

PROTOCOL REVISION AND AMENDMENT FORM for NUNM's Institutional Review Board (IRB)

Please complete this form and attach all changes made to the research proposal, including all changes to the protocol, consent form, reception script, advertisements, questionnaires, and data collection forms. Please submit a copy of the original and modified documents and highlight the areas in each that have been changed. For additions to and/or changes in research personnel, please explain why the addition/change is required and include a curriculum vitae for all new personnel.

Study Title: _____

Principal Investigator (PI): _____

PI Telephone Number: _____

PI E-mail: _____

IRB Number: _____

Current Status:

- ☐ In progress
- ☐ Not started

Proposed Revisions/Modifications:

- | | |
|--|--|
| ☐ Protocol | ☐ Instruments/Devices |
| ☐ Consent Form | ☐ Personnel (list RCR/HSR/DSFI dates below if adding personnel) |
| ☐ Study Methods | ☐ Other |

Please summarize the proposed change(s):

Please summarize the purpose of the proposed change(s):

Protocol Revision and Amendment Form

Study Short Title:

PI:

IRB #:

Approval Date:

Will the proposed change(s) affect the study subjects?

If yes, please explain.

☐ Yes

☐ No

Principal Investigator Signature

Date

Institutional Review Board Decision:

☐ Approved

☐ Not Approved (Please see comments on original documents.)

For approvals, please replace the obsolete proposal documents with the currently approved proposal documents in a research study binder or file (along with this approval form) where they can be easily accessed and identified. Retain the obsolete documents in a separate file for future reference. If the Consent Form was changed and approved be sure to include the IRB number and new approval date on all pages. Be sure to re-consent active subjects already enrolled in the study using the currently approved Consent Form. Once IRB approval has been granted, all subsequent revisions to the research proposal must be reviewed and approved by the IRB before being implemented. Please complete a Research Proposal Revision /Amendment Form to submit future changes to the IRB.

IRB Comments:

IRB Chairperson

Date

Protocol Revision and Amendment Form

Study Short Title:

PI:

IRB #:

Approval Date: