Institutional Review Board & Human Subjects Office

Compliance Monitoring

Purpose

The Institutional Review Board (IRB) Compliance Program conducts pre- and post-approval monitoring of human subjects research under the purview of the University of Iowa IRB and the Western Institutional Review Board.

The main goals of the program are:

1. To assess human subjects research for compliance with federal regulations and institutional policies through:
   a. an independent review of the HawkIRB application as well as associated research materials, and
   b. a personal interview with the Principal Investigator and any affiliated research team members, as applicable;

2. To provide researchers one-on-one and group educational opportunities regarding human subjects research; and

3. To facilitate communication between the IRB/Human Subjects Office and researchers at the University of Iowa.

Types of Visits

The IRB Education and Compliance Specialists conduct three main types of monitoring visits described below. Other category specific research requires monitoring of additional regulations or institutional policies, e.g. DoD, FDA, IND/IDE, VA, SPI-FA and Exempt. See the University of Iowa IRB Standard Operating Procedures (SOP) & Researcher Guide, Section 1, Part 11E Compliance Monitoring for specific information on these additional monitoring visits.

1. Post-Approval Responsibilities Review (PARR)

PARR is an educational session that occurs after a study is approved by the IRB. During the session, the IRB Compliance and Education Specialist reviews post-approval responsibilities of the investigator and research team members based on university policies and federal regulations.

This includes:

- Recruitment Process
- Consent Process
- Study Enrollment
- Reporting Requirements
- Continuing Review
- Modifications
- Reportable Events
- Record-Keeping
- HawkIRB System

2. Post-Approval Monitoring and Education (PAM and Ed)

PAM and Ed encompasses monitoring and follow-up education activities of open, IRB-approved human subject research studies conducted by University of Iowa faculty, staff or students.

During the PAM and Ed process, the IRB Compliance and Education Specialist reviews current study procedures (compared with IRB-approved study procedures) and may also review research records including:

- Signed consent documents
- Screening records and logs
- Enrollment logs
- Research subject files
- Sample storage
- Study data records and transmission procedures

3. Directed Monitoring

Directed monitoring is any monitoring that is done at the request of the IRB or IRB Chair. This monitoring results from information obtained from outside sources such as subjects or research team members, etc. or information that comes to light during the review of an application or another study by the IRB.

Directed monitoring provides the IRB with additional information to substantiate or refute allegations of noncompliance on the part of the researchers. The focus of a Directed visit varies based on the nature of the visit.

Process

Notification

Once a study has been selected for compliance monitoring, an IRB Compliance and Education Specialist sends an e-mail notice to the PI and contact persons for the study. The e-mail notice requests time to conduct an in-person study review meeting. Depending on the type of monitoring visit and the status of the study, the notice may also request a time for the Compliance and Education Specialist to review Informed Consent Documentation (ICD).

If the Compliance and Education Specialist does not hear back from the research team within two business days, s/he will either send a second notification via e-mail, or call the PI and/or research study contact person(s) until contact is made.

Number of Visits and Length

Consent Document Review

If signed Consent Document review is required, the Compliance and Education Specialist (CES) prefers to complete this prior to the Monitoring Visit, so any findings can be discussed during the in-person visit. The CES will inform the team of approximately how much time will be needed for reviewing ICD. The PI is not required to attend this meeting; however, one member of the research team must be available to provide and collect the ICD as well as answer questions. The CES will provide specifics details when scheduling the visit.

EPIC Review

Certain monitoring visits require a review of the EPIC electronic medical record (EMR). The CES must ensure that appropriate documentation of consent was obtained from each subject prior to obtaining access to their EMR. The EMR review will have a defined focus and the CES will meet with the PI/research team after to discuss issues and gather additional information.

Monitoring Visit

The PI is required to attend this meeting. S/he may invite any members of the research team to the meeting that s/he wants to attend or thinks would benefit from attending. Those in attendance typically include the PI, the study coordinator, and persons who conduct the recruitment and consent process, or study procedures. If the Principal Investigator is a student, the Faculty Advisor is also an expected attendee. The length of the visit is approximately two hours. However, the length may vary based on

complexity of study and the focus of the visit. Visits are typically held in a space reserved by the researchers; the space must have a computer and projector available.

Both visits should occur within one month of the investigator's receipt of the monitoring notice. Exceptions may be granted with appropriate justification.

Reporting and Response Process

After the monitoring visit, the IRB Compliance and Education Specialist will write a report of the monitoring process. This monitoring report will include, a summary of the information discussed throughout the process, additional educational information, regulations and guidance that pertain to the conduct of research involving human subjects, and any applicable required actions for the research team.

The goal is to send the monitoring report to the PI within two weeks of the visit. The PI may be required to provide additional information via e-mail to the IRB Compliance and Education Specialist or the Chair of Record. The PI will receive an e-mail notice when the report is available for review and will be able to access the report from the Monitoring Tab (found on the Project Summary page) in HawkIRB. If applicable, a Modification form to submit any changes required as a result of the monitoring process will be created in the PI's Draft Forms section of his/her HawkIRB inbox. If you have not received a final report within three weeks of the visit and have not had any interim contact, please contact the IRB Compliance and Education Specialist that conducted the monitoring visit.

Review Process

Typically, the PI's response to the monitoring report requires the submission and review of a HawkIRB Modification form. However, in instances where the Chair of Record decides that the report findings may constitute serious and/or continuing noncompliance, reports will be referred to the IRB Full Board for review. This information will be described in the Monitoring Report under the section entitled 'Noncompliance Determinations'. Refer to the University of Iowa Institutional Review Board Standard Operating Procedures and Researcher Guide - Section 1, Part 9.C IRB Determinations Requiring Reporting