



RE-OPENING A CLOSED STUDY

12/19/2023

Once a study has closed, no further activity can take place. Occasionally, however, there may be a request for study data after a study has closed. Because the Common Rule requires that use of identifiable private information for research occur either with an IRB-approved protocol in place or with an IRB exemption of the research, the DUHS IRB has a mechanism available to allow for the re-opening of a closed study.

Generally, a closed study can be re-opened for one or more of the following reasons:

- Audit or QA Site Visit is upcoming
- There is a query for data clarification involving data existing at the time of study closure
- There is a request for some additional data analysis involving data existing at the time of study closure
- There is a query for new Follow-Up data related to events occurring since study closure
- There is the need to notify subjects of their randomization status, the study results, or a newly identified risk.

In the case of a data query from the study sponsor or other, the investigator must ensure that appropriate HIPAA authorization has been received from the study participants. If not, then the investigator also will need to obtain authorization from the participant(s) or request a waiver of authorization from the DUHS IRB.

The request to re-open a closed study when the purpose is to conduct *new prospective data collection* on the individuals who participated in the study requires more than a simple re-open. Requesting collection of new data requires the submission of a new study application in iRIS.

Process Within iRIS Electronic System

To request the re-opening of a closed study, the investigator must submit a re-open request in the iRIS system. The re-opening request is expeditable and a Chair, Vice Chair, Administrative Reviewer or the Executive Director will review the request. An IRB fee, normally charged for commercially sponsored studies, will be waived.

The re-open is approved for a period of twelve months (one year), with the termination date being twelve months after the date the IRB approves the request. If the investigator needs to extend the re-open for a period longer than twelve months, they must submit a new study application in iRIS.

The study teams will receive email reminders from iRIS prior to the expiration date of the re-opened study. Re-opens will need to be administratively closed in iRIS. Study teams

should contact their IRB specialist prior to the expiration date to request closure. If no action is taken by the study team, the re-open expires.

Previous Version Date(s): 4/5/2010, 10/16/2014, 1/6/2016, 12/23/2020