

From the May 16 RESCUE Meeting

RESearch Coordinators United in Excellence

Announcements

HAC - Ivy Tillman reminded everyone that, for an amendment requiring full review, don't forget to provide three copies of the paperwork/amendments for the reviewers. If not, your amendment may be held up (which none of us want that.)

OHRP - Angie Randazzo directed everyone's attention to the handout about the Procedures for Using the Human Assurance Committee (SOP Number 07). These procedures can be found on the OHRP website at

http://www.mcg.edu/research/ohrp/documents/32SOP07_Using_the_HAC.pdf

Angie also noted the Procedures for Using Chesapeake Research Review, Inc. (SOP Number 06) which can be found on the OHRP website, at

http://www.mcg.edu/research/ohrp/documents/31SOP06_Using_CRRI.pdf

Angie reviewed the Clinical Study Document Cover Sheet, which is the HAC Form 100.

There have been a few revisions added. This can be found on the OHRP website at

<http://www.mcg.edu/research/ohrp/irb/hac/documents/HACform100rev1.DOC>

Finally, Angie introduced the Institutional Charter on Research Involving Human Subjects. This charter, which was approved by Dr. Rahn on April 22, 2008. **(see page 2 to read a copy of the charter.)** It can also be found on the OHRP website at

<http://www.mcg.edu/research/ohrp/irb/hac/charter.html>

OCIS - Lynette Henley introduced a new team member to OCIS, Nancy Flippen, who is a registered nurse and will be working as a research nurse clinician.

The Medical College of Georgia (MCG) agrees with the principles of the Department of Health and Human Services (DHHS) policies, the Belmont Report, the Nuremberg Code and the Declaration of Helsinki with regard to investigations involving human subjects. This institution agrees that a review, independent of the investigator, is desirable and necessary to safeguard the rights and welfare of human subjects of research investigations, and to fulfill the moral and legal obligations and commitments of the institution and implemented this review process in October 1967 under the direction of the Dr. Harry Barron O'Rear. Since 1967, each President of MCG has served as the institutional official and that tradition and respect for research continues today with Dr. Daniel Rahn serving as the current institutional official.

The MCG has assured the DHHS that it maintains an institutional review board (IRB) known as the Human Assurance Committee (HAC) in compliance with state and federal regulations to review plans of investigations involving human subjects, prior to the initiation of the investigations, to insure adequate safeguards. This review will be carried out in reference to:

1. The rights and welfare of the individuals involved The appropriateness of the methods used to obtain informed consent
2. The risks and the potential benefits of the investigations

The Medical College of Georgia also agrees to exercise surveillance of DHHS supported as well as all research projects using human subjects for changes in protocol which may alter the investigational situation with regard to the criteria cited above. The Medical College of Georgia further assures that it will provide advice and consultation to investigators on matters of employing human subjects in investigation, and also that it will provide whatever professional attention or facilities may be required to safeguard the rights and welfare of human subjects involved in investigation.

The Medical College of Georgia, Medical College of Georgia Health, Inc., and the Charlie Norwood Veterans Affairs Medical Center has granted the authorities to the Human Assurance Committee and the Chesapeake Research Review, Incorporate to:

- Approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organizations of MCG, MCGHI and the Charlie Norwood VAMC
- Suspend or terminate approval of research
- Observe, or have a third party observe, the consent process and the conduct of the research.

All research involving human subjects must be approved by an institutionally designated IRB. No one on the organization may approve research that has not been approved by an institutionally designated IRB.

Records of review and decision on the use of human subjects and of informed consent will be developed and kept by the Medical College of Georgia Human Assurance Committee in compliance with state and federal regulations. The Human Assurance Committee will be administratively and financially supported by the Office of Human Research Protection but shall report directly to the President of the Medical College of Georgia.

Approved by:
 Daniel W. Rahn, MD
 President, Medical College of Georgia and
 Senior Vice Chancellor for Health and Medical Programs
 University System of Georgia

Approved on:
 April 22, 2008

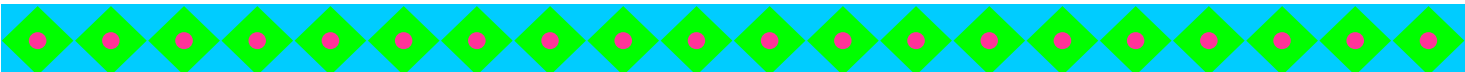


May Top Ten—Adverse Events and Serious Adverse Events

1. **Expected Adverse Event** is any adverse event that is identified in nature, severity or frequency in the: Protocol, Description of Research Proposal, Informed Consent Document and/or Children’s Assent Document, Investigator Brochure/Package Insert (for drugs), Manufacturer’s Information or Technical Manual (for devices)
2. ***Expected Adverse Event** - Does not have to be reported to the HAC (see bottom of page for exception)
3. **Unexpected Adverse Event** - The events weren’t listed/described in the: Protocol, Description of Research Proposal, Informed Consent Document and/or Children’s Assent Document, Investigator Brochure/Package Insert (for drugs), Manufacturer’s Information or Technical Manual (for devices)
4. **Unexpected Adverse Event** – Additionally, these could be cases where subjects with an underlying diseases/conditions, where the diseases or conditions worsen above the levels of “natural progression.”
5. **Unexpected Adverse Event** (Unrelated to research) – An underlying disease, disorder or condition of the subject, which is the sole reason for the adverse event (or)
adverse event is caused by circumstances unrelated to either the research or underlying disease, disorder or condition of the subject. Does NOT have to be reported to the HAC
6. **Unexpected Adverse Event** (Related to research) – The procedures involved in the research are related to the adverse event. Must be reported to HAC
Complete the HAC Form 110 Unexpected and Related Adverse Event/Serious Adverse Event (SAE) within 72 hours of any team member becoming aware of the event
<http://www.mcg.edu/research/ohrp/irb/hac/forms.html>
7. **Serious Adverse Event** is: death due to any cause; an immediate, life-threatening event; hospitalization (inpatient, overnight or prolongation of hospitalization); a permanent or substantial disability; report of overdose (intentional or not); report of congenital anomaly/birth defect.
8. **Reporting a Serious Adverse Event** - Any and all Serious Adverse Events must be reported to the HAC even if they are not related to the Study. (examples: unrelated deaths, all hospitalizations to include elective admissions, etc., must be reported even if they are unrelated to the study.) Complete the HAC Form 110 Unexpected and Related Adverse Event/Serious Adverse Event (SAE) within 24 hours of any team member becoming aware of the event.
<http://www.mcg.edu/research/ohrp/irb/hac/forms.html>
9. **Missed Deadlines for Reporting** - If you miss the deadline for reporting 72 hour deadline for reporting Unexpected, Related Adverse Events, or miss the 24 hour deadline for reporting Serious Adverse Events, note the cause of the reporting delay on the HAC Form 110.
10. **When in doubt, report it. Report! Report! Report!**

***from # 2 – You would report this if the event increases in frequency, duration and/or severity or if any additional measures are needed. Complete the HAC Form 110 Unexpected and Related Adverse Event/Serious Adverse Event (SAE) within 72 hours of any team member becoming aware of the event**

<http://www.mcg.edu/research/ohrp/irb/hac/forms.html>



Research Professionals from MCG Attend the ACRP Global Conference and Exhibition

The ACRP (Association for Clinical Research Professionals) Global Conference and Exhibition was held this past April in Boston, MA. There were several research professionals who represented the Medical College of Georgia at the conference. They brought back ideas and learned a lot from their week. Below are some items that may be of interest. For RESCUE, a panel discussion consisting of Mary Anne Park, Brenda Rosson, Barbara Covington, Jennifer Kenrick and Gina Matosian, talked about their “take-away” from the classes and the event as a whole.

For one session, there was discussion about source documents. Currently, there are sponsors who will tell you that you can't copy case report forms because of the FDA (Food and Drug Administration) regulations. **Not true** – there are no FDA regulations that support that assertion. When making a copy of a CRF, simply remove the headers.

At this same session, the topic shifted to Sponsor and FDA audits. The speaker stated that the FDA and Sponsors want documentation / verification that, with regards to subjects who continually miss appointments, additional appointments were scheduled. In essence, by documentation, they can see the “trail of non-attendance”. Suggestions on how to document included typing the appointments and subsequent “no shows” in the Group-wise calendar, which can be printed for a hardcopy. Another suggestion on overall documentation, was to initial any emails that are in the study file.

Another session included a topic that focused on the importance of study coordinators' role in research. Among the items discussed was the advice to always use the GCP (Good Clinical Practice) guidelines when conducting research. Also, it was discussed that there is a common problem across the U.S. with budgeting. The biggest challenge that all of the session attendees agreed upon is **separating standard-of-care costs and research costs**.

Each session of the ACRP Conference was taped. All ACRP members can go to the website and view any/all sessions. The website is <http://www.acrpnnet.org>.

Also, with some of the sessions, **contact hours may be earned**, when viewed by an ACRP member (please see the website for more details regarding contact hours.)

Finally, with the exception a lost cell phone, “not enough drink tickets”, and “the food was better last year”, the attendees from MCG agreed that each of them took a lot of good information from the 2008 ACRP National Conference.

Next Meeting: June 20th