Guidance for Study Closure

This guidance provides study closure policies and timelines. It also provides a description of when a study can be closed, even if analysis of data may still be ongoing.

1. What is a Study Closure?

Researchers are expected to submit a notice of closure to the IRB when a currently approved study has been completed or if the researcher has decided to discontinue the protocol. Failure to submit a notice of closure to the IRB, including for studies that have expired, constitutes noncompliance. Repeated failure to submit a notice of closure to the IRB may constitute serious and ongoing noncompliance, which may result in limitations on the researcher's ability to apply for IRB review in the future.

2. How can a Researcher submit a notice of closure to the IRB?

A Study Closure Form is available online. This form will need to be completed and uploaded to IRBNet for review by the IRB.

3. When should a Closure Form be submitted?

A Study Closure Form should be submitted when all of the following apply:

- All collection of data through intervention or interaction with participants has been completed. No additional further contact with participants may be necessary.
- All data collection from all sources has been completed.
- Any use or analysis of identifiable data has been completed. This includes any identifiable private information captured in documents, records, images, or recordings during the conduct of research.
- The study is funded and the sponsor or funding agency has recommended closure.

4. What activities are permissible after Study Closure?

After a Study Closure Form has been submitted, all human subjects research activities must stop. The following activities are permissible after the study has been closed:

- Analysis of deidentified, anonymized, or aggregate data sets, provided a description of this use was disclosed during the consent process.
- Sharing of tissue or data for secondary research, provided written authorization for this use was obtained during the consent process and a record of this authorization is retained by the researcher.

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IRB Policy & Guidance
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