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**Upcoming Events:**

Ethics Seminar

February 8, 2007

4:00 – 5:00pm

Shock Trauma Auditorium

“The Ethics of Social Behavioral Research”

Speaker: Mary Simmerling, PhD

Director, Social Behavioral IRB, MacLean Center for Clinical Medical Ethics, University of Chicago

Inquiries: [hsilverm@medicine.umaryland.edu](mailto:hsilverm@medicine.umaryland.edu)

Research Round Table

February 21, 2007

Reporting Requirements

12–1 pm HSF I, #162

RSVP Required

Contact Khristy Bozylinski at

[kbozylinski@som.umaryland.edu](mailto:kbozylinski@som.umaryland.edu)

Research Grand Rounds

March 6, 2007

12:00pm – 1:00pm

MSTF Auditorium

FDA & Devices – HDE’s & IDE’s

Sheila Brown, RN, CCRC, nurse consultant for the IDE/HDE programs from the FDA, will be presenting on what investigators and the IRB need to know when submitting and reviewing protocols using HDE’s and IDE’s

**Special Announcement**

Unaffiliated & non-scientist members are needed for the IRB. If you know of someone who may be interested, please have them contact the HRPO at 410-706-5037.

**NEWS OF THE MONTH:**

**Clinical Monitoring  
(Part One of a Two Part Series)**

*Clinical Monitoring Services Provided by the HRPO Quality Improvement Team*

Sponsor-investigator studies are research studies where the PI assumes the responsibilities of both the Sponsor AND the Investigator. In a clinical trial, the sponsor is ultimately responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and reported in compliance with the protocol, Good Clinical Practice Guidelines, and applicable regulatory requirements. In a Sponsor-investigator study, this responsibility becomes that of the PI. In order to facilitate this process and assist the Sponsor-investigator in ensuring the highest level of study conduct, the HRPO’s Quality Improvement Program offers monitoring services. Greater than Minimal Risk studies with the highest relative risk to participants receive priority, but all Sponsor-investigator studies are eligible for this service.

**What is the purpose of Clinical Monitoring?**

According to ICH guidelines 5.18, the purpose of monitoring is to assure adequate protection of the rights and safety of human subjects involved in clinical investigations, and to assure the quality and integrity of the data.

**What is the extent of Monitoring?**

a) *Pre-investigation Visits:* Prior to the initiation of a clinical investigation, the monitor should visit the site of the clinical investigation to assure that the investigator:

- Understands the investigational status of the test article (drug or device) and the requirements for its accountability.

- Understands the nature of the protocol.

- Understands and accepts his or her obligations to conduct the clinical investigation in accordance with 21CFR Parts 312, 511, 812, 813, or any other applicable regulations.

- Understands and accepts his or her obligations to obtain informed consent in accordance with 21 CFR Part 50.

- Understands and accepts his or her obligation to obtain IRB review and approval of a clinical investigation before the investigation may be initiated and to ensure continuing review of the study by the IRB in accordance with 21 CFR Part 56.

b) *Periodic Visits:* The monitor should visit the investigator at the site of the investigation frequently enough to assure that:

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**Mission:**

The University of Maryland School of Medicine HRPO’s mission is to cultivate a culture of conscience in the University of Maryland, Baltimore’s research community to ensure the highest levels of human participants’ advocacy and protections.

The UMB IRB uses a web-based system to manage all human research protocol submissions, called the Biomedical Research and Assurance Network (BRAAN). To access the BRAAN system go to - <http://medschool.umaryland.edu/orags/hrpo/>

**Contact Information:**

The HRPO hours of operation are Monday - Friday 8:30 am - 4:30pm  
[University of Maryland School of Medicine](http://medschool.umaryland.edu/)  
<http://medschool.umaryland.edu/>  
Human Research Protections Office  
Health Science Facility I (HSF I)  
685 W. Baltimore Street, Room 146  
Baltimore, MD 21201

<http://medschool.umaryland.edu/orags/hrpo/>  
[HRPO@som.umaryland.edu](mailto:HRPO@som.umaryland.edu)  
Phone: (410) 706-5037

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- The facilities used by the investigator continue to be acceptable for the purposes of the study.
- The study protocol is being followed.
- Accurate, complete, and timely reports are being made to the sponsor and IRB.
- The investigator is carrying out the agreed-upon activities and has not delegated them to other previously unspecified staff.

c) *Review of Subject Records:* During a periodic visit, the monitor should compare a representative number of subject records and other supporting documents with the investigator's reports to determine that:

- The information recorded in the investigator's reports is complete, accurate, and legible.
- There are no omissions in the reports of specific data elements.
- Missing visits or examinations are noted in the reports.
- Subjects failing to complete the study and the reason for each failure are noted in the reports.
- Informed consent has been documented in accordance with 21 CFR Parts 50 and 56.

d) *Record of On-Site Visits:* The monitor and the PI should maintain a record of the findings, conclusions, and action taken to correct deficiencies for each on-site visit to an investigator. The record will include such elements as:

- The date of the visit.
- The name of the individual who conducted the visit.
- The name and address of the investigator visited.

- A statement of the findings, conclusion and any actions taken to correct any deficiencies noted during the visit.

Note: In addition, the monitor will follow-up with any actions taken by the PI to correct deficiencies at the next scheduled visit.

***What is the difference between clinical trial auditing and monitoring?***

***Audit:*** A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice guidelines (GCP) and the applicable regulatory requirements.

***Monitoring:*** The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and applicable regulatory requirements.

**Please watch for the upcoming SOP for the complete Clinical Trial Monitoring Procedures.**

References:

1. Code of Federal Regulations; ICH Guidelines, ICH 5.18
2. Code of Federal Regulations; ICH Guidelines: Guideline for the Monitoring of Clinical Investigations.

*Submitted by Sarah Edebe, B.S., QI Specialist*

**UMB HRPP In The News**

- \* Susan C. Buskirk, MS, BSN, RN, HRPP Executive Director, has been appointed as a site visitor and team leader for the Association of the Accreditation of Human Research Protection Programs (AAHRPP)
- \* Dr. Robert Edelman, MD, FACP, Professor of Medicine and Pediatrics, Associate Director for Clinical Research, Center for Vaccine Development, and UMB IRB Chair, was interviewed for the *AAHRPP Advance*, Spring 2006 issue, "HRPP Innovations, UMB: Raising the Bar for Data and Safety Management."
- \* Leslie I. Katzel, MD, Ph.D., Associate Professor of Medicine and Clinical Director Baltimore VAMC GRECC, is a site visitor for the AAHRPP. In December 2006 he was appointed to AAHRPP's Council on Accreditation.
- \* Julie Doherty, MSN, RN, HRPO Director of Quality Improvement presented an overview of the program to the Association of Clinical Research Professionals Baltimore-Washington Chapter Meeting on October 16, 2006. The HRPO's Monitoring component subsequently became the feature of an article in *The Guide to Good Clinical Practice*, December 2006, Vol. 14, No. 3, "University Begins Its Own Trial Monitoring Program." The article also described the auditing component of the program. See the HRPO web site (main page) for the link to the full presentation.