

health research 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.

INFORMATION



Minimal risk

brief guide

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.



 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

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.



questions as this helps you to check understanding. Allow for time for people to reflect

• Encourage conversation and

- 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.

VOLUNTARINESS



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

Depending on what information is - or is

- 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.



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.

COMPETENCE/CAPACITY



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

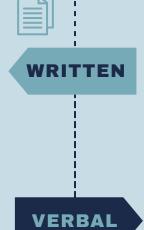
Even if individuals and minors cannot

give consent, they should be able to give

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. **DOCUMENTATION OF**



capacity are not considered legally competent to provide consent. The assistance of a suitably qualified person must be enlisted to

Adults with diminished mental

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

Health guidelines) must be obtained for children to participate in research.

of suitable adults (see **Dept. of**

CONSENT



whenever possible. In some circumstances, the consent form may be signed by someone other than the participant - see proxy consent above.

 Written (signed) consent on a consent form is the gold standard

and should be obtained as

documentation of consent

Protect privacy and confidentiality

The budget should also include

remuneration for participants where

appropriate. See T.I.E. guidelines for

A feasible budget and ensuring that you

have sufficient funding to complete the research is a way of respecting participants'

throughout the research.

time and contributions.



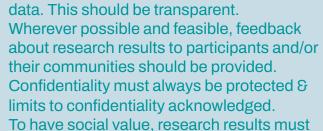
- some generic guidance can be found on our UREC FAQs page. Under certain circumstances and with justification, telephonic consent may be obtained, for which a systematic process must be
- followed. General guidance on obtaining telephonic consent can be found on our **UREC FAQs page**. Detailed guidance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

Participants continue to have the right to Treat participants with respect and dignity. throughout the research.

There are limits to how long after the research is completed (and with anonymised withdraw or to refuse to answer questions even after they have agreed to participate. data) that participants can still withdraw their

DURING

AFTER



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

payment of participants (NHREC, and use the data in future research. SAHPRA). 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

Visit the





page for

<u>ġuidance</u>

on consent

<u>for</u>

<u>secondary</u>

use

HREC Forms & <u>Instructions</u> <u>page</u> for informed consent templates



- Important guidance to consult on informed consent processes & issues
 - structures (2nd ed). Department of Health: Pretoria. HREC (2019). Terms of Reference and Standard Operating Procedures, V5. Health Research Ethics Committee: Stellenbosch University.