NORTH-WEST UNIVERSITY
NOORDWES-UNIVERSITEIT
YUNIBESITI YA BOKONE-BOPHIRIMA

Faculty of Theology

INFORMED CONSENT CHECKLIST[1]

Here are just a few pointers when preparing your informed consent documentation

The text in the informed consent:

The text:

- is in plain language and appropriate to the participant's level of understanding, clear and direct
- is free of jargon and unexplained acronyms
- is clear and explains technical terminology e.g. randomisation
- is translated into other languages as appropriate to the context

  (***The translation has to reach the REC within one week after the final informed consent document was approved in English***)
- conforms to the proposal
- the readability level is on grade 8 level
- the language and translation is appropriate

Examples of readability tests:

- Flesh Readability Formula (Flesh, 1948)
- Fry Readability Scale (Fry, 1968)
- Flesh-Kincaid Readability Scale (See Paasche-Orlow MK, Taylor HA, Brancati FL) – informed consent should be at the 8th-grade level (USA)

[1] The Faculty of Health Sciences Ethics Office of the North-West University is acknowledge for the use of their document with minor adjustment for the use in the Faculty of Theology at the North-West University.

TICK LIST FOR YOUR CONFENINCE:

These are important aspects that should be included in the informed consent documentation as expected by the National Health Research Ethics Council (2014):

Make a tick in each block. If not applicable indicate N/A

Item	Yes	No	N/A
The informed consent document is official and on the letterhead of the NWU			
The information should explain:			
• that the person is being asked to participate in the research			
• who the researchers are and the nature of their expertise (qualifications)			
• what the research is about (purpose and nature)			
• the choice whether to participate is voluntary			
• the refusal to participate will not be penalised			
• that choosing to participate can be reversed, i.e. the person may decide to terminate participation at any time without explanation or prejudice			
• that a participant is free at any time to withdraw consent without having to face negative consequences			
• a description of the procedures to which the subject will be subjected			
• the expected duration of participation			
• the nature of the researcher's responsibilities			
• the total number of participants that will be involved in the research			
• the anticipated risks of harm or discomforts			
• If risk of bodily harm how this will be covered by insurance			
• how these risks or discomforts will be managed			
• the potential benefits, if any, for participants themselves (direct) and for others after the research (indirect)			
• the extent to which privacy and confidentiality is possible			
• what will happen to the findings or samples - only for this study or further studies - If further studies for what and related to what - further studies will be approved by a REC on their behalf - how the data/samples will be used - where will it be stored and analysed - permission that it can be done overseas if that is the intension			
• whether there will be any financial implications e.g. out of pocket costs like travel			
• whether there will be any remuneration			
• identify the funder, where applicable and any potential conflict of interest			
• how the person will be informed of findings and when			
• their right to be informed of relevant new findings and how this will be done			
• that sponsors of the research and regulatory authorities (REC) may inspect research records			
• that the research has been approved by a registered REC (include identifying details)			

• that queries about the research may be directed to the researcher concerned (include contact details)			
• that queries and complaints about being a research participant may be directed to the REC concerned (include contact details)			
Only add if applicable			
• that the research may be terminated early in particular circumstances			
• the consequences of withdrawal			
In addition to the above, where clinical trials is intended, the information should explain:			
• the procedure and the activities that will take place, including whether any is experimental, innovative or novel in humans			
• that research is separate from clinical care for the illness or condition that the person may have			
• whether research-related injuries will be treated and remedied at the cost of the sponsor			
• explanation as to whether compensation will be given for research-related injuries			
• the contact details of the person to contact in the event of a research-related injury			
• the alternative procedures or treatment available			
• the approximate number of participants			
• the possibility of randomisation and the implications			
• the meaning and implications of placebo			
• the difference between experimental and control groups			

What the REC-FT will look for in the proposal:

- The process of obtaining informed consent is described in full
- The principle of *respect* for persons were followed, that it is *voluntary*, and based on *information* that allows an *informed choice*
- Environment where process of consent is conducted
  - private, confidential and safe
- Assessment of capacity to consent
  - age
  - legally informed consent
  - decisional impaired persons
  - legal authorized representation
  - literacy
- Assessment of participant's comprehension
- Presentation of all mentioned *elements* of IC and the *process* that will be followed
- Whether gatekeepers/mediators are involved and their roles in this process
- Time to talk to researcher to ask questions
- Documentation of IC (language level, language offered in)
- Use of delayed consent procedure
  - time to think
  - time to discuss with family/friends etc.
- Who is going to obtain the consent (independent person)
- Ongoing consent/re-consent if necessary due to the nature of the research

Developed by: Prof Minire Greeff