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Questions, Comments, Suggestion?

If you have questions, comments or suggestions about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Education Updates!

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Contact Us

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The Center for Clinical Research and Technology Presents "To Discover" Days

Stop by the Atrium Bridge Thursday, September 3, 2009 from 11 a.m. to 1 p.m. to learn about medical discoveries taking place at UH. The goal of "To Discover" Days is to educate patients, visitors and employees about how UH is making a difference in advancing health care through clinical research.

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, in order to avoid a lapse of IRB approval. In order to avoid a lapse in Continuing Review, the 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.

Continuing Review Reminders and Notices of Expiration

As a courtesy to the investigators, the IRB has established a Continuing Review Notice System to remind investigators when an approved IRB research protocol is due to expire. Notices are sent to the Principal Investigator by e-mail or inter-office mail, ten weeks and six weeks prior to the expiration date of the protocol. 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

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**. The date by which a protocol must receive its continuing review is listed on the approval notice. 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](#). 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.](#))