



Human Research Protections Office (HRPO)

Newsletter VOL. 1, NO. 3

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.

Contact Information:

The HRPO hours of operation are
Monday - Friday 8:30 am - 4:30 pm
 University of Maryland School of Medicine
<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
 Phone: (410) 706-5037
 Fax: (410) 706-4189

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/>

Schedule of Events:**PRIMR Conference:**

December 5th - 6th
 HRPO Offices Closed

Research Grand Rounds Education Session:

December 12th, 9AM
 HSF II auditorium, Rm. 130 S

Susan Buskirk will be presenting an update on AAHRPP for the research community.

Holiday Break: December 24th - January 2nd
 HRPO Offices Closed

CITI Training Refresher Deadline:
 December 31st

Happy Holidays !

The staff of the HRPO wishes you & your families a Safe and Happy Holiday !

**News of the Month:****HRPO Quality Improvement Team****Who we are:**

We would like to introduce the HRPO Quality Improvement (QI) Team! This team is comprised of one Program Manager for QI, ten HRPO QI Specialists and one Education and Support Specialist. The QI Team have clinical research experience from a variety of backgrounds, including nursing, medicine, dentistry, emergency health, neuroscience, psychiatry, regulatory and data management in both academic and private industry environments. To contact members of the team, please visit the staff page on the HRPO website found at <http://medschool.umaryland.edu/orags/hrpo/staff.asp>.

Why we are here:

The goal of the Quality Improvement team is to strengthen safeguards for research participants through the activities of auditing to assure protocol conduct according to regulations, monitoring the ongoing quality of the IRB review process, and providing research operations training and guidance for the UMB research community. For more information on quality improvement activities, see HRPO Standard Operating Procedure 2G found at <http://medschool.umaryland.edu/orags/hrpo/policies.asp>.

What we do:

The Quality Improvement team employs a wide variety of activities in service to the UMB research community:

- Education and Support:** HRPO personnel are available to assist Investigators and research personnel with BRAAN applications, informed consent document construction, regulatory consultations, and study implementation.

- Routine Audits:** Selection of research studies for audit is prioritized according to certain audit triggers, such as Investigator-initiated studies, Phase I research, or Significant Risk Device Studies.

- Monitoring:** The Quality Improvement Specialists are available to provide monitoring of Investigator/Sponsor studies for which there is no other mechanism of monitoring, such as a Clinical Research Organization or Industry Sponsor. The HRPO, IRB, or Investigator may request this service.

- Quality Improvement Consultations:** Investigators and research personnel may request consultation with a Quality Improvement Specialist at any point before, during, or at the close out of the research study. These consultations will focus on assisting the Investigator with developing a study implementation plan including mechanisms to enhance compliance with research conduct, reporting, and recording requirements of *Good Clinical Practice's*.

- For Cause Audits:** Audits are conducted by the Quality Improvement Specialists to assess the Investigator's compliance with federal regulations, state and local laws, and Human Research Protections Program and/or UMB IRB policies and procedures. These audits of IRB approved research studies are in response to identified concern(s). Concerns may be identified by an IRB Committee, an external source (e.g. OHRP, FDA or Sponsor), or an internal source (e.g., participant, family member, or Institutional personnel).

Contributed by: Kim Odam, Quality Improvement Specialist