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**Upcoming Events:**

**December 14th —**

**Human Participant Research @ UMB 101: "What You Need To Know To Get Started" HSF II Auditorium**

**Dec 25th to Jan 1st, 2007**

**The HRPO office will be closed for the Winter Break. We will reopen on January 2nd, 2007.**

**Dec 7th, 2006**

**Making it public!**

**Privacy and confidentiality in Human Research participant**

*For More Details visit the HRPO Website.*

**Special Announcement**

Unaffiliated members are needed for the IRB. If you know of someone who may be interested, please have them contact the HRPO's office at 410-706-5037.

**NEWS OF THE MONTH:**

**University of Maryland, Baltimore Radiation Safety Committee (RBC)**

The University of Maryland Baltimore (UMB) Radiation Safety Committee is established as a sub-committee of the Risk Management Committee. The RSC is responsible for ensuring that radioactive materials and radiation producing machines are acquired, used, handled, stored and disposed of in accordance with the Maryland State Regulations for the Control of Ionizing Radiation, COMAR26.12.01.01. Under this structure, the authority of this committee covers, UMB, University of Maryland Baltimore (UMBC), University of Maryland Medical Center (UMMC), Center of Marine Biotechnology (COMB), and University of Maryland Biotechnology Institute (UMBI). Unlike the Institutional Review Board (IRB), the RSC does not have the authority to approve or regulate activities at other institutions, e.g., the VA. In situations involving research at other sites, the RSC can act as a technical consultant to the IRB.

The RSC has three standing subcommittees:

the Human Use Subcommittee (HUSC), the Radioactive Drug Research Committee (RDRC) and the Basic Research Subcommittee (BRSC). The HUSC/RDRC has established a three-tier classification scheme for research involving the administration of radiation to human subjects.

**Tier 1:**

These are protocols where the exposure of subjects to ionizing radiation is required as part of their routine medical care and is not necessitated by the research. Tier 1 research would not require completion of the application or review by the HUSC.

For example, research where a population of subjects has been shown to qualify for inclusion or exclusion in a study based on the results of radiation procedures conducted as part of their medical care would qualify as Tier 1 since the dose was not necessitated by the research.

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**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.

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/>

**Contact Information:**

The HRPO hours of operation are Monday - Friday 8:30 am - 4:30pm  
[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](mailto:HRPO@som.umaryland.edu)  
Phone: (410) 706-5037

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However, research, which proposes to “screen” subjects using a radiation procedure, e.g., chest x-ray, to determine if they qualify for inclusion or exclusion in a study, would not qualify as routine medical care

**Tier 2**

These are proposals where exposure of subjects to ionizing radiation is required as part of the research, there is no direct medical benefit to the patients, and the total radiation dose to the subjects is within the accepted dose limits established by the RSC. If the criteria are met, the application will be reviewed by the Technical Review Panel (TRP) on the HUSC.

**Tier 3**

These are proposals which do not qualify as either Tier 1 or Tier 2. These studies include procedures where, either the projected dose(s) exceed(s) the accepted limits or the procedure is investigational, e.g., a radioactive research drug. Tier 3 research proposals must be reviewed by the full HUSC and/or RDRC.

For more information on the RSC, contact Candi L. Schaub at 410-706-6281 or at [cschaub@af.umaryland.edu](mailto:cschaub@af.umaryland.edu). The applica-

tion and instructions for submission of research protocols for RSC review are found at

<http://www.ehs.umaryland.edu/rad/radforms.cfm>

*Contributed by: Candi L. Schaub, BS.  
Radiation Safety Officer*

**HRPO Welcomes New Staff Members**

Sue Tindall - IRB Analyst Team Leader

Dawn Bozzolo - IRB Analyst

Karen Stewart - IRB Analyst

**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.

**Did You Know That:**

**CITI Good Clinical Practice Training and ICH.**

An online course is now available for the entire research community and is strongly recommended for all those involved in Biomedical Research. For more information on how to access the training, visit the HRPO website. [http://medschool.umaryland.edu/hrpo/education\\_citi\\_gcp.asp](http://medschool.umaryland.edu/hrpo/education_citi_gcp.asp)

If you have any questions please contact Khristy Bozylinski, MS, CCRC, HRPO Program Manager for Education at 410-706-4514 or [kbozylinski@som.umaryland.edu](mailto:kbozylinski@som.umaryland.edu)

**New Electronic Protocol Management System Announced**

The Human Research Protections Office is pleased to announce that the Dean's office has provided funding for a **new electronic protocol management system** and that a contract has been secured with **Click Commerce**. Click Commerce is a publicly traded company (NASDAQ symbol CKCM). Their product is currently installed and operating in six of the top ten NIH-funded research institutions in the country, with over thirty clients that use them in the IRB Operations venue...

*(Read the rest of the press release on the HRPO Website)*