Rev 07/19/16 kbk

REACTIVATION REQUEST for NUNM's Institutional Review Board (IRB)

- Studies with a Final Review Approval Letter signed less than six (6) months ago, may use this Reactivation of a Closed Study Request Form. However, studies with a Final Review Approval Letter signed more than six (6) months ago, must file a new study application.
- Principal investigators may request reactivation of a study using the Reactivation Request Form only if the study was closed in IRB compliance and with a signed and dated Final Review Approval Letter. If a study is closed by the IRB for non-compliance for any reason, the principal investigator must contact the NCNM IRB Chair, Liz Sutherland, ND at 503-552-1847 to determine the appropriate course of action for reactivation to be considered.

Instructions: Please answer each question. If a question is not applicable, please put N/A in the box.

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 Original IRB Approval Date: _____

2.4 Location(s) of Study Activity:

3.0 Protocol Status

3.1 Date Final Review Form was signed by the IRB: _____

3.2 Have there been any enrollments, interventions/interactions since the closure date?

☐ **Yes** ☐ **No**

If yes, please explain:

3.3 Have any data been obtained since the closure date?

☐ **Yes** ☐ **No**

If yes, please explain:

3.4 Are you requesting that data collected since the closure date be used in data analysis?

☐ **Yes** ☐ **No**

If yes, please explain: (Note: This request for reactivation must be approved by the IRB prior to any use of the data.)

3.5 Have there been any other research activities not addressed above since the closure date?

☐ **Yes** ☐ **No**

If yes, please explain:

4.0 Justification

4.1 Please thoroughly justify the need for reactivation of your study:

5.0 Data Handling

5.1 Will you be using a study key?

☐ Yes ☐ No

If yes, please initial to attest that only one person will have access to the study key: _____

5.2 Will data is to be transmitted outside of NCNM?

☐ Yes ☐ No

If yes, please describe plans for how the data will be transmitted, received, stored and returned/destroyed:

5.3 Please attest to the following statements by initialing each:

_____ **5.3.1** Hard copies of study data will be stored in a secure environment (locked cabinets in a locked office).

_____ **5.3.2** Electronic data will be stored on password-protected computers.

_____ **5.3.3** Only data necessary to meet the specific aims of the study will be collected and analyzed.

_____ **5.3.4** No data will be collected or shared until all necessary approvals and forms are signed and in place.

_____ **5.3.5** The study will remain open during the publication period.

6.0 Adverse Event or Unexpected Problem

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

☐ Yes ☐ No

If yes, please describe:

6.2 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.

6.3 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.)

7.0 Protocol Modifications and Revisions

7.1 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 and include the RCR and HIPAA training dates for each.

7.2 Were there any deviations from the final approved protocol in the past approval period?

☐ **Yes** ☐ **No**

If yes, please summarize these deviations:

7.3 Do you wish to submit a protocol modification at this time?

☐ **Yes** ☐ **No**

If yes, please describe the purpose and rationale for the changes and attach proposed changes in all applicable IRB document, using track-changes:

8.0 Consent Form

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

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

☑ **Original** ☑ **Revised** ☑ **N/A**

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

9.0 Publications, Presentations and Recent Findings

9.1 Have there been any presentations or publications resulting from this study since the closure date?

☐ **Yes** ☐ **No**

If yes, please attach 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:

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

☐ **Yes** ☐ **No**

10.0 Conflicts of Interest and Commercialization

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

☐ **Yes** ☐ **No**

If yes, please describe the conflict of interest here, and disclose it in the consent form:

10.2 Does the PI, Co-I and other researchers have a current conflict disclosure form on file at NCNM / Helfgott Research Institute?

☐ **Yes** ☐ **No**

10.3 If there are conflicts of interests, please describe the ways in which you have and will minimize harm to research subjects and/or the objectivity of research: *(If not applicable, please write 'N/A'.)*

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: _____