Study Closure

Background

Federal regulations require that non-exempt research involving human participants undergo continuing review by the IRB at a frequency appropriate to the level of risk to participants and in accordance with federal regulations (45 CFR 46.109(e) & 21 CFR 56.109(f)). Continuing review and re-approval of research is required until a project no longer involves human participants as defined by federal regulations. This document describes circumstances under which ongoing IRB review is required, and when such review can end and the project should be formally closed to IRB oversight.

Guidance

In accordance with regulations, ISU requires that all non-exempt research involving human participants be submitted for continuing review at the interval specified by the IRB 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.

A research project no longer involves human participants once the investigators have finished obtaining data through interaction or intervention with participants or identifiable private information about the participants, which includes using, studying, or analyzing identifiable private information. For example, when the only remaining activity of a research project involves the analysis of data sets without any individual participant identifiers, no further continuing review is necessary. Data sets with ID codes or other methods of indirect identification require review until it is no longer possible to link the data to the identities of the individual participants (e.g., 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.).

Once all such activities described in the IRB-approved protocol are finished, the research project no longer requires review, and a Project Closure Form should be submitted to the Office for Responsible Research.

Document History

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