Rev 05/25/16 kbk

CONTINUING REVIEW FORM for NCNM'S Institutional Review Board (IRB)

In accordance with Federal Regulations 45CFR46, the IRB must review nonexempt protocols at least annually, or more frequently if warranted. Please type your responses in the boxes provided. Use as much space as necessary (boxes will expand). Answer each question – if a question is not applicable, please put N/A in the box. Studies that are in the data analysis phase are considered open, and researchers must complete this form. (**Note: Past approval period is date of approval to date listed on approval letter for most recently submitted continuing or final review**).

1.0 Investigator Information

1.1 Principle 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:
If project is funded or funding is being sought, provide list of all sponsors and grant numbers. Please indicate the grant status for each source of funding as active or pending.

2.4 Location(s) of research activity:

2.5 Active Protocol?

☐ **Yes – Please indicate anticipated date of study completion.**

☐ **No – Please submit a Final Review Form in place of this form.**

3.0 Participant Information

3.1 Is this study closed to enrollment of new subjects?

☐ Yes ☐ No

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

3.3 Total number of participants enrolled since study began: _____

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

3.5 Total number of participants screened in the past approval period (if applicable): _____

3.5.1 If applicable, what percentage of the total number of participants screened in the past approval period were ineligible to participate in the study? _____

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

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Please state the mean reasons(s) the participant(s) was/were withdrawn:

3.8 Total number of participants still to be enrolled: _____
If this brings the sample to greater than what is listed in 3.2, submit a request for modification (see 6.4).

3.9 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 Data Sources

4.1 Please check all that apply:

☐ Human subject intervention with use of informed consent form
☐ Interviews or questionnaires
☐ Medical records or other records from human subjects
☐ Other please specify**:** _____

5.0 Adverse Event of Unexpected Problems

5.1 Have there been any complaints from subjects in the past approval period?

☐ Yes ☐ No

If yes, please describe:

5.2 Have there been any *adverse events* or unexpected problems in the past approval period?

☐ Yes ☐ No

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.

5.3 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.)

6.0 Protocol Modifications and Revisions

6.1 Have there been any modifications or revisions to the protocol in the past approval period?

☐ Yes ☐ No

If yes, please indicate the dates of the approval from the IRB Committee for the modification or revisions (dates of the PRAFs submitted/approved).

6.2 Have there been any deviations from the approved protocol?

☐ Yes ☐ No

If yes, please describe the changes to the protocol and submit the changes highlighted within the referred to document(s).

6.3 Do you want to add any new co-investigators to the study?

☐ Yes ☐ No

If yes, indicate who you are adding, and submit their names on an updated IRQ form.

6.4 Do you wish to submit a modification at this time?

☐ Yes ☐ No

If yes, please describe the modification request and rationale for the changes:

7.0 Consent Form

7.1 Please attach a copy of your current consent form for renewal if you are enrolling new subjects.

☐ Consent Form ☐ N/A

7.2 Is this the original consent form or a revised form?

☐ Original ☐ Revise ☐ N/A

If revised, please provide date of NCNM IRB approval for the revision. Electronically send the current consent forms and HIPAA forms.

8.0 Progress Report

8.1 Please submit a summary progress report. The progress report must include the goal(s) of the study, findings to-date, and plans for the next year/review period (no more than 750 words):

9.0 Publications, Presentations and Recent Findings

9.1 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.

9.2 Have there been any significant new findings either from this study, or a related study (through a literature review for example), that would have an effect on participants' willingness to continue participating in this study?

☐ Yes ☐ No

If yes, please describe and cite references:

9.3 If applicable, have participants been informed of the new findings?

☐ Yes ☐ No ☐ N/A

10.0 Significant Financial Interest and Commercialization

10.1 Does any member of the research team have a potential significant financial interest with this study that could affect study participants and/or study outcome?

☐ Yes ☐ No

If yes, please describe and disclose in the consent form:

10.2 Does the PI, Co-I and other researchers have a current Disclosure of Significant Financial Interest form on file at NCNM / Helfgott Research Institute?

☐ Yes ☐ No

10.3 If there are significant financial interests, please describe the ways in which you have and will minimize harm to research subjects and/or the objectivity of research:

11.0 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: _____