

INFORMATION FOR THE UH RESEARCH COMMUNITY

# Collaboration Corner

## Education Update

UHCMC IRB / iRIS-Submitting a New Study | Jan 12 | 2-4 pm | Lakeside 1400

UHCMC IRB / Requests for Revisions, Revising Documents and Responding to the IRB | Jan 20 | 3-4 pm | Lakeside 1400

UHCMC IRB / iRIS-Other Submissions (Amendments, AEs, CRs, etc.) | Jan 24 | 2-3 pm | Lakeside 1400

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## iRIS Reminder

Help bubbles are available throughout the system for more information or to open the user manual.

## Quick Links

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[William T. Dahms, MD Clinical Research Unit](#)

For questions, comments or suggestions, email [clinicalresearch@uhhospitals.org](mailto:clinicalresearch@uhhospitals.org)

## **Center for Clinical Research & Technology**

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## ***Research Participants - Withdrawal from Research***

On September 21, 2010, the Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS) issued guidance on the withdrawal of subjects from research discussing data retention and other related issues.

There are numerous reasons a research participant may choose to the withdraw from a study or why an investigator may decide to terminate an individual's participation in research regardless of the participants' wish to continue participating. In these circumstances, questions arise, including whether an investigator may use already collected data from participant who has withdrawn or whether the investigator can continue to obtain data about the participant and if so, under what circumstances.

### **What does it mean with a participant withdraws from a research study?**

If a participant withdraws from all aspects of the research study, the investigator or study staff must discontinue all research activities involving that person's participation in the study, including:

- Interacting with the participant to collect data for the research;
- Obtaining additional identifiable private health information (PHI) (by collecting or receiving the information from any source); and
- Obtaining additional PHI for the research by observing or recording private behavior without interacting or intervening with the subject.

Sometimes the participant wants to withdraw from the interventional component of the study, but is willing to allow the investigator to continue other research activities described in the protocol and IRB approved consent form such as obtaining data through interactions with the subject (e.g., follow-up visits, tests, etc.) or by obtaining PHI from through medical, educational or social services records.

It is recommended that when a participant chooses to withdraw from a study, the investigator should clarify whether the participant wants to withdraw from all aspects of the study or only from the primary interventional component.

### **Can an investigator retain and analyze already collected data about a subject who withdraws or whose participation is terminated by the investigator?**

OHRP interprets the HHS regulations at 45 CFR part 46 as allowing investigators to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the true even if that data includes PHI about the subject.<sup>1</sup>

### **Should withdrawal of a participant be documented?**

Yes. Documentation should include: 1) whether the withdrawal resulted from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and 2) whether the withdrawal was from all components of the research study or just the primary interventional component.

<sup>1</sup> [Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues, OHRP, September 21, 2010.](#)