



CICERO LIVES!!

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Congratulations!

Susan Buskirk, MS has been appointed Assistant Dean for Human Research Integrity and Compliance. In this expanded role, Susan will assume additional responsibilities related to oversight of human research involving conflict of interest.

CICERO Transactions

Thank you UMB Research Community!

CICERO has been live since September 8, 2008. The following activities have occurred in the live system as of November 20, 2008:

Draft protocols	223
Protocols submitted and passed Dept review	70
Protocols approved	19
Reportable events submitted	2
Modification submitted	1

UPCOMING EVENTS

HRPO Research Grand Rounds
Shock Trauma Auditorium

December 10, 2008 2pm
“Unanticipated Problems Involving Risk to Research Participants or Others”
 Presented by Mary MacFadden

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

Topic: Renewals
 December 9 12:00-1:00pm

“Human Participant Research @ UMB: What You Need To Know To Get Started”
 T1R15 (Shock Trauma Classroom)
 RSVP Requested

December 5 12:00pm-1:00pm

For more information or to RSVP please contact **Deb Grady** at **HRPOEducation@som.umaryland.edu**

The 2009 HRPO Education Calendar will be distributed and posted on the HRPO website in December!!

HRPO FY2008 Accomplishments:

IRB Operations

Transactions turnaround times (average)

Full Protocol review	21 days
Expedited transactions	11 days
Total number of transactions	23,086
Approval of New Protocols	549
Approval of Continuing Review	1133
Modification Transactions	1760
Expedited Transactions	2243
Reportable events	2388

Quality Improvement/Compliance

Total Activities 2938

Federal Reports	21
For Cause Audits	16
Routine Audits	40
Spot Audits	13
Investigator Self Assessments	15
Participant Complaints	20
Monitoring Visits	19
IRB Operations Effectiveness	294
IRB Checklist Monitoring	2500

Education and Investigator Support

Total Programs 387

HRPO Staff	55
IRB Member Education	87
UMB Research Community	133
External	8
Investigator Support	104

CONGRATULATIONS TO THE HRPO AND UMB IRB!

By December 1, 2008, all Schools at UMB will be using CICERO for all new human protocols and continuing reviews. The BRAAN system will remain active over the next year to allow the gradual conversion of existing protocols. For those protocols currently approved in BRAAN, all modifications and reportable events will be submitted into BRAAN until the protocol has been successfully converted into CICERO via continuing review.

We appreciate the research community's patience as we work through development challenges that are experienced with implementation of such a robust and complex system.

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

Mission of the UMB Human Research Protections Program (HRPP):

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.

International Research

The University of Maryland Baltimore faculty conduct research in 18 different countries: Africa—8; Europe—4; Asia—3; South America—2; North America (non-US)—1. Types of studies conducted include epidemiological, interventional, prevention, social/behavioral, and clinical trials. The HRPO is committed to providing education, support and oversight of UMB research faculty and staff for human subjects research conducted within the institution and has expanded these services to UMB international sites. In the past two years, HRPO staff members visited three UMB international sites as part of the UMB HRPP which promotes a spirit of collaboration to provide the best protections for our research participants.

Susan Buskirk, assistant dean, Human Research Integrity and Compliance, provided leadership for all three visits, each with a specific purpose and focus. Dr. Bruce Jarrell, Executive Vice Dean, UM SOM and the UMB Institutional Official, allocated personnel and other resources necessary to successfully conduct these site visits. Site selection was determined by a variety of factors including stage of research activity, investigator request, study risk category/phase/design, number of subjects enrolled, and vulnerable populations recruited. The sites visited were Abuja, Nigeria; Bandiagara, Mali; and Bamako, Mali. UMB will continue to provide support and resources to ensure that international sites conduct ethical research that protects research participants.

Unanticipated Problems Education

Thank You for Your Participation!

During the AAHRPP re-accreditation site visit which included interviews with various members of the UMB research community, the site visitors reported a lack of knowledge or familiarity with the terminology “Unanticipated Problems Involving Risk to Research Participants or Others.” In response, the HRPO initiated an intensive education and outreach program to raise awareness and increase the knowledge base of the UMB research community. Following are the results thus far of the educational initiatives:

- 172 people attended one the special Grand Rounds sessions—there were 18 sessions held from July through September.
- 6 sessions were held for individual departments/divisions with a total of 58 attendees.
- As of October 9, 841 people have completed and passed the on-line training.

The education has been successful! Since July, 16 unanticipated problems involving risk to research participants or others have been reported to the IRB. In comparison, during the entire FY 2008, 6 unanticipated problems were reported.

Thank you to all that completed this important training!!

The HRPO Welcomes New Staff Members

Galina Tucker, CCRC, Research Compliance Specialist comes to us from the Department of Radiation Oncology, where she managed the Clinical Research Office for five years and coordinated oncology trials for two years prior to that. Galina holds a Doctorate Degree in Pediatrics/Medicine from the State University in Russia and a Clinical Research Coordinator Certification by ACRP (Association of Clinical Research Professionals). Galina has experience with developing clinical trials, setting up research sites, negotiating contracts, conducting compliance reviews and working with patients and research subjects. She also has served on the UMB IRB as a Board member

Kate Wimer, Office Assistant is new to the UMB School of Medicine and is responsible for assisting HRPO staff with administrative and organizational duties. She most recently worked as the primary contact between management, personnel, clients and vendors in the disbursement department at Omni Land Settlement Corporation. Previously, Ms. Wimer worked as a sales associate and as an office administrator in Irvine and Pleasanton, California.



Congratulations to HRPO staff!!

Carley Benham promoted to Program Manager, Quality Improvement

Demian Lewis promoted to Program Manager, IRB Operations

In these new capacities, Carley and Demian will coordinate with the HRPO Directors to manage the day-to-day functioning of their respective programs.

We congratulate them on their new positions!!

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 for consideration.