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Quick Links

UHHS

Center For Clinical Research

Office of Research Compliance
(Coming Soon!)

UHC IRB

UHC Grants and Contracts

Quick Question?

Would you or your research team be interested in a class intended to help with understanding the IRB? Which areas of the IRB would be most helpful to learn about? Let us know!

Quick Question Results:

Last Month's Question: My study monitor identified a protocol deviation. Do I need to report this to the IRB?

Major Deviations should be reported to the IRB within 10 working days of discovery. Minor Deviations are kept in the investigator's file.

Contact Us

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Research Compliance Monitoring Program

What is the purpose of the Research Compliance Program?

The goal of this program is to prospectively review compliance with clinical research policies and procedures, provide education to research professionals, and to promote research quality improvement initiatives.

What should be expected?

- 1) The program begins with a brief interview with the study coordinator and/or principal investigator to review the study, identify roles and responsibilities of the research team, and identify a mutually agreeable time to conduct the monitoring review;
- 2) Prior to the monitoring visit, the Center for Clinical Research (CCR) staff will review the corresponding UHC IRB record and grant file as applicable to ensure an understanding of the research study objectives and procedures;
- 3) During the monitoring visit, the regulatory binder and a portion of the subject's research records, executed informed consent forms and HIPAA documents will be reviewed. During the monitoring review, the presence of the investigator is not necessary;
- 4) Additionally, we will also observe the presentation of the informed consent document to a potential participant. This does not need to occur on the same day as the monitoring review;
- 5) Once the monitoring review and observation of the informed consent document are complete, a summary of the observations will be sent to the principal investigator and applicable study staff. A copy will be filed with the CCR.

We have already conducted several monitoring visits to offer assistance in preparation for sponsor audits. If you would like us to help you prepare for an upcoming sponsor audit, please [contact us](#).

Helpful Tip: Reporting Adverse Events for Related Studies

Adverse events (including fatal events) which occur in another study using the same drug / device / procedure and which do not result in a change in the protocol, consent form, or the risk/benefit ratio for the UHC study, do not need to be reported to the IRB but should be kept on file by the investigator.

For example:

- Study Y is an active study at UHC.
- The investigator is informed of an E-AE that occurred in Study X, which uses the same drug as Study Y.
- The event does not change anything in relationship to Study Y here at UHC.
- Per IRB policy, this event does not need to be reported to the IRB.
- If the investigator would like to inform the IRB of the E-AE, they can submit the E-AE using a File (F) form.

Additional information regarding reporting of AEs for related studies can be found in the following policy: [Event Reporting: External Events at another Site Occurring on a Protocol Related to a Protocol Active at UHC \(Page 6\)](#)