For IRB Office Use Only

Date Received: _____

Date of IRB Approval: _____

_____

IRB Authorized Signature

IRB Approval Valid Thru: _____

For IRB Office Use Only

Original Application #:

_____

Modification #:

_____

State of Connecticut Department of Developmental Services
Office of the Commissioner Institutional Review Board
Application for Continuation, Addendum, Modification, or Termination of Existing Approved Project

Instructions: It is the responsibility of the investigator to submit this application in a timely manner. IRB approval cannot be extended without full review and approval of the project. Submit one copy of complete application to:

Office of the Commissioner Institutional Review Board
Department of Developmental Services
460 Capitol Avenue, 3rd Floor
Hartford, CT 06106
Attn: IRB Chair

Continuation--At least one month prior to the expiration of the current IRB approval, the investigator must submit (a) a completed application and (b) a copy of the consent form currently in use.
Addendum/Modification--In order to obtain approval for any change in the research procedures involving human participants or in the consent form, the principal investigator must submit (a) a complete application, outlining the proposed change and rationale for the change; (b) the consent form; and (c) other relevant documents as appropriate.
Expiration/Termination--A final report must be submitted within 90 days of the study termination or expiration date of the study.

I. General Information

Date of Request:	Date of Original IRB Approval:	
Type: ◯ Continuation ◯ Addendum/Modification ◯ Expiration/Termination		
Title of Project:		
Funding Agency or Research Sponsor:		
Principal Investigator (or Major Advisor, if student project):		
Department/Agency/University:		
Address:		
Phone:	Fax:	E-mail:
Co-Investigator(s) (or student):		
Department/Agency/University:		
Address:		
Phone:	Fax:	E-mail:

Has Addendum/Modification/Continuation been reviewed and approved by another IRB?

◯ Yes * ◯ No

** If yes, attach a copy of that IRB protocol and letter of consent approval.*

II. Addendum/Modification

- ✓ Number of subjects entered since last continuation report: _____
- ✓ Total number of study subjects enrolled (since initiation of the trial): _____
- ✓ Number of subjects withdrawn and reasons for withdrawal (since the initiation of the trial):

Describe below the implications of the proposed changes on the likelihood for increased risks to study subjects. Specify whether modification(s) are strictly administrative, clinical with no increased risk to subjects, or clinical with increased risk to subjects.

III. Continuation

Describe below the progress to date that includes a statement justifying the continuation of the investigation, including (a) any proposed changes, (b) a summary of any recent pertinent literature, or clinical findings, or other relevant information, especially information about risks associated with the research. Provide a summary of all adverse events that have occurred in the last year. Also provide any reported patient complaints.

☐ I have reviewed the current literature on this subject and I feel that this study should be continued.

IV. Termination

Summarize the findings of the research.

If the consent form has been modified since the last report, or if this is a request for continued approval, please attach a copy of your consent form(s) for IRB approval and validation.

I certify that the approved protocol and the approved method for obtaining informed consent have been followed during the period covered by this report.

Signature: _____ Date: _____
Principal Investigator (or Major Advisor, if student project)

Signature: _____ Date: _____
Co-Investigator(s) (or student)

Signature: _____ Date: _____