

On occasion, researchers seek to temporarily re-open a study after study closure has occurred. This is typically related to a request from the sponsor or the FDA for clarification of existing data or for follow-up communication to subjects. This form provides the IRB with the basic information to consider the request.

Re-opening of a closed study will require the same level of review as the original study. If the PI or protocol has changed, an Amendment/Modification Form must accompany this request. If the IRB determines the study to be significantly different from the original, with a substantially different endpoint or outcome, a new application will be required.

Federal regulations (45CFR46.109(e)) require that all human subjects research be reviewed at least annually. If the study in question was closed and at least 12 months since the last IRB approval have passed, a Request for Continuation Form must accompany this submission.

*****This form should not be used if the researcher is seeking to re-open due to a lapse in continuing review.***

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Reason for Re-opening the Study at this Time

Audit Site Visit

Query for data clarification/data existing at the time of study closure

Query for new data related to events occurring since study closure

To Notify Subjects of their Randomization and the Study Results

Other (please explain why this was closed and must now be reopened):

If Audit: provide the anticipated date of the audit:

Who is conducting the audit (regulatory agency, sponsor, other institution for which we were a sub-site, etc.)?

Attach the audit notification and any other relevant communications.

Adverse Events / Unanticipated Problems

Have there been any study-related unanticipated problems or serious adverse events since the study was closed?

No

Yes. **Include copies of these reports with this submission.**

N/A

Subject Notification

If subjects will be notified of their randomization and study results, describe how subjects will be notified and attach any documents that will be sent to subjects for IRB review.

Who will coordinate the notification process?

Name:

Role in Study:

Phone:

Who will sign the letters to the subjects? (**should be the PI)

Name:

Role in Study:

Phone:

Principal Investigator Acknowledgement

P.I.'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 Request to Re-open a Closed Study (Completed by IRB Office Only)

Date of Receipt: _____

Is the Form Complete? Yes No

Full Board Review Date:

Approved

Not Approved. Reason(s):