

**CLINICAL INVESTIGATOR ASSURANCES for
NUNM's Institutional Review Board (IRB)**

Study Title: _____

By initialing each statement below and signing this form, I, the Clinical Investigator, assure my understanding of and responsibility for the following: *Please initial the grey text boxes, type your name, and sign below.*

_____ As a licensed clinician with clinical privileges at NUNM Clinics, I agree to assume medical responsibility for this research project.

_____ I will conduct this research study as reviewed and approved by the NUNM Institutional Review Board (IRB).

_____ I will promptly notify the NUNM IRB of any proposed changes to the project protocol, consent form, recruitment materials, reception scripts, and data collection forms including questionnaires.

_____ I will not implement any changes to this research study, except where necessary to eliminate apparent immediate hazards to the subject(s), until approved by the NUNM IRB.

_____ I will promptly report changes or additions to research personnel who will be involved in subject care.

_____ I will submit current curriculum vitae for new research personnel.

_____ I will report any unanticipated problems including Adverse and Unexpected Events (AEs) to the IRB in writing within ten (10) days of occurrence.

_____ I will report these problems to the Department of Health and Human Services (DHHS) for research supported with DHHS funds.

_____ I will promptly report any significant new findings and submit statements of significant new findings provided to subjects.

_____ I assure that a signed copy of the Consent Form will be included in the medical records of the subjects where appropriate.

_____ I agree to retain research documents for three (3) years after the research study has been completed or discontinued.

_____ I agree to furnish relevant information when requested and to submit annual and final reports to the IRB.

_____ I will be responsible for the ethical conduct of this research study, and for protecting the rights, welfare, and privacy of the research subjects.

Printed Name of Clinical Investigator

Signature of Clinical Investigator

Date

Clinical Investigator Assurances

Study Title:

PI:

IRB #:

Approval Date: