Re-opening a Closed Study

I. Description

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 GRU IRB has a mechanism available to allow for the re-opening of a closed study under special circumstances.

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 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 subjects. If not, then the investigator also will need to obtain authorization from the subject(s) or request a waiver of authorization from the GRU IRB.

The request to re-open a closed study is not appropriate if the investigator is proposing to conduct new prospective data collection on the subjects who participated in the closed study.

If a study has been closed for a year or longer, re-opening the study will not be permitted; instead the investigator must prepare a new protocol submission.

II. Submitted the Request via IRB Net Electronic System

To request the re-opening of a closed study, the investigator must submit a re-open request in the IRB Net system, by creating a new package. The submission type should be other and you will need to complete the Request to Re-Open A Study form located in IRB Net Forms and Templates. The re-opening request is expeditable and the Chair or Vice Chair will review the request.
III. IRB Fee Information

An IRB fee, normally charged for industry sponsored studies, will be waived.

*Note*: This policy does not apply to studies that have expired in IRB Net. If you would like to re-activate an expired study you will need to submit a Continuing Review/Progress Report. Please see the Continuation Policy for more information.