



EMBRYONIC STEM CELL RESEARCH

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RAAC

On November 3, 2009, Susan Buskirk, Dr. Robert Edelman, and Sharon Bowser attended the Research Affairs Advisory Committee (RAAC) meeting to discuss activities and progress of the HRPO, IRB and CICERO. At the invitation of Dr. Jeff Hasday, Chair, this was an excellent forum for RAAC members to learn about the mission and scope of the HRPO, the IRB review process and factors affecting turn-around times, and to have their questions answered about CICERO development and capabilities.

The Research Affairs Advisory Committee (RAAC) was established to evaluate and provide advice to the Dean on enhancing research within the School of Medicine. This committee is comprised of department chairs, well-established investigators and Dean's office personnel. The mandate of the RAAC is to review current research activities and make recommendations on approaches to improving SOM research resources and capabilities.

CONGRATULATIONS!

Tiffany Smolinski Gommel, HRPO Director of IRB Operations, gave birth to a baby girl on September 23, 2009. Corinne Sophia weighed 6 lbs 15 oz and was 20 inches long.

Congratulations to Mom, Dad Eric, and big brother Ethan!!



BRAAN INACTIVATION

As of 11:59 pm on Monday, November 30, 2009, BRAAN was INACTIVATED and content is available as "Read Only."

This means that you will be unable to submit any transactions in BRAAN, regardless of the protocol expiration date. This includes new studies, continuing renewals, modifications, reportable events, and closure reports.

Please contact the HRPO with any questions.

HRPO UPDATES

HRPO FY2009 Accomplishments:

IRB Operations

Total Protocols in Process	1427
New full board protocols	282
New expedited review	1032
New exempt review	113
Total Modifications in Process	649
Full board	124
Expedited	523
Exempt	2
Total Reportable Events	927

Compliance

Total Activities	236
Federal Reports	37
Total audits	102
For cause	29
Routine	52
Spot	21
Investigator Self-assessments	62
Serious or Continuing Non-compliance	21
Participant Complaints or Issues	12
Study Monitoring	11
IRB Operations Monitoring	49

Education and Investigator Support

Total Attendance	3016
Total Programs	442
HRPO	37
IRB member	135
UMB research community	172
CICERO training	43
External education	10
Investigator support	45

STEM CELL RESEARCH

Last year the University of Maryland Baltimore welcomed stem cell research pioneer, Curt I. Civin, M.D., as the founder and director of UMB's Center for Stem Cell Biology and Regenerative Medicine. Dr. Civin brings to UMB a wealth of scientific knowledge and experience in the field of stem cell research as well as an acute understanding of the national and international guidelines governing embryonic stem cell research set forth by the National Academies of Sciences (NAS) and the International Society for Stem Cell Research (ISSCR).

Over the course of this past year, UMB established institutional policies for the review and oversight of embryonic stem cell research and constituted an Embryonic Stem Cell Research Oversight (ESCRO) Committee. The ESCRO Committee is charged with the review, approval, and oversight of all embryonic stem cell research to be conducted by University Researchers. Due to the multidisciplinary nature of projects involving embryonic stem cell research, the ESCRO Committee has been constituted and works in conjunction with the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB).

The ESCRO Committee is comprised of six voting members and a Committee Chair.

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HRPO Contact Information:

Hours of Operation:
Monday - Friday 8:30 am - 4:30pm

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STEM CELL RESEARCH, cont.

Leslie I. Katzel, M.D., Ph.D. serves as the UMB ESCRO Committee Chairperson. The Committee's membership includes representation from varied relevant scientific and ethical disciplines and includes a non-scientist member. Several *ex officio* members also provide a range of additional scientific and regulatory expertise. The fully convened UMB ESCRO Committee meets once per month. Five ESCRO Committee meetings have occurred to date, and the Committee has reviewed and approved thirteen ESCR Applications.

The UMB ESCRO Committee is committed to serving as an advisory panel and a resource for the UMB community; and under Dr. Katzel's direction, the ESCRO Committee has worked closely with Susan C. Buskirk, M.S., Assistant Dean Human Research Integrity and Compliance, and Drs. Jarrell and Civin in order to expand committee's role beyond the scope of research oversight. In addition, the ESCRO Committee has and will continue to review additional research projects involving use of other types of stem cells at the request of an investigator, another institutional committee (e.g., IRB, IACUC, etc.), or other entity such as a sponsor or funding agency (e.g., Maryland Technology Development Corporation (TEDCO)).

UMB has kept pace with the rapid scientific, ethical, and regulatory advancements in the field of stem cell research; and with the newly constituted ESCRO Committee, UMB is well-positioned to continue providing essential support to the community it serves.

As one of many components within the framework of the institutional Human Research Integrity and Compliance program, the ESCRO Committee is administratively supported by the UMB HRPO. For additional information, please contact Cynthia Shaffer at 6-5037 or cshaffer@som.umaryland.edu.

CICERO INFORMATION

[Frequently Asked Questions \(FAQs\)](#)

Did you know that there are currently over [50](#) 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.

HRPO WELCOMES NEW STAFF

Faith Beverly, BS, Program Management Specialist is new to the UMB School of Medicine. She most recently worked as an IRB Coordinator for Baylor Research Institute providing staff support for the IRBs and maintaining IRB records. Faith holds a Bachelor of Science in Biochemistry with a minor in Physical Science.

Summer Gonzalez, BS, CIP, IRB Analyst was formerly at Chesapeake Research Review, Inc, in Columbia, Maryland where she worked for three and half years as a Project Coordinator. She worked as a liaison between major Pharmaceutical companies and numerous CROs to the IRB. She is a certified IRB professional and she received her Bachelors of Science in Biology at UMBC.

Ericka Greer, BA, Research Compliance Specialist returns to the University of Maryland after having worked three and a half years as a Clinical Research Associate for a major contract research organization. Prior to that position, she worked as a Study Coordinator for both Pediatrics as well as Shock Trauma at UMB. She has experience coordinating investigator initiated protocols and monitoring industry sponsored protocols. Ericka received her Bachelor's of Arts degree in Psychology with a concentration in Biology from UMBC.

Jessica Rowe, M.A., IRB Analyst comes to us from the Department of Anesthesiology, where she worked as a Clinical Research Specialist. Prior to that position, Jessica work in the Department of Neurology, Division of Neuropsychology as a Research Assistant for two years. Jessica also interned at Hershey Medical Center as a research assistant with the Department of Neurology. She received her Master's of Arts in Applied Psychological Research from Pennsylvania State University.

Jason Smith, MS, CCDP-D, Research Compliance Specialist was previously the Director of Clinical Services at Roxbury Treatment Center, before returning to UMB. Several years ago, Jason was involved in research at UMB in the Center on Behavioral Treatment of Schizophrenia (CBTS), and the Mental Illness Research Education and Clinical Center at the VISN 5 Veterans Affairs Medical System. Jason received his Bachelor's of Arts degree in Psychology and Masters in Science from Shippensburg University

HRPO COMMENTS BOX

Do you have an issue, comment, suggestion or feedback for the HRPO staff or IRB? You can leave an anonymous comment in the [HRPO Comments Box](#)

on the HRPO website <http://medschool.umaryland.edu/hrpo>

Remember that all comments are anonymous.

If you have a general question that needs to be answered, please use the HRPO email at HRPO@som.umaryland.edu

Your email will be answered by the appropriate HRPO staff member.

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.