Minimal risk health research brief guide

THE INFORMED CONSENT PROCESS

Informed consent is a conversation and a process, not simply the signing of an informed consent form. The process continues throughout and beyond the research study.

Informed consent is made up of 5 components: information, understanding, voluntariness, competence/capacity, and documentation of consent. Respect for autonomy and dignity must be upheld during and after the research is completed.

1 INFORMATION

Information that should be included on the information and consent form minimally includes:

- What the activity is that they are being asked to participate in.
- The purpose of the activity, making it clear that this is for research purposes.
- Where and when it is being conducted and the duration of the activity.
- A clear description of what their participation will involve and how long it will take.
- A clear description of the potential risks and benefits of participation.
- What will be done with and who will have access to the information they provide.

WRITTEN

VERBAL

- Have a conversation with potential participants to explain what the research is about, what their participation would entail, and that they have the right to choose not to participate or to withdraw with no negative consequences.
- Give time to ask questions and reflect on whether they would like to participate.
- Check in and allow for questions throughout data collection.
- Download informed consent templates from the HREC Forms & Instructions page.

2 UNDERSTANDING

- The information leaflet should be written in simple (grade 8 level) language. Refer to consent form readability guidance and summary.
- The information sheet should be written in a conversational style, as if you are speaking to the participant and explaining the research to them.
- Information and consent sheets should be available in the first language of all relevant participant groups.

WRITTEN

VERBAL

- Encourage conversation and questions as this helps you to check understanding.
- Allow for time for people to reflect and consider whether participation is consistent with their values and interests.
- Observe verbal and non-verbal cues of understanding.
- Consider issues of first/second language and the need for interpreters.

3 VOLUNTARINESS

Depending on what information is - or is not - included in the information and consent sheet, participants may understand the information provided but still may not feel free to choose. For example:

- Being promised undue incentives (rewards) for participation that makes it difficult to choose not to.
- Not making it clear in the form that this research won't affect their treatment in any way (or, if students, for example, their assessment, etc.), whether they choose to participate or not.

WRITTEN

VERBAL

People may not feel free to choose because of implicit or explicit actions of researchers, including:

- Coercion to participate (threat of negative/punitive consequences).
- Undue influence to participate. This may be because of perceived authority and power differentials, or because of what is not made clear about the consequences (or lack thereof) of their choice (perceived incentives or disincentives).
- Explicit incentives offered: e.g., offering amounts that are unreasonably high, or free health care, might make it difficult for people to choose not to participate.

4 COMPETENCE/CAPACITY

- Even if individuals and minors cannot give consent, they should be able to give their assent to participate in the research, which should also be documented.
- Assent form templates that can be adapted for children between 7-18 years can be accessed on the HREC Forms & Instructions page.
- Written proxy consent must be obtained for adults with diminished capacity, from a legal guardian or caregiver.
- For minors, a range of individuals could give proxy consent - see the Department of Health ethics guidelines, which include situations in which there are no appropriate adults to provide consent.

WRITTEN

VERBAL

- Adults with diminished mental capacity are not considered legally competent to provide consent.
- The assistance of a suitably qualified person must be enlisted to make such assessments of mental capacity.
- In South African law, children under the age of 18 ("minors") do not have the capacity to consent to research.
- Proxy consent from one of a range of suitable adults (see Dept. of Health guidelines) must be obtained for children to participate in research.

5 DOCUMENTATION OF CONSENT

- Written (signed) consent on a consent form is the gold standard and should be obtained as documentation of consent whenever possible.
- In some circumstances, the consent form may be signed by someone other than the participant - see proxy consent above.

WRITTEN

VERBAL

- Under certain circumstances and with adequate justification, verbal consent may be permitted, for which some generic guidance can be found on our UREC FAQs page.
- Under certain circumstances and with justification, telephonic consent may be obtained, for which a systematic process must be followed. General guidance on obtaining telephonic consent can be found on our UREC FAQs page.
- Detailed guidance will soon be available in the HREC SoPs.

6 ONGOING RESPECT FOR AUTONOMY

- Participants continue to have the right to withdraw or to refuse to answer questions even after they have agreed to participate.
- Treat participants with respect and dignity. throughout the research.
- Protect privacy and confidentiality throughout the research.
- A feasible budget and ensuring that you have sufficient funding to complete the research is a way of respecting participants' time and contributions.
- The budget should also include remuneration for participants where appropriate. See T.I.E. guidelines for payment of participants (NHREC, SAHPRA).

DURING

AFTER

- There are limits to how long after the research is completed (and with anonymised data) that participants can still withdraw their data. This should be transparent.
- Wherever possible and feasible, feedback about research results to participants and/or their communities should be provided. Confidentiality must always be protected & limits to confidentiality acknowledged.
- To have social value, research results must be publicly disseminated. Participant confidentiality must protected.
- Participant consent must be obtained to share information/data with journals or other researchers, as well as if you plan to store and use the data in future research.

Remember: Informed consent is an ongoing process that does not end with the signing of a consent form.

There may also be circumstances in which the consent form itself may need to be updated or revised when new information comes to light.

Visit our ethics FAQS page for guidance on when consent can be waived

Visit our ethics FAQS page for guidance on consent for secondary use

Visit the HREC Forms & Instructions page for informed consent templates

Important guidance to consult on informed consent processes & issues

- Department of Health (2015). *Ethics in health research: principles, processes and structures (2nd ed).* Department of Health: Pretoria.
- HREC (2019). *Terms of Reference and Standard Operating Procedures, V5*. Health Research Ethics Committee: Stellenbosch University.

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For more information visit the UREC website and Frequently Asked Questions page