Rev 08/03/16 kbk

FINAL REVIEW FORM for NUNM's Institutional Review Board (IRB)

A close out report should be submitted when data collection and data analysis are complete. Please type your responses in the boxes provided. Use as much space as necessary (boxes will expand). Please answer each question – if a question is not applicable, please put N/A in the box.

1.0 Investigator Information

1.1 Principal Investigator (PI): _____

1.2 PI Telephone Number:_____ **1.3 PI E-mail: _____**

1.4 PI Fax Number: _____

1.5 Co-Investigator Name(s) and Contact Info:

2.0 Study Information

2.1 IRB Number: _____

2.2 Study Title: _____

2.3 Project Funding
Please include the agency and grant number if applicable:

2.4 Study Status:

☐ **Completed – must have concluded interventions and data analysis.**

☐ **Never Commenced – please state reasons(s) why below.**
Please, explain:

3.0 Participant Information

3.1 Total number of participants approved to be enrolled in the study: _____

3.2 Total number of participants enrolled since study began: _____

3.3 Total number of participants enrolled during the past approval period: _____

3.4 What percentage of the total number of participants screened were ineligible to participate in the study?

_____

3.5 Total number of participants that withdrew from the study: _____
Please state the mean reasons(s) the participant(s) withdrew:

3.6 Total number of participants that the investigator withdrew from the study: _____
Please state the mean reasons(s) the participant(s) was/were withdrawn:

3.7 Participant enrollment breakdown by gender, age and ethnicity.
This information is required for all studies that are NIH-sponsored. It is recommended, but not required, that other researchers provide this information.

4.0 Adverse Event of Unexpected Problems

4.1 Have there been any *adverse events* or unexpected problems encountered in the study?

☐ Yes ☐ No*(If no, proceed to question 4.3.)*

If yes, please explain in detail and indicate when the IRB was notified of the event or problem. Indicate dates that the Adverse Events Reporting Form(s) was (were) submitted to the NCNM IRB.

4.2 Have all adverse events been reported to the IRB?

☐ Yes ☐ No- *(If no, attach a letter of notification with an explanation.)*

4.3 Does the study have a Data Safety Monitoring Board (DSMB)?

☐ Yes ☐ No

If yes, please indicate the date of the last DSMB review. (Please note that investigators are required to submit DSMB reports to the NCNM IRB at the time they are made available to the investigator.)

5.0 Publications, Presentations and Recent Findings

5.1 Have there been any presentations or publications resulting from this study during the past approval period?

☐ Yes ☐ No

If yes, please submit a copy of the abstract, or the publication, with this application.

6.0 Protocol Progress Report

6.1 Please submit a summary progress report. The progress report must be substantive and complete. The report should include the goal(s) of the study, findings to-date, and reason (s) why the study is closed:

7.0 Required Signatures

_____ _____
Principal Investigator Date

_____ _____
Clinical Investigator (if different than PI) Date

_____ _____
Name of person completing this form Date

IRB USE
Institutional Review Board Decision: ◯ Approved ◯ Not Approved Chair or Committee Member Name: _____ Signature: _____ Date: _____