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Faculty of Health Sciences

Faculty of Health Sciences Research Ethics Committee

Standard Operating Procedure: Obtaining Informed Consent and Informed Consent Documents

1. Purpose of this document

The purpose of the SOP is to define the circumstances and the conditions that apply for obtaining informed consent from research participants to volunteer to take part in a research study. No researcher may involve participants without written informed consent of the potential research participant or his or her legal authorised representative.

2. Scope of the REC

The SOP is intended to inform and guide all researchers, members of the Research Ethics Committee, and the REC in its deliberations regarding informed consent and its requirements. It gives effect to the Ethics Guidelines of the Department of Health (2015), section 3.1.9:

“Obtaining informed consent” and specifically section 3.2.2: Minors (children and adolescents), 3.2.2.2: “Parental permission” and section 3.2.4.4: “Minimum conditions for research involving incapacitated adults”. This SOP should be interpreted within the Terms of Reference of the REC and other SOPs that may be relevant.

Informed consent should be seen as an on-going process, through which potential research participants are informed and learn about the key facts of the proposed research study, before they decide to take part or not.

The previously narrow focus on the health care professional’s duty to disclose information – is now replaced by emphasis on the quality of the patient’s understanding of that information. Therefore: Informed consent has become the expression of a patient’s fundamental right to self-determination.

Please note where informed consent documents are amended, full ethical approval needs to be obtained (in the normal way) for the amended informed consent document. There after the research participant needs to be re-consented and the written consent document needs to be kept with the original consent document in the research participant’s file.

Expedited approval of an amended informed consent document will only be so evaluated when participant's safety may be compromised if review and approval were not expedited. This must be justified in writing by the researchers.

3. Definitions

- 3.1 Assent is where children 7 years and older indicate in writing if they want to take part in the proposed research.
- 3.2 Coercion is an extreme form of undue influence, involving a threat for failure to participate in research.
- 3.3 Delayed consent is where potential research participants get sufficient time to decide as to take part in the proposed study or not.
- 3.4 DoH Guidelines: Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2nd Edition).
- 3.5 Informed consent is an indication of agreement by the potential research participant to participate in the proposed research study, and is based on adequate knowledge and understanding of relevant information about the proposed study and is given freely, without coercion.
- 3.6 Informed consent document (ICD) is the document that is signed by the research participant and the researcher, before the participant is enrolled into the research study.
- 3.7 Legal guardian is defined as a person appointed by a court to look after the financial and welfare interests of a minor, or a person appointed by a parent with sole responsibility for the minor in terms of that parent's will.
- 3.8 Minors are defined as children and adolescents (12 -17 years) who are all younger than 18 years.
- 3.9 Non- therapeutic research in children. Section 71(3)(a)(11) of the National Health Act requires the Minister of Health to consent to "non-therapeutic" health research with minors, after considering certain criteria. The minister has empowered accredited ethics committees to evaluate and approve such research after Form A has been completed by the researcher.

- 3.10 Parental Informed consent needs to be obtained when minors are requested to take part in a potential research study.
- 3.11 Principal Investigator is the researcher who is primarily responsible for the research study.
- 3.12 Proxy consent is applicable where potential adult research participants are incapacitated and cannot give informed consent. The National Health Act (Act 61 of 2003) specifies the sequence of legally appropriate treatment-proxies as: spouse or partner; parent; grandparent; adult child; brother or sister.
- 3.13 Re-consent is where a research participant is re-consenting to an amended ICD or when a child turns 18 years of age and need to sign a participant ICD.
- 3.14 Research participants older than 18 years of age can give informed consent for themselves to take part in a research study, if capable to understand all the research procedures when approached to take part in a research study.
- 3.15 Therapeutic research in children is defined where research interventions directed towards them have direct health-related benefit for the child.
- 3.16 Undue influence - effect of unequal power relationship on voluntariness to participate in a research study.
- 3.17 Waiving of the need to obtain individual informed consent is when the participant cannot be contacted to give consent to use his/her data or when the risk to include the participant's data minimal. This waiving may be granted by the Research Ethics Committee, when doing so holds no more than minimal risk for the research participant.

4. Researchers Responsibilities in terms of Obtaining informed consent

- 4.1 Researchers are responsible to ensure that the informed consent process are dually done and correctly applied, by making sure the potential research participant understands and can give informed consent. Research participants also need to have sufficient opportunity to decide and discuss their taking part in a potential research study, before signing the ICD.

- 4.2 No undue influence or coercion may be used when recruiting research participants for a particular research study.
- 4.3 Assurances need to be given to research participants and parents/legal guardians, that the participant's rights, safety, dignity and well-being will be protected.
- 4.4 A full description of where and how the potential research participants' will be recruited as well as the consenting process, where possible research participants cannot give consent themselves, needs to be documented in the research protocol.
- 4.5 The ICD should be in plain language (grade 6 level) and free of medical jargon, to ensure that potential research subjects can comprehend the information regarding the research study.
- 4.6 The information that is given to a potential research participant needs to be presented in language and format that optimally promotes understanding of the proposed research by the research participant.
- 4.7 The English version of the ICD needs to be submitted together with the research proposal for ethical approval. ICDs in other languages need to be submitted together with a verified translation certificate.
- 4.8 No independent medical practitioner may sign consent on behalf of a potential research participant.
- 4.9 Waiving of individual informed consent: if needed, the researchers can apply for the need to obtain waiving of individual informed consent. This request should be justified by the researcher.
- 4.10 For data analysis of secondary data, retrospectively from medical files or from data bases in public domain, the curator of that specific dataset needs to give permission for the researcher to use it.

5. Informed Consent Documents

- 5.1 On the REC website there are specific pro-forma ICD templates available. These can be adapted, as applicable, to fit the specific research study design.
- 5.2 Pages of the ICD needs to be numbered accordingly, i.e. page 1 of XXX, page 2 of XXX, etc, to indicate that the information and consent parts form one document.

- 5.3 Parental and/or legal guardian ICD: For children younger than 18 years, the parent/s or legal guardians need to give written informed consent as per required document.
- 5.4 Assent document: children 7-18 years of age need to give written assent, indicating they are willing to take part in the research study. When the child turns 18, the researcher needs to re-consent the child as an adult research participant.
- 5.5 Waiving of the need for obtaining individual informed consent, from a specific participant for a research study, can be motivated and requested in writing from the Research Ethics Committee.
- 5.6 Requirements for the signature of witnesses: There is a distinction between a signature confirming that the consent process was performed on the one hand, and a contractual witness that merely confirms the authenticity of the signatures by the contracting parties but not the consent process. The UP Health Sciences REC requires that the consent process be witnessed (i.e., the former) and duly signed for subjects who are not fully capable of consenting or illiterate. The UP Health Sciences REC agree with GCP that for these cases, someone who is not research personnel would suit better as a witness.
- 5.7 "The REC may approve a delay in obtaining informed consent for emergency care research if:
- the research is based on valid scientific hypotheses that support a reasonable possibility of more benefit than that offered by standard care;
 - participation is not contrary to the medical interests of the patient;
 - the research interventions pose no more risk of harm than that inherent in the patient's condition or alternative methods of treatment;
 - the participant and her relatives or legal representatives will be informed of the participant's inclusion in the research as soon as reasonably possible, and advised of her right to withdraw from the research without any reduction in quality of care."
- [See section 3.2.4.3: Ethics Guidelines of the Department of Health: Ethics in Health Research: Principles, Processes and Structures (2nd Edition) (2015)].
- 5.8 As ICDs are amended please indicate the version, as well as the PI's name, in the footnote of the document.
- 5.9 If anonymous questionnaires are used, research participants need not sign the ICD.

5.10 For electronic questionnaires there need to be an option after the information section, where the potential research participants can indicate if they want to take part or not.

6. The Elements of Informed Consent

6.1 Basic Elements of Informed Consent

The following information needs to be provided to each participant when seeking informed consent:

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the procedures to be followed, and identification of the specific procedures which are to be done specifically for the research study;
- A disclosure of appropriate alternative procedures or treatments, that are available as standard care of treatment;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participants themselves or to the community;
- A statement that participation is voluntary and that refusal to participate will not involve any penalty or loss of benefits or of care to which the participant is otherwise entitled to;
- A statement regarding the confidentiality of the participants' information;
- A statement that the participants will be reimbursed for any out of pocket expenses related to the research;
- Researchers' names and 24 hour phone numbers must be provided on the ICD for any questions about the research; and
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

6.2 Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information can also be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant);
- Anticipated circumstances under which the participant's participation may be terminated by the investigator, if the investigator is worried about the safety of the participant;
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and
- The approximate number of participants involved in the study.

7. Templates of ICDs

- 7.1 ICD 1 (a): Participant's information & informed consent document;
- 7.2 ICD 1 (b): Parental or guardian information & informed consent;
- 7.3 ICD 1 (c): Assent & information document for children 7-18 years;
- 7.4 ICD 2 (a): Participant's information & informed consent document for a participant anonymous administered questionnaire;
- 7.5 ICD 2(b): Information & assent document for children 7-18 years for a participant anonymous administered questionnaire;
- 7.6 ICD 3 (a): Participant's information & informed consent document for a medication trial;
- 7.7 ICD 3 (b): Parent or guardian information & informed consent document for a medication trial.
- 7.8 ICD 3 (c): Assent & information document for children 7-18 years for a medication trial;
- 7.9 ICD 4: Participant's information and informed consent document for a focus group interview research study;

- 7.10 ICD5: Participant’s information and informed consent document for an in depth interview research study;
- 7.11 ICD 6: Participant informed consent for human immunodeficiency virus (HIV) testing;
- 7.12 ICD 7: Consent to use health records and information for a case study;
- 7.13 ICD 8: Participant information and informed consent form for research involving genetic studies;
- 7.14 ICD 9a: Participant’s information & informed consent document for critically ill patients admitted in an intensive care unit [once a patient has become capable of consenting to the research]; and
- 7.15 ICD 9b: Participant information & informed consent document for relatives of critically ill patients admitted in an intensive care unit [once a patient has become capable of consenting to the research].

8. This SOP was approved by the Research Ethics Committee on and replaces all previous SOP’s in this regard.