



Human Research Protections Office (HRPO)

Newsletter VOL. 1, 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/)
<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/>

From the Director:

We encourage you to visit the HRPO website often for breaking news and updates. Scroll just below the "NEW" BRAAN Log-In Section.

The HRPO has recently added to its staff several new Analysts and Quality Assurance personnel. You can familiarize yourself with their names and faces by clicking on the **STAFF** button on the left side of our website.

We hope that the new people we've hired and the new tools we've instituted will better facilitate the research protocol submission and review process.

News of the Month:

As required by federal law, 42 U.S.C. 282(j), any FDA or HHS regulated clinical trial for a drug, device or biological product to treat a serious or life-threatening disease or condition, or to test the effectiveness of an experimental treatment for patients with a serious or life threatening disease or condition, must be registered at the publicly available clinical trials data base at www.clinicaltrials.gov.

When new submissions come in to the HRPO, the Analysts will verify that the trials are registered. If they are not registered, and it is an investigator initiated study, the analyst will contact the PI, and/or register the trial. If it is an industry/federal sponsor, the analyst will contact the PI and inform them of the institutional policy so they may work with the sponsor to get the trial registered.

It is the policy of UMB that no trial subject to 42 U.S.C. 282(j) may be carried out by UMB faculty or staff unless the sponsor timely registers the trial at www.clinicaltrials.gov or provides the Human Research Protections Office with a copy of a waiver of the registration requirement from the federal government, in accordance with 42 U.S.C. 282(j)(4). This policy applies to all faculty and staff of all UMB professional schools.

Schedule of Events:

Veterans Day: November 11th
HRPO Offices Closed for Staff Seminar

Thanksgiving: November 24th & 25th
HRPO Offices Closed