**Form D** Eastern Illinois University

For IRB use only

IRB File No.: Date received: Approval expires:

**Institutional Review Board**

for Review of Research Involving Human Subjects PROPOSED MODIFICATIONS

TO PROTOCOL OR INFORMED CONSENT/ASSENT FORM(S) AFTER IRB APPROVAL

1. Title of Project:

IRB File Number:

1. Principal Investigator\*:

Status:  Faculty Student\*  EAP Staff  Other—specify:

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address:

Phone: E-mail:

Department or Unit

Co-Investigator or Sponsor:

Status: Faculty Student  EAP Staff Other—specify:

Mailing address:

Phone: E-mail:

Department or Unit

List additional co-investigators, including above information, on a separate sheet.

1. Are there any proposed changes in the protocol requested?

No

Yes—describe proposed changes to the protocol and submit protocol with revisions incorporated:

Click or tap here to enter text.

1. Are there any proposed changes to the informed consent/assent form(s)?

No

Yes— describe changes and attach new consent/assent form(s) with changes highlighted:

Click or tap here to enter text.

1. Are there any additions and/or changes in sites where data are being collected?

No

Yes— list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A):

Click or tap here to enter text.

1. Are there changes in key personnel assisting in the research project?

No

Yes— list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project:

Click or tap here to enter text.

1. Describe any proposed changes, not listed above.

Click or tap here to enter text.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study’s protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

Principal Investigator’s Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this proposed modification request and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

Faculty or EAP Staff Sponsor’s Signature Date