

Continuing Review: All continuing, nonexempt research must be re-reviewed and re-approved on an annual basis, unless the initial IRB review stipulated that IRB review is required more frequently. So that the appropriate level of review can be completed before the project's approval expires, this form must be submitted at least 30 days prior to the deadline indicated in the IRB Office notification. Human Participants research may not continue beyond a project's approval expiration date.

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Renewal Questions

1. Current state of this research

Study is open to enrollment and no participants have been enrolled to date.

Study is open to enrollment and participants have been enrolled to date.

Total Number of Subjects Enrolled:

Study is closed to enrollment but participants are still on the protocol regimen.

Study is closed to enrollment but follow-up of participants continues.

Total Number of Subjects in Follow-up:

Study is closed to enrollment but analysis of identifiable/coded data continues.

Study is closed to enrollment but awaiting close-out visit by Sponsor.

Enrollment, data collection, and analysis of identifiable/coded data have finished or have been terminated.

Provide date of termination:

2. Are there any changes in the original approved protocol/methodology that relate to the research conducted and/or human participants utilized in your research?

Yes – **YOU MUST COMPLETE AND ATTACH AN AMENDMENT/MODIFICATION REQUEST FORM**

No

3. Have there been any adverse events or unanticipated problem(s) that relate to the research conducted and/or human participants utilized in your research?

Yes – **YOU MUST COMPLETE AND ATTACH AN ADVERSE EVENT REQUEST FORM**

No

Attachments

Please attach the following:

Informed Consent Form(s)

Study Protocol

Amendment / Modification Form, if applicable

Adverse Event Form, if applicable

Principal Investigator Assurance and Signature

The information and answers to the questions above are true and accurate to the best of my knowledge and I understand that prior IRB approval is required before initiating any changes that may affect the human participant(s) in the originally approved research protocol. I also understand that in accordance with federal regulations, I am to report to the IRB or administrative designee any adverse events that may arise during the course of this research.

P.I.'s Name: _____ Date: _____

Electronic Signature:

Faculty Advisor

(If the Investigator is a student, a Faculty Advisor must sign below.)

I have read and approved this protocol. I believe this is research as defined by the Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the activity as described therein.

Faculty Advisor's Name: _____ Date: _____

Electronic Signature:

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

**IRB Review of Continuing Review Request Form
(Completed by IRB Office Only)**

Date of Receipt: _____

Is the Form Complete with Required Documents? (Including Informed Consent form?)	Yes
	No

Report returned to Investigator (indicate reason):

Type of Review:	Full Board Review	Expedited Review	
		Expedited Review Category:	

Continuing Review Approval Date: