

**NWU-EMELTEN-REC**

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the NWU Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Science Research Ethics Committee (NWU-EMELTEN-REC) of the North-West University.

**INFORMED CONSENT CHECKLIST FOR NWU-EMELTEN-REC**

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 NWU-EMELTEN-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)

**TICK LIST FOR YOUR CONVENIENCE:**

**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 (NWU-EMELTEN-REC) may inspect research records
 |  |  |  |
| * that the research has been approved by a registered NWU-EMELTEN-REC (include identifying details)
 |  |  |  |
| * that queries about the research may be directed to the researcher concerned (include contact details)
 |  |  |  |
| **Item** | **Yes** | **No** | **N/A** |
| * that queries and complaints about being a research participant may be directed to the NWU-EMELTEN-REC concerned (include contact details)
 |  |  |  |
| ***Only add if applicable*** |
| * that the research may be terminated early in particular circumstances
 |  |  |  |
| * the consequences of withdrawal
 |  |  |  |

**What the NWU-EMELTEN-REC 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

 - decisional 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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