Understanding Consent in Human Research

Defining consent in human research

The National statement on Ethical Conduct in Human Research states that the consent of participants must be both voluntary and informed. When recruiting participants, their Informed consent must be sought in relation to their participation in the research.

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

For consent to be informed, participants need to have an understanding of the purpose, methods, potential risks and benefits of the research. For consent to be voluntary, participants need to know how they can withdraw from a project and that there are alternatives to being participants.

Plain language

Information needs to be communicated all prospective participants with appropriate plain language information explaining the nature of the information to be collected. Such factors such as the participants' level of understanding of English, age, level of education, understanding of the matter being researched need to be considered. If English is not the first language for many of the participants, translations may be required, both verbally and in writing.

Voluntary and Informed Consent

Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research. The aim of providing information to participants and seeking their consent is for it to lead to a mutual understanding between researchers and participants.

Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. A payment or reimbursement should not act as an incentive for individuals to participate. Adequate time should be allowed for prospective participants to understand and consider what is proposed and for their questions and expression of concerns to be addressed by those obtaining their consent. Situations involving relationships between researchers and participants, e.g., lecturers or teachers recruiting students, students recruiting family or friends, or recruitment through employers require care to ensure that the effect of unequal relationships on the decision to participate, including any perception of coercion need to be addressed and minimized.

A potential participant may lack the capacity to consent. This can include people with a cognitive impairment, mental illness or intellectual disability or if highly dependent on medical care. In these instances 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.

Information to be provided to participants

To give informed consent participants need to be provided the following information (*National Statement* *Section 2.2 General Requirements for Consent* & *Section 2.3 Qualifying or waiving conditions for consent*)

- What the research involves, i.e, sufficient information to provide an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research
- That participation is voluntary, it is possible to withdraw and that there are alternatives to participation
- How the research will be monitored
- Services available, such as access to psychological support, in case participants become distressed or adversely affected as a result of participating
- How to contact Victoria University Research Ethics and Integrity, in case they wish to make a complaint
- How their privacy and confidentiality will be protected
- How participants can withdraw from participation, including the implications of withdrawal and whether it is possible to withdraw data
- How the research is being funded, as appropriate
- Financial or other relevant declarations of interests of researches, sponsors or institutions, as appropriate
- Any payment or financial reimbursement to participants, if appropriate
- The form of dissemination of the results including by publication
- Any expected benefits to the wider community

- Who is conducting the research

Processes of consent at VU

Victoria University Information to Participants and Consent Form templates

Depending on the nature of your research project, you may be required to provide an 'Information to Participants Involved in Research' form and/or a 'Consent Form for Participants Involved in Research' with your ethics application. The Office for Research has developed templates of these forms. You are required to use the VU templates when developing your forms as they are designed to capture all the information that needs to be provided to potential or actual participants:

- Information to participants involved in research form [Template]
- Consent form for participants involved in research [Template]

These forms should be tailored for the appropriate audience, and their level of literacy. If translations into other languages are required, these should be provided by accredited translators and include the official stamp. Simplified consent forms and information should be provided for young people. Please see useful information on this topic at this website: Royal Children's Hospital Melbourne – Ethics and Consent

Collecting participant data on campus

If your research project will involve the **collection of participant data on campus,** your participants will need to be screened for symptoms or signs suggestive of COVID-19 by phone 24 hours prior to each in-person visit and will also need to complete the COVID-19 screening assessment. (Download and save this locally before completing.)

Human research trials in biomechanics at VU

If you plan to conduct a human research trial in biomechanics at VU please refer to VU's protocols for human research trials in biomechanics.

Developing your Consent strategy

Research involving multiple methods or different groups of potential participants may require more than one consent strategy or may require consent to be revisited and renegotiated over time.

While written information and consent are often used, this method, as with other methods

should:

- Provide information that is not too long or overly detailed
- Allow time for potential participants to understand and consider what is proposed and to discuss any questions that may arise
- Is particularly suitable for research involving focus groups or interviews.
- Ensure potential participant's know if a recruiting party will receive a payment or benefit for recruiting them, include a process to record consent to being recorded where this is appropriate, a process to consent for future use of data if this is to be requested.

Written consent

Written consent is often used in research. The potential participant is provided with an Information to Participants form with information and contact details that they will retain and would provide their consent in writing by returning a signed Consent Form to the researchers.

Oral consent

A record of oral consent is needed where this form or consent is used. A verbal script must be developed and included as an attachment in the Human Research Ethics application. The script must cover the important areas in an Information to Participants form, describing the project, it's risks benefits and whether the interview will be recorded. This can be used in cases where individuals or groups from a particular culture are uncomfortable with providing written consent, where interviews are conducted over the phone or internet and with blind and sight impaired individuals.

Implied consent

Implied consent is commonly used in online surveys, essential participant information about the project is provided on the first screen, and the participant is considered to have consented by completing and submitting the survey. Other examples are the return of completed written surveys and user testing of a prototype.

Consent waiver

When the HREC grants a waiver of consent for research conducted prospectively or retrospectively, research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

A consent waiver request may be 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. If it would be difficult but not impractical to gain consent or the research is higher than low risk, a consent waiver is not considered appropriate.

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 the full VUHREC. Where data is archival, has been reviewed through a non-Australian review process, was originally collected for quality assurance (e.g. the use of student data) or for administrative purposes.

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. Some projects involving observation may be appropriate for opt-out consent. It is used only where it is considered impracticable to obtain an individual's explicit consent for the use of their information for the purpose of research, not where a researcher finds it may be inconvenient! The opt-out approach is unlikely to constitute consent when applying commonwealth privacy legislation to the handling of sensitive information, including health information.

Extended/future use consent

Extended 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 extended consent must be clearly explained to potential participants, with its terms clearly recorded.

Resources

Victoria University's guide to research ethics in the time of COVID-19

Links to Human Research Ethics Resources

Contact us for information

If you would like further information about the conduct of research or the human research ethics approval and review process, please contact:

Research Ethics and Integrity
Victoria University Research

Email: Reseachethics@vu.edu.au
Phone: +61 3 9919 4461 | +61 3 9919 4781

Victoria University Human Research Ethics website

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