State of Connecticut Department of Developmental Services
Office of the Commissioner Institutional Review Board

Application for IRB Review

IRB meetings are scheduled once a month. Applications for review must be received no later than 10 business days prior to the next scheduled meeting.

A submission for review by the IRB must be prepared for each research study using human subjects or human materials. All of the appropriate forms must be neatly typed and accurately completed. IRB review cannot be accomplished unless all of the sections are completed. Attach a copy of the "Informed Consent Form" and vita(e) for the Principal Investigator, co-investigators, or student as appropriate. 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

Upon receipt of the Application for IRB Review, the IRB Chair will conduct a preliminary review of the application. As a result of this review the chair may: a) return the application to the requestor for additional information, b) forward the application to the IRB for a full review, or c) expedite the review process. Any application that is not completed properly will be returned, resulting in a delay in the review process.

For IRB Office Use Only
Date Received: _____

Date of IRB Approval: _____

_____
IRB Authorized Signature

IRB Approval Valid Through: _____

For IRB Office Use Only

Application #: _____

State of Connecticut Department of Developmental Services
Office of the Commissioner Institutional Review Board

Application for IRB Review

Instructions: *Answer all items as completely as possible. Attach a copy of the "Informed Consent Form" and vita(e) for the Principal Investigator, co-investigators, or student as appropriate. Submit 1 copy of the complete application with attachments to the Office of the Commissioner Institutional Review Board, Department of Developmental Services, 460 Capitol Avenue, 3rd Floor, Hartford, CT 06106 Attn: IRB*

I. General Information

Date of Request: Project Start Date: Project End Date:

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:

Type of Review:
_____ Full Board _____ Expedited _____ Exempt

Type of Project:
_____ New _____ Continuation* _____ Modification/Addendum*

* *Include: Title/IRB #/Last Approval Date:*

Has the project been reviewed and approved by another IRB?
_____ Yes * _____ No
** If yes, attach a copy of that IRB protocol and letter of consent approval.*

II. Project Location and Cooperating Agencies *:

** List DMR region(s) and any public or private agencies that have agreed to cooperate with or effected by this project.*

Describe any DMR resources that may be needed to implement the project (e.g., family addresses, access to records).

III. Project Description:

1. This abstract should contain a clear and succinct description of the long-term objectives and specific aims of this project. It should also include an accurate description of the experimental design and methods of achieving these goals. This abstract is meant to serve as a complete description of the proposed study. DO NOT EXCEED THE SPACE PROVIDED.

2. In the space below, provide a flow diagram or outline of the experimental design of the investigation focusing on those aspects that involve human subjects and emphasizing the specific time sequence of the procedures to be performed.

3. What new information may arise from this work? How and where do you intend to disseminate it?

4. Does the project involve the use of FDA regulated products (drugs or devices)?

Project involves the use of an Investigational Drug?

_____ Yes _____ No

If yes, list IND by name and number.

IND Name: #: Sponsor:

Project involves the use of an Investigational Device?

_____ Yes _____ No

If yes, list IDE by name and number.

IDE Name: #: Sponsor:

IV. Human Subjects:

1. List the type, number and age range of human subjects to be used.

	Type	*Number*	*Age Range*
_____	children/adolescents	_____	_____
_____	adults	_____	_____
_____	males	_____	_____
_____	females	_____	_____
_____	clients	_____	_____
_____	family members *	_____	_____
_____	employees **	_____	_____
_____	other:	_____	_____

** siblings, parents, or grandparents of clients ** public or private*

2. Describe any notable characteristics of the human subjects to be used (e.g., culture, ethnicity, health status).

3. Describe the rationale for the use of *special classes* of human subjects (e.g., children, elderly, prisoners, persons who are or may be decisionally impaired).

4. List specific eligibility requirements for subjects, including those criteria that would exclude otherwise acceptable subjects.

Inclusion: *Exclusion:*

5. Describe how subjects will be recruited.

6. Identify the records or data to be obtained from individually identifiable living human subjects.

7. Explain process for obtaining consent, including additional safeguards if potentially vulnerable persons are to be studied (e.g., children, elderly, prisoners, persons with cognitive impairments).

8. List all procedures (both experimental and non-experimental) to be performed on human subjects. Also list alternate procedures available to the subject.

Experimental:

Non-experimental:

Alternate procedures/treatments:

9. Clearly state all the potential risks (e.g. psychological, social, legal, drug toxicities) associated with the proposed procedures.

10. Describe procedures to protect against or minimize potential risks and to assure confidentiality.

Protections against potential risks:

Assure confidentiality:

10. What benefit, if any, is to be gained by the subject? In the event of monetary gain, include all payment arrangements, including reimbursement of expenses, free medication, and so on.

11. Describe any costs related to the research procedures that are over and above those incurred by standard treatment, and indicate who will be responsible for them.

V. Signatures and Assurance of Continued Compliance with Regulation Regarding the Use of Human Subjects.

1. If procedures for obtaining consent of subjects change, or if the risk of physical, psychological, or social injury increases, or if there should arise unanticipated problems involving risk to subjects or others, I shall promptly report such changes to the Chair of the IRB in writing.

2. I will report unanticipated adverse event, defined as an experience or reaction related to the conduct of the research that is not identified or outlined in the research procedure and the informed consent form, including a change in the nature, severity or frequency of the experience or reaction; and/or any unanticipated problem associated with the conduct of the research related to the level of risk to the participant to the IRB within five business days of occurrence.

3. I will report serious adverse events including, but not limited to those that result in death; are life threatening or potentially life-threatening; result in disability; result in hospitalization or other significant and unanticipated treatment; or other events deemed to be serious by the investigator in writing or by phone to the IRB within 24 hours. Immediate notification is required in the case of client deaths. If reported by phone, a written report must follow within three business days.

4. I will forward a final report to the IRB upon completion of the research project. I understand that the research is considered completed when the following applies 1) no additional participants are being enrolled, 2) all intervention with human participants has ended, 3) data analysis is complete, and 4) all other research related activity has ended. I will forward the final report using the Application for Continuation, Addendum, Modification, or Termination of Existing Approved Project (Appendix C).

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

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

Signature: _____ Date: _____