



Consent in Human Research Swinburne Research

Consent in Human Research

Recruitment of research participants involves seeking their consent regarding their participation in the research.

Consent must be **voluntary** and **informed** (see *National Statement on Ethical Conduct in Human Research 2018 (N.S.) 2.2.1*).

Informed consent means that participants have an adequate understanding of the purpose, methods, demands, risks, and potential benefits of the research, as well as any alternatives to participation (see *N.S. 2.2.2 & 2.2.6 (a)*). This means information regarding the following must be conveyed to them:

- What the research involves (see *N.S. 2.2.1 - 2.2.2*)
- What are the risks, benefits and alternatives to participation (see *N.S. 2.2.2 & 2.2.6 (a)*)
- How the research will be monitored (see *N.S. 2.2.6 (b)*)
- Services available to participants, in case they experience distress as a result of participating (see *N.S. 2.2.6 (c)*)
- How to contact the Ethics Office, in case they wish to make a complaint (see *N.S. 2.2.6 (d)*)
- How to contact the researchers (see *N.S. 2.2.6 (e)*)
- How their privacy and confidentiality will be protected e.g. how their data will be stored, who will access it, how it will be accessed (see *N.S. 2.2.6 (f)*)
- How, and up to at what point, participants can withdraw from participation, including the implications of withdrawal and whether it is possible to withdraw data (see *N.S. 2.2.6 (g) & 2.2.20*)
- How the research is being funded, if applicable (see *N.S. 2.2.6 (h)*)
- Financial or other relevant declarations of interests of researchers, sponsors or institutions, if applicable (see *N.S. 2.2.6 (i)*)
- Participant reimbursement, including payment/s, if applicable (see *N.S. 2.2.6 (j)*)
- How the research results will be disseminated, including in what form (see *N.S. 2.2.6 (k)*)
- How the wider community will benefit from the research, if applicable (see *N.S. 2.2.6 (l)*)



Information needs to be communicated to potential participants in a way that can be understood and using plain language (see N.S. 2.2.3 & 5.2.17). It must be tailored to the specific participants group/s and take into consideration factors such as participants' understanding of English, including whether or not English is their first language, level of education, and understanding of the subject matter of the research in question (see N.S. 2.2.3 & 5.2.17).

Voluntary consent means that participants have decided by themselves that they wish to participate in the project - without having had pressure placed on them to participate by someone else. This includes recognising, and addressing, situations involving relationships between researchers and participants, for example: projects of academics recruiting students as participants; projects of students recruiting family / friends as participants; projects in which employers are being asked to nominate employees as participants. In these situations it is important that this unequal relationship can create a perception of coercion that needs to be minimised as much as possible to facilitate voluntary consent. (see N.S. 2.2.9, 3.1.18 (d), 4.3.1 - 4.3.3).

If a participant lacks the capacity to provide voluntary and informed consent, a person of appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information in order to decide whether or not they should participate. Participants falling into this category include: people highly dependent on medical care; people with a cognitive impairment, intellectual disability or mental illness; and children (see N.S. 2.2.12 & chapters 4.2, 4.4, and 4.5).

Research participants can consent to participation in research projects via:

- **Written consent**
- **Oral consent**
- **Implied consent** (see N.S. 2.2.5)

Written consent

- Participants consent to their participation in the research project by providing their consent in writing, e.g. returning a signed Consent Form to the research team. This approach is useful for projects involving activities where participants are required to consent to multiple matters, including, for example, consenting to being recorded; consenting to the future use of their data; consenting to making themselves available for future information if required. Projects which involve interviews and/or focus groups usually obtain consent in this manner. For examples of written consent instruments, please see our ['Guide to Informed Consent Instruments'](#).

Oral consent

- Participants consent to their participation in the research project by informing a research team member or a representative of the research team verbally of their decision to participate. This approach is useful for projects, for example, involving cultural groups uncomfortable with providing written consent or projects involving interviews or surveys that are conducted via telephone, Skype etc. or projects involving participants with limited vision. A verbal script must be developed. This script must describe the project and the risks, benefits, and alternatives to participating.

Implied consent

- Participants imply their participation by participating. This approach is useful for low-risk projects involving a simple, discrete activity. Examples include projects involving online surveys, where consent is implied by participants submitting the survey; projects involving surveys to be completed in hard copy form, where consent is implied by participants returning completed surveys to the research team; and projects involving testing a prototype, where consent is implied by carrying out the user testing.

Consent waiver

- Waiving consent means that consent will not be sought from the participants whose data is to be used in the project – rather, consent is provided by an ethics committee on behalf of the participants (who remain unaware that their data or actions have been included in a research project). A consent waiver request is appropriate if the project involves access to pre-collected data for the purpose of research or involves prospective access to data for the purpose of research where the activity is low risk and it is impractical to obtain consent. In order to request a consent waiver, responses to all nine points of *N.S. 2.3.10* are required. Projects requesting consent waivers for the use of personal information in medical research or personal health information must be reviewed by a full ethics committee which at Swinburne is the SUHREC. Examples of projects involving consent waivers include projects using data originally collected for the purpose of quality and assurance; projects using data originally collected for commercial purposes; projects using data originally collected for administrative purposes; projects using archival data; projects seeking to use data collected under ethics clearances obtained from institutions outside of Australia; projects using social media data, where it is impractical to obtain consent; projects using student data for the purpose of research. (see *N.S. 2.3.9 – 12*)



Opt-out consent

- Opt-out consent involves providing information to potential participants regarding the research and their potential involvement on the basis that their consent to participate is presumed unless they take action to decline to participate. Opt-out consent is allowed on the basis that potential participants are provided with an adequate amount of information beforehand in order to decide whether they wish to participate. Opt-out consent is used when it is feasible to contact some or all of the participants, but using explicit consent is either impractical or not feasible. In order to request the use of opt-out consent, responses to all nine points of *N.S. 2.3.6* are required. Please note that requests for opt-out consent for research to which Guidelines under Section 95 or 95A of the *Privacy Act 1988* apply can only be reviewed by SUHREC. Examples of projects involving opt-out consent include projects involving observation (see *N.S. 2.3.5 – 8*).

Unspecified consent

- Unspecified consent involves participants providing consent for the future use of their data/samples and includes participants providing consent to being contacted again in the future. The terms and ramifications of unspecified consent must be clearly explained to potential participants, with its terms clearly recorded. Depending on the future use of the data/samples, permission for the inclusion of participant data/samples in a databank or tissue-bank may need to be obtained from participants. If it is determined that unspecified consent is necessary after data collection has been completed, participants will either have to be re-consented or a consent waiver will need to be requested (*see N.S. 2.2.14 (c) & 2.2.15 – 18*).

Consenting on behalf of others

- Where participants are unable to give consent, a person (or relevant statutory body) can provide consent on their behalf. Examples of such participant groups are young children and people highly dependent on medical care. Please note that, depending on the children's age, children's assent should be obtained in order to give them the opportunity to decline participation and withdraw from participation and as a sign of respect, as well as the consent of their parent/guardian. Age-appropriate consent instruments should be developed for this purpose (*see N.S. 2.2.12, 2.2.3, & 5.2.17 and chapters 4.2, 4.4, and 4.5*).

FOR MORE INFORMATION

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