

INFORMATION FOR THE UH RESEARCH COMMUNITY

Collaboration Corner

Education Update

[HIPAA and Clinical Research | Feb 2 | 3-4 pm | Wolstein Research Building Room 1413](#)

[HIPAA and Clinical Research | Feb 9 | 9-10 am | Biomedical Research Building Room 105](#)

[HIPAA and Clinical Research | Feb 18 | 10-11 am | Wolstein Research Building Room 1413](#)

For more information contact Deborah.Marko@uhhospitals.org

iRIS Reminder

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

Quick Links

[Center For Clinical Research & Technology](#)

[Grants and Contracts](#)

[Institutional Review Board](#)

[Research Compliance and Education Technology Management](#)

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

For questions, comments or suggestions, email clinicalresearch@uhhospitals.org

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Continuing Review

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) have specific regulations regarding IRB continuing review of ongoing research, to ensure that the rights and welfare of human subjects are protected. They both require that the IRB conduct the continuing review at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e) and 21 CFR 56.109(f)), and do not allow for the conduct of research beyond the expiration date of IRB approval.

The Principal Investigator is responsible for ensuring the research is submitted to the IRB for continuing review in an appropriate time frame to avoid a lapse of IRB approval. In order to avoid a lapse in Continuing Review, investigators must plan ahead to meet the required continuing review dates specified by the IRB. The UHCMC IRB recommends that a continuing review application is submitted by the Principal Investigator 6 weeks prior to the expiration of the study. ***It is the investigator's responsibility to ensure compliance with the Federal Regulations.***

Continuing Review Reminders and Notices of Expiration

As a courtesy to investigators, the UHCMC IRB utilizes an electronic Continuing Review Notice System to remind investigators when an approved IRB research protocol is due to expire. Notices are sent to the Principal Investigator at eight, six and three weeks prior to the expiration date of the protocol and after the protocol has expired. Once the transition to iRIS is complete, you will receive automatic notices through the electronic system. In order for you to receive information from iRIS, you must be sure to enter your email address in your personal information. This can be found under My Assistant → My Account Information.

If a study has expired because the IRB has not granted continuing approval by the expiration date (regardless of whether the application materials have been received by the expiration date), a member of the IRB staff will send a correspondence to the investigator to inform them that all research activities must cease once the study expiration date is reached.

Study Expiration

The expiration date for an IRB approved study is clearly indicated on the IRB approval letter and is the last day that the study is approved. For example, an IRB approval letter that indicates a protocol expires on "2/1/2010" means that the protocol is active through midnight on 2/1/2010 and no longer has IRB approval on 2/2/2010 if continuing review has not been obtained.

If the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, all research activities must stop.

Research activities include, but are not limited to the following:

- Recruitment and enrollment;
- Study interventions and subject interactions (i.e., any involvement of current participants including the scheduling of study visits); and
- Data analysis, including looking at new subject information.

Ramifications of Conducting Research Activities after Study Expiration

If an investigator continues to conduct research after the study has expired, this becomes an issue of human subject non-compliance and will be processed as described in the UH IRB Non-Compliance policy. In addition, the IRB is required to report Federally funded studies where subjects have been studied after approval has expired, to the Office for Human Research Protections (OHRP). If the study involves investigational drugs or devices, a report to the FDA is required (see, IRB Policy, Non-Compliance with Human Subjects Regulations; and IRB policy, Reporting to Regulatory Agencies, Department Heads and Institutional Officials.)