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Guidance Document for Informed Consent

Informed Consent is a Requirement of all ERB/IRB Reviews

Informed consent involves providing potential subjects with adequate information about a research study to allow for an informed decision about the subject's voluntary participation. Informed consent must include a process to facilitate a subject's comprehension of the information, in a language understandable to the subject, and to allow adequate opportunity for the subject to ask questions and consider whether to participate.

Informed consent should be designed to meet the standards as set in the *UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis*. The Procedure is designed to ensure effective processes and accountability for ethical oversight of these processes; to ensure the protection of, and respect for, human and child rights within all research, evaluation, and data collection processes undertaken or commissioned by UNICEF.*

Informed consent should:

1) **Explain the purpose of the study**
   An age-appropriate statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2) **Explain risks and benefits of the study**
   A description of any risks or benefits to the subject or to others which may reasonably be expected from the research;

3) **Explain the voluntary nature of participation**
   A statement that participation is voluntary and negotiable, refusal to participate or to not respond to any question will involve no penalty or loss of benefits, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

4) **Describe privacy and confidentiality for participation**
   A statement describing the extent to which privacy and confidentiality of records identifying the subject will be maintained, any limitations to confidentiality (e.g., mandatory reporting of abuse, etc.), and when data will be destroyed;

5) Provide contact information
   An explanation of who to contact for answers to questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject;

Informed consent may also need:

6) A disclosure of appropriate alternative procedures or courses of assistance, if needed, that might be advantageous to the subject;
7) For research involving more than minimal risk, an explanation of the risk involved and any support services that will be made available.

See: *UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection, and Analysis*; Document Number: CF/PD/DRP/2015-001 Effective Date: 01 April 2015 Issued by: Director, Division of Data, Research, and Policy (DRP).