

Human Subjects Project Closure

Complete this form when an approved human subject research project is CONCLUDED or CANCELLED. Projects that involve long-term follow-up of subjects must remain open, even if enrollment of new subjects has ended.

Name of Principal Investigator:

Project Title:

Original IRB Approval #:

WORK HAS ENDED ON THIS PROJECT FOR THE FOLLOWING REASON(S):

Project completed – no further contact with human subjects is planned

Project not funded – project never began and no human subjects enrolled

Project cancelled for other reason (specify): _____

BRIEFLY SUMMARIZE RESULTS FOUND FROM THIS STUDY:

DID ANY ADVERSE EVENTS/REACTIONS OCCUR WITH THIS PROJECT?

No adverse events/reactions – *If No, sign at the bottom of the page*

Yes – anticipated as included in protocol or stated in consent form

Yes – unanticipated, not part of protocol or consent form language – *If YES, were they reported IRB?*

Yes, reported on _____

No, not reported – ***Adverse event form must be completed and turned in with Closure form***

I certify that the approved protocol and the approved method for obtaining informed consent were consistently and correctly followed during the period covered by this IRB authorization, and that the study now has been completed.

Principal Investigator

Date

Faculty Sponsor (if applicable)

Date