

1. Informed Consent

Informed consent is to be collected from those who are prospectively recruited to participate in research before being screened, observed, administered research measures, interventions, data collection tools, investigational medical products/devices, or participating in any research activities. Informed consent involves providing sufficient information about the research to allow a person to decide whether to consent to participate in research.

2. Participant Information Statement and Consent Form

The participant information statement is used to explain the purpose of the research and provide a description of what participants will be required to do, how they will be involved, and how they will be used in the research. Academic, medical, scientific, and technical terminology must be presented using language or terms suitable for the general public and presented according to the UNSW writing style guide. The participant information statement can be converted into verbal scripts or translated into the local language to facilitate local cultural requirements or assist those who may experience reading or comprehension difficulties. Participant Information Statement templates for specific research methodologies can be downloaded from the UNSW Human Research website. National Statement, item 2.2.6 lists the information that is to be communicated to participants when seeking consent.

3. Accessible Version of the Participant Information Statement

National Statement, item 2.2.3 specifies that the research's information is presented in ways suitable for each participant. An accessible version of the participant information statement and consent form can assist an individual in their capacity to understand what the research involves before being asked to provide consent. Easy English is another format of information often used for people with low English literacy skills, such as adults who experienced a disrupted education or where English is not their first language.

Typically, Easy Read and Easy English information are characterised by:

- Only including the main points of information.
- Using subheadings and bullet points to break up the information.
- Using short sentences and accessible terminology.
- Clear formatting, e.g., black text on white background only, large text, large margins, left-justified text, sans serif fonts and extra white space between lines.
- Simple graphics and pictures are often included to complement the text and assist with comprehension. These are included along the left-hand margin.

A list of guides and resources to assist with the development of accessible read information is provided below:

- [Easy Read Participant Information Statement and Consent Form](#), UNSW
- [Easy English Writing Style Guide](#), Communication Resource Centre, SCOPE for people with a disability.
- [Accessible written information resources for adults with intellectual disability](#), Centre for Applied Disability Research
- [Easy Read](#), The Information Access Group

3.1. Ethical Review and Approval of a Participant Information Statement

National Statement, item 5.2.25 specifies that the participant information statement and consent form must be provided for review with a human research ethics application. For this reason, researchers are to provide the reviewing HREAP or HREC with a copy of each participant information statement that will be provided to participants. The HREAP or HREC is to review and approve each participant information statement and consent form or consent script administered to a participant before recruitment or data collection commences.

4. Methods for Obtaining Participant Consent

The National Statement, item 2.2.5 indicates that consent may be expressed orally, in writing or by some other means depending on:

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

It is recommended that the following methods for obtaining consent are to be used in human research. Additional methods for obtaining consent can be used if the procedure for collecting consent is described and it meets National Statement, items 2.2.1, 2.2.2, 2.2.3 and 2.2.4.

4.1. Written Consent

Written consent is to be obtained in situations where the research involves person-to-person contact. The participant information statement and consent form are to be provided to participants, and they are to be provided with an adequate amount of time to read the information, consult with others (e.g., family member or a medical practitioner), and ask the research team any questions before they are asked to provide written consent by signing the consent form. Those that sign consent forms are provided with a copy of the participant information statement and consent form for their information. Written consent is to be used for human research involving the following methodologies unless an appropriate justification for alternative methods for obtaining consent can be made:

- Face to Face Interviews.
- Clinical Trials and Clinical research.
- Focus Groups conducted in person.
- Laboratory-based interventions, assessments, or experiments.
- Complex mixed methods research

4.2. Email Consent

Email consent is to be used in situations where written consent is the most appropriate method of obtaining consent based on the research methodology. The data collection will not take place in person. Participants are emailed a copy of the participant information statement and consent form, or the body of an email includes the participant information statement and consent form text. Individuals are encouraged to read the information and consult with others (e.g., family members or medical professionals) before providing their consent. Contact details for the research team are included for participants to raise any research-related questions that they may have. Participants who agree to participate should be directed to return consent using one of the following methods:

- Send via return email consent form that has been signed using an e-signature.
- Send a return email that confirms that the participant information statement has been read. They agree to provide their consent to participate in the research (e.g. participants could be advised to cut and paste the consent declaration into a reply email). Researchers should consider whether participants will have the technology to add e-signatures to documents when developing their email consent process. Email consent is to be used for human research involving the following methodologies unless an appropriate justification for alternative methods for obtaining consent can be made:
 - Tele interviews or surveys.
 - Video interviews or surveys.
 - Focus Groups conducted online.

4.3. Online or Implied Consent

Online or implied consent is used in situations where survey/questionnaires are administered online, in person or in a format that facilitates anonymity to protect participant populations. When using online or

implied consent, a copy of the participant information statement and consent form is provided to the participant population (e.g., in an expanded format for online surveys, via email, or attached to the front of a hard copy survey). Participants are instructed to read the information and consult with others (e.g., a family member or medical professional) before indicating their consent by selecting consent checkboxes or implying consent by returning a completed survey or questionnaire. Participants will be provided with the research team's contact details to discuss any questions about their research participation. Participants will be provided with a copy of the participant information statement and consent form in hard copy or via email for their records or provided with a link to a downloadable version. Implied consent is to be used for human research involving the following methodologies unless an appropriate justification for alternative methods for obtaining consent can be made:

- Online surveys, questionnaires or measures administered via Qualtrics, Redcap or other web-based platforms.
- Paper-based surveys, online surveys, or questionnaires.
- Research that has the potential to uncover illegal behaviour.

4.4. Research involving video or telephone consultation and e-consent processes. Verbal Consent

Verbal consent is to be used in situations where the research requires telephone/video conferencing contact, where there is the potential for the target population to have reading and comprehension issues, or where a verbal consent process is more culturally appropriate. The participant information statement and consent form are to be provided to participants in a format that is accessible to the target population. They are to be provided with an adequate amount of time (e.g. at least 30 minutes for direct approach (e.g. introduction of research in a clinic setting), or up to a week before attending a verbal consent appointment) to read through the information and consult with others (e.g. family member or a medical practitioner). The research team provides a verbal description of the information included in the participant information statement and consent form during a scheduled telephone or video conference appointment. Participants are to be provided with the opportunity to discuss any questions they may have. Participants will be asked whether they provide their permission for the research team to audio record their agreement for consent. If they agree, the research team commence audio recording. The following questions are to be asked by the research team, and the participant responses must be recorded:

1. Please confirm that I have provided you with a verbal description of what the research involves and you understand what your involvement in the research requires.
2. Please confirm that I have answered any questions you have raised concerning the research.
3. Do you agree to provide your consent to take part in this research project?
4. Please state your name, the time, and the date for the recording.
5. End this recording of the consent process.

A new recording will be commenced for the data collection to store the identifiable consent separately to the interview data securely. If the participant disagrees for their consent declaration and interview data to be audio recorded, record their consent by entering their responses to questions 1-5 into an excel spreadsheet or a word document. The document is to be securely stored separately from the interview data.

4.5. Qualifying or waiving conditions of consent

A waiver of consent is to be requested where existing information about an individual is to be accessed and used in research, and one of the following applies:

- Evidence of the individual's consent to access and use their information for a research purpose cannot be provided to the ethics review panel or committee.
- It is impracticable to obtain an individual's explicit consent to the use of their information in research.

4.5.1. Justifying a request to waive the requirement for obtaining consent to use non-identifiable data

National Statement, item 2.3.10 advises that before deciding whether to approve a waiver of consent, reviewing HREAP or HREC is to be provided with a justification for this request. The justification must detail the process to ensure that:

- a) Accessing and using the data will not cause harms, and the activity is considered no more than low risk.
- b) A clear statement specifying the overall benefits of the research and how these benefits justify any risks of harm associated with not seeking consent.

- c) Why it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
- d) The research team has determined that there is no known or likely reason for thinking that participants would not have consented if they had been asked.
- e) There is a procedure for ensuring that there is sufficient protection of privacy.
- f) There are measures to ensure an adequate plan to protect the confidentiality of data when accessing, using, or publishing the research results.
- g) There is a plan to ensure an adequate plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media) if the results of the research will have significance for the participants' welfare?
- h) The research team will ensure that any commercial benefits generated from using an individual's data or tissue will not deprive the participants of any financial benefits to which they would be entitled.
- i) The research team have specified how they have established whether the waiver is not prohibited by State, federal, or international law.

4.5.2. Waiver of consent using identifiable or potentially identifiable data

Guidelines approved under Section 95 of the Privacy Act 1988 are to be applied, and all items outlined in section 2.4 of this document are to be addressed throughout the research proposal.

4.5.3. HREC review of a waiver of consent

National Statement, item 2.3.9 specifies that only an HREC can grant requests to waive the requirement of consent for research using

- Personal information in medical research or personal health information
- Research aiming to expose illegal activities
- Research, where it is impracticable to obtain an individual's consent to use their information and the research, will involve using potentially identifiable information.

4.5.4. Low-Risk HREAP review of a waiver of consent

The Low-Risk Panels can grant requests to waive the requirement of consent for research using personal information in other types of research (i.e. non-medical research and research that does not aim to expose illegal activity).

4.5.5. Negligible Risk HREAP Executive review of a waiver of consent

The Negligible Risk Executive can grant requests to waive the requirement of consent for research using non-identifiable datasets. The data must be non-identifiable before it is provided to the research team.

4.6. Opt-out approach to consent

National Statement, item 2.3.5 advises that an opt-out approach to participant recruitment 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. An opt-out approach involves providing an information statement that outlines what a participant's involvement in the research will require, and the person's consent to participate is presumed unless they take action to decline to participate. An opt-out consent process is commonly used for human research involving the following methodologies:

- Secondary use of large datasets, where the researchers cannot justify a waiver of consent due to it being possible to contact participants, but where the number of participants' records the researchers intend to access makes it impossible to obtain explicit consent from all participants
- Prospective collection of observational data from large public gatherings where it is possible to provide all participants with information about the research, but is not feasible to collect explicit consent from all participants

4.6.1. Justifying a request for an opt-out approach to consent

National Statement, item 2.3.5 advises that before deciding whether to approve an opt-out approach to consent, the reviewing HREAP or HREC is to be provided with a justification for this request. The justification must detail the process to ensure that:

- a) Accessing personal information using these details to contact individuals to introduce the research will infringe upon their privacy.

- b) Accessing and using the data will not cause harms, and the activity is considered no more than low risk.
- c) The research team has assessed and determined that the public interest in the research outweighs the public interest in protecting privacy.
- d) The research team can evidence that it completed an assessment to confirm that the requirement for explicit consent would compromise the necessary level of participation to answer the research aims.
- e) There is a plan to ensure that participants are provided 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.
- f) There will be a specified period (at least two weeks) that participants will be provided between introducing the research, providing a participant information statement, and the opt-out consent form to decline to participate before the research begins.
- g) The consent process provides prospective participants with instructions for obtaining further information and decline to participate.
- h) An explanation of how the data collected will be managed and maintained following relevant security standards.
- i) An outline of the governance process that will be put in place that delineates specific responsibility for the project and the appropriate management of the data.
- j) The research team have specified how they have established whether the opt-out consent process is not prohibited by State, federal, or international law.

5. Where others need to be involved in participation decisions

National Statement, item 2.2.12 advises that in situations where a potential participant cannot 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. For this reason, consent is to be obtained from a legal guardian, the person responsible, carer, community elder/leader, or by corrective services (who may be guardians, carers, persons responsible, community leaders or a statutory body exercising lawful authority) before including participants from the following groups of vulnerable populations in research:

- Individuals with cognitive impairment, an intellectual disability, or a mental illness.
- People high highly dependent on medical care.
- Residents in aged care facilities.
- Indigenous communities

The consent process must describe how others will be involved in the consent process, how their consent will be obtained before collecting consent from the individual and detail the measures that will be put in place to ensure that consent decision is not contrary to the person's best interests. A participant information statement and consent form for both the participant and the person or appropriate body exercising lawful authority for the potential participant are provided for ethical review.

5.1. Justifying a request for participants of vulnerable populations to provide their consent.

National Statement, item 4.5.5 advises that consent to participate in research by someone with cognitive impairment, an intellectual disability, or a mental illness should be sought from that person if he or she can consent. The protocol for obtaining consent from vulnerable populations must include the following to justify the requirements of this National Statement:

- a) Information advising how the research team have assessed and determined whether obtaining consent from an individual and not involving others will not breach any relevant jurisdictional laws.
- b) A protocol for assessing and determining a person's capacity to provide their own consent.
- c) A plan for establishing whether a person's representative or others might be unwilling to provide their consent include a person they are responsible for in the research.
- d) The measures to respond to complaints from families, groups, or individuals determine that a person's inclusion is not in their best interest.
- e) An explanation of how the research the potential for participants, their family or the wider community to experience research harms or discomforts is minimised through the research design.

6. Children and young people

National Statement, item 4.2.7 requires the consent of parents, guardians, or caregivers before a child or young person that they are responsible for participates in most research. Consent from the child or young person should also be sought if their person responsible agrees that a child or young person can participate in research. The National Statement makes provisions for young people who are mature enough to consent to participate in research (refer to section 6.1). Research proposals involving children and young people must describe:

- a) The process includes the parent, guardian, carer, child and young person in the recruitment and consent process.
- b) The measures to assess whether a parent, guardian, or carer has the legal right to include a child or young person in research.
- c) The measures to minimise a child or young person's risk of feeling coerced or pressured into participating.
- d) The process for managing the inclusion of a child and young person if they indicate that they do not wish to participate in the research and this decision conflicts with their parent, guardian, or carer.

6.1. Justifying a request for children and young people to provide their consent

National Statement, item 4.2.8 requires justification for including a young person in research without their parent, guardian or carer providing consent. The justification must confirm that:

- The research, data collection methods, activities that the young people will complete, recruitment and consent processes offer no more than a risk of discomfort.
- The benefits of the research for children or young people.
- A protocol for establishing capacity and maturity to understand the participant information statement, the research risks before providing their consent.
- The reasons for not seeking consent from a parent, guardian, or caregiver and evidence of stakeholder engagement supporting young people's inclusion without this consent.
- The measures to respond to complaints from a parent, guardian, or caregiver advising the young person's inclusion is not in their best interest.

Accountabilities	
Responsible Officer	Director Research Ethics Compliance Support
Contact Officer	Human Research Manager
Supporting Information	
Legislative Compliance	This Standard supports the University's compliance with the following legislation: Guidelines under Section 95 of the Privacy Act 1988 (s95 guidelines) Guidelines approved under Section 95A of the Privacy Act 1988 (s95A guidelines) Privacy Act 1988. The Australian Privacy Principles Guidelines
Parent Document (Policy)	UNSW Human Research Procedure
Related Documents	National Statement on Ethical Conduct in Human Research (2007) updated 2018
Definitions and Acronyms	
National Statement	National Statement on Ethical Conduct in Human Research (2007) updated 2018
HREC	Human Research Ethics Committee

HREAP		Human Research Advisory Panel			
Revision History					
Version	Approved by		Approval date	Effective date	Sections modified
1	Director, Research Compliance Support	Ethics	29 April 2021	29 April 2021	Nil