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2007 Monitoring Schedule

The University Hospitals Case Medical Center (UHCMC) Office of Research Compliance (ORC) is now scheduling monitoring reviews for 2007. If your protocol will be externally audited (e.g., FDA, sponsor, etc.) during the following year, you are encouraged to access the services offered by the ORC to prepare for these audits. Please contact the [Office of Research Compliance](#) to schedule a monitoring review. Reviews should be scheduled no less than three (3) weeks prior to the external monitoring.

Laboratory Reference Ranges: Update for Regulatory Binders

As referenced in the August 2006 Volume 1, Number 6 issue of Research Collaboration Corner, the Study Regulatory Binders should contain a list of normal laboratory values and reference ranges that is obtained from UH Laboratory Services. For your convenience, a copy of the current reference list is attached [here](#). Please be informed that the list of reference ranges is updated every three months. Therefore, you should contact the Center for Clinical Research or UH Laboratory Services every three months to ensure that your list of references ranges is current.

Top 10 Monitoring Findings: 2006

As a mechanism to evaluate the responsible conduct of research, the UHCMC ORC had launched the Research Compliance Monitoring Program in February 2006. Any protocol reviewed and approved by the UHCMC IRB was eligible to be chosen for review. The goal of this program is to help ensure the research community is in compliance with investigational policies and procedures and to assist with quality improvement initiatives. Over 30 protocols were monitored during the initial phase and the following is a list of the Top 10 areas where attention and/or corrections were required:

- 1) Informed Consent Document
- 2) Regulatory Binder
- 3) Source Documents and Data collection
- 4) Protocol Amendments / Clarification
- 5) Human Subjects Protections Certification
- 6) Study Personnel
- 7) Drug Accountability
- 8) Screening and Recruitment
- 9) Grant and Contract Administration (Research Billing)
- 10) Device Tracking