



## Human Research Protections Office (HRPO)

Newsletter VOL. 2, NO. 4

**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  
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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:**

**Labor Day** - September 4th  
 - HRPO Offices Closed

**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.

**The HRPO welcomes NEW Staff Members:**

Valerie Agwale - Vanessa Anderson  
 Julie Doherty - Suzanne Grim  
 Cynthia Shaffer

**News of the Month:****The Informed Consent Document**

The informed consent process begins with a discussion of the consent document with a potential study participant; however, it must be an ongoing process between the research staff and the participant through the course of the study. The informed consent document, often considered to be the foundation of the informed consent process, provides only a summary of the clinical trial. This written document can not alone ensure that the participant fully understands what his or her participation means. It is the responsibility of the research staff to explain the study and answer all questions so that the potential participant is better enabled to make decisions about enrolling and continued participation.

Due to the increasing complexity of medical research, it has become more challenging to write a useful and understandable consent document. The consequences of a participant not understanding all the information provided in the consent document could be costly for both the participant and the researcher. "In *Health Literacy: A Prescription to End Confusion*, the Institute of Medicine reports that ninety million people in the United States, nearly half the population, have difficulty understanding and using health information. As a result, patients often take medicines on erratic schedules, miss follow-up appointments, and do not understand instructions like 'take on an empty stomach'." A potential participant may be hindered from making an informed decision to participate, could be confused enough by the materials that performance in the study is compromised, or may be at greater risk for adverse events. Vulnerable populations, including low income, elderly, and ethnic minorities, often exhibit low literacy rates and may have the greatest need for an informed consent process that secures their protection. A study performed at a public hospital showed that "81% of patients age 60 and older could not read or understand basic materials such as prescription labels. Furthermore, according to the 2000 US Census Bureau, by 2050 almost half of the US will be members of a minority group with English as their second language. Many health care providers may overestimate the information that patients are able to understand. It is important to remember though, that low literacy should not be equated with low intellect. Increased verbal communication between the researcher and study participant can greatly overcome the challenges of low literacy and incomprehension.

A consent document that will facilitate clear health communications with potential study participants should consist of:

- simple and commonly understood language,
- short sentences that are 15 words or less
- brief paragraphs containing only one idea.
- technical terms explained in lay person language, using the technical term only once
- conversational tone written in the active voice (ex: The pharmacist is filling your prescription RATHER THAN Your prescription is being filled by the pharmacist.)
- present tense when explaining or instructing and future tense when discussing things to be expected
- lists or bullets to simplify rather than long paragraphs
- ample white space on the page
- titles, subtitles, and other headers to clarify organization of text
- diagrams, charts, and pictures to help simplify complex ideas or study visits
- an attached glossary if the consent document contains medical or technical terms that can not be easily simplified or are repeated through the document

For additional information and resources, please see the document titled *Tools & Tips for Writing a Clear and Appropriate Informed Consent Document* located in Industry Sponsored Research, Federal or Other Funded Research or Investigator Initiated Research sections of the Investigator's Toolkit (<http://medschool.umaryland.edu/orags/hrpo/toolkit.asp>)