



# CICERO UPDATES

## INSIDE THIS ISSUE

<i>Upcoming Events</i>	1
<i>CICERO Update</i>	1,2
<i>HRPO News</i>	2
<i>AAHRPP</i>	2
<i>Compliance Update</i>	3

## UPCOMING EVENTS

**HRPO Research Grand Rounds**  
Shock Trauma Auditorium

March 24, 2009 4pm  
**"Unanticipated Problems Involving Risk to Research Participants or Others"**  
 Presented by Mary MacFadden

**HRPO Research Round Table**  
 T1R15 (Shock Trauma Classroom)  
 \*RSVP Requested\*

Topic: **Recruitment and Advertising**  
 March 27 12:00pm-1:00pm

Topic: **Informed Consent Waivers**  
 April 14 12:00pm-1:00pm

Topic: **Device Regulations**  
 May 20 12:00pm-1:00pm

**"Initiating Human Participant Research at UMB"**

Offered Bi-Monthly  
 T1R15 (Shock Trauma Classroom)  
 \*RSVP Requested\*

**March 9** 10:00am-11:00am  
**May 5** 11:00am-12:00pm

For more information or to RSVP please contact **Deb Grady** at

[HRPOEducation@som.umaryland.edu](mailto:HRPOEducation@som.umaryland.edu)

## WEEKLY CICERO UPDATES

### CICERO Updates - Every Friday!

Every Monday the School of Medicine IT group performs as needed upgrades to CICERO. Periodically these upgrades can affect CICERO users and their existing transactions.

CICERO users now receive emails every Friday afternoon indicating any changes that will result from the up grade performed to the system on that coming Monday. Some recent upgrades are below:

<b>Closure Reports</b>	For all <u>approved</u> studies in CICERO you will now have the option to submit a closure report.
<b>Change to "Unsure if this proposal requires IRB review"</b>	You will now be able to <u>attach any supporting documents</u> to your "Unsure if this proposal requires IRB review" application.
<b>Withdraw Submission</b>	You will now be able to <u>Withdraw</u> your submission when Administrative Modifications are required. You will not have to address the modifications to withdraw your application.
<b>Change to contact activity</b>	When selecting "Contact HRPO Staff" you will now be able to <u>attach documents</u> .

### Frequently Asked Questions (FAQs) in CICERO:

You may now use the use the Frequently Asked Questions (FAQ) option in CICERO to submit your CICERO questions/issues. Someone will respond to these issues promptly.

The Help/FAQ button can be located in the upper left hand corner of CICERO when you are logged into the system.

## INFORMED CONSENT

### Informed Consent Approvals in CICERO

The process for generating approved consents in CICERO is slightly different for expedited transactions, in that the HRPO staff manually prepares approved consent documents after the approval letter is sent to the research team. This is done to ensure that the approval date on the consent is consistent with the date the transaction was approved by the Executive Committee. This means that there is a slight lag between the time a transaction receives approval, and the time the approved consent forms are prepared. HRPO staff does follow through on the completion of all approvals and consent documents, and typically prepares these approved consent documents within the business day.

### CICERO Online Training

- ▶ How to create a sponsored study
- ▶ 10 minute introduction to the new features

<http://medschool.umaryland.edu/ORAGS/hrpo/cicero.asp>

**CICERO Continued, Page 2**

### 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](mailto:HRPO@som.umaryland.edu)

<http://medschool.umaryland.edu/hrpo>

**Check the HRPO website for additional educational offerings throughout the year:**

<http://medschool.umaryland.edu/hrpo>

*CICERO Continued*

**Continuing Review Applications in CICERO**

The HRPO has received numerous Continuing Review of Previously Approved BRAAN applications in CICERO with the following issues:

**1. Incorrect Risk Level Designation**

Please remember that the CICERO application contains 2 risk level designations: minimal risk and greater than minimal risk. If your BRAAN application was previously designated Low, Moderate or High risk then please select “Greater Than Minimal Risk” as the risk designation in your CICERO application. Failure to indicate the BRAAN approved risk level can result in a **significant** delay in the processing of your application. Also, please note that minimal risk applications do not necessarily equate to being reviewed **expeditiously**.

**2. Modifications**

When submitting Continuing Review of Previously Approved applications in CICERO please remember that **NO** changes are allowed. Once a Continuing Review application has been started in CICERO amendments in BRAAN can **NOT** be submitted. For example, do not add or remove research staff members to your application or modify recruitment activities and research procedures. The exact same information contained in the BRAAN application should be reflected in the CICERO application. Any changes must be submitted via a modification after the application has been approved in CICERO.

**3. Continuing Review Delays**

UMB HRPP SOP II.2.D: Continuing Review of Research states “To allow adequate time for IRB review and to avoid delay, the investigator will submit a Renewal Request in the electronic system preferably **six weeks** prior to the IRB expiration date”. It is the **Principal Investigator’s responsibility** to ensure that their continuing review applications are submitted within six weeks prior to the IRB expiration date. If a study has expired NO research activities may be conducted. If you do not submit your Continuing Review according to our policy, the HRPO cannot guarantee your study will be IRB approved prior to your expiration date.

*CICERO Continued*

**New CICERO Account Requests**

When requesting a new CICERO account online it is important to ensure you provide the correct information for the account. If invalid information is provided for the account request, that request will be automatically deleted.

If you are requesting an account on the behalf of someone else, please inform the individual you are doing so and obtain their correct information.

If you have any questions regarding establishing new CICERO accounts please contact Khristy Bozylinski at 410-706-4514 or kbozylinski@som.umaryland.edu

*HRPO News*

**HRPO FY2009 Quarter 1 and 2 Accomplishments:**

(July 1, 2008–December 31, 2008)

**IRB Operations**

**Transactions turnaround times (average)**

Full Protocol review	36 days
Expedited transactions	12 days

**AAHRPP**

On December 12, 2008, the UMB Human Research Protections Program (HRPP) earned full accreditation by the Association for the Accreditation of Human Research Protections Programs (AAHRPP). This is a voluntary process for high quality HRPP’S in order to promote excellent, ethically sound research. AAHRPP accredits institutions who reach performance standards that surpass the threshold of state and federal requirements. To date, 159 institutions have achieved accreditation.

THANK YOU to all who participated in the re-accreditation site visit June 2008 and to the entire UMB research community for your dedication.

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>**

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.



## COMPLIANCE UPDATE

### INFORMED CONSENT: FINDINGS OF NONCOMPLIANCE

The HRPO Quality Improvement team continues to find numerous instances where participants are being consented on unapproved or expired informed consent documents. Twelve out of 21 audits conducted within the past 3 months included one or more of the following findings:

- Participants signed informed consent documents while the study was expired
- Research procedures were initiated prior to participants signing the informed consent documents
- Participants signed informed consent documents that were not approved by the UMB IRB
- Participants signed informed consent documents from institutions other than UMB
- Participants signed expired informed consent documents

Participants signed incorrect version of informed consent documents

**Please note that this is NONCOMPLIANCE with Federal regulations and institutional policies and must be reported accordingly.**

Principal investigators are responsible for ensuring that participants are consented using only the current UMB IRB-approved version of the informed consent document and that no research procedures are conducted prior to obtaining informed consent.

• Please see **UMB HRPP Policy I.3.I: Investigator Noncompliance**, **UMB HRPP Policy III.1.F: Investigator Responsibilities for Prospectively Obtaining Legally Effective Informed Consent** and **UMB HRPP Policy II.7.A Informed Consent: IRB Review of Legally Effective and Prospectively Obtained Informed Consent**.

- Pay particular attention to SOP II.7.A:
  - o Section III (using approved informed consent documents),
  - o Section V (obtaining consent prior to any research procedures),
  - o Section VI (obtaining approval prior to implementing modifications).

**Please review your research studies to determine that all participants were consented appropriately. Report all deviations to the IRB via CICERO, or BRAAN if the study has not been converted to CICERO.**

For questions, contact Sue Hines, MS, CRNP, HRPO Director of Quality Improvement at 6-1080 or [shines@som.umaryland.edu](mailto:shines@som.umaryland.edu)