



**Yale University School of Medicine
Human Investigation Committee
Request for Approval of Amendment**

HIC Protocol Number: _____

Date: _____

Title of Research Project: _____

Name of Principal Investigator : _____

Signature of Principal Investigator: _____

Position or Association with Yale University: _____

***Faculty Advisor, If applicable** _____

**Principal Investigators who are students and trainees must have the guidance of a Faculty Advisor. Faculty advisor must be full time Yale Faculty member and listed on this form.*

Campus Address:

| | | | |
|----------------------------|-------------|----------------|----------------|
| Campus phone: | Fax: | Pager: | E-mail: |
| Correspondent Name: | | E-mail: | |
| Campus phone: | | Pager: | |

Instructions to Investigators: A research protocol must be carried out in accordance with the protocol as approved by the HIC. 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 HIC prior to implementation.

Formatting: 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. Also, include the sponsor's amendment summary, if available, as well as any other supporting information that may prompt this amendment request (i.e. DSMB report, sponsor letter, unanticipated adverse event, etc). To facilitate the review process use Microsoft Word [tracked changes](#) while you are revising your document; this will track each insertion, deletion, or formatting change that you make to the document.

- Amendment requested by:**
 - PI
 - Sponsor (Include a copy of correspondence from Sponsor)
- Please check from the following list all documents that were revised as a result of this amendment (include 2 copies of each document).**
 - HIC 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 _____
- Will changes affect the risk to subjects enrolled in the study?**
 - Yes No



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Describe changes including the page and section in which part(s) of the approved protocol will be amended. In the space provided below provide the rationale for requesting these changes. Use Microsoft Word [tracked changes](#) feature to indicate the addition and removal of information in the body of the document. 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. Explain which sections of these materials are being changed, include page number if applicable and use Microsoft Word [tracked changes](#) feature while you are revising your document. Please note in this box the document name, page and section number or title where the changes have occurred.

For HIC Use Only

Amendment Approved date

Human Investigation Committee