**State of Connecticut Office of Early Childhood**

**Institutional Review Board (IRB)**

**Instructions: Application for Continuation or Addendum/Modification of Approved Project**

The Office of Early Childhood (OEC) values research that contributes to the field of services and supports, and is committed to protecting the rights of human subjects involved in research. When an approved study is expected to continue beyond the approval date, this form must be submitted to the IRB for approval 30 days prior. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Scan completed document and submit electronically to **oec.irb@ct.gov**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Upon receipt, the IRB Chair will complete a preliminary review and may (A) contact the researcher for more information, (B) exempt the research from OEC IRB approval, (C) expedite the review process, or (D) forward the application to the full IRB for review.

The OEC IRB meets quarterly in October, January, April and July and approval is not guaranteed. Please submit your application far enough in advance to allow time for a full review by the IRB. Incomplete applications will be returned before review.

Please be sure that all of the following are complete and included in your application, as needed:

\_\_\_\_\_ Application for Continuation or Addendum/Modification *(required)*

\_\_\_\_\_ Consent form *(required when modifications affect subjects’ involvement in any way)*

\_\_\_\_\_ Assent form *(required when modifications affect subjects’ involvement in any way)*

\_\_\_\_\_ Request for Use of Protected Health Information or Personally Identifiable Information

and Assurances *(to reflect any changes)*

\_\_\_\_\_ Curriculum vitae (CV) of principal investigator *(when P.I. has changed)*

\_\_\_\_\_ CV of co-investigator(s) or student advisee *(for newly added study personnel)*

\_\_\_\_\_ Application and approval already obtained from all other IRBs for this same

Continuation, or Addendum/Modification *(required, if applicable)*

Required forms may be found at: <http://www.ct.gov/oec/cwp/view.asp?a=4546&q=569276>

Detach this instruction sheet before submission

P.I. Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ page \_\_\_\_ of \_\_\_\_ total pages submitted



**State of Connecticut Office of Early Childhood**

**Institutional Review Board (IRB)**

**Application for Continuation or Addendum/Modification of Approved Project**

*For IRB Use only*

*Date received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Original Application #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date of IRB Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ New Approval End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Notification Sent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*IRB Authorized Signature*

Date of This Request:       Total # of pages submitted:

Project Start Date:       Expected end date:

Dates of prior Continuation/Modification Requests:

Project Title:

Funding agency or Research Sponsor:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator *(or major advisor, if student project):*

Department, university, hospital, or agency affiliation:

Mailing Address:

E-mail:       Phone:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator(s) or student advisee:

Department, university, hospital, or agency affiliation:

Mailing Address:

E-mail:       Phone:

P.I. Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ page \_\_\_\_ of \_\_\_\_ total pages submitted

**Project Activities to Date**

Participants:

      # Enrolled to date

      # Withdrawn since start of project

 Reasons:       # Who withdrew consent without any adverse event noted

       # Who experienced adverse events

       # Other:

Successes:

Challenges:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**REQUEST FOR CONTINUATION**

Reasons for Continuation:

      Continued enrollment of participants only, no change in protocol\*

      Data analysis only

      Other: *(please describe)*

\*If you plan to change your protocol, please complete the Addendum/Modification section.

P.I. Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ page \_\_\_\_ of \_\_\_\_ total pages submitted

**REQUEST for MODIFICATION**       **or ADDENDUM**       ***(please check one)***

Is the Modification or Addendum related to:

1. Change in principal investigator or other study personnel
2. Change in funding source
3. Change in eligibility criteria
4. Addition of a new project activity
5. Elimination of an approved project activity
6. Modification of data analyses
7. Modification of Consent Form
8. Other:

Does the change affect: *(please mark* ***all*** *that apply)*

      OEC administrative office       OEC funded or operated agencies

      Neither

Access to OEC consumers?       No

      In-person

      Family members, e.g., parent or sibling

      Medical or community service providers

      Agency staff:       Public employees and/or       Private agency employees

      Participant Records       De-identified data

Please describe each change and the supporting reason, specifically noting any new or elevated risks or benefits for participants:

**Related Research Published/Presented since approval**

I have reviewed research similar to this protocol and am unaware of any risks recently revealed (if applicable):

P.I. Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ page \_\_\_\_ of \_\_\_\_ total pages submitted

**Signatures and Assurance of Compliance with Regulations Regarding the**

**Use of Human Subjects**

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

      *(initial)* I certify that I will:

      continue to report any adverse events

      have reported any adverse events

according to the terms of the original OEC IRB approved application #

signed by       me       the original principal investigator

on       *(date).*

Signature:       Date:

 Principal Investigator (or Major Advisor, if student)

Signature:       Date:

 Co-Investigator(s) or student

Title of Research: