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**INFORMED CONSENT CHECKLIST FOR HREC**

Compiled by: Prof Minrie Greeff

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 HREC 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)

**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 (HREC) may inspect research records |  |  |  |
| * that the research has been approved by a registered HREC (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 HREC 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 are 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 HREC will look for in the proposal:**

* The process of obtaining informed consent is described in full
* The principle of *respect* for persons was 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

- decisionally impaired persons

- legally 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

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