



From the October 17th RESCUE Meeting

RESearch Coordinators United in Excellence Newsletter

Announcements

Michelle Christiano, OHRP - Sharon Willing, who works in the HAC Administration office, is leaving to take another position. She will still be in research, but is transferring to Surgical Research, and will be working with Mary Anne Park and the Surgical Research Team.

Kim Koss, OHRP - We are still soliciting feedback with regards to the scheduled day of the week and time of the RESCUE Meeting. Please email me (kkoss@mcg.edu) any ideas you have regarding:

What are some days and times of the week that would be more convenient for you, with regards to RESCUE meetings?

What are some topics you would like to have at next year's RESCUE Meetings?

HAC Policies Update—WEBinar and class session scheduled for **October 30th**. More details in an email, but this webinar will cover new HAC policies updates to include revisions to the HAC form 107 (Continuation Submission Form). Watch your email for specific times and locations.

RESCUE *Top Ten* for October 2008

" Submission Anxieties "

#1 Routing – How can I remember all of the approvals needed?

OHRP Website:

- HAC Form 100 (Clinical Study Document Cover Sheet)
- HAC Policies and Procedures (for Initial Submission)

#2 Submission Packet – How do I know if I have included all of the required materials?

OHRP Website:

- HAC Form 100 (Clinical Study Document Cover Sheet)
- HAC Policies and Procedures (for Initial Submission) *Documents for Submitting for Initial Review and Approval*

#3 Submission Deadlines – Where are these published?

OHRP Website:

- Human Assurance Committee
- Other Approvals Needed

#4 Budgets – I don't know how to get started?

Office of Clinical Investigative Services

Sponsored Program Administration

#5 Regulatory Binder – How do I set this up?

OHRP Website:

Standard Operating Procedures

- Research Team Member SOPs
- #4 Regulatory Documentation

#6 Training and CVs – How do I get this information?

OHRP Website:

- HAC Form 100 (Clinical Study Document Cover Sheet)
- Policies and Procedures (OHRP)
 - *Required Education
- Training Requirements Checklist
 - *HAC Forms

#7 HAC Forms – I Need to Get a Handle on These. . .

OHRP Website:

- HAC Form 100 (Clinical Study Document Cover Sheet)
- HAC Policies and Procedures
- HAC Forms

#8 I don't know how to write an Informed Consent Document.

- Research Tools and Templates (found under OHRP and also under HAC)
- OHRP SOPs



#9 What if I receive stipulations?

It's okay—just complete the stipulations. If you have questions, call OHRP if you have questions. (HAC Administration Office at ext. 3110, 8397,1482)

10# Anything else?

Please call the Office of Human Research Protection. We are glad to help point you in the right direction—706.721-1481.

Guest Speaker—Richard Sattin, MD, FACP—HAC Chairman

Dr. Sattin discussed his background in medicine, to include his work at the Centers for Disease Control in Atlanta, GA, prior to joining MCG.

Currently, Dr. Sattin is the Director of Research for the Emergency Department at MCG. He has served on the Human Assurance Committee for over two years, and was appointed HAC Chairman this past September 15th.

Things on the horizon for researchers and the HAC:

Electronic submissions—Michelle has been working on this for about five years now and hopefully will see implementation in July 2009.

HAC going to two committees—split in half, and will meet twice monthly

HAC deadline—12:00 noon instead of 4:00 pm

Advice regarding stipulations: “You are almost always going to receive some type of stipulation. You can either complete the stipulation according to the direction in which it was given, or if you disagree with the stipulation, justify your initial position and communicate it to the HAC.”

Next RESCUE Meeting: November 21st **Speakers: Lee Little and Andrew Newton**
from the Legal Affairs Office at MCG.