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## MASENO UNIVERSITY ETHICS REVIEW COMMITTEE (MUERC)

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### REQUIREMENTS OF INFORMED ASSENT

#### Important points:

1. Where a proposed participant/group is a minor (aged thirteen (13) to seventeen (17) years of age) with sufficient understanding to grant informed consent but is precluded from granting such consent solely on grounds of age, the applicant/investigator may obtain a written assent in addition to permission from a parent or legal guardian.
2. Level of language and syntax used should be appropriate to the age, comprehension and reading level of study study/project minors.
3. Use of legal phrases, scientific and medical terminologies should be avoided.
4. Volumes, weights and measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls).
5. All consent documents must have a version number, date and be signed and stamped by MUERC Chairperson or Secretary.

#### Title of research study/project:

**Investigator(s) – Local and International Collaborators:** Provide name and institutional affiliation of all investigators on study/project. List Principal Investigator first followed by co-investigators.

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

**Purpose of research study/project:** Briefly describe purpose of study/project.

#### Description of assent process:

- i. Describe procedures put in place for obtaining parental or guardian permission (consent) to have his/her child or children participate in study/project.
- ii. 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.
- iii. Parental permission and child assent is done in writing unless MUERC grants a waiver of documentation.





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- iv. 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?
YES	YES	YES
YES	NO	NO
NO	NO	NO
NO	YES	NO

- v. Ethical standards required in obtaining informed consent shall apply to assent.
- vi. 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.

### Obtaining Consent from a Mature Minor

- i. A mature minor is any individual/participant less than eighteen (18) years of age who is married, pregnant, a mother or a household head.
- ii. A mature minor is permitted to give consent for him or herself and for their child/children but not allowed to consent on behalf of a sibling.

### Contact:

- i. For any questions or concerns about a study/project or in the event of a study/project-related injury, contact person is principal investigator and/or their representatives who should provide his/her 24-hour contact telephone number. Physical address must be provided.
- ii. For any questions pertaining to rights as a research participant, contact person is: **The Secretary, Maseno University Ethics Review Committee, Private Bag, Maseno; Telephone numbers: +25405751622; Email address: [muerc-secretariate@maseno.ac.ke](mailto:muerc-secretariate@maseno.ac.ke)**

