



From the August 15th RESCUE Meeting

RESearch Coordinators United in Excellence

Announcements

OHRP - Congratulations to Angie Randazzo, whose son was born on Monday, August 11th. Christopher Isaiah weighed 8 lbs 8 ounces. Both Isaiah and Angie are doing fine.

Coordinator University is scheduled for October 6-10, 2008. This is a great opportunity for not only new coordinators, but also coordinators who left research and have recently returned. For more information and to register, go to

<http://www.mcg.edu/research/ohrp/training/documents/WebsiteversionRegistrationandAgendaOctober2008.doc>

Need your input: We are trying to get feedback with regards to the scheduled day of the week and time of the RESCUE Meeting. For the next few months, we will be asking for feedback on your evaluation forms for the following:

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

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

OCIS - New Timeline for OCIS REVIEWS. Beginning September 1, 2008, the timeline for turning in Human Assurance Committee submissions to the OCIS Review Office will be the Monday prior to the HAC submission deadline. Submissions will continue to be reviewed in the order received. Review recommendations will be provided no later than 2-3 days of receiving a complete submission. This new timeline should provide research staff with sufficient time to make any changes and corrections prior to routing HAC submission documents for signature. HAC submissions received after 5 p.m. on Monday can not be guaranteed the 2-3 day turn around time.

Any questions on the new timeline or the review process can be answered by calling the OCIS at extension 1-6247. Visit the OCIS website at www.mcg.edu/OCIS

August Top Ten (*Plus Ten More*) Acronyms Every MCG Researcher Should Know

OHRP	Office of Human Research Protection	Office that provides an internal monitoring function and educational forum for MCG
OCIS	Office of Clinical Investigative Services	Office that assists faculty with clinical investigations and provides a service to review clinical research studies to ensure adherence with institutional policies
DSPA	Division of Sponsored Program Administration	Office that provides an internal monitoring function and educational forum for MCG
IRB	Institutional Review Board	A group of professionals designated to review and approve clinical research to ensure that the studies are safe and effective for human participation
HAC	Human Assurance Committee	MCG's primary IRB charged with reviewing all research studies involving human subjects
CRRRI	Chesapeake Research Review, Inc.	Commercial IRB support and facilitate industry-sponsored clinical trials
IBC	Institutional Biosafety Committee	Committee responsible for assisting researchers in safely conducting research with biological materials
MCGHI	Medical College of Georgia Health, Inc.	Not-for-profit corporation formed to support the research / education mission of MCG and provide an environment for faculty of MCG, employees of PPG, and community physicians to deliver primary and specialty health-care
AAHRPP	Association for the Accreditation of Human Research Protection Programs	Organization whose accreditation process ensures the quality and integrity of a human research protection program of an institution
FWA	Federal Wide Assurance	A contract between MCG and the federal OHRP that states that all research within the MCG Health System is treated and regulated the same way regardless of funding source or status
GCP	Good Clinical Practices	Provides uniform standards for designing, conducting, monitoring and reporting in research involving human subjects
DSMB	Data Safety Monitoring Board	A committee established to monitor safety and data throughout the life of the study or specified time period
DRP	Description of Research Proposal	Used to describe how a research protocol will be conducted locally

ICD / CAD	<p>Informed Consent Document</p> <p>Children's Assent Document</p>	<p>Primary legal document for ensuring subject comprehension and understanding of the voluntary nature of research, and all that it entails</p> <p>Same as ICD, but written for children</p>
AE	Adverse Event	Unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research
SAE	Serious Adverse Event	<ul style="list-style-type: none"> -Death -An immediate life-threatening event -Hospitalization; -A permanent or substantial disability - Report of overdose -Report of congenital anomaly/birth defect
UAP	Unanticipated Problem	<p>Incident, experience or outcome that meets all of the following criteria:</p> <ul style="list-style-type: none"> -Unexpected -Related to the subject's participation -Suggests that the research places subjects or others at a greater risk of harm than was previously known
SOP	Standard Operating Procedure	Written instructions for the management of clinical trials to ensure that all activities and functions are carried out in a consistent and efficient manner
CITI	Collaborative Institutional Training Initiative	Web based training that is required by the HAC for all research team members before the protocol can be approved

Topic **Common Study “Goofs”
(and how to fix them)**

Goof #1 - Informed Consent Documents

Examples:

Missing Initials on pages

Blanks _____ where witnesses are supposed to sign

What to do? Note to file why the pages are missing initials; Note to file why the blank witness signature

** On the last page of the ICD, where the subject signs, he/she doesn't have to initial.

** In some studies, there doesn't always have to be a witness on the ICD. (With some of the exempt and expedited studies, the HAC may not require a witness for the informed consent document and process. Please call OHRP/HAC for further guidance.)

Goof #2 - Protocol Deviations

Examples:

Sponsor approves dose increase - but HAC is never notified

Protocol requires blood draw on week four, but blood is drawn on week five

What to do?

Complete a Protocol Deviation Form (HAC Form 120 PDV).

**Protocol deviations happen - it is oftentimes out of the study coordinator's hands, and not necessarily your fault. Don't let this stress you - it's okay.

Goof #3 - Submission Returned / Lack of Support Documentation

Examples:

Amendment to drop a site; forgot to drop the investigators at the site

Amendment to change PI or add Sub I; forgot to change support documents (ICD, etc.)

What to do?

One amendment can have a trickle effect across the entire study. Review your SOPs; maybe the SOPs can be written for some team members in a “visual” method (flow charts), etc.

Goof #4 - Expirations

Examples:

CITI

CVs

What to do?

For CVs, set one month out of the year where all team members are required to submit an updated CV.

For CITI, set up a spread sheet with everyone’s CITI completion dates, groups completed, and recertification dates. (For assistance with this, please call Kim Koss at ext. 1-1481).

**MCG CITI certification lasts for three (3) years. VA CITI certification lasts for one (1) year.

Next RESCUE

September 19th - *The Lowdown on Submissions*

October 17th - *Meet MCG’s HAC Chairman, Dr. Richard Sattin*

