

A. Protocol Information

NEIU IRB Protocol #:	Date of Report:
Project Title:	
Principal Investigator: Name (Last, First)	Degree(s):
<p>Reason For Final Report (<i>check all that apply</i>)</p> <p><input type="checkbox"/> Research was not funded and was never initiated. (Skip to the last page –Assurance Page)</p> <p><input type="checkbox"/> Research was initiated, but no subjects were ever enrolled. (Skip to the last page –Assurance Page).</p> <p><input type="checkbox"/> Research has been completed, and there will be no further data collection (including long term follow-up) or data analysis for this research (and any thesis defense is completed). <i>For Sponsored projects, please include the Sponsor’s “close-out” letter when applicable.</i></p> <p><input type="checkbox"/> The P.I. is terminating the research. (Please specify the reason(s) why research was stopped before meeting approved goals/objectives).</p> <p><input type="checkbox"/> The Sponsor is terminating the research. (Include the reason(s) for termination, e.g. interim analysis revealed substantive findings).</p>	

1. PURPOSE AND PROGRESS:

a. Briefly describe the purpose (scientific aims) of the research:

b. Please provide a summary of the progress of the research at NEIU and at any other sites where this study has been or is being conducted. *For multi-site trials, please submit a recent sponsor’s summary as an attachment to this application:*

2. RESULTS OR FINDINGS FROM THIS RESEARCH:

Describe any important results or findings from this research at NEIU and other sites, if appropriate.

3. SUBJECT COMPLAINTS:

Have any subjects made complaints about the research?

Yes No If yes, summarize the following for each complaint including a description of the complaint, the number of times it occurred, your opinion as to whether it was related to the research, and any actions taken by the investigator in response to the complaints.

4. SUBJECTS AND/OR PARENTS/GUARDIANS/LEGALLY AUTHORIZED REPRESENTATIVES DECLINING TO PARTICIPATE:

Have any subjects and/or parents, guardians, or legally authorized representatives declined to participate in the research after being approached?

Yes No *If yes, indicate the number of subjects and/or parents, guardians, or legally authorized representatives, the reason(s) they declined to participate.*

5. SUBJECTS WITHDRAWALS:

A. Have any subjects and/or parents, guardians, or legally authorized representatives withdrawn from the research after initial enrollment and participation?

Yes No

B. Have any subjects been withdrawn from the research by the Investigator, the study sponsor, or for other administrative reasons?

Yes No

If yes to either, please explain; include the total number of subjects who have withdrawn or been withdrawn, the reason(s) for their withdrawal, the phase of the study in which the withdraws have occurred (i.e., during screening, intervention, follow-up); and whether any changes to the research protocol and informed consent process and/or documents were made in response to the withdrawals.

6. ADVERSE EVENTS OR UNANTICIPATED EVENTS OR PROBLEMS:

Summarize all serious and unanticipated adverse events or other unanticipated problems involving risks to subjects or others that have occurred involving this research

protocol *since either the* initial review or the last continuing review (*whichever is most recent*). Include information regarding the frequency and severity of the events, whether or not they were related to the research (e.g., experimental procedure, drug, device and/or biologic, whether they resulted in a change in the risk-benefit analysis and change in the research protocol and/or Informed Consent Document.

There were no unanticipated problems involving risks to subjects or others, or adverse events to report since the initial approval or last continuing review approval.

7. SUSPENSION (STOPPING) OF SUBJECT ENROLLMENT:

Since the last review, has there been suspension of any research activity (for any reason) that has not already been reported to the IRB?

Yes No *If yes, please explain. Provide the specific dates and reasons.*

8. PRESENTATION(S) AND/OR PUBLICATION(S):

Have there been any presentations or publications (including abstracts) from this research since the last review?

Yes No *If yes, please list and attach copies of each.*

9. ASSURANCES

INVESTIGATOR'S ASSURANCE FOR FINAL REPORT OF RESEARCH

I certify that the information provided in this Final Report is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, and the ethical conduct of this research. I confirm that I have complied with applicable NEIU policies and procedures, as well as with applicable federal, state and local laws. I also agree to the following:

The research was performed by qualified personnel as specified in the approved research application and/or protocol. No changes were made to the research protocol (except when necessary to eliminate apparent immediate hazards to the subject), or the consent process (if one was required) without prior approval by the NEIU IRB. Legally effective informed consent/assent was obtained from all human subjects, unless the NEIU IRB waived this requirement. Unanticipated problems involving risks to subjects or others (including adverse events) and subject complaints were reported to the IRB in a timely manner.

Principal Investigator

Date

FACULTY SPONSOR'S ASSURANCE

By my signature as sponsor on this Final Report, I certify that the student or guest investigator was knowledgeable about the regulations and policies governing research with human subjects and had sufficient training and experience to conduct this particular study in accordance with the approved protocol.

Faculty Sponsor¹ (if PI is a student or a fellow)

Date

¹ The faculty sponsor must be a member of the NEIU faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.