



STATE OF CONNECTICUT DEPARTMENT OF CHILDREN AND FAMILIES



Institutional Review Board



PROTOCOL REVISION AND AMENDMENT FORM

Instructions: Please complete this form for any change, in content or form, to your DCF IRB approved protocol. In addition, please attach: (1) the **currently approved** page(s) from the affected materials; (2) the affected pages with requested **changes marked** by **highlighting** (to add information); **strikethrough** (to delete); and the **final versions** of all affected pages as amended, with changes incorporated.

All modifications to human subjects research must be reviewed and approved prior to implementation.

Minor modifications: Minor modifications to previously approved projects include those that do not alter the risk-benefit assessment for the research. Examples may include: changes in the investigators; minor, non-substantive changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation or subject recruitment; or the use of a new site that is not materially different from the previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.

Major modifications: Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involved increased level of risk to the physical, emotional or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

IRB number:	Title:	
Date:	Amendment No. (start with 01):	
Principal Investigator:	Academic Degree(s):	
Organization/Agency:		
Phone:	Fax:	E-mail:



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Minor or Major Modification? In the Principal Investigator's judgment, which category of modification is this?

- Minor
 Major
 Not Sure

Submission Changes: This submission changes the status of this study in the following way(s):

- | | |
|--|---|
| <input type="checkbox"/> Protocol Revision (Study Methods) | <input type="checkbox"/> Protocol Revision (Study Instruments) |
| <input type="checkbox"/> Protocol Amendment | <input type="checkbox"/> Revise Consent Form(s), Recruitment Flier(s)/Letter(s) |
| <input type="checkbox"/> Addendum (New) Consent Form | <input type="checkbox"/> Increase in Number of Subjects |
| <input type="checkbox"/> Change of Principal Investigator ¹ | <input type="checkbox"/> Additional Investigators/Key Personnel ² |
| <input type="checkbox"/> Additional funding | |
| <input type="checkbox"/> Other: _____ | |

Does the change affect subject participation (e.g., procedures, risks, benefit costs, etc.)? Yes No

If Yes, please detail:

Does the change affect the consent document? Yes No

If Yes, please detail:

Does the change affect the statistical integrity of the study (e.g., change in objectives, sample size justification, randomization scheme, etc)? Yes No

If Yes, please detail:

Are there any planned changes for the uses and disclosure of protected health information (PHI)? Yes No

If Yes, please detail:

¹ For "change in principal investigator," the signatures of both new and old PI are required on this form and attach an additional letter from the new PI indicating the change in responsibility of the research. The new PI's curriculum vita must be attached with this amendment form.

² Include a brief description of background, expertise, and involvement in the project.



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Do currently enrolled subjects need to be informed/re-consented?

Yes No

If Yes, explain how this will be done (e.g., informed through a letter from the PI, re-consented on a revised consent form or an addendum consent form, etc.):

If No, but the previously approved consent form is being modified, please explain above why currently enrolled subjects do not need to be informed:

Describe the amendment: Describe the requested change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk-benefit assessment for the research is likely to change as a result of the proposed amendments(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject populations(s), research sites or the confidentiality of private, identifiable subject information.

If additional information is attached, check here:

Assurances: The original, inked signature of the Principal Investigator is required. Other investigators are also responsible for this assurance and are encouraged to sign. In addition, for student protocols that are being amended/revised, that student's faculty advisor must also sign below. Neither stamps nor proxy signatures are accepted in this section.

I certify that the information supplied in this form, with attachments, is complete, accurate and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until all needed IRB approval has been obtained.

Signature
of Principal
Investigator:

Date:

Signature
of Investigator:

Date:

Signature
of Investigator:

Date:

Signature
of Faculty Advisor
(for student protocols):

Date:



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**Please submit your completed protocol revision and amendment form,
both electronically and hard copy, to:**

DCF Institutional Review Board
c/o DCF Bureau of Continuous Quality Improvement • 505 Hudson Street • Hartford, CT 06106
Email: dcf.irb@ct.gov