EASTERN CONNECTICUT HEALTH NETWORK
Institutional Review Committee
Request for Approval of Amendment

Title of Research Project:

Date:

Name of Principal Investigator: :

Signature of Principal Investigator:

Address:		
Phone:	**Fax:**	**E-mail:**
Student/Resident Investigator:		
Phone:		**E-mail:**
Student/Resident Investigator:		
Phone:		**E-mail:**

Instructions to Investigators: A research protocol must be carried out in accordance with the protocol as approved by the IRC. Any changes in the protocol, including but not limited to changes in subject population, dosage, recruitment activities, advertisement material, study procedures, study instruments, study sites or research personnel must be approved by the IRC prior to implementation.* If applicable, include the sponsor's amendment summary, as well as any other supporting information that may prompt this amendment request (i.e., DSMB report, sponsor letter, unanticipated adverse event, etc.). Documents must contain a version number and date. If you are amending a protocol, consent form(s), parental permission form and/or study information sheet(s), please update the version number/date on all affected documents.

*The only exception is when changes are necessary to eliminate apparent immediate hazards to the research subjects. In this instance, please communicate to the ECHN IRC Chair/IRC Staff promptly and submit the completed ECHN Protocol Deviation Report form and this form within five (5) business days.

1. **Amendment requested by:**
   - ☐ PI
   - ☐ Sponsor (Include a copy of correspondence from Sponsor)

2. **Please check all documents that were revised as a result of this amendment (include 2 copies of each document).**

   - ☐ IRC protocol
   - ☐ Sponsor's protocol
   - ☐ Informed consent
   - ☐ Assent form
   - ☐ Parental permission form
   - ☐ Information sheet
   - ☐ Addendum to Informed consent
   - ☐ Investigator's Brochure
   - ☐ Advertisement, flyer or other recruitment activity
   - ☐ Other, please specify_____

3. **Sponsor Protocol Version and Date (if applicable):**

4. **Number of enrolled subjects to date:**

5. **Number of subjects currently receiving study intervention:**

6. **Will changes affect the risk to subjects enrolled in the study?**

☐ Yes ☐ No

<u>Summary of Protocol Changes</u>: Please explain what modifications are being proposed at this time, and why the modifications are necessary. Compare the modifications to the currently approved protocol and explain their necessity as well as their effect, if any, on the risks and benefits to subjects. Please note in this box the document name, page and section number or title where the changes have occurred.
Describe changes to the consent form/assent form/recruitment ad. Current participants must be informed about any significant new findings or protocol changes that might relate to their willingness to continue participation. Please explain how you will inform subjects of this new information (if applicable). Explain which sections of these materials are being changed. Please note in this box the document name, page and section number or title where the changes have occurred.

7. Any additional comments: