

Institutional Review Board & Human Subjects Office

Principal Investigator Oversight Responsibilities and Assurances

Purpose

The Principal Investigator (PI) is responsible for the content of the HawkIRB application and the conduct of the study. Even when responsibilities are delegated to members of the research team, the PI is ultimately responsible for the study. To assist investigators in complying with federal regulations and institutional policies for the protection of human subjects, this supplemental handout highlights important PI oversight responsibilities and assurances.

PI Oversight Responsibilities

Submitting HawkIRB Forms After IRB Approval

Modifications

The PI must submit a Modification form in HawkIRB for any change in the conduct of a study. All changes must be reviewed and approved by the IRB prior to the change being implemented. The exception to this is when the change is necessary to eliminate hazards to subjects. The PI is required to promptly notify the IRB via a Modification form of any changes made without IRB approval to eliminate hazards to subjects.

Modifications include, but are not limited to:

- Changes to study procedures
- Adding or removing investigators or research team members
- Changes to the title of the project
- Requests for additional subjects beyond the original approved number
- Change in funding sources
- Changes in how subjects are being recruited or followed-up
- New or revised advertisements
- Changes to Informed Consent Documents, surveys, questionnaires, correspondence with potential or current subjects, or new data collection tools

Continuing Reviews

The PI must submit a Continuing Review form prior to 12:01 am on the date the approval for the study expires. The IRB is required to conduct a Continuing Review of all non-exempt research projects at intervals appropriate to the degree of risk, but not less than once a year.

Reportable Event Forms (REFs)

REFs are the mechanism that the PI uses to self-report incidents in which IRB policies or federal regulations with respect to protection of human subjects in research were not followed or to report an unanticipated event.

Project Closure

The PI must submit a Project Closure form when a study ends, is closed, canceled for any reason, or is prematurely completed. A Project Closure form serves as notification to the Human Subjects Office that IRB Continuing Review of the study is no longer needed. Once the HawkIRB application is closed, the PI may not work with any identifiable human subjects data collected for the project. Student PIs should consult with their faculty advisors before closing a project in HawkIRB.

Record Keeping

Every PI is required to maintain records of all correspondence relating to the use of human subjects in research. Copies of the HawkIRB application forms, notices of approval (stored in HawkIRB), and signed Informed Consent Documents must be maintained in the investigator's records. All records of human subject research are subject to inspection by federal authorities and the University of Iowa IRB. When leaving an institution, the PI should leave the signed consent documents at the institution where consent was obtained. Student PIs should consult with their faculty advisors and make arrangements with their departments regarding the storage of signed consent documents before leaving the UI. Faculty advisors must be informed of where signed consent forms will be stored and are responsible for the records when the student PI leaves the UI.

Copies of all research records for studies that do not involve protected health information must be kept for at least three years after the close of the study in HawkIRB.

Data Leaving the University of Iowa

To transfer or take data collected at the UI to another institution, the PI should consult with their department and ensure that they have permission from the owner of the data to take the data. Depending on the nature of the data, the PI may also need to consult with the Clinical Trials Office (CTO) or the Division of Sponsored Programs (DSP).

The University of Iowa owns the primary research results generated from all research, development, and related activities conducted under its jurisdiction. Therefore, when a Principal Investigator (PI) plans to leave the University and wants to take the original data to the new institution, the transfer of the original data must proceed according to established guidelines.

PI Assurances

When the New Project Application was submitted to the IRB, you as the PI signed an Assurance Document. The Assurance Document lists the agreements you make with the IRB about how you will oversee and conduct the research to protect human subjects.

As PI, I assure that:

- I ultimately responsible for the conduct of the study.
- I agree to comply with all applicable UI policies and procedures, and applicable federal, state and local laws.
- The HawkIRB application is consistent with proposal(s) submitted to external funding agencies (if applicable).
- The research will only be performed by qualified personnel.
- All persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
- I will not implement any changes in the approved IRB application, study protocol, or informed consent process without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of a human participant).
- If unavailable to conduct this research personally, as when on sabbatical leave, I will arrange for another investigator to assume direct responsibility for the study. Either this person is named as another investigator in this application, or I will notify the IRB of such arrangements.
- I will obtain Continuing Review approval prior to 12:01 am on the date the approval for the study expires. I understand if I fail to apply for Continuing Review, approval

for the study will automatically expire, and all study activity must cease until IRB approval is granted.

- If protected health information is used or created as part of this research project, the research team agrees NOT to reuse or disclose the information to any other person or entity (beyond the named research team) except as required by law, for authorized oversight of the research project, or unless subsequent IRB approval is obtained for such reuse or disclosure.
- If members of the research team access protected health information from a covered component in order to seek consent/authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered component.
- Neither I nor any member of the research team has a significant financial interest, as defined by the University of Iowa Operations Manual, whereby the value of the interest to me or any member of the research team could be influenced by the outcome of the study.
- If the above stated research study has a plan to compensate the research subjects participating in this project, I acknowledge that our unit has a Cash Handling Procedure that has been approved by Accounting Services.
- I further assure that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.