may be provided with informed consent materials in their language. Such an approach may be the most appropriate and practical approach to some, but not all, language/communication issues. Matters such as illiteracy or the need to respond to questions or give feedback may not be addressed by such an approach.

Translated documents must be provided to the UniSC HREC in the original and translated form. When the research is high risk or involves potentially serious ethical issues, the HREC may insist upon a certified translation.

20. Ethical issues in survey-based research

Surveys are an increasingly popular research tool because most can be administered online where it is possible to reach large pools of participants. When designing research using surveys researchers will need to consider the methods for recruiting, the identifiability of the data, and the mechanism for consent. A copy of the survey must be attached to the ethics application.

Identifiability of survey data

Chapter 3 of the [National Statement](#) includes a discussion regarding the identifiability of information and data. Researchers should consider what level of identifiability they require for their data and what risks may be present at that level. Many surveys about innocuous topics are completed anonymously whereas some projects may require that survey responses are coded to allow matching over multiple data collection points. In deciding on identifiability of data collection, researchers might consider such issues as whether illegal activity may be disclosed through the survey, whether mental health or other issues may be revealed that would require researchers to suggest interventions, or whether survey questions might provoke adverse reactions. Whatever approach is chosen, participants must be aware of the identifiability of their information and what the researchers intend to do with it.

Surveys and consent

Consent can be obtained for an online survey by having participants tick to confirm consent via a survey question at the end of the research project information sheet—see the RPIS and consent templates available on the [Portal](#). This method of consent removes identifiability that would be inherent in a signed consent form. There are some cases in which signed consent might still be used (e.g. the survey is only one component of data collection).

Distribution and return of completed surveys

The advertisement, distribution, and collection of surveys can raise ethical issues and concerns for participants. If surveys are to be posted or emailed to potential participants, consideration must be given to legal and privacy issues as outlined in [Guideline 5](#). It may be suitable to have third parties distribute the survey to their mailing lists as they already have approval to use contact information. If using third parties, researchers must ensure that they only forward ethics approved material.

The distribution and/or return process may make it possible for researchers or others (e.g. employers) to know whether an individual has participated. Potential risks, such as coercion or unequal relationships, must be addressed in the application and where possible, measures should be taken to reduce these risks (e.g. anonymous online surveys, locked return boxes).

Information for potential participants

For surveys involving ethically sensitive or intrusive questions, the recruitment materials and/or RPIS should give examples of questions to allow participants to make an informed decision. Details of support services (e.g. Lifeline) should be provided. A realistic estimate of the time it will take to complete the survey should also be provided.

21. Ethical Issues in focus group research

The use of focus groups is a common data collection technique. Unlike an individual interview or a survey, a focus group includes participants sharing information in a group.

If the topic under discussion is sensitive, if the participant pool is vulnerable, or there are other risk factors, researchers should consider whether focus groups are appropriate. Issues may become more acute if participants are likely to know each other, or if the issues discussed could impact on the professional or personal standing of some participants. It can still be ethical to conduct a focus group in such situations (e.g. individuals may share and support each other in the discussion of a shared experience), but strategies to manage the confidentiality and risk issues associated with the activity must be implemented (e.g. experienced facilitators).

Informed consent materials for focus groups should do the following:

- define 'focus group' to potential participants who may be unfamiliar with the term/process
- briefly describe topics to be discussed, number of participants, and who will facilitate
- advise participants that discussions are strictly confidential and that they must respect the privacy of other participants
- notify participants if audio-visual recordings will be made and how these recordings will be used and disposed of –see [Guideline 22](#).

Collecting data from non-research focus group activities

A researcher may collect data from a focus group activity being conducted by another party for a non-research purpose. It is only appropriate to collect data from such a session if the voluntary and informed consent of participants is obtained for the research use of their data; such consent should be sought at the beginning of the session.

22. Audio-visual recordings and photographs

Human research often involves the use of audio-visual recordings (e.g. audio recording an interview, video recording participant interactions) or photographs of participants and/or artefacts (e.g. art therapy creations, mind maps). Care must be taken to ensure the privacy of participants. Informed consent materials must make the use of such recordings or photographs clear and transparent.

Recordings

It is a legal requirement to advise participants that conversations will be recorded, to obtain consent for such a recording, and to retain a record of that consent. recordings will be transcribed, where possible, they should be deleted following transcription to further protect participant's privacy.

In some instances, a researcher may wish to retain recordings. This may occur when:

- the recordings are so significant or unique that subsequent analysis may be undertaken
- the use of extracts may be used in presentations or other work
- the recording will form part of the report or publication
- the recordings may be used for teaching and learning purposes
- elements of the recording cannot be recorded in transcriptions (e.g. tone of voice, gestures, interactions).

Such uses of recordings are appropriate if the participants have consented to such use. If the subject matter is sensitive, further consent may be required for specific use of quotes or extracts. If an unanticipated use arises after the initial consent, an amendment request must be submitted and should address whether consent needs to be re-sought. In some cases, commercial and legal considerations may apply (e.g. where a recording will be used for promotional purposes); researchers are responsible for adhering to the relevant legislation and UniSC policies and procedures.

Photographs

Photographs may be taken of actual participants or of their outputs or artefacts. Increasingly, photovoice is a popular research methodology in which participants take photographs, which may include other people—where this is possible, the subjects of the photos are considered participants and must be given project information and must provide consent for their images to be used for research purposes. Researchers should provide participants with clear guidelines for taking photos and obtaining informed consent from anyone who may be identifiable as a result of the photovoice process. This should clearly specify who will have access to the photos and whether they will be published.

Many of the issues and considerations for photographs are the same as outlined above for recordings. Informed consent materials must outline the use of the photographs and participants should be given options as to whether the photographs are displayed in research outputs, and if they are, if the participants are explicitly identified and/or if their works are credited.

Consent

The UniSC RPIS template includes standard text that can be used to make the use of recordings or photographs clear to participants. This includes:

- how long the recordings/photographs will be retained for
- who will have access to the recordings/photographs
- an assurance that recording will be erased following transcription and/or analysis
- whether the recordings/photographs will be used for any other purposes.

In some instances, it may be appropriate to include options on the consent form such as:

- consent to record
- consent for future use of recordings
- whether participants wish to be consulted if direct quotes or extracts will be presented
- whether participants wish to verify transcriptions
- whether participants want to be identified in presented quotes or photographs.

This may be useful when potential participants might be prepared to take part in the research but have reservations about recordings or photographs.

If recordings or photographs may be used for UniSC marketing or teaching purposes, participants must also sign the *Consent Release Form –Audio Video and Photographic*, which is available on MyUniSC.

Cultural considerations

Some cultures might have taboos regarding videos or photographs; others, such as Aboriginal and Torres Strait Islanders, may have issues with photographs or recordings of deceased persons. If recordings or photographs are to be taken and their use is fully disclosed to participants, a researcher could reasonably assume that consenting participants have done so with their own culture in mind. That said, this does not preclude the researcher from addressing cultural sensitivities within their research design and ethics application.

Identification and confidentiality

Audio-visual recordings and photographs of participants, by their nature, mean that participants are identifiable. In most instances, participants will only be identifiable to the research team. In instances where transcriptions are coded, or where recordings or photographs may be used more widely, it may be possible for others to identify participants. The inherent ethical issues and risks depend on the sensitivity of the topic of research and the participant's situation and wishes. Most issues and risks can be addressed by adequate disclosure to participants through the informed consent materials.

Limited disclosure, waivers, opt-out, and non-participants

In some situations where recordings will be made, researchers may not want their research revealed, it may be impossible or impractical to get consent, or some people have indicated that they do not want to be recorded as part of the research project. This may occur where:

- researchers wish to observe participants in a natural situation (where if participants were aware of the research they may act differently)
- large groups of people are being recorded and it is not practical to get their consent (e.g. recording behaviour at a large event)
- some people consent, and others do not (e.g. recording students in a classroom setting where some have consented and some haven't).

Strategies to address these issues may include:

- applying for a waiver of consent or using the opt-out approach—either of these approaches must be justified according to the relevant sections in Chapter 2.3 of the National Statement
- seeking general consent from a community Elder or leader to observe and/or to use the waiver or opt-out approach for community members
- setting up recordings to exclude non-participants from the frame—if this is not feasible, assuring non-participants that their information and data will not be used for the research
- in compulsory educational situations, an activity of equal value and attractiveness must be offered to non-participants or the same activity must be run separately.

Any such arrangements should be explained in the ethics application and in the informed consent materials. It is important that potential participants do not feel coerced to participate or that researchers are attempting to collect data without their consent.

Copyright issues

Researchers who intend to use recordings or photographs that were created by another person should be aware that the term of copyright for such media is the same as other types of artistic works—the life of the author plus 70 years. In the case of recordings of live artistic performances, in addition to copyrights, the performer may have moral rights that apply to any use of the recording. These rights may impact upon the way in which a researcher can use or ‘publish’ the recordings or photographs.

23. Ethical issues in online research

Research can be facilitated by using email, online surveys, publicly available internet or social media content. Participants can be recruited online through social media, websites, and research companies. Data may be collected, stored and/or managed online. These technologies may help researchers contact a broader participant pool, collect data anonymously, or conduct research at lower costs; however, they have also created ethical issues and blurred lines that must be considered.

Email

See [Guideline 9](#) (Recruiting participants) and [Guideline 5](#) (Regulatory and ethical privacy considerations) for ethical considerations and regulations regarding accessing email lists and protecting the privacy of potential or current participants. When conducting research via email, consider the following:

- all recruiting emails must be included in the ethics application
- consent may be implied where appropriate (e.g. online surveys), which assists with anonymity (rather than requesting returned consent forms)
- where responses are returned via email, implement strategies to separate or remove identifying information such as:
 - printing attachments upon receipt and permanently deleting the electronic file
 - removing hidden properties on files (e.g. where software might have saved the users name and/or IP or computer details)
 - saving responses separately from identifying details(These strategies should be explained in informed consent materials. If research is sensitive, such as potentially exposing illegal activity, consider methods to collect data anonymously.)
- how results will be distributed to participants (e.g. participants request them via email or they are sent to the whole group of potential participants via an email list)
- whether participants may be sent newsletters or other communication about ongoing research opportunities and how this will be managed (e.g. consent, opting out etc.)
- whether using email to conduct research may inadvertently exclude certain populations (e.g. the elderly, lower socio-economic groups), how this will impact the validity of findings, and whether this raises ethical issues of distributive justice and if so, how this can be rectified.
- social, economic, legal, or other risks that may exist when sending information via email (e.g. when internet use may be monitored by employers or by law enforcement agencies)
- privacy and security issues and how related issues might be minimised (e.g. ensuring care is taken when selecting reply or reply all, or using bcc rather than cc)
- who will have access to email accounts used for the research?

Online surveys and tests

Online surveys and tests have many advantages, including:

- broad, cost-effective distribution
- participant can access and complete them quickly and easily
- the ability to create rules to get relevant answers (e.g. only allowing numbers where numeric answer are required)
- easy creation of dynamic surveys or tests (where responses to questions trigger other relevant questions)
- increasing anonymity of participants.

Ethical and methodological challenges may include:

- many of the above considerations regarding use of email
- participants completing a survey more than once

- the exclusionary criteria may not be adhered to (e.g. excluding people under 18)
- limited ability to refer a participant to a support service if they become distressed or if the nature of their responses warrants intervention
- ensuring participants have, or can easily add, the correct software, plug-ins, or security measures.

Ensuring that individuals only participate once may be important for the validity of the results. Strategies to ensure individuals only participate once include:

- giving each participant a unique login, which can only be used to complete the survey once
- setting up the survey to ask for names and email, and setting a limit so this combination can only be used once
- allowing surveys to only be completed once per IP address.

With the first two approaches, measure would need to be taken to separate identifiable information from survey responses and this should be explained in the ethics application and the informed consent materials.

Online communities, blogs, chat rooms, and social media

Online communities and social media applications can facilitate vibrant and unique dialogues; as such they can be useful sources of data for researchers. Although this data is often considered publicly available, an ethics applications is required as per [Guideline 2](#).

When it is important to observe natural interactions and language (not biased by participants knowing that they are being observed for research), it may be possible to request a waiver of consent—this must be justifiable as per section 2.3.10 of the National Statement.

When a waiver of consent is not appropriate, other options for consent include, but are not limited to:

- the researcher and/or page moderator posting regular notices about the presence and objectives of the researcher with a link to an information sheet about the project—individuals may be given an avenue to ‘opt-out’ of the research, or, if not, they can at least decide whether to post comments or materials
- if individuals have posted material that the researcher wishes to use, the researcher might contact them to seek consent by email or private messaging if available
- researchers might set up their own project pages or communities where consent to use data for research purposes is built into the process for joining the page/community.

Research conducted within online networks face challenges such as:

- the fluid nature of participation, which can make it impractical or difficult to seek consent
- anonymous participants who are identified only by a screen name or alias—no private contact details may be available
- concerns that seeking prior consent could distort the discussion and data.

Researchers should be mindful that:

- there may be eligibility criteria for joining a group (e.g. having a certain medical condition) and it would be unethical to lie to gain access
- participants in online communities often consider these groups to be private and would not expect, or appreciate, their comments or information being collected, analysed, or shared outside of the group
- participants in online groups may be part of a vulnerable group (e.g. living with a mental illness) and/or may be discussing highly sensitive matters
- the terms and conditions of some online platforms may state that data will be used by third parties and/or researchers, but participants rarely read these terms and it would be unethical to use this as a blanket approach to consent.

Research project websites

Researchers may choose to have specific websites set up for their projects. This may be for one specific project, or a suite of related projects. These sites might be useful for:

- recruiting participants
- collecting data
- displaying results (this eliminates participants contacting researchers to request results)
- creating an ongoing relationship with potential participants (passive recruiting for new project, sharing research results and actions arising from research, acknowledging participant contributions, discussing or collaborating on ideas for future research).

Web content and accessibility

To ensure that web content is as widely accessible as possible, the following coding strategies may be used:

- allow the size of the text to be increased by visitors
- allow text to be accessed and interpreted by a screen reader
- ensure that all elements are accessible via the keyboard, the screen, or a mouse.

24. Research involving children and young people

Refer to Chapter 4.2 of the [National Statement](#).

It may be necessary to conduct a UniSC risk assessment as a result of the inclusion of [children / young people / vulnerable people](#) in your research. Please contact ASUOffice@usc.edu.au for further advice and support.

Research involving children and young people can raise additional ethical, moral, legal, and practical challenges. It is not ethically appropriate to exclude people based on age unless there is a sound justification. When planning a project, consider the following:

- Could the potential participant pool include children or young people?
- Should this group be included or excluded, and, if so, how can this be justified?
- If young people will be invited to participate, who will consent to their participation?
- Does the research provide for the safety and welfare of young participants?
- Are there any legal or other considerations that need to be addressed?

On the HREA form, Q1.19, 'children and young people' should be ticked if the research targets young people OR if there is likely to be a significant number of young people participating.

Justifying the inclusion or exclusion of young people

The following are example rationales for the inclusion or exclusion of young people:

- the research is likely/unlikely to contribute to the body of knowledge related to the health, welfare, or other area of importance to young people
- the variables of interest are/are not age-dependent
- the topic, data required, or participation requirements are/are not relevant or appropriate for young people
- there are legal considerations (e.g. participants drinking alcohol).

Informed consent for young people

Having determined that young people will be participants, researchers must consider who will consent, the most appropriate consent mechanism, and who informed consent materials should be written for and addressed to—see sections 4.2.7 to 4.2.12 of the National Statement.

Informed consent for young people can be sought in the following ways:

- directly from the young person where:
 - the research is low risk and will not overly burden participants, and
 - they are of an age/maturity level where they can make decisions and the research team has a mechanism to assess this capacity (e.g. prior knowledge of participant pool, verbal consultation with young person, or a testing mechanism), and
 - the nature and context of the research is not overly complex, and
 - provisions are made to protect their safety, security, and wellbeing, and/or
 - they are estranged from their parents and/or seeking parental/guardian consent could be contrary to their best interests.
- from the young person following consultation with parents/guardians (this is recommended to keep parents informed and to minimise the possibility of future complaints)
- from the young person with the consent form countersigned by the parent/guardian
- from the young person and the parent/guardian (two sets of informed consent materials may be required—one addressed to the parent/guardian and one to the young person)

- from the parent/guardian with consultation with the young person
- from the parent/guardian with no consultation with the young person (for research involving infants or very young children)
- standing parental consent where research is conducted within an educational context (following provision of standing consent, parents are informed of individual projects and can either opt-out or do nothing thus implying ongoing consent).

If parental consent is required, consider whether consent needs to be sought from both parents or all guardians. In modern mixed families, and/or in families with issues and challenges, consent must be approached with sensitivity.

The views and interests of the parents or guardians may be different to that of the young person. As a general principle, when consent is required from both the young person and the parent or guardian, the young person can only participate when both parties agree. Where they have capacity to consent, a child or young person's refusal to participate in a project must be respected; where capacity is lacking, refusal can be overridden by the parent or guardian.

Third party approval

In many cases, research involving young people will be conducted in a context where the approval of a third party is required (e.g. research conducted in schools). See [Guideline 6](#) (Research requiring endorsement by third parties) for more information. Researchers conducting research in Queensland schools should refer to [Education Queensland Research Services](#) for more information and for a link to their online application form.

School-based research

Many projects involving children or young people are conducted in childcare centres or schools. Research design, ethics applications, and informed consent materials must clearly distinguish between school activities and research activities. Focussing on elements of the activity that are research related makes it easier to identify and address the ethical issues that are the researcher's responsibility. Even though a young person, and/or their parent/guardian may not be able to withhold consent for a school activity, they could still withhold consent for the research activity. This might mean that the entire class will participate in an activity that is of interest to a researcher, but that data can only be collected from those participants who have consented.

This distinction can become problematic when researchers are commissioned by the school to lead the school activity. In such circumstances, the researchers should consider the following questions:

- Would the activity occur with or without the presence of the researcher?
- Is the school activity happening to enable UniSC research activity to occur?
- Would such an activity already normally occur within the school context?

The responses to these questions can determine whether the school activity is treated as part of the research proposal and ethics application.

Activity management

Where not all students will be participating in a project, researcher must determine if it is possible to exclude those students from the data collection but still allow them to participate in the activity. This can be problematic in group activities and/or where audio-visual recordings will be made; it may be necessary to exclude them from the recording.

In situations where a non-consenting student must be excluded from a school activity because it is inseparable from the research activity, or where the student is among a minority of students excluded from a research activity conducted in 'normal class time', appropriate alternative arrangements must be made. These arrangements

should provide an alternative learning activity of equal perceived worth and desirability. If no such provision is made, the researcher and/or the school could be accused of an injustice—this is a common area of concern that must be addressed.

Peer pressure on potential student participants

Researchers must address the potential for peer pressure to impact participant decisions. Students must be given time and space to consider participation and must not be asked to express consent as a group in front of their peers. This is especially important when the research topic is sensitive and/or the research involves more than a low risk of harm.

Additionally, the fact that someone is included or excluded from participation could impact relationships or cause stigma within peer groups—these potential risks must be considered and addressed.

Teachers as researchers

If the potential participants are students and a member of the research team is their teacher or a senior staff member in their school, this can create an unequal relationship between participants and researchers. In these instances, 'people in dependent or unequal relationships' should be ticked in Q1.19 of the HREA. Refer to [Guideline 26](#) for more information on research involving unequal relationships.

Students vs teachers as participants

Within a teaching and learning context the student and/or the teacher may be the focus of the data collection. When the non-participating party can genuinely be omitted from the data collection, it is not necessary to seek their consent. When the party who is not the focus of the research cannot be omitted from the data collection (e.g. students might be visible in a video recording a teacher's instructional techniques) then both parties should be considered participants with consent sought from both.

Where students are the non-participants it is courteous to inform the students and/or their parent/guardian about the research. When students are the participants and the teacher is not the focus of the data collection, researchers must consider the degree to which the class could be identified (e.g. within the school) and whether reported results could reflect negatively on the teacher and expose them to risk. It may be necessary for the teacher to be considered a participant and for their consent to be sought.

Regulatory requirements

In many jurisdictions, formal regulatory approval is required for any work with children. In Queensland, researchers (including student researchers) may require a blue card. Refer to bluecard.qld.gov.au for more information. Other requirements may apply to research conducted elsewhere in Australia or overseas.

25. Research involving university or other students

Research projects may recruit UniSC or other post-secondary students as participants. Researchers must consider the ethical issues outlined below and should design their research accordingly. Using students as participants should be justifiable on research grounds and not just for convenience. Some cohorts of students may feel 'over-researched' and may not provide quality data.

Unequal or dependent relationships

Refer to Chapter 4.3 of the [National Statement](#) and [Guideline 26](#). Potential student participants may be in an unequal or dependent relationship if their lecturer/teacher/tutor is conducting the research or if they perceive that the project is of value to the institution. These participants may believe their decision to participate or not could impact their relationship with the institution or the researcher, or could impact on their grades or academic progression. To minimise associated risks, consider the following strategies:

- stating on the RPIS that the decision to participate or not will not affect the student's relationship with UniSC and/or the researcher nor will it affect grades or academic progression
- presenting information in such a way that there is no perceived coercion or peer pressure to participate (e.g. online surveys rather than in class)
- using an independent research assistant to discuss research and/or collect data
- collecting data after grades are finalised or, if data is identifiable in any way, delaying analysis until after grades are finalised
- collecting data in a non-identifiable format
- offering activities to all students (if they will be of benefit to their learning) and then using an opt-out approach whereby students who do not want their data to be used can contact a researcher or independent person after the activity (e.g. their comments may be stricken from the record or not included in the transcription)
- allowing appropriate time and space for students to consider participation, for example by:
 - distributing project information one week and returning the following week to undertake data collection
 - presenting information on the study at the beginning of the lecture and providing surveys for completion at end of the lecture
 - using online surveys or allowing paper questionnaires to be completed after the lecture and returned later.

Institution approval

Researchers who wish to survey UniSC students must refer to the [Student Survey – Managerial Policy and Procedures](#). They will need to apply for *approval to survey students* (available on MyUniSC). This form should be submitted with the ethics application.

If participants are from other institutions, or research will be conducted at another institution's premises, researchers should liaise with the institution to obtain the relevant permissions. Often formal approvals are not necessary but, as a matter of courtesy, it is prudent to make contact. Approval may be required before the research commences but is not required prior to seeking UniSC ethics approval; however, in the ethics application, researchers should provide assurances that the relevant permissions will be sought, and that evidence will be provided upon receipt.

Consent - first year or young students

Refer to Chapter 2.2 (General Requirements for Consent) and Chapter 4.2 (Children and Young People) of the [National Statement](#).

The UniSC HREC considers tertiary students who may be under 18 years of age as capable of consenting (without requiring consent from parents or guardians) for research that does not involve significant risks. If a participant pool includes younger people at another institution the research team will need to confirm that institution's policies.

Incentives, reimbursements, and credit for participation

[Guideline 10](#) discusses using prizes as an incentive to participate.

Reimbursing students for their time and effort may be appropriate as long as the amount offered does not appear coercive and does not undermine the voluntary nature of participation.

Some disciplines encourage students to participate in a research project by offering marks or other credit for their participation. Such participation can be an important part of practitioner development and may provide students with an understanding of how participants experience research in their field. For example, this strategy is used at UniSC in the psychology discipline through the 'Take Part' system. Credit for participation may be perceived as coercive; as such, the UniSC HREC recommends such incentives only where:

- students have a choice of participation in any one of several projects
- students have access to an alternative for credit if they do not wish to participate in any of the projects on offer.

Managing non-participants

In projects that look to use a whole class of students as participants and where some students may not want to participate in the research, researchers need to consider the following:

- whether there will be 'peer pressure' to participate
- whether participants or non-participants should be removed from class or whether the research activities will need to take part outside of class time
- whether other activities need to be provided for non-participants
- whether non-participants will be disadvantaged (e.g. participation might improve knowledge or skills and/or could lead to improved grades)
- in a class being observed and/or recorded, how non-participants will be excluded from observation or recordings
- whether consent will be requested specifically from each student or if an opt-out approach can be used (and how that will be managed to ensure privacy and voluntary participation).

Accessing student data

Please refer to [Guideline 14](#), Secondary use of data or information for more detailed information.

Student data can only be used for defined purposes. While staff may have access to student data (e.g. course grades), ethics approval and permission from the data custodian to use this data for research is required. If it is unclear who the relevant UniSC data custodian is advice should be sought from the Insights and Analytics Unit, who can assist with identifying and obtaining authorisation from the appropriate data custodian. In cases where the data custodian is associated with the research project, authorisation from a higher level custodian will be required. As much as possible, researchers must obtain specific consent from students before accessing their data for research purposes.

An exemption may be possible if the research can be justified against the criteria set out in section 5.1.17 of the National Statement. See [Guideline 3](#). In other cases, an opt-out approach or a waiver of consent can be requested via an ethics application. When using the opt-out or waiver approach, the HREA application form will

ask researchers to justify this approach against each criteria point in the relevant section of Chapter 2.3 of the National Statement.

26. Human research and unequal relationships

Refer to Chapter 4.3 of the [National Statement](#). Examples of unequal relationships include:

- teachers/lecturers conducting research on their students
- employers or supervisors conducting, or sponsoring, research on their staff
- medical practitioners conducting research on their patients
- service providers sponsoring research on their clients
- law enforcement or other agencies conducting research involving homeless participants.

Unequal relationships can raise ethical issues and may result in concerns about the ethical conduct of a project. Although a researcher or sponsor may not intend to exploit an unequal relationship, the perception that an unequal relationship has not been appropriately addressed can be damaging.

Ethical principles

When considering human research involving an unequal relationship, these principles of ethical conduct apply:

- **respect for persons:** research must acknowledge the presence of the unequal relationship and ensure that the dignity and well-being of participants is maintained
- **beneficence:** risks to participants, whether real or perceived (e.g. impact on employment, academic results, or personal relations), must be minimised
- **justice:** unequal relationships can make participants feel used—benefits and burdens must be fairly distributed
- **consent:** informed consent materials must address the unequal relationship and participants must be able to make an informed decision free from coercion or pressure.

Recruitment and coercion

In research where unequal relationships exist, a common ethical concern is the presence of real or perceived pressure to participate. Potential participants may feel pressured if they believe that not participating could damage their relationship, employment, grades, access to services, etc.

Some typical strategies to address this issue are:

- participation is anonymous or is coded in such a way that participants will be anonymous until after the period of the unequal relationship has passed (e.g. after release of grades)
- recruiting is conducted by a third party
- informed consent materials include a clear statement that participation will not impact access to services, the relationship etc.
- potential participants are given time and space to consider their participation
- a clear distinction is made between the existing relationship and the research activity.

How necessary and how thorough these strategies are will depend on a combination of the following:

- risks and burdens associated with the research
- extent of the unequal relationship
- vulnerability of potential participants
- sensitivity of the topic and/or the data to be collected.

Risk issues

Unequal relationships can create risks for participants (e.g. employees risk losing their job if inappropriate activities are exposed via the research). Often the best way to manage such risks is for participation to be anonymous and/or for data to be de-identified as soon as possible. It is not always possible to conduct the research in this way and sometimes the number and nature of participants means identification by inference is possible. It may still be ethically appropriate to conduct the research as long as:

- participants have been advised of the risks and burdens
- measures have been put in place to minimise the risks
- potential participants are not characterised as vulnerable.

Captive relationships

Captive relationships are a kind of unequal relationship where potential participants are under the direct control of the researcher. Examples of captive relationships include:

- a prison officer conducting research on inmates
- defence force or law enforcement personnel as research participants
- clinicians and their patients (particularly if the patients are highly dependent on medical care and/or there are currently no effective treatments for their condition).

The issues identified above also apply to captive relationships, but they are more acute when a degree of authority can be exercised over the participants. Consequently, a much higher standard applies in determining the sufficiency of strategies to manage issues such as coercion, consent, and risks.

27. Participants with mental impairments or those unable to give consent

Research involving participants who may have no ability, or limited ability, to provide informed consent requires full review by the HREC. Depending on the location of the research, or the potential participants, review may be required by Queensland Health prior to applying for UniSC ethics approval.

Such research must be designed to adhere to:

- Chapter 4.4 of the [National Statement](#): People highly dependent on medical care who may be unable to give consent. This may include research conducted in:
 - neonatal intensive care
 - terminal care
 - emergency care
 - intensive care
 - the care of unconscious people.
- Chapter 4.5 of the [National Statement](#): People with a cognitive impairment, an intellectual disability, or a mental illness
- Queensland [Guardianship](#) legislation
- any standing [Advanced Health Directives](#) or [Substitute decision-makers](#).

Consultation with legal guardians

Where participants can provide consent, researchers should consider whether they also need to consult with, or inform, the legal guardians. This may be important in cases where the cognitive abilities of the participants can fluctuate.

Where there will be no consultation with, or consent sought from, the legal guardians, researchers will need to show that there has been appropriate alternate consultation (e.g. with the institution where the potential participant resides). They may also need to justify the potential participant's ability to be considered the primary consenting agent.

Wherever possible, consent should be obtained from the participants themselves, but the HREC may still insist on the consent of their legal guardians as well.

28. Vulnerable, disadvantaged, or powerless participants

Chapters 4.1 to 4.7 of the [National Statement](#) address ethical considerations specific to groups of participants who could be considered vulnerable, disadvantaged, or powerless ('vulnerable' for the remainder of this guideline). In addition to the groups discussed in the statement, other categories of vulnerable participants could be:

- homeless people
- single and/or alienated parents
- prisoners
- drug or alcohol addicts
- victims of abuse
- people with physical disabilities or disfigurements
- the elderly
- immigrants and refugees
- people subject to prejudice (e.g. LGBTIQ).

Research must acknowledge these vulnerabilities and be conducted in a way that safeguards the welfare and rights of these participants. Vulnerable participants should not be excluded unless this can be justified for a valid scientific reason. Research design and ethics applications should consider these groups when they are specifically targeted or where there they may form a large proportion of the participant pool.

Also refer to the [UniSC Working with Vulnerable People – Managerial Policy](#).

Recruiting and consent

Extra consideration and precautions may be required when recruiting vulnerable participants. Researchers might consider the following issues and strategies:

- vulnerable participants may experience or perceive risks due to the recruiting process (e.g. an abusive family member may check their emails)—anonymity or passive recruiting processes (e.g. flyers in community centres) may be used
- vulnerable participants may experience anxiety or distress in certain recruiting situations (e.g face-to-face recruiting during admission to a facility)—the experience and sensitivity of the person conducting the recruiting will be important
- vulnerable participants may perceive that their access to services may be affected by their participation (or not)—recruiting material should stress the voluntary nature of participation and might specify that X organisation will not be given any information
- incentives such as financial reimbursement or the provision of a good or service may be considered coercive (e.g. offering cash to a homeless person or special privileges to a prisoner)—careful consideration of the nature and value of incentives is required
- language or cognitive issues may require that recruiting and informed consent materials are simplified, offered in other formats, or translated
- where participants may fear legal implications, recruiting and consent materials should specifically state that no information will be shared with authorities or government departments.

Risks and burdens

Risks to vulnerable participants may be amplified and their ability to cope with risks, or to take actions against those who might cause them harm, can be severely limited. Research must be designed to manage and minimise risks and to make provisions to assist participants if risks or harms are realised. Informed consent materials must clearly and comprehensively outline potential risks, the likelihood of them happening, and the strategies in place to minimise them or to help participants if the risks are realised.

Risks to be considered may include how researchers will address secondary or incidental findings (e.g. discovering abuse or neglect) and what their legal obligations and/or duty of care may be.

The degree to which participation might burden participants (e.g. time required and time of day issues for single parents) needs to be considered; alternate arrangements may be required (e.g. going to their home to conduct interviews during the child's nap time).

29. Research and the discovery of illegal behaviour

Refer to Chapter 4.6 of the [National Statement](#): People who may be involved in illegal activities

In most instances, projects that are designed to, or are likely to, discover illegal activity must be reviewed by the HREC; however, projects that involve the collection of non-identifiable data and are considered negligible risk (e.g. an anonymous survey about drug use) may be expedited.

Research projects may:

- specifically relate to illegal behaviour and/or the exposure of
- look at factors related to illegal activity
- be likely to discover illegal activity
- inadvertently discover illegal activity.

These projects raise issues that must be addressed in ethics applications such as:

- the researcher's duty of care or legal obligation to address or disclose such activities (e.g. reporting the discovery of child abuse)
- the likelihood of a law enforcement agency requesting the information
- the degree to which participants are put at risk and how those risks can be minimised
- whether there may be risk to the researcher
- whether a participant's identity could be inferred through the data collection process or in publications or other outputs
- whether a researcher may have a dual role (e.g. a parole officer) and the degree to which that role and the research may overlap
- legal ramifications and risks for research undertaken in other jurisdictions (for both researchers and participants)
- participant awareness and expectations regarding any of the above.

Anonymity and re-identifiable data

As with most research projects, where data can be collected and/or stored in a de-identified way, this is always preferable. There may be situations where researchers need to match responses of participants across different data collection points or where they need to be able to re-identify participants (e.g. for verification of comments).

Strategies for managing this process may include:

- permanently destroying the records that allow re-identification as soon as feasible
- ensuring that participants are aware of, and consent to, their data being re-identifiable and up to what point
- allowing participants to create their own 'code' (to match responses across time) so that the researcher has no data that links the data to the specific participant
- limiting access to the re-identifiable record to certain researchers
- ensuring that re-identifiable records are kept securely and separately from the data
- ensuring that any coding used cannot be identified by third parties (e.g. use of a student number).

Disclosure

Disclosure refers to situations where a researcher chooses, is required to, or is compelled to provide identified information about illegal conduct to third parties. Such disclosures may expose participants to significant harm. As per Section 4.6.6 of the [National Statement](#), potential participants must be informed about the degree to

which their information will be protected and what the researcher will do if an agency or court seeks to compel release.

Required disclosure

Examples of three categories of required disclosure are:

- **Contractual:** As a condition of access, corrective services may require researchers to disclose identified information about drug smuggling and distribution. When planning the project, researchers must consider that such a contractual limitation might impact the validity of the data collected. They must also make this potential disclosure known to participants.
- **Professional:** The conduct of registered clinical nurses is guided by a professional code of conduct that requires nurses to take action if they witness or become aware of unsafe or inappropriate health care. Researchers, whether they are nurses themselves or not, would have the same duty of care to report such activity.
- **Legal:** Some professional groups (e.g. teachers) are obliged by law to bring cases of suspected child abuse to the attention of the authorities; researchers should employ the same duty of care.

When designing their project and seeking ethics approval, a researcher must consider disclosure requirements and:

- whether it is necessary or appropriate to collect the data in an identifiable form
- how this situation will be discussed in informed consent materials.

Elective disclosure

Elective disclosure refers to situations where there is no legal, professional or contractual obligation to disclose, but where a researcher feels that there is a moral obligation to do so. For example, a researcher may learn that an employer is using intimidation and threats to force its employees to accept pay and working conditions which are less than those prescribed in the relevant industrial award. While there is no external obligation to report this situation, a researcher may feel a responsibility to do so.

Where it is possible to predict such situations, the project design and ethics application should discuss how these situations will be handled and how potential participants will be informed of the possibility.

Where it is impossible to predict these situations, researchers should seek an amendment to their project and/or discuss possible avenues with the HREC Chair. If the disclosure will expose someone to risk, the disclosure will need to be justifiable in terms of public interest.

Compelled disclosure

Regardless of a researcher's intentions, a legal entity may seek to compel the researcher to release the information via a court order or subpoena. Such requests may be legally contestable; researchers may need to seek legal advice in these situations.

Maintaining good faith with participants or prosecuting those who break the law may be a difficult question in some research. Some researchers reasonably point out that it would be impossible to conduct research in some areas without giving participants assurances of confidentiality and being prepared to protect that confidence. Where it is possible to predict these situation, project design and ethics applications should discuss how these issues will be addressed.

Because of the serious consequences and risk factors, where possible, projects should be designed to collect de-identified data or codes related to re-identifiable data should be destroyed as soon as possible so that it would be impossible for a law enforcement or other agency to request the identifiable data.

30. Research involving Aboriginal and Torres Strait Islander participants, communities, locations or topics.

The following resources are available for researchers conducting research with or about Aboriginal and Torres Strait Islander people:

- [AIATSIS—Code of Ethics for Aboriginal and Torres Strait Islander Research](#)
- [NHMRC—Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders](#)
- [NHMRC—Keeping research on track II: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics](#)
- [NHMRC Road Map: A strategic framework for improving Aboriginal and Torres Strait Islander health through research](#)

When is research Aboriginal and Torres Strait Islander research?

It is acknowledged that Aboriginal culture and Torres Strait Islander culture are two unique cultures; all efforts should be made to be respectfully inclusive of either or both cultures in research projects. Research that is considered Aboriginal and Torres Strait Islander research must be reviewed by the Human Research Ethics Committee, and researchers must tick 'Aboriginal and Torres Strait Islander peoples' on Q1.19 of the HREA form when:

- Aboriginal and/or Torres Strait Islander people or communities are the target participant group
- Aboriginal and/or Torres Strait Islander archives, artefacts, country, or topics of significance are the focus of the research
- Aboriginal and /or Torres Strait Islander people are known, or are likely, to be significantly over-represented in the group being studied
- there are Aboriginal and/or Torres Strait Islander people who use services being studied in distinctive ways, or who have distinctive barriers that limit their access to the services, or
- research will separately identify data or results relating to Aboriginal and/or Torres Strait Islander people and/or will be presented as a comparison case study.

Aboriginal and Torres Strait Islander people may be participants in a research project that targets the general population. Researchers should acknowledge this possibility in their ethics application and should consider whether any risks or other considerations need to be addressed.

Submitting an Aboriginal and Torres Strait Islander ethics application at UniSC

Please note that large, nationally focussed, or highly sensitive projects may be referred to the AIATSIS Ethics committee for review. Please contact humanethics@usc.edu.au to discuss the appropriate reviewing committee if you are unsure.

When submitting an application to UniSC, researchers must:

- Address the six core values as outlined in the [NHMRC—Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders](#)
- Provide clear evidence of consultation with, and support from, the community being studied. This should be in the form of a letter, on letterhead, which clearly outlines the community's role in developing the project and the benefit that the community will get from this research.
- Include an Aboriginal and Torres Strait Islander researcher on the project team—if this is not possible this should be clearly justified and clarified. The above letter of support could include confirmation of this as well.
- Clarify the ownership of the research data and outputs upon project completion, and, if available, submit the data sovereignty agreement.
- Carefully consider and address how consent will be sought at both the community and individual level.

- Ensure that the peer review checklist is completed by an Aboriginal and Torres Strait Islander person or someone with demonstrated cultural competence when projects have a primary focus Aboriginal and Torres Strait Islander participants or topics.
- Ensure that the people engaging with the community and/or collecting data, have cultural competence and the relevant experience (e.g. are trained in how to run a yarning circle).

31. Research conducted in other countries

Refer to

- Chapter 4.8 of the [National Statement](#)
- [International Compilation of Human Research Standards](#)
- [Ethics approval processes in the Pacific](#)

When research is conducted in another country, Australian requirements still apply because the research is being conducted under the auspices of UniSC. Where there are additional ethical and regulatory requirements in the other country, both sets of requirements may apply. Where they may conflict, the highest standard should be applied. When planning a project in another country, it is the researcher's responsibility to determine whether there are any local ethics review processes or regulatory requirements that apply to their research.

Even if a project does not require local ethics approval, some form of local approval may be required (e.g. from the local education authority, or a village Elder). All local requirements, or the lack thereof, should be outlined in the ethics application and the relevant approvals should be attached. In rare cases, researchers may only become aware of local requirements once they are 'on the ground'. Research should not commence until local requirements can be met. Where applicable, a project amendment should be submitted as soon as possible.

Review Pathways

As per Section 4 of the [National Statement](#), ethics review by an HREC is required for research discussed in Chapter 4.8: People in Other Countries'.

Some negligible-risk projects that will be conducted with participants from another country may still qualify for expedited review such as conducting an online survey that is intended to capture participants from several countries or conducting interviews remotely on a low-risk topic. Research that has been approved by an equivalent HREC may still qualify for the prior review pathway if it can be demonstrated that their review was in line with the expectations set out in the National Statement.

Examples of research in other countries that would require full review include:

- research conducted in a country that is politically unstable
- research that may be seen as being critical of an oppressive regime
- research that may be at odds with local laws
- research where there are significant conflicts between Queensland/Australian regulations and local regulations
- research involving indigenous people and/or issues that may be sensitive to them
- research with vulnerable groups
- research that involves significant risks to either the participants or the researchers.

Submitting an application at UniSC to conduct research in other countries

When submitting an application to UniSC to conduct research in other countries, researchers must:

- Determine whether ethics approval also needs to be obtained from an ethics review body in the local country. If so, determine whether local ethics approval or UniSC ethics approval should be sought first. If not, clearly justify why ethics approval is not being obtained locally and provide relevant supporting documents or links, including evidence of: Consultation with a local ethics review body where possible.
- Where appropriate, provide a letter of support from a local organisation/collaborator or the relevant community.

- Where appropriate, provide clear evidence of consultation with, and support from, the community being studied.
- Carefully consider and address how consent will be sought at both the community and individual level, as necessary
- Ensure that the people engaging with the community and/or collecting data, have cultural competence and the relevant experience (e.g. are trained in local customs and practices).

Research considerations

As relevant to the project, issues that need to be addressed include, but are not limited to:

- respect for culture, religion, social norms, and local traditions and practices during all stages of the research (advertising and recruiting, collecting data, presenting findings)
- risks as they relate to culture and norms (e.g. participants may be exposed to risk by discussing a topic that is taboo in their culture) or legal considerations (e.g. talking to researchers about an oppressive regime)
- the degree to which communities may place emphasis on the 'collective good' as opposed to individual benefits (i.e., participants may be more willing to accept risk if there may be a benefit to the whole community)
- whether a cultural adviser or local representative needs to be on the research team, including:
 - how they will be acknowledged in research outputs
 - whether the research may impact on their reputation within the community
- placing respect for, and consultation with, the community ahead of the objectives of the researcher; there should be genuine consultation with the Elders, leaders, or representatives of the community, which includes:
 - confirming that the research is useful, important, and valuable to the community
 - ensuring that the community feels that the benefits of the research justify the risks and burdens
 - designing the research in a way that is appropriate and respectful
 - agreeing on how the results of the research will be fed back to the community
- language considerations such as:
 - what language the research will be conducted in (Is this language familiar to all potential participants? If not, how will this be addressed?)
 - whether the researchers are familiar with the language, and if not, how this will be addressed
 - whether an interpreter or bilingual co-researcher will be employed
 - whether participant documents require translation (documents produced, or received, in another language must be provided to the UniSC HREC in the original form and the translated form—when the project is high risk or involves serious ethical issues, the HREC may insist that the translations are certified)
- the use of incentives or payments for participation and whether they are in line with the time taken and/or social norms (e.g. a shared meal that benefits the whole family or group may be more appropriate than a cash payment) and whether the value of any incentives may be seen as coercive
- determining the most appropriate person to direct concerns to—usually this is the researcher or the HREC Chair; however, for some participant groups, it may be appropriate to also refer them to a member of the community (concerns or complaints should still be forwarded to the Office of Research for investigation)
- whether consent will be sought from individuals, or collectively (e.g. a village Elder may give consent for the researcher to observe the community rather than each person giving consent).