Rev 07/19/16 kbk

NUNM Institutional Review Board (IRB)
PROTOCOL DEVIATION/VIOLATION FORM

Minor or administrative deviations from approved IRB documents, defined as those that are not likely to affect the scientific soundness of the research plan or are highly unlikely to affect the rights, safety, or welfare of human subjects, may be reported on the continuing review form only. *Note: minor administrative deviation does not include lapses in approval (a late filing of your continuing review).*

To be considered in compliance, the investigators must submit a completed Protocol Revision and Amendment Form (PRAF) to the IRB **prior to implementation** of any changes from an IRB-approved protocol. Failure to correctly report significant changes to IRB-approved study documents results in a protocol deviation or violation and may result in corrective action by the University and/or the NUNM Institutional Review Board.

Reporting timeline for major protocol deviations or violations to IRB-approved study documents

- In the event a significant deviation from IRB-approved study documents occurs without a prior approved PRAF, the Principal Investigator(s) are required to submit a Protocol Deviation/Violation Form to the Institutional Review Board within 10 business days of the time the PI becomes aware of the event.
- A deviation/violation that results in an unanticipated study-related death or serious adverse event, or an emergency deviation that is implemented in order to protect the life and well-being of study participants must be reported to the NUNM IRB *as soon as possible* but no later than 10 business days after the occurrence of the event.

Study Title:
IRB Number:
Today's Date (date of submission of this form):

Principle Investigator(s) (PI):
PI Telephone Number:
PI e-mail:

Date(s) of the deviation/violation:
Note: If more than 10 business days prior to the date of submission of this form, please explain the delay in reporting.

Please describe in detail the specific deviation/violation:
*Provide a succinct description of the protocol deviation/violation and attach any other pertinent documentation. Include a list of the study personnel involved, including the name of the involved person(s) on the study team, and the date(s) on which it was reported to those involved, also include a description of whether or not this event was inadvertent (**protocol deviation**; e.g. accidentally enrolling an ineligible participant by misreading a lab analysis value to be within inclusion perimeters) or if the event was intentional (**protocol violation**; e.g. seeing a participant outside the established study visit window as a convenience to study staff)***:**

Please explain how participants were adversely affected by this deviation/violation:
(If applicable, please attach an NUNM IRB Unanticipated Adverse Event Reporting Form.)

Please provide a plan for preventing the recurrence of the deviation/violation:

Please describe any corrective actions, if applicable, for the deviation/violation;

Does this protocol deviation/violation require revision of the protocol, consent or other previously IRB approved documents?

☐ Yes ☐ No

If yes, please submit a PRAF with changes highlighted within the referred to document(s).
If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse:

Signatures

By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that upon receipt of the IRB's review I will fully and immediately implement any corrective actions required by the IRB.

_____ _____
Principal Investigator Date
Electronic signatures are allowable provided the form is emailed directly by the named individual(s).

_____ _____
Clinical Investigator (if applicable) Date

IRB USE ONLY
Required corrective actions to be taken by the investigating team: Chair or Committee Member Name: _____ Signature: _____ Date: _____