Form D

For IRB use only
IRB File No.: _____
Date received: _____
Approval expires: _____

Eastern Illinois University
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: _____

2. 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.

3. Are there any proposed changes in the protocol requested?
   ○ Yes—describe proposed changes to the protocol and submit protocol with revisions incorporated.
   ◉ No

4. Are there any proposed changes to the informed consent/assent form(s)?
   ○ Yes—describe changes and attach new consent/assent form(s) with changes highlighted.
   ◉ No

5. Are there any additions and/or changes in sites where data are being collected?
   - ○ Yes—list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A).
   - ◉ No

6. Are there changes in key personnel assisting in the research project?
   - ◉ 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.
   - ○ No

7. Describe any proposed changes, not listed above.

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