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INSTITUTIONAL ETHICS REVIEW COMMITTEE

GUIDELINES FOR INFORMED CONSENT/ASSENT

This document provides a guide on the development of research consent/assent form. Please read the guidelines to ensure that the consent form submitted is clear, complete and understandable. Please refer to the **guidelines** before you fill the form.

KEYPOINTS:

1. For Minors (0-13) years, parents must give written consent. For major/minors (14-17) (Adolescents), informed consent to be given in addition, permission from parent/legal guardian should be sought.
2. Avoid use of jargon, language used should be simple as possible and target specific groups/age and easily understood by a lay man. This should include potential discomfort, inconveniences, injuries, harm, risks and potential benefits if any.
3. Use of legal phrases, scientific and medical terminologies should be avoided.
4. Unit of measure should be expressed easily in meaningful scales (e.g. blood draws in numbers of teaspoonfuls).

Title of research study/project:

Researcher(s) (Local and International Collaborators): Provide name and institutional affiliation of all investigators on study/project. Starting with PI

Study location: Indicate where study/project will be conducted.

Purpose of study/project: Briefly describe a simplified format on the purpose of study/project.

1. **Description of consent/assent process:**

   a) Describe the procedures in place for obtaining parental/guardian consent to have his/her child or children participate in study/project.
   b) If study/project proposed is determined to present greater than minimal risk and there is no direct benefit to an individual study/project participant/project, then parental permission from both parents/guardians shall be required unless one parent is Deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
   c) Parental permission and child assent is done in writing unless LUIERC grants a waiver of documentation.
   d) The goal of an informed consent process is to provide sufficient information so that a participant can make an informed decision about whether or not to enroll in a study or to continue participation.
   e) Informed consent document must be written in a language easily understood by the participants and it must minimize coercion or undue influence and the subject must be given sufficient time to consider participation.

Introduction/Key Points:

i. Potential participants must be provided with sufficient information to allow them decide whether or not they want to take part in the study.
ii. The information must be in a easily understood language
iii. The Consent form is a step in the process
iv. Consent must be obtained prior to the commencement of the study
v. Consent is an ongoing process through which the participant are involved in the study

Consent Process:

1. Verbal Explanation:

The potential participants must be given the sufficient information to allow them to decide on whether or not they want to take part in the Research study.

2. Verbal Consent:

Participants give verbal consent or a substitute decision maker in cases where the participant is not capable of giving consent.

3. Written Consent

Obtaining Consent from:

a) Minor: Written consent must be obtained from the parent /legal guardian who must be of sound mind.

b) Mature Minor;

   i. Mature minors are any participants who are less than eighteen (18) years of age who is married, pregnant, a mother or a household head.

   ii. Mature minors are permitted to give consent for their child/children but not allowed to consent on behalf of a sibling. In this case, consent from the mature minor's parent/guardian will be required.

c) Adults: All adults should give both a verbal and a written consent.

4. Table below should be used as a guide in deciding whether or not to enroll a child, aged eight (8) to 17 years, in research.

If Parent Says (YES/NO) to Participate	**If Child Says (YES/NO)to Participate**	**Can Child Participate?**

5. Ethical standards required in obtaining informed consent shall apply to assent.

6. A waiver requirement for obtaining assent from a child if any of the following conditions apply in which case, consent from parent(s) is sufficient:

   a) Intervention stands to directly benefit the health and welfare of child and is available only in study/project setting.

   b) Child is unable to provide assent due to age [twelve (12) years of age and below] or a condition.

c) Study/project meets same conditions for a waiver of informed consent in study/project involving adults.

Contact:

For any questions or concerns about a study/project or in the event of a study/project-related injury, contact person is applicant/investigator and/or their representatives who should provide his/her 24-hour contact telephone number. Physical address must be provided.

For any questions pertaining to rights as a research participant, contact person is:

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