MASENO UNIVERSITY ETHICS REVIEW COMMITTEE (MUERC)

FORMAT AND CONTENT OF AN INFORMED CONSENT DOCUMENT

Important points:

1. Level of language and syntax used should be appropriate to the age, comprehension and reading level of study study/project population.
2. Use of legal phrases, scientific and medical terminologies should be avoided.
3. Volumes, weights and measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls).
4. 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 principle 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 the research study/project:

i. Provide a brief description of proposed research study/project as it will be experienced by research study/project participants.

ii. Interventions or procedures that are part of standard care and those that are research study/project must be distinguished.

iii. If study/project participant/group is receiving any therapy prior to enrollment in study/project and this therapy will or may be altered or discontinued as a result of participation in the study/project, this must be explained.

iv. If randomization or sequential assignment is planned, this must be explained.

v. If blood will be drawn, total volume must be indicated. A statement about possibility of bruising or swelling while giving blood, or some other discomforts at site of blood draw should be indicated. Include a statement on minimal chance of infection.

vi. If other specimens (e.g. urine, stool, saliva etc) will be collected, study/project participants/groups must be informed.

vii. Frequency and duration of specific testing, as well as duration of entire study/project should be specified.

viii. Study/project participants/groups should be informed that any changes made to study/project or should new information become available, he/she will be so informed.

ix. If future use of research study/project data beyond the current study/project is anticipated, this should be clearly explained.

x. If research study/project data/samples are to be destroyed after study/project is complete, study/project participants/groups must be informed of the plan.

xi. If any tests will be done at other locations, study/project participants/groups must be informed of the location and purpose for tests. This information must also be reflected in the body of research study/project protocol.

xii. If a questionnaire will be administered or interview conducted, a description of questionnaire/interview and time taken must be provided.

xiii. Participants/groups must also be informed that they may choose not to answer any questions or withdraw at any time.

xiv. If data will be abstracted from medical records or from other confidential sources, this must be so described.

xv. Study/project participants/groups must be informed if a study/project involves videotaping, taking photographs or audio recordings.

xvi. If products of commercial importance may be developed from blood samples, DNA, RNA extracted, state and describe plans for benefit sharing.

Potential discomforts, inconvenience, injuries, harm or risks:

i. If there is no known or known harm/risk to study participants, this should be clearly stated.

ii. If there is known or anticipated risk, this must be clearly enumerated.

Potential Benefits:

i. If study/project participants/groups will not benefit or might benefit directly from participation in the study/project, this should be stated and potential benefits described.

ii. If community in general or patients with a similar condition stands to benefit from the results of study/project, this should also be explained.

Alternative Procedures or Treatments:

i. If there is no treatment alternative, alternative to participation in study/project is non-treatment and this should be explained.

ii. If there is/are a treatment alternative(s), alternative(s) should be identified and described.

iii. If research study/project is not about a treatment, this section may be omitted.

Confidentiality:

i. No information that reveals identity of any study/project participant/group should be released or published without consent.

ii. If access is required by a sponsor, MUERC or other health regulatory authorities for purposes of monitoring study/project, this must be explicitly stated.

iii. Plan for maintaining confidentiality of research study/project records and materials must be clearly explained.

Reimbursement:

i. Study/project participants/groups or their parents/guardians can be reimbursed for loss of wages, transportation expenses and for their time. Under no circumstances should payment be offered for harm or discomfort.

ii. It should be clearly stated that if study/project participants/groups withdraws from research study/project, that there shall be appropriate pro-rated reimbursement, where applicable.

iii. A token of appreciation may be presented after completion of study/project. This should not be mentioned in research Study/project consent document but must be indicated in body of study/project protocol.

iv. Include specific information whenever study/project participants/groups shall receive an inducement.

Participation:

i. If there are parts of research study/project in which a study/project participants/groups may choose not to participate, this should be clearly explained.

ii. Parents/guardians of study/project participants/groups should be made aware that assent may be required from their children.

iii. All Study/project participants/groups must be given a copy of signed and dated consent form to keep.

Sponsorship:

i. In situations where a study/project may be terminated at the discretion of investigator or study/project sponsor even if study/project participants/groups are benefiting, provide a provision for discussing next course of action with study/project participants/groups and/or procedures for orderly termination.

Contact:

i. 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.

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: 057-51622, 0722203411, 0721543976, 0733230878; Email address:** muerc-secretariate@maseno.ac.ke; muerc-secretariate@gmail.com.