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Upcoming Events:

November 2nd

Human Participant Research @ UMB 101: "What You Need To Know To Get Started"

November 10th

Veteran's Day

Coming in December...

**December 7th— Making it Public! Privacy and Confidentiality in Human Participant Research
Time: 12 Noon - 1:00pm
MSTF Auditorium**

For More Details visit the HRPO Website.

Special Announcement

The HRPO Office will be closed November 23rd to 24th for the Thanksgiving Holiday. We will reopen on November 27, 2006

NEWS OF THE MONTH:

IRB Operations FAQ (Part 1)

Q: What information do I need to provide to the IRB in a final report?

A: According to Policy and Procedure 3.J.3 – System Closures – the following information should be provided to the IRB when closing out a study:

1. Has informed consent been obtained from all participants and are signed consent forms on file for all participants? If not, explain?
2. Did enrollment exceed the number approved by the IRB? If so, explain?
3. Summarize any information pertaining to risks obtained since the last reporting period and not yet reported to the UMB IRB (Serious adverse events at this site or other sites; participants withdrawn voluntarily or involuntarily; complaints received from participants, data safety reports etc).
4. For drug studies, summarize all adverse drug reactions in which a relationship to the study drug cannot be ruled out. Was the frequency of serious but expected side effects different from what you anticipated? If yes, please explain.
5. Have all obligations to the research participants been fulfilled (for example, promises to provide them with results of clinical tests or overall study findings)? If not, explain.

6. What were the principal findings of the study? Summarize any results (preliminary or final) obtained in the study. Please state whether the results to date have been consistent with what you expected.

Q: In BRAAN, there is a place for me to respond to Board Modifications. Is there a place for me to respond to Administrative Modifications?

When you receive Administrative Modifications, the requested changes should be made directly to the stated section of the protocol or consent. There is no place to "respond" to the Administrative Modifications as this is not a letter from the IRB or the Executive Committee. The Administrative Modifications are sent so that the protocol, amendment or renewal is complete and consistent throughout prior to being reviewed by the fully convened IRB or Executive Committee. If you wish, a Word or PDF document can be attached in Section S with responses to the Administrative Modifications. However, this is not required.

Q: Why does the IRB Meeting date assigned to my protocol change?

The Biomedical Research And Assurance Network (BRAAN) assigns a meeting date to all
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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)
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transactions (i.e. New Protocols, Renewals, and Amendments) as the PI submits them in the system. This date corresponds to the fully convened IRB Meeting whose minutes will document the review and determination of the transaction (i.e. Expedited or Full Board). Expedited transactions, as defined by HRPP policies and procedures, are transactions that do not require review and determination by the fully convened IRB Committee. The assigned IRB Meeting date can change because the review of the transaction is in progress and has not been completed by the occurrence of the currently assigned IRB Meeting Date. Therefore, the IRB Meeting date is changed in the system so the Minutes for the next available IRB meeting can document the transaction in its entirety.

Full Board transactions as defined by HRPP Policies and Procedures are transactions that do require review and determination by the fully convened IRB Committee. The assigned IRB Meeting date can change because the protocol requires more information or revision, the PI has not responded to the administrative modifications in a timely manner, or the review of the transaction requires specific expertise (i.e., an oncologist to review to review Oncology protocols), which may or may not be available at each IRB Meeting. So, a protocol's assigned IRB Meeting date may be changed to an earlier or later IRB Meeting whose Committee possess the required expertise.

Q: How often do I need to complete the CITI training modules?

A: All members of the UMB scientific and research community who are engaged in human subjects research are required to complete the CITI Training Modules. Once you have taken the Basic CITI training, you are required to take the refresher course annually (on or before the anniversary of your basic training completion date). Failure to complete the refresher course may result in loss of research privileges. CITI training may be accessed through the HRPO website at <https://medschool.umaryland.edu/hrpo> and clicking on "Education and Training" or by logging onto <https://www.citiprogram.org/default.asp>

Submitted by: Cynthia Shaffer, IRB Analyst, Joe Smith, IRB Analyst, Suzanne Grim, IRB Analyst & Tiffany Smolinski, Director, IRB Operations.

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 is now offering a GCP/ICH online training course, which is recommended for all those involved in research. See the HRPO website for instructions on how to access the training.

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

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)