

# Study Closure

## Background

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Federal regulations require the IRB to maintain oversight of research until all human subjects research activities are complete. Therefore, IRB approval (or determination of exemption) must remain in effect until the research no longer involves human subjects. This document describes circumstances under which the IRB oversight must remain active and when oversight can end and 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](mailto:IRB@iastate.edu)).

## When is Ongoing IRB Oversight Required?

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Iowa State University requires continued IRB oversight for all research involving human participants as long as the following activities are in progress:

- Enrollment of participants (including screening);
- Interaction 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 from any source, data repositories, etc., including that 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.

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.

- 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 approval, the study under which the information/biospecimens were collected may be closed, provided all other human subjects research activities are complete.
- Data analysis or manuscript preparation that involves the use of or access to identifiable data or information;
- If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

## 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 all 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 with the PI at the site of the Reviewing IRB for guidance.

## When Should a Study be Closed to IRB Oversight?

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

- When human subjects research activities have ended (as described below),
- When 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 of the following are true:

1. Data/information collection is complete
  - Researchers have finished obtaining data through interaction or intervention with participants, and/or
  - Researchers have finished obtaining identifiable information or biological specimens from any source, AND

2. All information about the participants has been completely de-identified or destroyed.

Example:

- a. The only remaining activity is the analysis of fully de-identified data sets, and
- b. All “keys” linking any ID codes back to the identities of individual participants have been destroyed, aggregation of any possible indirect identifiers has occurred, etc.

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

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

### Closure Upon PI or Supervising Investigator Departure

Adequate supervision of the 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 in this section.

### 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 60 calendar-day period to obtain IRB approval for a new PI or Supervising Investigator. If this process is not completed within 60 days, 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.

## 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

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Studies are administratively closed when

1. IRB approval or determination 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 and oversight is not formally transferred 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. PIs, Supervising Investigators, co-investigators, and any external PIs and IRB contacts are notified by IRBManager upon closure due to expiration of approval/exemption. Notification of administrative closure due to lack of an eligible PI/Supervising Investigator is sent to the PI and Supervising Investigator (if their ISU email address(es) is/are still active) and the chair of the department overseeing the research.

## Reestablishing IRB Approval After Administrative Closure

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The PI or Supervising Investigator may request to reestablish approval for a closed study. If closure was due to expiration of approval, an Amendment for Continuing Review or 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.

## Document History

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