



From the June 20th RESCUE Meeting

RESearch Coordinators United in Excellence

Announcements

HAC - Ivy Tillman introduced a new member of the OHRP staff, **Christy Wise**. Christy has filled the vacancy left by Lynnette Butler in the HAC Administrative Office. Christy has only been with HAC Administration for a few weeks, so Ivy asked that everyone give her a little time to get her feet wet before the “barrage” of requests begins!

OHRP - Angie Randazzo reminded everyone about the **HAC fee increase**, effective July 1, 2008. See below:

Effective July 1, 2008, all industry sponsored projects submitted for HAC review will be charged an initial submission fee of \$2,500 and a fee of \$500 for each continuing review. There will be no fees for amendments or other protocol related items at this time. These fees are exempt from indirect cost calculations and apply only to the budget's direct cost.

This is the first time since July 1, 2000 that we have increased our fees and our department has conducted intensive benchmarking with other universities regarding these fees. Please note that any studies that are currently in the budget negotiation phase will need to include these fees if they will be submitted to the HAC for review after July 1, 2008. Also, all current HAC approved industry sponsored studies will not be charged the continuing review fee; however, all submitted after July 1, 2008 will be charged. The Office of Human Research Protection will bill for these charges related to the study.

**MCG's Human Research Protection Program was awarded accreditation by AAHRPP!
See article on page 3 of this newsletter.**



June Top 10

Top Ten Issues Found During an **Audit**



1. **Disorganized and/or incomplete study records and regulatory files**
2. **Informed Consent Document (ICD) not signed and dated by the IRB approved investigator**
3. **ICD not signed and dated by a witness**
4. **Utilization of an outdated ICD**
5. **Subject did not initial all pages of the ICD to verify the entire document was read by the subject**
6. **Poor, or no, documentation of the informed consent process and/or continuing informed consent process**
7. **Individuals not approved by the IRB obtained informed consent and/ or conducted research related activities**
8. **The investigator deviated from the protocol without obtaining permission from the HAC or CRRI**
9. **Education and/or training not current**
10. **Curriculum Vitae of research team members not filed in regulatory documents**



AAHRPP

Association for the Accreditation of

Human Research Protection Programs, Inc.®

MCG Human Research Protection Program is Awarded AAHRPP Accreditation

The Association for the Accreditation of Human Research Protection Programs, Inc. has awarded the Human Research Protection Program at MCG “Full Accreditation” effective immediately.

Accreditation demonstrates the overall excellence of a Human Research Protection Program, by providing the most comprehensive protections for research. Recognized both nationally and internationally, AAHRPP accreditation is the **Gold Standard** for institutions that conduct human subject research.

The Medical College of Georgia is among various institutions across the United States who are accredited by AAHRPP, some of which include Emory, Harvard, Baylor, Cedars-Sinai Medical Center, Johns Hopkins, Syracuse and Vanderbilt.

This arduous process began in 2007, with the initial application. Because the Human Assurance Committee (HAC) serves not only as the Institutional Review Board (IRB) for MCG, but also as the IRB for the Charlie Norwood VA Medical Center, each institution had to apply for accreditation, and both institutions had to earn accreditation. One could not be accredited without the other.

The application process took several months of reviewing and collecting information from research at MCG and the VA. On April 30, 2007, the initial application, 1700 pages in all, was sent to AAHRPP.

Officials from AAHRPP made two site visits. The first site visit took place in May 2007 at the VA. MCG’s site visit took place in November 2007.

Each site visit lasted approximately three days. During the visit, officials would review files, and perform “audits” of several studies that had been pre selected by AAHRPP. Interviews were also conducted by the officials, and included PIs, Study Coordinators, HAC members, as well as colleagues from SPA, OCIS, Legal, OHRP, VA, Compliance, and University and MCGHI officials including Dr. Rahn, Dr. Goldstein, and Don Snell.

AAHRPP sent their first draft of results after the site visit in December of 2007. After months of responses, policy revisions, more responses, and sleepless nights, Michelle Christiano, Director of OHRP, received the news on Friday, June 13th, that MCG had been awarded AAHRPP accreditation.

