**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?

[x] 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?

[x] 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