



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.

INSIDE THIS ISSUE:	HRPO NEWS	FEATURE ARTICLE																														
<p><i>Upcoming Events</i> 1 <i>HRPO News</i> 1 <i>Feature Article</i> 1 <i>Special Announcement</i> 1 <i>New Staff</i> 2 <i>HRPP Policy Update</i> 2</p>	<p>The mission of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is to accredit high quality human research programs in order to promote excellent, ethically sound research. Through partnerships with research organizations, researchers, sponsors, and the public, AAHRPP encourages effective, efficient, and innovative systems of protection for human research protections. "AAHRPP seeks not only to ensure compliance, but to raise the bar in human participant research protection by helping institutions reach performance standards that surpass the threshold of state and federal requirements." AAHRPP website: www.aahrpp.org</p>	<p>The Central Task of the IRB By Robert Edelman, MD, UMB IRB Chairman</p> <p>I was attending a seminar on research ethics last week, when a faculty member posed a question in the form of a complaint. "Considering that the IRB's role is to oversee the safety and welfare of the volunteer, why does the IRB insist on delving into the science? Why don't they leave this judgment to the experts?" I read and hear this comment often in the literature and at faculty meetings. It is based on a misconception of the IRB's central task, which is thought to focus solely on research safety. In fact, the task of the IRB is to judge the benefit-risk ratio; namely, do the potential benefits to the volunteer, and or knowledge gained to benefit society, outweigh the risks to the volunteer. One cannot judge risk in a vacuum. Without accounting for the benefits, it is impossible to judge the risk. To illustrate, the IRB may review research in which the risk of a simple standard-of-care venipuncture is judged to be unethical and where IV infusion of a known toxic drug is judged to be ethical. How can this be? In the first example, the venipuncture study was based on a seriously flawed scientific question or study design, or the study was likely to be conducted in a sloppy fashion. As a result, no benefit would accrue to the volunteer or to society because the outcome would be invalid or worthless. By contrast, the study of the potentially toxic IV drug may be approved because it was based on a clinically valuable question, using accepted scientific principles and methods to produce reliable data. This argument is clearly expounded in an article by Emanuel, Wendler, and Grady, <i>What Makes Clinical Research Ethical?</i> <i>Journal of the American Medical Association</i> 283:2701, 2000.</p>																														
<p>Upcoming Events:</p> <p><u>Research Grand Rounds</u></p> <p>September 18, 2007 2:00-3:00 pm Shock Trauma Auditorium "Seven Steps for Reviewing Pediatric Research" Susan Kornetsky, MPH, CIP Director Clinical Research Compliance Children's Hospital of Boston</p> <p>November 14, 2007 12:00-1:00 pm MSTF Auditorium "Patient Health Literacy and the Consent Form" Paula G. Raimondo, MLS, AHIP Head, Liaison & Outreach Services, HS/HSL University of Maryland</p>	<p>NEW LOCATION!! NEW ADDRESS!!</p> <p>The HRPO has moved to: 800 West Baltimore Street, Suite 100 Baltimore, MD 21201 All phone numbers remain the same</p> <p>The office is located in the UMB BioPark, Building One, first floor. Weekly IRB meetings will be held in the third floor Conference Room #309 of this building, 800 W. Baltimore Street.</p>	<p>FEATURE ARTICLE CONTINUED ON PAGE 2</p>																														
<p><u>Research Round Table: RVSP Required</u></p> <p>Topic: Consent Form Writing September 26, 2007 12:00-1:00 pm HSF I, Room 216</p> <p>Topic: Protocol Amendments October 17 2007 12:00-1:00 pm HSF-I, Room 216</p> <p>"Human Participant Research @ UMB 101: What You Need To Know To Get Started" RSVP Required</p> <p>September 17, 2007 11:00am-12:00pm T1R15 Shock Trauma Classroom</p> <p>October 23, 2007 1:00-2:00 pm HSF-II Auditorium</p>	<p>HRPO FY2007 Accomplishments:</p> <p>IRB Operations</p> <table border="0"> <tr> <td>Total number of transactions</td> <td>24,865</td> </tr> <tr> <td>Full board</td> <td>509</td> </tr> <tr> <td>Expedited</td> <td>1131</td> </tr> <tr> <td>Modifications</td> <td>1788</td> </tr> <tr> <td>Reportable events</td> <td>1420</td> </tr> </table> <p>Quality Improvement/Compliance</p> <table border="0"> <tr> <td>Total Activities</td> <td>167</td> </tr> <tr> <td>Federal Reports</td> <td>19</td> </tr> <tr> <td>For Cause Audits</td> <td>44</td> </tr> <tr> <td>Routine Audits</td> <td>49</td> </tr> <tr> <td>Spot Audits</td> <td>30</td> </tr> <tr> <td>Investigator Self Assessments</td> <td>14</td> </tr> <tr> <td>Participant Complaints</td> <td>11</td> </tr> </table> <p>Education</p> <table border="0"> <tr> <td>Total Programs</td> <td>298</td> </tr> <tr> <td>Internal</td> <td>193</td> </tr> <tr> <td>External</td> <td>105</td> </tr> </table>	Total number of transactions	24,865	Full board	509	Expedited	1131	Modifications	1788	Reportable events	1420	Total Activities	167	Federal Reports	19	For Cause Audits	44	Routine Audits	49	Spot Audits	30	Investigator Self Assessments	14	Participant Complaints	11	Total Programs	298	Internal	193	External	105	
Total number of transactions	24,865																															
Full board	509																															
Expedited	1131																															
Modifications	1788																															
Reportable events	1420																															
Total Activities	167																															
Federal Reports	19																															
For Cause Audits	44																															
Routine Audits	49																															
Spot Audits	30																															
Investigator Self Assessments	14																															
Participant Complaints	11																															
Total Programs	298																															
Internal	193																															
External	105																															
<p>For additional information or to RSVP please contact Khristy Bozynski at HRPOEducation@som.umaryland.edu</p>	<p>The Food and Drug Administration conducted a full inspection of the UMB IRB from May 7-14, 2007. There were NO findings to report. CONGRATULATIONS TO THE HRPO AND UMB IRB!</p>	<p>HRPO Contact Information: Hours of Operation: Monday - Friday 8:30 am - 4:30pm</p> <p>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/</p>																														
<p>HRPO 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.</p>																																

HRPP Policies and Procedures

History: The HRPP Policies and Procedures Manual was first published on-line June 30, 2005. Following UMB's AHRPP site visit in September 2005, major revisions were made to the Policies and Procedures manual in November 2005. Since that time, there have been ongoing changes to specific sections as needed. To see a detailed listing of the specific changes, visit the HRPO website:

<http://medschool.umaryland.edu/orags/hrpo/policies.asp>

****The on-line version of the Policies and Procedures, rather than printed hard copies, should be consulted in order to ensure compliance with the most current Policies and Procedures.****

Recent Updates:

8/20/2007: SOP 5B: IRB Fees for Industry-Supported Applications: The *red italicized* language below has been added. The Policy statement now reads: It is the policy of the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to assess a fee for all industry-supported initial IRB BRAAN Applications and continuing review applications submitted to the UMB IRB for review. *Studies that receive less than \$10,000 from the Industry Sponsor are exempt from this policy.*

5/23/2007: Signature Page: The HRPP Policy and Procedure Manual Signature Page has been updated with the signature of the current Institutional Official.

FEATURE ARTICLE CONTINUED FROM PAGE 1

The Central Task of the IRB, by Robert Edelman, MD, UMB IRB Chairman

The article, which should be studied by all IRB Members and clinical investigators, contrasts "valuable research" (research that will improve health or increase knowledge) from "valueless research." Characteristics of valueless research include trifling hypotheses, interventions that could never be implemented practically, and results that would be non-generalizable, already proven, or unlikely to be disseminated. In general, valuable research is worth the risk, while valueless research is not. Thus the IRB must judge if the study is valuable. Fortunately, such judgments are easier when protocols submitted to the IRB have undergone rigorous scientific pre-review by Federal scientific panels, by external scientific consults of drug companies and Foundations, by the FDA, or by UMB Divisional or Department review of research protocols initiated by faculty. Of these four external scientific review paths, the weaker external scientific reviews are more often (but not always) associated with small biotech companies and faculty investigator-initiated studies. The IRB has learned to pay closer attention to such studies.

In addition to value, the IRB must also judge if the study is methodologically rigorous. Even if the scientific value is laudatory, the protocol may be unethical, because it may expose volunteers to risks for no purpose if conducted in a methodologically unsound way. Some common examples of methodologically flawed research include inadequate clinical samples, biased questionnaires, invalid statistical tests, neglected critical endpoints, and the lack of sufficient volunteers to prove the hypothesis thus exposing the few treated volunteers to risks without purpose (the study is underpowered), or it exposes more volunteers to research risks than is needed to prove the hypothesis (overpowered). Of the small number of deficient studies at UMB, the most common flaws are those conducted in a slipshod fashion so that data collected is rendered uninterruptible. In the end, the IRB must determine if the investigator has enhanced the benefits and minimized the risks to the extent possible. Federal regulation now requires that at least one IRB member or ad hoc reviewer have sufficient medical expertise to review medical protocols (e.g. cardiology and cancer) or social behavioral research so that the benefit-risk analysis of each protocol is determined by at least one "expert". In addition, the IRB will frequently contact investigators before or during the IRB meeting to resolve protocol issues to ensure they arrive at the proper assessment of the study benefits and risks. IRB reviewers increasingly "Google" internet websites to discover risks not listed in protocols and consent forms.

The last misconception I want to correct is that "some research does not involve risk." In fact, all clinical research possesses some degree of risk. The physical risks (e.g. allergic reactions and toxic side effects of investigational drugs) are common and easily understood. The IRB is tasked to remember that other risks exist, including psychological (questionnaires that result in emotional discomfort), economic (medical costs that insurance companies refuse to pay), social (loss of confidential HIV and criminal records), and time burden (effort inadequately compensated or minimized). I think it remarkable that although the benefit-risk equation is non-quantifiable, an informed and disciplined IRB reaches a consensus on the vast majority of protocols, thereby protecting the research participants and our clinical research enterprise. *(Personal Reflection, 7/31/07)*

The HRPO Welcomes New Staff Members

Ofelia Rohan, Program Administrative Specialist

The Program Administrative Specialist is a new position at the HRPO. In her position, Ofelia will support the IRB Operations, Quality Improvement, and Educational activities, as well as provide specialized support to the HRPO Executive Director. Ofelia has served the UMB/UMMS in an administrative capacity for over 8 years. Prior to joining the HRPO, she worked in the Greenebaum Cancer Center, Department of Neurology, and Centers for Vaccine Development.

Susan Hines, MS, CRNP, CCRC, Director Education and Investigator Support

Sue was the Clinical Research Program Director for the Center for Clinical Trials since its opening in July 2000 where she had primary responsibility for assisting principal investigators and research teams in planning and executing research protocol implementation and for providing research coordination services. She has over 20 years of research experience. Ms. Hines is a Pediatric Nurse Practitioner and was the Program Coordinator for the Pediatric/Perinatal HIV/AIDS Program at UMB from 1987 to July 2000. In addition, she has developed and implemented a broad range of educational programs in the conduct of research according to Good Clinical Practice (GCP) standards at the local, national, and international levels, including Africa, Brazil, the Caribbean, and Japan.

Judy Murray, BS, CCRC, Quality Improvement Specialist

Judy comes to us from the Division of Urology. She has been a clinical research coordinator on campus for 7 years. Her background is in Orthopedic medicine but she discovered research while taking courses at UMCP. She started coordinating clinical trials at the VA in 2000 and has since moved to UMB. Judy understands the practical side of conducting research and uses this knowledge to assist investigators in improving the conduct of their research.

Jody Winkenwerder, BS MT, CQIA, Quality Improvement Specialist

Jody graduated from UMB with a BS in Medical Technology. She worked in clinical and reference laboratories prior to moving into the private sector. She has spent over 15 years in the Regulatory Affairs/Compliance field with a local medical device company. She has prepared product submissions for the FDA and USDA. As part of the submission process, Jody has worked with clinical research associates in reviewing study protocols, reviewing study data and ensuring study compliance to the applicable regulations. She has 3+ years experience in auditing and reviewing corrective actions as quality improvement activities.

If you would like to contribute a story, ideas, accomplishments related to human participant research in the HRPO Newsletter, email Sue Hines at shines@som.umaryland.edu for consideration.

Reminder: The HRPO Comments Box is on-line!

To access the comments box click on "[HRPO Comments Box](#)" on the HRPO website. All responses are anonymous.