

Study Closure

Background

Federal regulations require the IRB to maintain oversight of research involving human subjects at a frequency appropriate to the level of risk to participants and in accordance with federal regulations (45 CFR 46.109(e)&(f) and 21 CFR 56.109(f)). IRB oversight is required until a project no longer involves human participants, as defined by federal regulations. Some research requires formal continuing review and re-approval; others may undergo abbreviated review via status check (see [Continuing Review Guidance](#) for more information). This document describes circumstances under which the IRB needs to oversee research, and when such review can end and the project should be formally closed to IRB oversight.

When is Ongoing IRB Oversight Required?

In accordance with regulations, ISU 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 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;
- 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, including the following:
 - 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, 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 or teacher);
 - Identifiable biological specimens from any source, including specimens already in the possession of the investigator before the research begins;

- Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of the study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed;
- 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.

When Can I Close a Study?

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

- When human participant research activities have ended (as described below),
- When IRB-approved research never began and is being abandoned, or
- Prior to leaving the university. The ISU IRB only oversees research conducted by persons formally affiliated with ISU (e.g., employees, enrolled students, etc.). For ongoing projects, IRB oversight should be transferred to your new institution.

A research project no longer involves human participants when

- Investigators have finished obtaining data through interaction or intervention with participants, and
- All information about the participants has been completely de-identified or destroyed.
- Examples:
 - When the only remaining activity of a research project involves the analysis of data sets without any individual participant identifiers.
 - 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.

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 is securely archived for storage in a manner that assures confidentiality.

If data and corresponding oversight are transferred to an established repository.

Administrative Closure

Studies are administratively closed:

- When IRB approval lapses, or
- If the PI or Supervising Investigator has left ISU and oversight is not transferred to an eligible principal investigator.

Once a project is closed, IRB approval is no longer active. No human subjects research activities may take place after the date of closure. Investigators and supervising investigators are notified by IRBManager upon closure due to a lapse in approval.

Reopening a Study After Closure

Investigators may reopen a study following a lapse in approval by submitting an amendment for continuing review in IRBManager. If a long period of time has passed since closure, an application for a new study may be required. In most cases, investigators who wish to re-open projects that have been administratively closed due to departure of principal investigator or supervising investigator must submit a new IRB application for review. However, exceptions may be granted at the discretion of the IRB Administrator(s) or Co-Chair when there are no concerns about adequate supervision, protection of human subjects, etc.

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