MASENO UNIVERSITY ETHICS REVIEW COMMITTEE (MUERC)

ADVERSE EVENT REPORTING FORM

Title of Proposal: _____

Applicant/ Investigator(s): _____

MUERC No.: _____

1. Applicant/Investigator mailing address: _____

2. Date of Report: _____

3. Type of Report: Initial or Follow-up [_____]

4. Study study/project participant/group information: Identification number, age, height, weight, etc
_____
_____

5. Adverse event start date: _____ Adverse event stop date: _____ or Ongoing _____

6. State/Indicate location of the event, if applicable: _____

7. Describe the adverse event: Describe the signs, symptoms, severity, time course, relevant medical history and laboratory data. Include confirmatory results, if any. Indicate any medication required to treat the event and the outcome. _____
_____
_____
_____

8. Describe the investigational drug, medical treatment or procedure or device causing the event: ____
_____
_____
_____

9. Describe circumstances of the event, where applicable: Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study/project participant/group requires medical or surgical intervention to prevent other outcomes. _____
_____
_____
_____
_____
_____

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10. Describe the action taken: _____
_____
_____

11. Specify any simultaneous treatment. _____
_____

12. State relationship to drug/participation in a project: not-related, possibly, probably, definitely unlikely related to drug/participation and explain why. _____
_____

13. State if adverse event is described in current approved informed consent/assent document. _____
_____

14. State if event requires a change or changes in consent/assent documents and to the study/project procedures. _____
_____

15. State whether or not enrolled study/project participants/groups shall be advised of the event. If yes, explain how this new information will be conveyed. If not, explain why. _____
_____
_____
_____
_____
_____

16. Describe any other information not included/ covered above. _____
_____
_____
_____
_____
_____
_____
_____

_____ _____
Name and Signature of the Applicant/Investigator Date