MASENO UNIVERSITY ETHICS REVIEW COMMITTEE (MUERC)

GUIDELINES FOR SUBMISSION OF PROPOSALS BY RESEARCHERS/SCIENTISTS

Application should be addressed to MUERC Chairperson and submitted through MUERC Secretariat.

Application must be complete before being placed on the next available MUERC meeting's agenda.
Checklist for Completeness:

a. An electronic copy and one bound hard copy of application and all supporting documents. The hard copy must have the original inked authorization signatures. Research study/project proposal must be signed by all investigators on the study/project.

b. CVs/resumes of all investigators on the study/project duly signed and dated.

c. For international Principal Investigators, a proof of prior review and approval of the proposed research study/project from the applicant's home institution.

Guidance on Content of an Application

a. Research Study/Project Personnel:

Include a complete list of all key research study/project personnel involved in the conduct of the study/project, their CVs and clearly define their roles and responsibilities. All key personnel must have undergone training in Research Ethics. Certificates of ethics training should be included in the application submitted.

b. Provide a brief abstract of the proposed research study/project.

c. Study Protocol

i. Briefly describe background and significance of the research study/project.
ii. Specify question(s) (aims) of proposed research study/project.
iii. Describe study/project design, population and study/project procedures.
iv. If a control or comparison group shall be used, a justification should be provided.
v. Indicate number and age range of research study/project participants/groups whose records, data or specimens shall be used in the research study/project.
vi. Define inclusion criteria for each group of research study/project participants.
vii. Define the exclusion criteria, if any, for each group.
viii. If gender, race or ethnicity is to be used as variables in selecting individuals' records, data, or specimens for use in the research study/project, rationale should be explained.
ix. Specify time period in which these records, data or specimens shall be collected and/or stored and timeframe for entire study/project.
x. Describe the plan for monitoring conduct of the study/project to ensure participants safety; confidentiality and data integrity.
xi. Describe data management and analysis plan.
xii. Describe any study/project limitations and the expected results.
xiii. Provide an itemized budget neccessary to conduct the research study/project and a budget justification.

xiv. Provide copies of research study/project data collection forms to be used or a complete list of data variables that shall be collected.

d. Ethical Considerations

i. A clear description of risks, if any, to research study/project participants/groups should be provided.
ii. If a proposed research study/project cannot practically be carried out without access to protected health information, this must be clearly explained.
iii. Identify all sources of data, records or specimens to be used in the proposed research study/project.
iv. Indicate measures in place to maintain confidentiality of research study/project data and protect the privacy of research study/project participants/groups.
v. Provide a description of where research study/project data/specimens being collected shall be stored.
vi. Specify duration of storage and measures to be taken to ensure security of data/specimens; identify custodian and who shall have access to data/specimens.
vii. Describe the plan for controlling access to stored research study/project data and/or specimens.
viii. If persons not listed as applicant or research study/project team member shall receive or view research study/project data with identifiers, a justification for this must be provided.
ix. All members of research study/project team with access to confidential records, data or specimens collected must sign appropriate institutional agreement(s).
x. Describe potential benefits of research study/project to community and/or society.
xi. Consent issues: Describe how assent/consent will be obtained.