



# AAHRPP RE-ACCREDITATION SITE VISIT A SUCCESS—THANKS TO ALL THAT PARTICIPATED !

INSIDE THIS ISSUE:	HRPO NEWS	CICERO IS HERE!
<p><i>Upcoming Events</i> 1</p> <p><i>HRPO News</i> 1</p> <p><i>CICERO Update</i> 1</p> <p><i>New Staff</i> 2</p> <p><i>Policies—Section I</i> 2</p>	<p><b><u>When was the last time you checked the...</u></b></p> <p><b>UMB HRPP Policies and Procedures Manual?</b></p> <p>The UMB Human Research Protections Program and Institutional Review Board Policies and Procedures Manual has been re-organized into a new format (<i>updated August 15, 2008</i>):</p> <ul style="list-style-type: none"> <li>◇ Streamlined to eliminate duplication and reduce references to BRAAN</li> <li>◇ Organized according to AAHRPP’s five areas of responsibilities (Domains):               <ol style="list-style-type: none"> <li>1. Organization- <i>SEE PAGE 2</i></li> <li>2. Research Review Unit, including IRBs</li> <li>3. Investigator</li> <li>4. Sponsored Research</li> <li>5. Participant Outreach</li> </ol> </li> </ul> <p>It is your responsibility to be knowledgeable about and compliant with the UMB HRPP Policies and Procedures (SOP I.3.A). Please consult the HRPO website for current version:  <a href="http://medschool.umaryland.edu/orags/hrpo/policies.asp">http://medschool.umaryland.edu/orags/hrpo/policies.asp</a></p>	<p><b>WE HEARD YOU!!</b></p> <p>In response to your feedback about BRAAN and its limitations, we are bringing you a new electronic protocol management system called <b>CICERO: Comprehensive, Institutional Collaborative Evaluation of Research On-line</b>. This system was selected after extensive evaluation of 8 systems by key individuals and groups in the UMB research organization. It is the best product currently on the market and is in use by a variety of organizations. The new system is quite different from BRAAN. While the technology of CICERO is universal, it is being developed internally to meet the specific needs of the UMB research community. The system is flexible and can be modified and expanded as needs change.</p> <p>Here are a few new features in CICERO:</p> <ul style="list-style-type: none"> <li>⇒ User names and passwords can be retrieved via email</li> <li>⇒ Anyone can initiate a new protocol, however only the PI can submit the protocol</li> </ul>
<p><b>Upcoming Events:</b></p> <p><b><u>Research Round Table</u></b>          T1R15 (Shock Trauma Classroom)          *RVSP Requested*</p> <p><b>Topic: <u>Clinical Investigation of Drugs</u></b>          September 23, 2008 12:00-1:00pm</p> <p><b>Topic: <u>Exempt Research</u></b>          October 22, 2008 12:00-1:00pm</p> <p><b>Topic: <u>Amendments</u></b>          November 11, 2008 12:00-1:00pm</p> <p><b>Topic: <u>Renewals</u></b>          December 9, 2008 12:0-1:00pm</p>	<p><b>AAHRPP Site Visit</b></p> <p>On June 23-25, 2008, four AAHRPP site visitors conducted on-site review of the UMB HRPP and interviewed members of the research community, including IRB members, investigators, research staff and organizational leaders. In general, feedback was extremely positive and included commendation in four areas:</p> <ol style="list-style-type: none"> <li>1. Strong organizational leadership and support</li> <li>2. Data and Safety Monitoring Plan &amp; IRB review</li> <li>3. Protections for decisionally-impaired participants</li> <li>4. Dedication and attentiveness of Investigational Drug Service (IDS) Pharmacists</li> </ol>	<p><b>CICERO UPDATE CONTINUED ON PAGE 2</b></p> <p><b>HRPO Contact Information:</b>          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  <a href="mailto:HRPO@som.umaryland.edu">HRPO@som.umaryland.edu</a>  <a href="http://medschool.umaryland.edu/hrpo">http://medschool.umaryland.edu/hrpo</a></p>
<p><b><u>“Human Participant Research @ UMB 101: What You Need To Know To Get Started”</u></b>          T1R15 (Shock Trauma Classroom)          *RSVP Requested*</p> <p><b>October 7, 2008:</b> 1:00pm-2:00pm</p> <p><b>November 17, 2008:</b> 10am-11:00am</p> <p><b>December 5, 2008:</b> 12:00pm-1:00pm</p> <p>For more information or to RSVP please contact <b>Deb Grady</b> at <a href="mailto:HRPOEducation@som.umaryland.edu">HRPOEducation@som.umaryland.edu</a></p>	<p><b>Mission of the UMB Human Research Protections Program (HRPP):</b></p> <p>The mission of UMB 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. (<i>Updated 2/1/08</i>)</p>	

**UMB HRPP Policies and Procedures Manual**

**UMB HRPP Policies and Procedures Section I:**

**The Organization**

The UMB Human Research Protection Program (HRPP) is a dynamic, organization-wide, integrated program that serves to protect the rights and welfare of participants involved in human subject's research. The UMB President has delegated responsibility for the HRPP to Dr. Bruce Jarrell, Executive Vice Dean, School of Medicine. All components of the UMB HRPP work in tandem to protect the rights and welfare of research participants along the research continuum from conceptualization through and beyond study closure. *Section I* of the Manual provides information that includes:

- \* Description and plan of HRPP (SOP I.1.A)
- \* Scientific review of research (SOP I.1.B)
- \* Institutional Official (SOP I.1.C)
- \* Ethical standards and practices (SOP I.1.D)
- \* Communication of HRPP components (SOP I.2.D)
- \* HRPO (SOP I.2.G)
- \* Determination of human research (SOP I.3.C)
- \* Exempt research (SOP I.3.D-E)
- \* Regulatory guidance (SOP I.3.F)
- \* Conflict of Interest (SOP I.3.G-H)
- \* Investigator noncompliance (SOP I.3.I)
- \* Reportable events (SOP I.3.J)
- \* Plan for auditing and monitoring (SOP I.3.L-L.1)
- \* Education and training requirements (SOP I.4.A)
- \* Use of investigational or unlicensed test articles, including emergency use (SOP I.5.A-C)

**CICERO UPDATE CONTINUED FROM PAGE 1**

New features of CICERO, cont.

- ⇒ Help text to provide guidance with submission and regulatory issues
- ⇒ CICERO will interface with IBC, RSC, GCRC, VA and IDS and will help streamline the process for multiple approvals

There will also be a few new policies associated with CICERO, including:

- ⇒ Conflict of Interest documentation required for all research personnel
- ⇒ Current literature review summary
- ⇒ Continuing review will require departmental sign off

There will be a gradual "roll-out" of CICERO through December 2008—keep an eye out for informational emails!

**The HRPO Welcomes New Staff Member**

**Deborah Grady, RN, MS, CCRC, Quality Improvement Specialist**

Deb comes to us from the Department of Epidemiology and Preventive Medicine, where she worked for five years as a Clinical Research Coordinator in MRSA research. Prior to that position, Debbie instituted a new Clinical Research program in the Department of Urology at the University of Pittsburgh. In this position, she gained a variety of research experiences including running a multi-site, investigator initiated study. She is a Registered Nurse and worked for 10 years at the Johns Hopkins Hospital where she developed innovative education methods for patients. Debbie received her Master's of Science in Health Policy at the UMB School of Nursing and does consulting with a health policy think tank in Washington DC. Debbie is also the local Chapter Chair of the Association of Research Professionals (ACRP).

**Laura Evans, M.A., IRB Analyst** is new to the UMB School of Medicine. She most recently worked as a Consent Form Specialist for the Johns Hopkins School of Medicine, where she worked in the Office of Human Subjects Research, and with the IRB and the research community evaluating and improving consent documents for proposed and existing research protocols. Formerly, Ms. Evans worked as a Research Assistant at The Hilltop Institute reviewing state and federal health regulations, contributing to legislative and executive summaries, and providing qualitative and quantitative analyses to research studies involving access to healthcare, medical errors, respite care, and long-term hospitalization in Maryland. She holds a Master's of Arts degree in Applied Sociology with a background in health policy and medicine.



**Do You Know About . . .**

**ACHRP??**

ACHRP stands for Advisory Committee for Human Research Protections. The ACHRP is comprised of Institutional leaders from every School at UMB who advise the Institutional Official and Executive Director of HRPP. The ACHRP meets twice per year to receive formal updates on the HRPP and discuss issues that impact the entire HRPP (SOP I.2.E).

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!**

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.