Guidance - Study Closure

How do I close my study with Geisinger IRB?

Submit a Final Report to Geisinger IRB via iRIS, Geisinger's electronic IRB system.

When should investigators submit a Final Report to Geisinger IRB?

Studies ONLY conducted at Geisinger

Geisinger protocols may be closed when all research-related activities with human subjects have been completed, and all identifiable information (including identifiable biological specimens) are no longer being collected, received or analyzed. For example, if the information has been stripped of all identifiers, use of the information for analysis and publication may continue after the study is closed. However, if the information has not been de-identified, the information cannot be used after the study is closed.

Multi-site studies when Geisinger is not the primary site

Geisinger investigators can close the study with the IRB when all of the following conditions are met at Geisinger:

- The research is permanently closed to enrollment at Geisinger;
- All subjects enrolled at Geisinger have completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data;
- No additional identifiable information about the subjects is being obtained by investigator at the institution; **and**
- The statistical center at another institution will conduct the analysis of all study data that includes identifiable information about the subjects enrolled at Geisinger.

PLEASE NOTE: Even if your study status meets the above IRB criteria for study closure, study sponsors or funders may require the study to remain open longer. Please review the study contract/grant/award for any commitments related to study closure.

Once my study is formally closed with the IRB (final report completed), can it be re-opened?

Yes. There are instances that may occur that require an investigator to "re-open" a study that has been formally closed with the IRB (already submitted a Final Report). Some reasons to re-open include: a sponsor requests new data; an investigator notices more identifiable data needs to be analyzed, etc.

Re-opening of closed studies is handled on a case-by-case basis. If a study was recently closed and a justification can be provided for requesting re-opening of the study, the IRB will review the request. Please contact the IRB office to discuss any requests for re-opening closed studies.

Can I keep identifiable data after my study is closed with the IRB, and what can be done with it?

Yes. Investigators can retain identifiable study information after the study is closed. The length of time and potential uses for this information must be clearly described, as applicable, in the study application, protocol and consent form. Your application, protocol and consent form for example could state, "*identifiable information collected for the study will be kept (e.g.," indefinitely" or " for XX years") for future research that will be reviewed and approved by the IRB*". In addition, the protocol and application should describe data oversight and storage after the study is closed.

Any future use of the identifiable data will require a new study submission to the IRB for review and approval. The new protocol should describe the use and reference the name and IRB # of the study that generated the data.

References:

(Excerpt from *OHRP Guidance on IRB Continuing Review of Research*, 2010)

http://www.hhs.gov/ohrp/policy/continuingreview2010.html

K. Identifying the Point When Continuing Review is no Longer Necessary

Continuing review and re-approval of a research project at least annually is required so long as the project continues to involve human subjects. OHRP considers a research project to continue to involve human subjects as long as the investigators conducting the research continue to obtain:

- *Data about the subjects of the research through intervention or interaction with them; or*
- *Identifiable private information about the subjects of the research.*

With respect to obtaining identifiable private information, OHRP considers this to include obtaining identifiable biological specimens originating from living individuals. Furthermore, OHRP considers obtaining identifiable private information to include:

- *Collecting or receiving identifiable private information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator);*
- *Collecting identifiable private information by observing or recording private behavior without interacting or intervening with the human subjects; and*
- *Using, studying, or analyzing identifiable private information (including identifiable biological specimens), even if the information was already in the possession of the investigator before the research begins. This includes using, studying, or analyzing any of the following:*

- *Identifiable private information obtained by interacting or intervening with the human subjects;*
- *Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings provided to the investigators from any source;*
- *Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings already in the possession of the investigator before the research begins;*
- *Identifiable private information obtained about an individual by interviewing other people (e.g., an individual's healthcare provider or teacher);*
- *Identifiable biological specimens provided to the investigators from any source; or*
- *Identifiable biological specimens already in the possession of the investigator before the research begins.*

A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary. At that point the IRB can formally close the IRB file for that project and advise the investigator of that action.
Similarly, simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review.

See section D.1 above for additional guidance on determining when continuing review is no longer required for a particular institution involved in the conduct of a multicenter research project.

(Excerpt from Section D.1)

D. Additional Considerations for Continuing Review of Multicenter Research Projects

1. Multiple Institutions Relying on Local IRBs for Continuing Review

For any particular institution that chooses to rely upon a local IRB, continuing review of a multicenter research project by the local IRB at that institution must occur at least annually as long as the institution remains engaged in human subjects research activities involving the project (45 CFR 46.109(e)). Once the institution is no longer engaged in human subjects research activities under the project, there is no need for continuing review by the local IRB, even if human subjects research activities are occurring at other institutions. For example, consider a multicenter clinical trial in which the following conditions exist with respect to institution A:

- *The research is permanently closed to enrollment at the institution;*
- *All subjects enrolled at the institution have completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data;*
- *No additional identifiable private information about the subjects is being obtained by investigator at the institution; and*
- *The statistical center at another institution will conduct the analysis of all study data that includes identifiable private information about the subjects enrolled at institution A.*

In these circumstances, the local IRB for institution A does not need to conduct any additional continuing review of the research project. This is the case even if the overall study results base has not been locked, such that there is the possibility that the statistical center at the other institution may query the investigators at institution A about previously collected data about the subjects enrolled at institution A. (Note that once the study results base for a study has been locked, no further changes can be made to the data set, and the only remaining activity is analysis of aggregate data.)

On the other hand, the local IRBs relied upon by other institutions where investigators continue to enroll subjects, intervene or interact with subjects, obtain identifiable private information about subjects, or analyze identifiable private information in accordance with the IRB-approved protocol would need to conduct continuing review of the research project at least annually.