



## Human Research Protections Office (HRPO)

## Newsletter VOL. 2, NO. 1

**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:****Martin Luther King Jr.'s Birthday**

January 16th - HRPO Offices Closed

**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.

Additionally, as we enter a New Year, we continue to ask for your comments and feedback to help us improve the Human Research Protections Program. If you haven't done so already, please take 5 minutes to complete our survey located at <http://medschool.umaryland.edu/ORSurvey/SatisfactionSurvey.aspx>.

**News of the Month:****Frequently Asked Questions by Investigators****Q: What are the HRPO training requirements for Investigators and Co-Investigators?**

A: At a minimum, Investigators and Co-Investigators are required to complete CITI (Collaborative IRB Training Initiative) annually, and HIPAA 201. VA Investigators are responsible for completing the VA annual requirements for human research protections training, including HIPAA privacy training.

For further training opportunities and links to the training modules, please see the HRPO website at <http://medschool.umaryland.edu/orags/hrpo/>.

**Q: At the time of continuing renewal, do I report participants who participated in the study prior to the implementation of the BRAAN system?**

A: The investigator should report the total number of participants consented to participate to date (including any withdrawals by participant, Investigator or sponsor OR consented screen failures). This includes participants who have participated in the study prior to the implementation of the BRAAN system, if applicable. The investigator should also specify the total number of participants consented since the previous IRB review approval (including any withdrawals by participant, Investigator or sponsor OR consented screen failures).

For further information, please see *HRPP Policies and Procedures 3J*.

<http://medschool.umaryland.edu/ORAGS/hrpo/sop/3j.asp>.

**Q: Do I need a Data Safety Monitoring Plan for my study?**

A: A detailed plan is required for all research that is not "Exempt" under Federal regulations. The level of detail in the plan should be based on the degree of risk entailed by the research participants. For specific instructions for completing a Data Safety Monitoring Plan, please see *HRPP Policies and Procedures 6E*.

<http://medschool.umaryland.edu/ORAGS/hrpo/sop/6e.asp>.

**Q: I have DHHS/NIH supported research grant, do I need to submit a full study protocol?**

A: It is the responsibility of the University of Maryland, Baltimore (UMB) Investigator to create a research protocol for greater than minimal risk studies if a sponsor or multi-center group has not provided one. The UMB Human Research Protections Office will provide the necessary guidance and support to Investigators and research personnel for establishing the greater than minimal risk study protocol.

For further information, please see *HRPP Policies and Procedures 6B.2*

<http://medschool.umaryland.edu/ORAGS/hrpo/sop/6b2.asp>.

More questions and answers next month.

*Contributed by: Kim Odam, Quality Improvement Specialist*