University of South Australia

Frequently Asked Questions – Human Research Ethics

Updated August 2023

When is Human Research Ethics Approval Required?

1. What is the definition of 'Human Research'?

Ethics approval is required for most human research. If your project involves human research and requires ethics approval, you must apply for that approval and must not begin your research activity until you have received final approval.

Human Research is conducted with or about people, their data, and/or their tissue/fluids. The term 'participants' is used very broadly to include those who may not even know they are the subjects of research. If you are planning to conduct human research, you will require ethics approval unless your project is subject to specific exemptions.

Some examples of activities that count as human research:

- Surveys
- Interviews
- Focus Groups
- Observations
- Testing

Access to:

- Personal information
- Documents
- Data sets
- Social Media

Collection and use of:

- Bodily organs
- Cell lines
- Tissues
- Fluids
- Exhaled breath

What doesn't need approval?

The following activities do not require human research ethics approval:

- Research that doesn't involve humans, their data, or their tissues/fluids
- Research that meets the National Statement's conditions for exemption (s5.1.22) as explained on the Research Ethics Risk Definitions webpage.
- Activities that are not for a research purpose, including some quality assurance and evaluation activities.

If you are unsure whether your project requires ethics approval, please contact the Human Research Ethics office for advice.

2. Do I need ethics approval if I am conducting an evaluation activity?

The Guidelines for evaluation activities involving UniSA students and staff (PDF) provide guidance on UniSA evaluation activities. For the purpose of these guidelines, 'evaluation activities' may include methods such as surveys or focus groups and are often related to teaching and learning or the student experience. They include corporate evaluation instruments used to evaluate courses, programs, teachers or University products or services.

Some evaluation and quality assurance activities require ethics approval and some do not. To be classified as Exempt from ethical review, the activity must fit the following criteria:

- It is conducted solely for the purpose of internal quality assurance and will not be published or presented externally; or
- It is conducted solely for the purpose of internal quality assurance, and may be published externally only if the following criteria are met:
    - Data were gathered online or in writing
    - the responses were provided voluntarily
    - the respondents were advised of the possibility that data could be used for such purposes; and
    - the anonymity of the respondents is maintained

If you require further advice, please contact the Human Ethics Office on 8302 6330 or at humanethics@unisa.edu.au.

3. Do I need ethics approval if I am only accessing existing data?

If your research project will use existing data, stored in a database or another source, this may or may not require ethics approval.

If your project fulfils one of the following Exempt categories, your research is exempt from requiring ethics approval:

EITHER

- It is considered negligible risk (i.e., no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience); and
- It involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

OR

- It is conducted solely for the purpose of internal quality assurance and will not be published or presented externally; or
- It is conducted solely for the purpose of internal quality assurance, and may be published externally only if the following criteria are met:
    - data were gathered online or in writing
    - the responses were provided voluntarily
    - the respondents were advised of the possibility that data could be used for such purposes; and
    - the anonymity of the respondents is maintained

If you believe your research may fall within an 'Exempt' Risk Category, you should still create an ethics application in the online system. The system will automatically assess the risk level of your research

based on your responses to the 'Project Scope' questions at the beginning of the form. If your application is assessed as 'Exempt', the form will be automatically shortened.

When you submit the form, your application will be reviewed by the Ethics Office to confirm that it is Exempt. You will be notified via email of the outcome of this review. If your research does not meet the requirements for exemption you will be required to provide additional information and your application will require further review.

You must not commence your research until you have received Human Research Ethics Committee (HREC) confirmation that the project is Exempt.

4. Do I still need to apply for UniSA ethics approval if I already have approval from another Human Research Ethics Committee?

The UniSA HREC seeks to avoid the unnecessary duplication of ethical review. If your research protocol has already been approved by another NHMRC-registered Australian Human Research Ethics Committee, you may use this approval as the basis for obtaining ethics approval from the UniSA HREC.

You are required to create a new application in the online ethics system. When completing your online ethics application, under the section 'Non-UniSA HREC', you should answer 'yes' when asked whether another HREC has approved the protocol. This will shorten the application.

You will need to attach copies of the following documents to your UniSA ethics application:

- The full ethics application submitted to the external HREC
- The approval letter from the external HREC
- Other supporting documents as necessary - for example: recruitment materials (Participant Information Sheet(s), Consent Form(s), etc.) and research tools
- Confirmation of UniSA Insurance Cover (please see below for further details)

The UniSA HREC Chair will review these documents, and, if satisfied, will ratify the decision of the other committee.

Please note that the approval from the other HREC must be current (i.e., not expired), and must cover the entire period of the project. If you need to extend the approval period you must do that with the original approving HREC.

Insurance Cover

Confirmation of insurance cover is required from the UniSA Insurance Office for projects that have received prior approval from an external ethics committee. For further information regarding this requirement, please see the following webpage:

https://i.unisa.edu.au/staff/finance/services-we-provide/insurance-landing-page/insurance-cover-for-research-projects/

Please complete the brief insurance application form (which can be accessed from the above webpage) and submit this the Insurance Office, who will assess your request within 5 business days. Please state in your application form that you are seeking individual insurance assessment as your study has received prior approval from an external ethics committee.

Once email confirmation of insurance cover has been received, please include this as a PDF or Word document in the 'Attachments' section of your ethics application (or forward to humanethics@unisa.edu.au).

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

Please contact the Insurance Office directly with any enquiries relating to insurance (insurance@unisa.edu.au / (08) 8302 1678).

5. Do I need ethics approval if I plan to access publicly available data on the internet?

If you are collecting data online – for example, from social media sites – you may or may not require ethics approval, depending on the specific details of your project. Please seek advice from a Research Ethics Advisor or the Human Research Ethics Team in the UniSA Research Office.

Your project may be exempt from requiring ethics approval if:

- you are accessing publicly available data; and
- you will only publish or present these data in a non-identifiable way; and
- your research does not pose any risks to those from whom the data are sourced.

You must also comply with the terms and conditions of any website or social media platform from which you are collecting data.

6. Can I seek course-level ethics approval for a cohort of students?

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

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

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

Confirmation that all students are covered by the course approval must be received before students commence their research. The course coordinator is responsible for ensuring that all individual projects fall within the scope of the course approval and that all students have been trained in ethical human research.

7. Do I need ethics approval to work with human biological samples?

If you are planning to work with human tissue or fluid samples, you will very likely require ethics approval. Please seek advice from a Research Ethics Advisor or the Ethics Office. Guidance is also available in Chapter 3.2 of the National Statement on Ethical Conduct in Human Research.

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

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

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

Please also investigate if biosafety approval is required for your project.

The Human Research Ethics Application and Review Process

8. How do I submit an ethics application?

UniSA has implemented an online system, My Research Management (MyRM), for submitting and reviewing Human Research Ethics applications. This system is based on the requirements of the National Statement on Ethical Conduct in Human Research.

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

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

REMINDER: The research activity must not commence until ethics approval is finalised.

Important Note: If you are accessing the My Research Management (MyRM) system from outside the University campus, please ensure you are connected to the virtual private network (VPN) first. Information on how to connect to the VPN can be found here. Please contact ISTS ((08) 8302 5000) if you experience any issues connecting using the VPN tool.

Logon - My Research Management (MyRM) System
(Use your UniSA logon credentials)

If you have difficulty accessing the Online Ethics system, please forward a request for access to research.information@unisa.edu.au with the following details:

- Full Name
- Staff or Student ID
- Academic Unit
- UniSA username
- Email address

User guides

These user guides provide detailed instructions on how to use the online ethics system.

Applicant (2.1Mb)
Principal Supervisor (1.6 Mb)

Systems queries and troubleshooting
Please check our Application Assistance information for any system-related queries. If you require further assistance, contact the Human Research Ethics Office on 8302 6330 or at humanethics@unisa.edu.au.

9. How does the human ethics review process work?

The Human Ethics Application Review process has multiple steps, which are described below.

Step 1
Applicants logon to **MyRM** and complete the application by answering a number of questions. You can enter and leave the system prior to finishing the application; user guides for the system are available here.

Important Note: If you are accessing the My Research Management (MyRM) system from outside the University campus or home, please ensure you are connected to the virtual private network (VPN) first. Information on how to connect to the VPN can be found here. Please contact ISTS ((08) 8302 5000) if you experience any issues connecting using the VPN tool.

Step 2
Once the application is completed, the applicant submits the application for review.

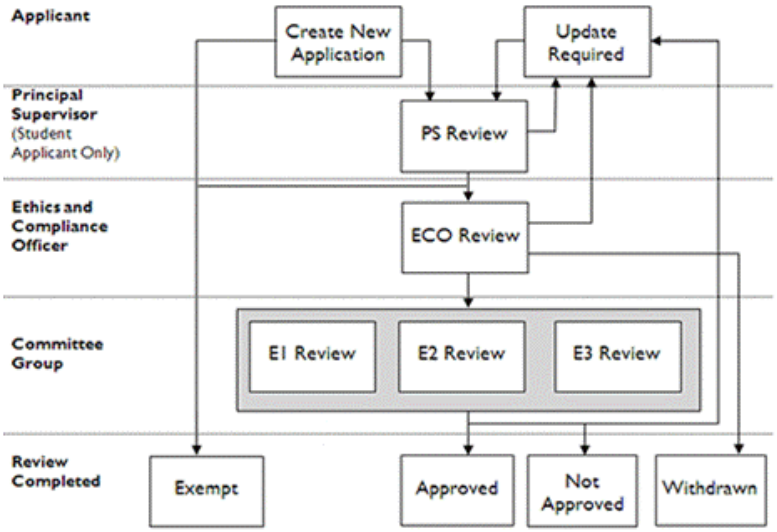
Step 3
Upon submission, an assessment is made of the risk associated with the project (based on the requirements of the National Statement on Ethical Conduct in Human Research, legislation, relevant codes and guidelines and University compliance requirements). Information associated with risk levels are available here.

Step 4
A Human Research Ethics Officer (ECO) will review the application and provide feedback to improve the application. The ECO forwards the completed application to the relevant committee group for review via MyRM.

Step 5
The Committee Review Group reviews the application online and enters their decision.

Step 6
The applicant is notified of the review outcome via email. **The research activity must not commence until ethics approval is finalised.**

Workflow stages of an online ethics application:



10. What are the different levels of risk and review?

There are a number of different Human Research Ethics risk levels and associated Committee Review Group processes.

'Exempt' research

If you believe your research may fall within the **'Exempt'** Risk Category, you should still create an ethics application in the online system. The system will automatically assess the risk level of your research based on your responses to the **'Project Scope'** questions at the beginning of the form.

If your application is assessed as 'Exempt', the form will be automatically shortened.

When you submit the form, your application will be reviewed to confirm that it is Exempt. You will be notified via email of the outcome of this review. If your research does not meet the requirements for exemption you will be required to provide additional information and your application will require further review.

You must not commence your research until you have received Human Research Ethics Committee (HREC) confirmation that the project is Exempt.

Research is classified as Exempt from ethical review where:

EITHER

- It is considered negligible risk (i.e., no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience); and
- It involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

OR

- It is conducted solely for the purpose of internal quality assurance and will not be published or presented externally; or

- It is conducted solely for the purpose of internal quality assurance, and may be published externally only if the following criteria are met:
    - data were gathered online or in writing
    - the responses were provided voluntarily
    - the respondents were advised of the possibility that data could be used for such purposes; and
    - the anonymity of the respondents is maintained

E1 – Negligible risk research
Research projects in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience (and which are not exempt).

E2 – Low risk research
Research projects in which the only foreseeable risk is one of discomfort

E3 – All other research projects
All other research projects, i.e., more than low risk

Committee Review Groups for each Risk Level:

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

Participant Considerations

11. Do I need approval to recruit UniSA staff or students as participants in my research?

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

For permission to recruit/access UniSA staff, students or data for research purposes, including permission to send emails and/or display flyers/posters, please seek permission from the Dean/Director/Senior Manager or delegate of the relevant Academic Unit. This is ideally requested to occur before final ethics approval is obtained.

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

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

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

Relevant University policies and guidelines:

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

12. Do I need approval from organisations to recruit employees?

Researchers are required to obtain written permission from any organisation to access their employees or clients, data associated with these people or other organisational data for research purposes.

Similarly, where you wish to post material on an organisation's website or social media account, or where you plan to promote your project in private/closed social media groups, you will need to investigate and (if applicable) seek approval to post this recruitment material from the relevant senior manager and/or moderator for those organisations or sites.

Ethics approval does not mean that permission to access staff, clients, students, data or other information is guaranteed. This permission is separate from the ethics approval process and is usually required from the Chief Executive Officer or another authorised person. The decision to grant researchers permission to access staff, clients, students, data or other information is entirely up to the authorised person in the organisation.

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

Relevant Commonwealth Acts:

- Privacy Act 1988
- Spam Act 2003

13. I am recruiting children, vulnerable adults or aged care residents as participants in my research – what screenings do I need?

Researchers who intend to undertake research in South Australia with minors or to enter a school, pre-school, childcare centre or other educational facilities in any capacity are required to obtain a Working with Children Check.

Researchers who undertake research with vulnerable adults or aged care services are also required to obtain an appropriate clearance before undertaking the relevant research. Clearances can be obtained from the South Australian Department of Human Services Screening Check system. Individuals can only obtain a clearance via their organisation.

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

- Staff: https://screening.sa.gov.au/home
- Students: Please consult with your Academic Unit regarding local processes.

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

14. I am conducting research in schools – what additional approvals do I need?

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

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

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

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

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

Please note that researchers who intend to undertake research in South Australia with minors or to enter a school, pre-school, childcare centre or other educational facilities in any capacity are required to obtain a Working with Children Check. Further information is available at https://screening.sa.gov.au/home.

15. I am undertaking research with/about Aboriginal People – what do I need to consider?

The HREC will review ethics protocols with significant or targeted participation of Aboriginal people and communities with the expectation that the researchers have involved Aboriginal people and/or communities from project inception (research design and methodology) through to the reporting of the research outcomes (to whom and in what form, considering cultural expectations etc.). Where possible, it is important to remunerate Aboriginal community members for their time and sharing their knowledge for the research project. It is critical that appropriate acknowledgements and recognitions are extended to all Aboriginal participants of a research project, and opportunities to co-author publications are established. It is also important to establish appropriate governance arrangements involving an Aboriginal advisory group and ensuring that all consultation and engagement pathways occur. Researchers should consider inviting Aboriginal researchers to the study team in order to ensure that the study places the needs, priorities and wellbeing of Aboriginal communities first and present a partnership approach at all phases with a feasible knowledge translation strategy engaging with relevant Aboriginal organisations.

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

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

Careful consideration must also be given to cultural and intellectual property. Aboriginal and Torres Strait Islander Peoples have the right to assert and retain ownership of the cultural and intellectual property related to the information that is provided to a research project and it is important that these rights are respected. Ownership may take many forms, including as rights recognised under Australian and international intellectual property laws. However, cultural and intellectual property is not limited to only those forms of knowledge. Please see the NHMRC's guide on Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities for further information.

Researchers need to show how each phase of the research process is ethically defensible, based on the NHMRC guidelines relating to ethical research with Aboriginal and Torres Strait Islander peoples. Researchers must complete, and provide with their ethics application, the Aboriginal and Torres Strait Islander Research Ethics Engagement Plan. Researchers may also benefit from undertaking cultural exchange, cultural awareness, cultural safety or anti-racism programs and noting the name of the program and completion dates in their application.

Researchers may benefit from signalling an understanding of:

- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
- AIATSIS Guide to evaluating and selecting education resources
- UniSA's Aboriginal Research Strategy
- The Maiam nayri Wingara Indigenous Data Sovereignty Principles
- Any academic unit, industry or discipline-relevant guidance and protocols.

Research claiming an Indigenous approach, methodology and/or research practice should consider including citations of Indigenous scholars in the Reference List accompanying their application.

Researchers can seek further advice from Michael Watkins, the Aboriginal Research Ethics Advisor: michael.watkins@unisa.edu.au; 8302 7413.

And please refer to the University's webpage on Aboriginal engagement, including the downloadable guide titled 'Yurirka: Proppa Engagement with Aboriginal Peoples' and the University's Aboriginal Research Strategy 2019 – 2025.

Aboriginal Health Research Ethics Committee (AHREC)

- All research about the health or well-being of Aboriginal people in South Australia must be reviewed by the Aboriginal Health Research Ethics Committee (AHREC), a subcommittee of the Aboriginal Health Council of South Australia Inc. National Aboriginal Community Controlled Health Organisation defines health and well-being, where it is stated that Aboriginal health means not just the physical wellbeing of an individual but refers to the social, emotional and cultural wellbeing of the whole Community in which each individual is able to achieve their full potential as a human being, thereby bringing about the total wellbeing of their Community. It is a whole of life view and includes the cyclical concept of life-death-life.
- You may use this ethics approval as the basis for obtaining ethics approval from the UniSA HREC. You are required to create a new application in the online ethics system. When completing your online ethics application, under the section 'Non-UniSA HREC', you should answer 'yes' when asked whether another HREC has approved the protocol. This will shorten the application.
- You will need to attach copies of the following documents to your UniSA ethics application:
    - The full ethics application submitted to the external HREC
    - The approval letter from the external HREC
    - Other supporting documents as necessary – for example: recruitment materials (Participant Information Sheet(s), Consent Form(s), etc.) and research tools
- The UniSA HREC Chair will review these documents, and, if satisfied, will ratify the decision of the other committee.
    - Please note that the approval from the other HREC must be current (i.e., not expired), and must cover the entire period of the project. If you need to extend the approval period you must do that with the original approving HREC.
    - You will also need to obtain confirmation of insurance cover from the UniSA Insurance Office.

Further information

For further information please refer to the following documents and websites:

- Chapter 4.7 of the National Statement on Ethical Conduct in Human Research (2018) (NHMRC)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
- UniSA's Aboriginal Research Strategy 2019 - 2025

- Keeping research on track II was developed to provide advice on how the values and principles outlined in Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders can be put into practice in research
- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research

Contact the Executive Officer of UniSA HREC for further assistance regarding Ethics and Aboriginal research.

16. I am conducting research in a hospital or health network – what approvals do I need?

If you plan to conduct research in a hospital or local health network, you will need to first seek ethics approval from the relevant local HREC, identified via this list.

You may use this ethics approval as the basis for obtaining ethics approval from the UniSA HREC. You are required to create a new application in the online ethics system. When completing your online ethics application, under the section 'Non-UniSA HREC', you should answer 'yes' when asked whether another HREC has approved the protocol. This will shorten the application.

You will need to attach copies of the following documents to your UniSA ethics application:

- The full ethics application submitted to the external HREC
- The approval letter from the external HREC
- Other supporting documents as necessary - for example: recruitment materials (Participant Information Sheet(s), Consent Form(s), etc.) and research tools
- Confirmation of UniSA Insurance Cover (please see below for further details)

The UniSA HREC Chair will review these documents, and, if satisfied, will ratify the decision of the other committee.

Please note that the approval from the other HREC must be current (i.e., not expired), and must cover the entire period of the project. If you need to extend the approval period you must do that with the original approving HREC.

Insurance Cover

Confirmation of insurance cover is required from the UniSA Insurance Office for projects that have received prior approval from an external ethics committee. For further information regarding this requirement, please see the following webpage:

https://i.unisa.edu.au/staff/finance/services-we-provide/insurance-landing-page/insurance-cover-for-research-projects/

Please complete the brief insurance application form (which can be accessed from the above webpage) and submit this the Insurance Office, who will assess your request within 5 business days. Please state in your application form that you are seeking individual insurance assessment as your study has received prior approval from an external ethics committee.

Once email confirmation of insurance cover has been received, please include this as a PDF or Word document in the 'Attachments' section of your ethics application (or forward to humanethics@unisa.edu.au).

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

Please contact the Insurance Office directly with any enquiries relating to insurance (insurance@unisa.edu.au / (08) 8302 1678).

17. I am conducting research with defence personnel – what approvals do I need?

If you plan to conduct research with serving and/or ex-serving Australian Defence Force members, you will need to first seek ethics approval from the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

You may use this ethics approval as the basis for obtaining ethics approval from the UniSA HREC. You are required to create a new application in the online ethics system. When completing your online ethics application, under the section 'Non-UniSA HREC', you should answer 'yes' when asked whether another HREC has approved the protocol. This will shorten the application.

You will need to attach copies of the following documents to your UniSA ethics application:

- The full ethics application submitted to the external HREC
- The approval letter from the external HREC
- Other supporting documents as necessary - for example: recruitment materials (Participant Information Sheet(s), Consent Form(s), etc.) and research tools
- Confirmation of UniSA Insurance Cover (please see below for further details)

The UniSA HREC Chair will review these documents, and, if satisfied, will ratify the decision of the other committee.

Please note that the approval from the other HREC must be current (i.e., not expired), and must cover the entire period of the project. If you need to extend the approval period you must do that with the original approving HREC.

Insurance Cover

Confirmation of insurance cover is required from the UniSA Insurance Office for projects that have received prior approval from an external ethics committee. For further information regarding this requirement, please see the following webpage:

https://i.unisa.edu.au/staff/finance/services-we-provide/insurance-landing-page/insurance-cover-for-research-projects/

Please complete the brief insurance application form (which can be accessed from the above webpage) and submit this the Insurance Office, who will assess your request within 5 business days. Please state in your application form that you are seeking individual insurance assessment as your study has received prior approval from an external ethics committee.

Once email confirmation of insurance cover has been received, please include this as a PDF or Word document in the 'Attachments' section of your ethics application (or forward to humanethics@unisa.edu.au).

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

Please contact the Insurance Office directly with any enquiries relating to insurance (insurance@unisa.edu.au / (08) 8302 1678).

Consent

18. Which types of participants do not legally have capacity to consent?

According to Chapter 2.2 of the National Statement on Ethical Conduct in Human Research,

> *a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.*
> *[…]*
> *Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation.*

Participants in the following categories **may** lack the capacity to consent:

Children and young people

A child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation in research.

Different levels of maturity and of the corresponding capacity to be involved in the decision include:

a) infants, who are unable to take part in discussion about the research and its effects
b) young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required
c) young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research
d) young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.

It is not possible to attach fixed ages to each level – they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research.

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

a) the child or young person whenever he or she has the capacity to make this decision; and
b) either

(i) one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable
(ii) the guardian or other primary care giver, or any organisation or person required by law.

Please see Chapter 4.2 of the National Statement on Ethical Conduct in Human Research for further information

People highly dependent on medical care

Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them. Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should generally be sought from the participant's guardian or a person or organisation authorised by law.

An HREC may approve a research project without prior consent under the specific circumstances outlined in Chapter 4.4.13 of the National Statement.

Please see Chapter 4.4 of the National Statement on Ethical Conduct in Human Research for further information.

People with a cognitive impairment, an intellectual disability, or a mental illness

Consent to participate in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:

- the nature of the condition
- the person's medication or treatment
- the person's discomfort or distress
- the complexity of the research project
- fluctuations in the condition. For example, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic.

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

19. What is the difference between ‘specific’, ‘unspecific’ and ‘extended’ consent?

Question 70.7 of the Online Ethics Application Form asks whether you will be seeking specific, extended or unspecific consent.

Chapter 2.2.14 of the National Statement on Ethical Conduct in Human Research defines these different types of consent as follows:

Specific: consent is limited to the specific project under consideration

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

a) an extension of, or closely related to, the original project; or
b) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research)

Unspecified: consent is given for the use of data or tissue in *any* future research.

Extended or unspecified consent may include permission to enter the original data or tissue into a databank or tissuebank.

If consent is extended or unspecified, you must state in your Participant Information Sheet that deidentified data may be used in future research projects (for which ethics approval will be sought).

20. Can I utilise an 'opt out' approach to consent?

Chapter 2.3.5 – 2.3.8 of the National Statement on Ethical Conduct in Human Research details the circumstances in which an opt-out approach to participant recruitment may be approved:

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

Before approving the use of an opt-out approach for research, HREC must be satisfied that:

a) involvement in the research carries no more than low risk to participants
b) the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy
c) the research activity is likely to be compromised if the participation rate is not near complete, and the requirement for explicit consent would compromise the necessary level of participation
d) reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining the nature of the information to be collected, the purpose of collecting it, and the procedure to decline participation or withdraw from the research
e) a reasonable time period is allowed between the provision of information to prospective participants and the use of their data so that an opportunity for them to decline to participate is provided before the research begins
f) a mechanism is provided for prospective participants to obtain further information and decline to participate
g) the data collected will be managed and maintained in accordance with relevant security standards
h) there is a governance process in place that delineates specific responsibility for the project and for the appropriate management of the data
i) the opt-out approach is not prohibited by State, federal, or international law.

If you wish to seek approval to use an opt-out approach, please attach a document to your Ethics Application which addresses each of these points.

HREC will consider the sensitivity and the risks of the project, the potential participant pool, the context in which the research and opt-out approach will occur, and whether withdrawal from participation is feasible once identifiers have been removed from data.

Please see Chapter 2.3.5 – 2.3.8 of the National Statement on Ethical Conduct in Human Research for further information.

21. Under what circumstances can the consent requirement be waived?

Under Chapter 2.3.10 of the National Statement on Ethical Conduct in Human Research, before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk to participants
b) the benefits from the research justify any risks of harm associated with not seeking consent
c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
e) there is sufficient protection of their privacy
f) there is an adequate plan to protect the confidentiality of data
g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
i) the waiver is not prohibited by State, federal, or international law.

If you are applying for a consent waiver, please attach a document to your Ethics Application which addresses each of these points.

Please see Chapter 2.3 of the National Statement on Ethical Conduct in Human Research for further information.

22. Do I need special consent to take photographs of participants?

If you plan to take photographs during the course of your research, your ethics application should include details of what will be captured in these images and how they will be used. For example, will the photographs be used for the purposes of analysis only, or will they be published in the reporting of results?

If photographs will be included in the dissemination of results, please state whether they will include identifiable or potentially identifiable features (for example, will they capture people's faces or landmarks/objects that may make it possible for third parties to identify participants?) If so, participants must be forewarned of this in the Participant Information Sheet, and specific written consent must be sought for the publication of identifiable images.

Alternatively, researchers should consider (and detail, if applicable) if any measures that will be taken to protect the anonymity of participants. Such measures may include pixelating or blurring faces and other identifying features. A statement should be included in the Participant Information Sheet and Consent Form to the effect that "photographs will only be included in the reporting of results where visual de-identification techniques (such as blurring or pixelating faces and other identifying features or logos) have been used."

If images will be used for purposes beyond the scope of the research project (for example, in promotional materials or media reports), a separate consent process involving a Talent Release Form may be required. Please contact the Communications and Marketing Unit for assistance with this process.

23. Can I publish artefacts created by participants?

Artefacts may be generated during the course of a research project (for example, participants may create or collaborate on an artwork, resource or another outcome during a workshop). Your ethics application should include details of any outcomes that will be generated and how these will be used. For example, will the artefacts be used for the purposes of analysis only, or will they be published in the reporting of results?

If you plan to publish artefacts, consent must be explicitly provided by participants. Participants should be provided with the following information:

- A clear description of what will be developed and how it will be used.
- A statement on whether participants will be identifiable by way of the publication of the artefact/resource developed.
- Clarification as to whether participants will have the option to have their contribution acknowledged.

For further advice, please contact humanethics@unisa.edu.au.

Data Types and Management

24. What is the difference between identifiable, non-identifiable and re-identifiable data types?

The NHMRC defines the different types of data as follows:

- **Non-identifiable data**: Data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

- **Re-identifiable data:** Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.
- **Identifiable data**: Data where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address

25. Who owns research data?

Under the University's Ownership and Retention of Data Policy, research data created or developed by Staff Researchers and the intellectual property in and associated with such data are owned by the University, unless otherwise agreed in writing between the Researcher and the University or the University and a third party.

Research Data created or developed by Student Researchers and the intellectual property in and associated with such data are owned by the Student Researcher, unless otherwise agreed with the University or a staff member.

There are special considerations around cultural and intellectual property for research involving Aboriginal and Torres Strait Islander Peoples. Please see the NHMRC's guide on Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities for further information.

26. When is a data ownership agreement required?

Is your research a joint project involving UniSA Staff and students, or does your research involve collaboration with parties external to the University? If so, a data ownership agreement may be required. Should you require any assistance/advice regarding an agreement, please contact the UniSA Research Office's Contracts Team at research.contracts@unisa.edu.au.

If an Honours or Research Degree student is involved in a staff project, a Student Project Participation Agreement may be required. The student's Supervisor is responsible for ensuring that an agreement is signed by the student as a precondition to involvement in the University/Staff/Student Project if required. Please see the following website for further information: https://i.unisa.edu.au/students/research-students/commencing-students/intellectual-property/

27. Where should I store my research data?

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

Please see the University's Research Data Management and Data Management Planning websites for guidance on data storage, security and retention.

28. How long do I need to store my research data for?

Research Data, Primary Material and Research Records must be maintained for as long as specified by the Australian Code for the Responsible Conduct of Research (the Code) and other legislative, contractual and regulatory requirements.

The Code specifies the following retention time requirements for Primary Material, Research Data and Research Records:

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

Please see the University's Research Data Management and Data Management Planning websites for guidance on data storage, security and retention.

Risks and Benefits

29. How are harm, discomfort and inconvenience defined?

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

- physical harms: including injury, illness, pain
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation
- findings of previously unknown paternity status
- economic harms: including the imposition of direct or indirect costs on participants
- legal harms: including discovery and prosecution of criminal conduct.

Discomfort is less serious than harm. Examples may include minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.
Inconvenience is considered less serious again. Examples may include filling in a form, participating in a street survey, or giving up time to participate in research.

30. How do I manage the risk of psychological/emotional distress?

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

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

You may also wish to consider developing a Distress Protocol – this document should be attached to your Ethics Application.

31. Can I pay my participants?

Under Chapter 2.2 of the National Statement on Ethical Conduct in Human Research,

> *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.*

Where you plan to offer a reimbursement or honorarium to participants, please include full details in your ethics application so that HREC can determine whether it is appropriate and proportionate.

Reporting of Results

32. Do I need to provide participants with a summary of my findings?

HREC generally considers that it is the researcher's responsibility to proactively offer to provide participants with a summary of their findings wherever possible.

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

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

Other Approvals

33. Do I need insurance cover for my project?

Your responses to selected ethics application questions will be assessed to determine whether your research activity is covered by the University's standard insurance cover or whether individual insurance assessment is required.

Where individual insurance assessment is required, the ethics team will email you (following the submission of your application) to obtain any additional information not available from your ethics application.

Please refer to the Insurance Website for further information about insurance cover and for a full description of standard insurance conditions which cover all research projects.

34. What are the registration requirements for Clinical Trials?

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

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

Clinical drug trials notification forms can be accessed via the Therapeutic Goods Administration website.

35. My research involves radiation – what approvals do I need?

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

Where participants in human research are exposed to ionising or non-ionising radiation, approval must be sought from the University Radiation Safety Committee as a condition of ethics approval.

Please upload a copy of UniSA Radiation Safety Committee approval under the 'Attachments' section of your ethics application, or confirm that this will be forwarded to humanethics@unisa.edu.au once finalised.

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

36. I will be travelling to another country to conduct my research – what do I need to consider?

Research conducted in another country is defined as when you are travelling to that country, and not when you are simply collecting data from an online survey. Overseas research might have legal, social or cultural implications which would not be an issue if the research was carried out in Australia.

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

It is the responsibility of the researcher (and the research supervisor) to thoroughly investigate any legal, governmental, visa, ethical, cultural or research approval requirements when conducting research in another country. If applicable, final ethics approval may not be granted until written evidence of having met those requirements has been provided. **Please be advised that the onus of acquiring and maintaining the records of these requisite approvals and permissions solely lies with researchers.**

Overseas research might involve Indigenous people. As with research involving Australian Aboriginal and Torres Strait Islander people, you should ensure that your proposed research is culturally appropriate by consulting with representative bodies.

Approval of your research by UniSA HREC ensures that you will be appropriately covered by the University's insurance policy for research that you conduct offshore. For research in the US or Canada, please refer to the Insurance website for further information about insurance cover.

Post-Approval Requirements

37. What are the conditions of ethics approval?

Human Research Ethics Committee approval is always based on the standard conditions outlined in the HREC Conditions of Approval document. Researchers must be familiar with, and abide by, these conditions.

38. Do I need any other approvals before I start my research?

Your research must not commence until the UniSA HREC has granted full and final ethics approval. However, you may also be required to gain approvals and permissions through other HRECs or committees external to UniSA, or other UniSA internal approvals relevant to your research and activities. The onus of acquiring and maintaining the records of the requisite approvals and permissions lies with researchers.

These may include, but are not limited to, the following examples:

- UniSA Animal Ethics Committee approval if your research also involves animals.
- UniSA Institutional Biosafety Committee approval if using GMOs.
- UniSA Radiation Safety Committee approval if using radiation.
- UniSA Chemical Advisory Safety Committee approval for any requisite governance of chemical management activities.

- Permission to recruit UniSA staff and students and/or for the use of UniSA data.
- Permission to interact with and/or recruit from external organisations.
- Internal and/or external written agreements, or contracts for collaborative research projects.
- Relevant screening checks for research work involving children, aged care or vulnerable groups.
- Undertaking Therapeutic Goods Administration (TGA) processes relevant to the study for the use of any unapproved therapeutic goods.
- Relevant external HRECs and committees (including research involving Aboriginal communities, research in education, defence or child protection requiring relevant departmental clearances, research in a hospital or local health network).
- Any legal, governmental, visa, ethical, cultural or research approval requirements when conducting research in another country or with a foreign entity, including assessment for foreign interactions.
- Confirmation of insurance cover from the UniSA Insurance Office where you have been advised that individual insurance assessment is required.

39. What are the reporting requirements for my approved project?

Reports on the progress and completion of the project must be provided annually to the Human Research Ethics Committee. Ethics approval is granted for three years (unless otherwise stated) contingent upon annual review.

- An Annual Report is to be provided every 12 months after the listed commencement date for the approved protocol. Ethical approval will lapse if an Annual Report is not submitted.
- A Project Completion Form is to be submitted within three months of the project's completion.
- An Extension Request Form is to be submitted if you require more than 3 years in which to complete the research. This form must be submitted at least 1 month prior to the final expiration of the ethics approval for the project

40. How do I make changes to my approved protocol?

Once your research project has approval from the HREC, any changes you wish to make must be submitted for approval by the HREC. These include changes to:

- Participants
    - Selection of participants (e.g., changing the inclusion/exclusion criteria for participants or participant groups)
    - Organisations involved in the research (e.g., recruiting from a new organisation not previously approved, or deciding not to use a previously approved organisation)
    - Sample size (e.g., if your approved protocol was to conduct 10 focus groups but it was decided that 12 are needed, then approval must be sought before conducting the additional two focus groups)

- Recruitment materials (Altering the wording or any material, including recruitment flyers, information sheets, consent forms, letters sent to participants/potential participants and media advertisements)
    - Honorarium (introducing, removing or altering)

    - Research tools (e.g., new research tools (new surveys, interview/focus group questions etc.) or removing or changing approved research tools)
        - Questionnaire
        - Interview or Focus Group questions
        - Data collection protocols

- Project Team and/or Funding
    - Addition or removal of any investigators
    - Change to HDR student supervision team
    - Project funding and/or contractual arrangements
    - Study Status (e.g., study is placed on hold or suspended)

To request a variation, the Project Variation Form must be submitted to the Human Research Ethics Office (humanethics@unisa.edu.au) along with copies of any relevant documents (e.g., participant information sheets, research tools, recruitment materials) affected by the variation. Variations must be justified and be consistent with the original research aims and research questions.

Two copies of all amended documents are to be submitted:

- One copy of the document(s) using track changes
- One clean copy of the amended document(s)

Documents must have a version number and date.

The Human Research Ethics Officer will liaise with the Chair or Deputy Chair of UniSA HREC, who will consider your amendment(s). Feedback from the UniSA HREC should occur within 5 working days of receipt of your variation request.

Formal notification of approval from UniSA HREC/Chair must be received prior to implementing the change(s).

41. How should I report an Adverse Event?

Any adverse effects on research participants or reportable events must be reported to the Human Research Ethics Office in line with the NHMRC requirements (humanethics@unisa.edu.au) using the Adverse or Reportable Event Form.

In the case of SSIs, please review the NHMRC Guidance of safety monitoring and reporting available at: https://www.nhmrc.gov.au/sites/default/files/images/NHMRC-guidance-safety-monitoring-and-reporting.pdf.

42. How does the complaints process work?

Any complaints relating to research projects approved by UniSA's HREC should be directed to the Executive Officer of UniSA HREC:

Executive Officer, UniSA Human Research Ethics Committee
Tel: 08 8302 6330
Email: humanethics@unisa.edu.au

The Executive Officer will ensure the information is handled in a confidential manner and discussed with the HREC Chair/Deputy Chair as soon as possible. Depending on the nature of the issue identified, an investigation will be undertaken in consultation with the appropriate parties.

The Human Research Ethics Complaints process is detailed in section 1.6 of the Human Research Ethics policy.