Faculty Advisor Oversight Responsibilities and Assurances

Institutional Review Board and Human Subjects Office

Purpose

To assist investigators in complying with federal regulations and institutional policies for the protection of human subjects, this handout highlights important Faculty Advisor oversight responsibilities and assurances.

The Faculty Advisor listed on a HawkIRB application must be a member of the University of Iowa faculty and is considered the responsible party for the legal and ethical performance of the student Principal Investigator's (PI) project. As per the University of Iowa Operations Manual Ch. 27.4, teachers who assign or supervise research conducted by students also have an obligation to consider carefully whether those students are qualified to adequately safeguard the rights and welfare of subjects.

Faculty Advisor Oversight Responsibilities

Provide Instruction and Guidance about Study Design and Data Analysis

The IRB considers the scientific merit of the project to help ensure research does not unnecessarily put subjects at risk if the study is not designed in a manner to yield valid, useable results. The faculty advisor is responsible for making sure the research design is sound. This includes, but is not limited to:

- The identified subject population is the appropriate source of data to answer the research question
- The planned method for data collection is valid and will yield data that answers the study question
- The planned analysis of the data is appropriate and will answer the study question

Provide Assistance with HawkIRB Applications

The Faculty Advisor should review the entire HawkIRB application and all attached documents prior to its submission. This review should verify that the student PI has accurately documented the study design and procedures in the application.

Refer Student PI to Available Resources

The Human Subjects Office offers a variety of educational resources to assist researchers in complying with federal regulations and university policies regarding human subjects research. The Faculty Advisor and Principal Investigator are responsible for educating themselves about the regulations and policies that apply to the type of research being conducted. Additionally, the Faculty Advisor and Principal Investigator should be aware of and follow any departmental policies or expectations that apply to the research.

Provide Oversight and Guidance in the Conduct of the Research

The Faculty Advisor commits to provide oversight and guidance in the conduct of the research. Oversight includes ensuring student PI's know when to submit Modification forms, Continuing Review forms, Reportable Event Forms (REFs), and how and when to close the project in HawkIRB.

The faculty advisor must ensure that the student PI understands when to register and promptly update the study record on ClinicalTrials.gov and maintain track of the deadline for submitting the required results information for clinical trials, which is one year after the study's primary completion date. Results information needs to be submitted if required by FDAAA (Applicable Clinical Trials), NIH or other sponsors.

The faculty advisor must also ensure that the student PI has completed their *e*COI Annual Certification and submitted any disclosures for external activities and interests. Faculty advisors should also ensure the student PI has a basic understanding of what conflicts of interest in research are and how the University addresses them.

Additionally, the Faculty Advisor is responsible for monitoring the progress of the study, being aware of any issues or problems, and answering questions of the student PI.

The Faculty Advisor is responsible for providing oversight even if the research is conducted off-campus or outside the U.S. If the research is conducted off-campus, there must be a plan for regular communication that allows the advisor to meet his or her oversight responsibilities for the study.

Faculty Advisor Assurances

When a New Project Application is submitted to the IRB, the Faculty Advisor signs an Assurance Document. The Assurance Document lists the agreements s/he makes with

the IRB about how s/he will supervise the student PI's conduct of the research to protect human subjects.

As the faculty supervisor on this research application, I assure that:

- I will meet with the student investigator on a regular basis and monitor study progress.

- The student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.

- If I will be unavailable to supervise this research personally, as when on sabbatical leave, I will arrange for an alternate Faculty Supervisor to assume direct responsibility in my absence and I will advise the IRB by letter in advance of such arrangements.

- 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.