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Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion 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

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Spotlight on Research Compliance and Education Resources

The Center for Clinical Research and Technology (CCRT) is committed to providing on-going support and education to the research community. This commitment was the ultimate inspiration for the development of the **Office of Research Compliance (ORC)**. This Office offers dedicated support to all UHCMC researchers and ensures clinical research compliance. The Research Compliance Specialists conduct prospective on-site monitoring reviews, external (FDA, and sponsor) audit preparation, IRB submission assistance, and informed consent observations. In addition, ORC provide regular educational programs to study staff in order to ensure clinical research compliance and promote the conduct of human subjects' research.

In this edition, we would like to acknowledge our appreciation to the research community for your continued support and present a brief summary of the activities provided by the Office of Research Compliance and Education.

ORC SERVICES:

Monitoring:

Since 2007, the ORC has conducted over 100 monitoring visits with Investigators and their research staff. The Research Compliance staff conducts monitoring visits to ensure that the research teams understand research requirements, provide on-site education to improve the conduct of research and act as advisors and mentors to educate individuals regarding the requirements and ethical standards governing research and how to conduct research. The monitoring visits are also conducted to offer assistance in preparation for sponsor or FDA audits.

In addition to monitoring, Informed Consent Observations, arranged with the Compliance staff, are a constructive approach to provide guidance to the research team regarding obtaining consent and ensuring compliance. The compliance staff uses a discreet approach ("Fly-on-the-wall") and do not interfere with the conduct of the informed consent process. Once the observation is complete, the staff meets with the research team to provide feedback.

Additional resources include a variety of compliance checklists and tools. These tools include: Informed Consent Documentation Checklist; Staff Signature Log/Designation of Authority; Subject Screening Logs, and more.

Education:

The ORC offers a variety of workshops to help train new research investigators and coordinators on the responsible conduct of research. In addition, the ORC offers ongoing continuing education sessions for experienced researcher and their staff. Most sessions are eligible for Continuing Research Education Credits (CRECs). The following are a few examples of programs that are offered and may be individualized to your department and/or research team.

ORC Education Programs:

- ◆ Adverse Event Reporting
- ◆ Regulatory Binder Compliance
- ◆ Keys to a Successful IRB Submissions
- ◆ Informed Consent
- ◆ Top 10 Common Non-Compliance Findings
- ◆ Human Subject Research Billing
- ◆ Intellectual Property

If you would like assistance with prepare for an upcoming audit, would like a monitoring review or arrange for an education program, please [contact us](#).