Study Closure

Background

Federal regulations require the IRB to maintain oversight of research until all human subjects research activities are complete. Therefore, IRB approval (or certification of exemption) must remain in effect until the research no longer involves human subjects. This document describes circumstances under which IRB oversight must remain active and when the project should be closed. Researchers with unusual situations that do not clearly fit into this guidance should contact IRB staff for guidance (IRB@iastate.edu).

When Is Ongoing IRB Oversight Required?

Continued IRB oversight is required as long as any of the following activities are in progress:

- enrolling participants (including screening)
- interacting with participants for research purposes (including follow-up, "member checking," etc.)
- research-related interventions and/or follow-up
- collecting identifiable private information by observing or recording private behavior
- collecting or receiving identifiable private information or biological specimens from any source
- using, studying, or analyzing identifiable private information or identifiable biological specimens, such as:
    - identifiable private information obtained by interacting or intervening with the human participants
    - identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings, including information 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, teacher, family member, etc.)
    - identifiable biological specimens from any source, including specimens already in the possession of the investigator before the research begins
- maintaining identifiable information or biological specimens in a repository. If, however, the information or biospecimens are transferred to a separate repository with its own, active IRB

Information or biological specimens are ***identifiable*** when they contain any information that can be used to distinguish or trace an individual's identity, either alone (i.e., directly) or when combined with other personal or identifying information that is linked or linkable to a specific individual (e.g., indirectly).

Data that contain study ID codes or pseudonyms are identifiable if researchers have access to a "key" linking codes/pseudonyms to identifiers.

In some instances, demographic or background information renders data identifiable.

approval, the study under which the information/biospecimens were collected may be closed, provided all other human subjects research activities are complete.

- analyzing data or preparing a manuscript when doing so involves the use of or access to identifiable data or information
- if there is an external study sponsor that requires the study to remain under "active" IRB oversight. In this case, the study may be closed when the external sponsor provides permission to close the study.

Cooperative/Multi-Site Research

Iowa State is the Reviewing IRB

Continued IRB oversight is required until the activities noted above have been completed at all sites. The Iowa State PI must keep IRB approval active (e.g., via continuing review or status update), even if the Iowa State research team has completed its share of the human subjects research.

Oversight by an External IRB

When Iowa State's IRB is the relying IRB, continued IRB oversight is required in accordance with the policies and procedures of the external (reviewing) IRB. Consult the PI at the site of the Reviewing IRB for guidance.

When Should a Study be Closed to IRB Oversight?

Principal Investigators are expected to formally close studies in the following circumstances:

- all *human subjects* research activities have ended (as described below), or
- IRB-approved research never began and is being abandoned, or
- prior to leaving the university. The Iowa State IRB only oversees research conducted by persons formally affiliated with Iowa State (e.g., employees, enrolled students, etc.). For ongoing projects, IRB oversight must be transferred to another eligible Iowa State PI or to the IRB at the PI's new institution.

Projects must have an eligible Iowa State PI (and supervising investigator, when applicable) to remain active under IRB oversight.

A research project no longer involves *human subjects* and should be closed when both 1 and 2 are true.

1. Data/information collection is complete; the only remaining activity is data analysis:
   - researchers have finished collecting data through interaction or intervention with participants, and/or
   - researchers have finished obtaining identifiable information or biological specimens from any source.
2. All information about the participants has been completely de-identified and all identifiers have been destroyed:
   - identifying information has been removed from all forms of data (including any raw data, original recordings, screening responses, responses in survey platforms, etc.)

- any "keys" linking ID codes back to the identities of individual participants have been destroyed and
- aggregation, recoding, or removal of any possible indirect identifiers has occurred
    - Note: Data sets with ID codes or other methods of indirect identification require IRB oversight until it is no longer possible to link the data to the identities of the individual participants.

Additionally, IRB oversight is no longer required and studies should be closed in the following circumstances:

- In rare cases of data that cannot be completely de-identified (e.g., video recordings), IRB oversight may end when all use of the data for research purposes is complete and data are securely archived for storage in a manner that assures confidentiality.
- If data and corresponding oversight are transferred to an established repository.

PI-Directed Closure

Study closure is a simple process. Principal Investigators should complete an Amendment for Closure in OneAegis (formerly IRBManager), which is a brief form that confirms project status and verifies that no additional information is needed.

Closure Upon PI or Supervising Investigator Departure

Adequate supervision of research is a critical element of human subjects protection. Therefore, **all ongoing Iowa State research projects must be continually overseen by an eligible PI and, when applicable, an eligible Supervising Investigator**. Principal and Supervising Investigators are responsible for reporting departures to the IRB office (IRB@iastate.edu). If the research is complete, the project may be closed by completing an Amendment for Closure. If the project will continue, oversight should be transferred as outlined below. See also, IRB-Related Steps for Departing Researchers.

Research Will Continue at Iowa State

Oversight of ongoing projects must be formally transferred to an eligible PI/supervising investigator via an approved Amendment for Modification. Ideally, transfer occurs prior to departure. However, research teams are given a six-week period to obtain IRB approval for a new PI or Supervising Investigator. If this process is not completed within six weeks, the project will be administratively closed and all human subjects research activities must stop. IRB staff may, at their discretion, extend this period to accommodate unique circumstances.

Transfer of IRB Oversight to Another Institution

If the research will continue at the PI's new institution, the PI should

1. Obtain IRB approval at their new institution before beginning any human subjects research activities, and
2. Promptly inform the Iowa State IRB of the transfer and complete an Amendment for Closure in OneAegis (formerly IRBManager).

Cooperative/Multi-site Research

If the project will involve researchers at Iowa State and another institution (e.g., the PI's new institution), contact IRB staff for guidance (IRB@iastate.edu). Reliance agreement(s) between Iowa State and the other institution(s) may be needed. Iowa State IRB oversight covers only the activities of Iowa State researchers until a reliance agreement is established.

Administrative Closure

When necessary actions are not completed by the PI, studies may be administratively closed. For example, studies are administratively closed when

1. IRB approval or certification of exemption expires, or
2. The project lacks an eligible PI (or Supervising Investigator, if required). For example, if the PI or Supervising Investigator leaves Iowa State without transferring oversight to an eligible PI or Supervising Investigator.

Once a project is closed, IRB approval/oversight is no longer active. No human subjects research activities may take place after the date of closure. Notification of administrative closure is sent to the PI and any Supervising Investigator named on the IRB application if their Iowa State email address is still active, Iowa State co-investigators, and any external PIs and IRB contacts. The chair of the department overseeing the research is also notified of administrative closures due to lack of an eligible PI/Supervising Investigator.

Reestablishing IRB Approval After Administrative Closure

The PI or Supervising Investigator may request that approval for a closed study be reestablished. If closure was due to expiration of approval, an Amendment for Continuing Review or a Study Status Check-In form (whichever is applicable) must be completed. PIs must also confirm that no human subjects research activities occurred after the date of closure.

An application for a new study may be required if significant time has passed since expiration or if there are substantial changes to the study objectives or procedures.

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