

FORM – Amendments to Previously Approved Research

Office of Sponsored Programs (OSP)

Northeastern Illinois University
5500 N. St. Louis Avenue
Chicago, IL 60625-4699
Phone: 773-442-4670 Fax: 773-442-4673
<http://www.neiu.edu/~sprogram/>

Date Report Completed:		Protocol Number:	
I. Research Protocol Information			
1. Project Title:			
2. Principal Investigator			
Name (Last, First)		Degree(s)	University Status
Campus Mailing Address			
Campus Phone Number		Campus Fax Number	
College	Department		E-mail Address
3. Type Of Amendment (Please Check The Appropriate Box (es)):			
<input type="checkbox"/> Protocol Amendment	Version # _____	Date: _____	<input type="checkbox"/> Research Protocol Title Change
<input type="checkbox"/> Revised Informed Consent Document	Version # _____	Date: _____	<input type="checkbox"/> Change in Subject Enrollment/Number
<input type="checkbox"/> Change or Addition of Recruiting Materials	<input type="checkbox"/> Investigator Change		<input type="checkbox"/> Key Research Personnel Change
<input type="checkbox"/> Change or Addition of Performance Site(s)	<input type="checkbox"/> Change in the Sponsor		<input type="checkbox"/> Change in the Funding Source
<input type="checkbox"/> Other:			

4. Describe the proposed amendment(s) and provide the rationale for the amendments.

5. Is this an investigator-initiated amendment? Yes No

6. Is this a sponsor-initiated amendment? Yes No

If yes, provide the name of the sponsor and provide copies of the sponsor amendment.

Name of Sponsor: _____

II. Risk-Benefit Assessment

1. Are the risks to subjects affected (increased, decreased) by the amendment? Yes No

If yes, describe how the amendment will affect the risk-benefit ratio for the subjects.

III. Informed Consent/Assent Process or Document(s)

1. Does the proposed amendment affect the informed consent/assent process and/or document(s)? Yes No

2. Describe how the process and/or document(s) will be changed.

IV. Reaffirmation of Informed Consent/Assent Document(s) and/or the HIPAA Research Authorization

1. Is it necessary to inform subjects who have already consented to participate in the research of the amendment? Yes No

2. Is it necessary to inform subjects who have already authorized the use and disclosure of health information for research of the amendment? Yes No

If yes, should they be given and asked to resign the full revised informed consent OR should an addendum to the informed consent document be prepared for discussion with the subject? Select one and follow directions for submitting the revised documents.

Full Revised Informed Consent Document

Addendum

Full Revised HIPAA Research Authorization

V. Notification of Subjects Who Have Completed Participation

1. Is it necessary to notify subjects who have completed their participation in the research? Yes No

If yes, describe how this will be done and submit the documents (if applicable) that will be used.

Printed Name

Date

Investigator Signature

Faculty Sponsor Signature (if PI a student or a fellow)

Date