



## Human Research Protections Office (HRPO)

Newsletter VOL. 2, NO. 5

**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](mailto: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:**

**Human Participant Research @ UMB 101:  
 "What You Need To Know To Get Started"**  
 - October 5th

**Research Grand Rounds** - October 11

For More Details visit the HRPO Website.

**Important Information:**

The staff of the HRPO encourages you to visit our website frequently at  
<https://medschool.umaryland.edu/hrpo/>  
 for updated information and breaking news in the research community.

On our website you will find the most recent editions of the *Policies and Procedures Manual* in Word, PDF, and HTML formats. Please discard all manuals and versions prior to the posted dates.

**Correction:**

The August 2006 edition of the HRPO Newsletter inadvertently omitted the credit to Carley Benham for the submission entitled "*The Informed Consent Document*". We apologize for this oversight.

**News of the Month:****The Institutional Review Board (IRB)**

An IRB or Institutional Review Board is an administrative board whose purpose is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating in research studies. To accomplish this purpose, an IRB uses a group process to review research protocols and related materials such as informed consent documents, investigator brochures, and questionnaires. The IRB has the authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction as specified by the federal regulations, local institutional policy, and state laws.

In the United States, the only place that an IRB is formally defined is in the U.S. Code of Federal Regulations. The federal regulations 21 CFR 56.107 state that an IRB must have "at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution" and should be sufficiently qualified in different areas of experience and expertise. The IRB should also be diverse in terms of race, gender, profession, cultural backgrounds and in "sensitivity to such issues as community attitudes ....". Each IRB must include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in non-scientific areas. Furthermore, each IRB shall include one member who is not affiliated with the institution and does not have an immediate family member affiliated with the institution. One IRB member may satisfy more than one membership category. For example, one member could be unaffiliated with the institution and have a primary concern in a non-scientific area and therefore, would satisfy two of the membership requirements of the regulations. An IRB member with conflicting interest may not participate in the IRB's initial or continuing review except to provide information requested by the IRB. Lastly, an IRB may invite individuals with expertise in a specific area to assist in the review of complex issues, although these individuals may not vote with the IRB.

UMB IRB is comprised of four boards, with each board meeting monthly. The IRB is led by a Chair and four Vice-Chairs, who are former IRB Members, experienced researchers, and are respected among the research community. At each board meeting, there is representation from a non-scientist and a non-affiliated member, and there is an individual who serves in the capacity of a research subject advocate. The IRB functions independently but in coordination with other committees and is supported administratively by the Human Research Protections Office (HRPO). The Chair of the IRB reports directly to the Institutional Official, Dean of The School of Medicine.

- Contributed by: Carley Benham, Quality Improvement Specialist

Sources:

<http://www.fda.gov/oc/ohrt/irbs/faqs.html>  
<https://medschool.umaryland.edu/hrpo/irb.asp>  
<https://medschool.umaryland.edu/ORAGS/hrpo/policies.asp>  
 (Section 7A)