



Human Research Protections Office (HRPO)

Newsletter VOL. 2, NO. 2

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:

Lincoln's Birthday - February 13th

President's Day - February 20th

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 (Part 2)****Q: What is the difference between screened and enrolled participants?**

A: A screened participant is a person who may or may not have signed a research consent form to participate in the study and has not been exposed to the risks of the study. An enrolled subject is a participant who has signed a research consent form and has been exposed to the risks of the study.

For further information, please see *HRPP Policies and Procedures 3J*. <http://medschool.umaryland.edu/ORAGS/hrpo/sop/3j.asp>.

Q: How long do I need to store my research charts/records?

A: At a minimum, Investigators must maintain research records for at least three years from the date the research is closed with the UMB IRB. Beyond three years, requirements for record retention vary with the type of research conducted and provisions of the Investigator's funding source.

For further information, including HIPAA related documentation storage requirements, please see *HRPP Policies and Procedures 6B*. <http://medschool.umaryland.edu/ORAGS/hrpo/sop/6b.asp>.

Q: What kind of regulatory documents do I need to keep regarding any laboratories I use for my studies?

A: Investigators should maintain a copy of CLIA or CAP Certification (if sponsor requires) and normal lab reference ranges for any research-related laboratory tests to be used during the study.

For further information, including other study regulatory documentation requirements, please see *HRPP Policies and Procedures 6B.3*. <http://medschool.umaryland.edu/ORAGS/hrpo/sop/6b3.asp>.

Q: Do I need to submit a report to the IRB when my study closes?

A: Every IRB approved study must have a closure report submitted within 30 days of the end of the study. It is the ultimate responsibility of the Investigator to ensure that the report is accurate and submitted in a timely fashion. To be eligible for closure the IRB study must meet all of the following criteria: (1) Data collection is complete; (2) There is no more participant contact (i.e. phone calls, long term follow up, data collection visits, surveys are completed); and (3) The only research activity being conducted is data analysis of de-identified data. For further information, including how to submit a final closure report, please see *HRPP Policies and Procedures 3J.3* <http://medschool.umaryland.edu/ORAGS/hrpo/sop/3j3.asp>.

Contributed by: Kim Odam, Quality Improvement Specialist