



# NEW IRB VICE CHAIR

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## HRPP UPDATE

### RESEARCH EDUCATION



The HRPO is developing a series of audio-visual presentations regarding the IRB submission process, CICERO "how-to's" study conduct, and human subject protections that will be accessed via the HRPO website. Most presentations will be 10-15 minutes in length and can be viewed 24 hours a day.

Please check the [HRPO website](#) for any updated information.

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**COMING FALL 2009:**

**EMBRYONIC STEM CELL  
RESEARCH OVERSIGHT  
COMMITTEE**

**SOM CONFLICT OF INTEREST  
COMMITTEE**

● ————— ●

## ANNOUNCEMENT!

### Dr. Stephan Seliger, MD MS Appointed UMB IRB Vice Chair

Dr. Bruce Jarrell, MD has appointed Stephen Seliger, MD MS as UMB IRB Vice Chair, effective July 1, 2009. Dr. Seliger is an Assistant Professor in the School of Medicine Department of Medicine, Division of Nephrology and Attending Physician at the Baltimore VA Medical Center since 2005. He has over 12 years as a researcher, primarily in the area of chronic kidney disease and end-stage renal disease. Dr. Seliger has served as a UMB IRB member since 2006. He joins the UMB IRB Executive Committee as the 5th Vice Chair, under the leadership of Dr. Robert Edelman, IRB Chair.

## COMPLIANCE UPDATE:

### PRINCIPAL INVESTIGATOR OVERSIGHT

*The HRPO Research Compliance Team continues to find numerous instances where Principal Investigators (PIs) are not providing continuous and appropriate oversight of their research protocols and research staff. (Continued on 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>

## HRPO STAFF UPDATE

### Congratulations!

Kim R. Mathis has been promoted to Human Research Protections Office Manager. For the past 8 years, Kim has been solely responsible for the day-to day administrative functions of the HRPO. The HRPO is the coordinating office for the UMB Human Research Protections Program (HRPP) and the Institutional Review Board (IRB). *"The HRPP and HRPO would not be where they are today without Kim's efforts and commitment"* says Susan Buskirk, MS, Assistant Dean for Human Research Integrity and Compliance. **Please join us in congratulating Kim on this well-deserved accomplishment!**

## SAD NEWS



Vanessa Wildberger, wife of Dennis Wildberger, Information Systems Engineer in the Human Research Protections Office, died May 20, 2009 at their home in Stewartstown PA, after a long battle with cancer. Services were held on Sunday, May 24, 2009 in Stewartstown.

Vanessa was an antique dealer for over 27 years which led to client relations in several states. Vanessa enjoyed life to its fullest, being with family, and loving every moment with her daughter, Lily, 3 1/2 years old. In addition to her mother, husband and daughter, Vanessa is survived by two sons, two stepsons, three grandchildren, a sister and a brother.

### Compliance Update (CONT'D):

**Lack of appropriate PI oversight is NONCOMPLIANCE with Federal regulations and institutional policies and jeopardizes the rights, safety and welfare of research participants regardless of the risk level of the study.**

The following are excerpts from recent FDA Warning Letters available on the FDA website at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/>

**“You failed to personally conduct or supervise the investigation [21CFR312.60]:**

- “You did not adequately supervise individuals to whom you delegated study tasks.”
- “...you permitted individuals to conduct study tasks which they had not been delegated the authority to execute, and that your supervision of personnel to whom you delegated tasks was not adequate to ensure that the clinical trials were conducted according to the signed investigator statement, the investigational plan, and applicable regulations, and in a manner that protected the rights, safety, and welfare of human subjects.”
- “...per the Delegation of Duties & Authorized Signatures Form, you and/or your sub-investigator were the only individuals at your site designated by you to make trial-related medical decisions and to perform critical trial-related procedures. You informed FDA Inspector (...) that you gave your study coordinator, Ms. (...), the responsibility to determine subject eligibility into the study; the fact that she made such determinations is also evident in the medical and study records. Determination of subject eligibility is a trial-related medical decision, as well as a critical trial-related procedure. As such, this study task was not delegated to Ms. (...). Permitting Ms. (...) to conduct study tasks for which she did not have authorization demonstrates your failure to conduct the study in accordance with the study plan and applicable regulations.”
- “...your failure to personally conduct certain aspects of the study and/or to supervise study personnel adequately resulted in serious problems with the study including: the enrollment of ineligible subjects, the failure to follow numerous trial protocols, the failure to maintain adequate case histories, and the failure to report to the IRB unanticipated problems involving risk to human subjects.”

***DON'T LET THIS BE YOU!***

**“PI” does NOT stand for:**

**“Peripherally Involved” or “Present Infrequently”**

**THE SAFETY AND WELFARE OF RESEARCH PARTICIPANTS RESTS WITH THE PRINCIPAL INVESTIGATOR (PI)**

Section III of the UMB HRPP Policy and Procedure Manual is devoted to the Responsibilities and Oversight of Investigators.

### CICERO Information

#### Frequently Asked Questions (FAQs)

**Did you know that there are currently over 40 FAQs posted on the CICERO home page !**

- ⇒ Review the FAQ section in CICERO to obtain answers to the most frequently asked questions.
- ⇒ You can search to find a particular topic.
- ◆ Use the symbol % before and after the term to capture all questions with that word. For example, if you want to know how to change your password, type %password% into the search field and all FAQs containing the word “password” will appear.
- ⇒ ***If you do not see an FAQ related to your issue, you can submit that question and it will be addressed.***

#### Completing a Conflict of Interest (COI) Statement in CICERO

When a person is added as a study team member in CICERO, a COI statement must be completed. CICERO will send an email to the study team member stating “COI Disclosure Statement Required”. When the member logs into CICERO, the study needing the COI completed will be in their Inbox.

**To complete the COI statement, follow these steps:**

1. Click on the study name in Inbox
2. At the next screen (protocol workspace), click on “Submit COI” button on left side of screen.
3. Complete the required information. 4. If you answer “no” to all Part 1 questions, skip to the bottom of the page. Read and acknowledge the certification statement, then click “OK” on bottom right side of screen.
4. The COI disclosure statement will appear in the submission history.

**Remember that COI statements must be completed:**

- ◇ Annually for all study team members
- ◇ Any change in a study team member’s activities or financial status that may affect the protocol.

### CITI UPDATE

**ON MONDAY, AUGUST 3RD, AT APPROXIMATELY 8 AM EST, THE CITI PROGRAM WEB SITE WILL BE TAKEN OFF-LINE FOR A MAJOR SYSTEM UPGRADE. THE DOWNTIME IS EXPECTED TO BE APPROXIMATELY FIVE DAYS. PLEASE PLAN IN ADVANCE IF YOU NEED TO COMPLETE YOUR TRAININGS DURING THIS TIME !**

**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.**