




**SPECIAL ANNOUNCEMENT: THE UMB HUMAN RESEARCH PROTECTIONS PROGRAM PREPARES FOR AAHRPP RE-ACCREDITATION!**

Watch for related education programs coming soon! Check the HRPO website for details.

|                           |                  |                        |
|---------------------------|------------------|------------------------|
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**The Five Domains of Standards**

**Association for the Accreditation of Human Research Protection Programs (AAHRPP)** "AAHRPP allocates the criteria for accrediting Human Research Protection Programs into the following five domains:"


1. Organization
2. Research Review Unit, including IRBs
3. Investigator
4. Sponsored Research
5. Participant Outreach

Additional information on each domain will be covered in subsequent issues. Stay Tuned!



**CICERO**

*Stay tuned for details!*



**HRPP Standard Operating Procedure Manual**

The UMB Human Research Protections Program and Institutional Review Board Policies and Procedure Manual has been re-organized into a new format in response to feedback provided by the UMB research community.

**\*NO POLICY CHANGES**

- \*Updates to reflect current practice
- \*Streamlined to eliminate duplication
- \*Reduced references to BRAAN
- \*Structured according to the five domains of AAHRPP

**Look for the re-organized SOP Manual on the HRPO website NOW POSTED!**

***The Role of the Non-Scientist on the Institutional Review Board, a Personal Perspective***

**Paula Raimondo, MLS, AHIP**

Head, Liaison & Outreach Services  
Health Sciences and Human Services Library  
University of Maryland Baltimore

When I was asked to become a member of UMB's Institutional Review Board as an affiliated non-scientist I accepted with enthusiasm. At that time I was the Health Sciences/Human Services Library's liaison to the School of Medicine, and viewed membership on the IRB as an opportunity to get to know more of the faculty, and to learn more about the research activities of the campus. After three years I still enjoy my work on the IRB and have learned a lot.

An IRB meeting can not be held without the presence of a non-scientist. The non-scientist's primary functions on the IRB are to represent the participants in a study and to review participant consent forms, and at UMB is often the secondary reviewer of a protocol (a faculty member with expertise in the research discipline relevant to the study is typically the primary reviewer). When reviewing a consent form, I consider whether it contains language that is simple enough for the average participant to read and understand, and suggest alternatives when the original language is difficult. I make certain that the consent form accurately reflects the contents of the protocol, that the manner of participant recruitment for the study is not coercive, and that the consent form clearly states that the participant has the right to withdraw from the study at any time without penalty or loss of benefits.

**FEATURE ARTICLE CONTINUED ON PAGE 2**

**Upcoming Events:**

**Research Round Table**  
\*RVSP Required\*

**Topic: SAE's and Unanticipated Problems**  
April 8, 2008 12:00-1:00 pm  
T1R15 (Shock Trauma Classroom)

**Topic: IRB Approval Process**  
May 23, 2008 12:00-1:00 pm  
T1R15 (Shock Trauma Classroom)

**Topic: Preparing for a Monitor Visit**  
June 18, 2008 12:00-1:00pm  
T1R15 (Shock Trauma Classroom)

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**"Human Participant Research @ UMB 101: What You Need To Know To Get Started"**  
\*RSVP Required\*

**April 22, 2008**  
1:00pm—2:00pm  
T1R15 (Shock Trauma Classroom)

**May 5, 2008**  
10:00am-11:00 am  
T1R15 (Shock Trauma Classroom)

**June 3, 2008**  
9:00am-10:00am  
T1R15 (Shock Trauma Classroom)

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For more information or to RSVP please contact **Kristy Bozylinski** at **HRPOEducation@som.umaryland.edu**

**HRPO Mission:**

The mission of UMB's HRPP is to cultivate a culture of conscience in the research community to ensure the highest levels of protections and advocacy for research participants by: actively engaging and working cooperatively with the Institutional Official, Institutional leaders, and all components of the HRPP; facilitating ethical and scientifically sound research through institutional oversight and IRB review processes; contributing to the knowledge of investigators and research personnel through education and training programs; communicating with sponsors; and serving as a consistent resource for all current, past, and prospective participants. (Updated 2/1/08)

**HRPO Contact Information:**  
Hours of Operation: Monday - Friday 8:30 am - 4:30pm

**Human Research Protections Office**  
University of Maryland School of Medicine  
800 West Baltimore Street, Suite 100  
Baltimore, Maryland 21201-1559  
Phone: (410) 706-5037  
Fax: (410) 706-4189  
**HRPO@som.umaryland.edu**  
**http://medschool.umaryland.edu/orags/hrpo/**

**Additional Information**



In February 2008 the HRPO implemented a new system in BRAAN which assigns full board protocols to a meeting with in 2-3 weeks instead of 4-5 weeks!

**This new process has resulted in a decrease in turn around times for exempt and expedited protocols!**

**Exempt and Expedited Data**

| Average Calendar Days   | Submitted to Reviewed | Submitted to Approval | Reviewed to Approved |
|---|-----------------------|-----------------------|----------------------|
| <b>Old System<br/>(4-5 weeks)</b>   | <b>16</b>             | <b>33</b>             | <b>18</b>            |
| <b>New System<br/>(2-3 weeks)</b>   | <b>5</b>              | <b>7</b>              | <b>2</b>             |
| <b>Average decrease in turn around time for Exempt &amp; Expedited Trans-</b> | <b>-11</b>            | <b>-26</b>            | <b>-16</b>           |

**The HRPO Welcomes New Staff Members**

**Christina Diggs, BS, MS, IRB Analyst** transferred to HRPO from the Division of Infectious Diseases in the School of Medicine. She has been working in clinical research on campus for 5 years. Her background is in psychology, but she discovered research in undergraduate school while working as a student intern at the Johns Hopkins Bloomberg School of Public Health. Her research background experience includes specialties such as: Nutrition and Health, Psychiatry, and Infectious Disease research. During her research career of eight years, she has assumed the roles of clinical research coordinator, research assistant, and research supervisor. She understands the investigator's side of conducting research and will use this knowledge to develop her skills as an efficient IRB Analyst.

**Jane Eisinger, MS Quality Improvement Specialist** returns to UMB after spending 10 years as a Research Program Coordinator at the JHU School of Medicine in the Departments of Ophthalmology & Neurosurgery. Most recently she worked on a nationwide clinical research study for postsurgical adhesion barriers for spine surgery patients. She has an extensive background in working with sponsors, study site coordinators and clinical monitors and has experience in developing and maintaining research policies & procedures. Her past experience here at UMB consisted of four years in research in the Division of Cardiology. Jane holds a Master of Science in Developmental Psychology from JHU.

**Cecily Spaulding, DPM, Quality Improvement Specialist** is a podiatric physician with over 10 years experience in clinical research. She has served in various capacities, from clinical research coordinator to research manager, as well as a co-investigator on several pediatric orthopedic trials. In addition to orthopedics, her areas of clinical research expertise include endocrinology and cardiovascular diseases. Prior to joining HRPO, she managed the research and clinical activities for patients undergoing limb lengthening surgery, and lectured both locally and internationally on the topic. This is her first experience working in the regulatory side of research.

**Ellen L. Taylor, BS, MLA, COA, Quality Improvement Specialist** comes to us with over 20 years of research experience. She began her career as a laboratory coordinator where she was involved with validating tests and setting up local and international laboratories to monitor HIV infection in identified populations. She eventually became project director and oversaw operations including specimen collection, data analysis and clinic operations for a longitudinally study of HIV infection. She has been an IRB coordinator and most recently a member of the Quality Improvement Team with a contract research organization in Rockville, Maryland. She has four years experience as a quality specialist and holds a certificate as a certified auditor from the American Society for Quality.



The **HRPO Comments Box** is on-line!

To access the comments box click on "**HRPO Comments Box**" on the HRPO website <http://medschool.umaryland.edu/hrpo>

All responses are **anonymous!**

**FEATURE ARTICLE CONTINUED FROM PAGE 1**

**The Role of the Non-Scientist on the Institutional Review Board, a Personal Perspective** - By: Paula Raimondo, MLS, AHIP, Head, Liaison & Outreach Services, UMB

My experience reviewing the consent forms led me to learning more about the health literacy of adults in the United States and resulted in my development of a the class *Patient Health Literacy and the Consent Process*, which is offered through the library. Variants of this course have been presented to the IRB Committees and was offered as a Grand Rounds session in November 2007.

I received training in preparation for my role on the IRB, but had plenty to learn once I began my work on a committee, and the learning process is ongoing. To fully understand a protocol I frequently have to read further about a disorder or drugs that might be involved in the study. My experience as a medical librarian has made some of this easier. I am familiar with medical terminology, and I know where to look for additional information when I need it. I also benefit from the training sessions that are given at the beginning of most IRB committee meetings where we discuss a variety of issues relevant to human research. The IRB Analysts and other HRPO staff are also available to provide assistance.

I have enjoyed the opportunity to work closely with the staff of the Human Research Protections Office. I taught a session on searching Medline for them. I've also given a Grand Rounds session on comprehensively searching the databases in preparation for a grant proposal, and am on a committee that is participating in the configuration of the new electronic protocol management system that will some day replace BRAAN. My fellow IRB committee members have been supportive and willing to help when I need to understand something. I look forward to seeing them every month, and I'm proud of the work our campus is doing to protect human research participants, facilitate research, and ultimately benefit the health of our patients and society through the knowledge gained from the research endeavors.

If you would like to contribute a story, ideas, accomplishments related to human participant research in the HRPO Newsletter please email [HRPOEducation@som.umaryland.edu](mailto:HRPOEducation@som.umaryland.edu) for consideration.