



RESCUE Newsletter

RESearch Coordinators United
in Excellence

From the
Meeting on January 18, 2008

Announcements –

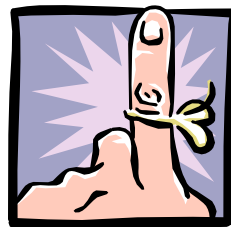
Joan Holloway from OCIS announced MCG Health, Inc. price increases. MCGHI announced a 12% rate increase across the board except for Pharmacy and room rates. (Room rates will be 6%. Pharmacy will have individual rate increases.) This rate increase went into effect January 1, 2008.

Angie Randazzo from OHRP announced that, 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. She also noted that this is the first time since July 1, 2000 that there has been an increase in fees, and that OHRP has conducted intensive benchmarking with other universities regarding these fees.

Kim Koss from OHRP announced that the 2008 Training Catalog would be online and that there would be training classes offered online this year (Webinars), in addition to face-to-face classes. Currently, there are 14 scheduled classes in all, and you can choose the sessions you would like to attend and register online. See the OHRP website for registration and course details. Hopefully, everything should be posted the week of January 21st – 25th.

January Top Ten-

Top Ten Reminders from Your HAC Team



1. For Informed Consent Document (ICD), make sure you are using the MCG seal with the trademark, or MCG letterhead.
2. Bar Code on ICD – Make sure the bar code is located at the bottom center of each page, if MCGHI is the performance site.
3. ICD bottom margin must be 1.25 inches to allow for HAC approval stamp.

4. ICD pagination – Must say “Page 1 of 5 Pages, etc.” in the upper right corner.
5. ICD version date – Place at the bottom left of each page.
6. ICD – Only the individuals who obtain consent should be listed on the ICD. Those listed on the ICD must be listed as PI and SubI in order to obtain consent.
7. CVs – Must be either printed with a current date, or if the printed date is not current, please sign and date the CV with the current date. Date must be listed as month, day and year.
8. CITI Training - Before adding individuals to studies, make sure they have completed CITI training; otherwise, they can't be added.
9. Study Terminations – When terminating a study, please provide a brief summary, to include study outcome. One sentence won't suffice.
10. Continuations – In the “Comments” section, please provide a detailed summary of the study progress. One sentence won't suffice.

RESCUE Topic-

"Changes to Policies/ Procedures as a Result of the AAHRPP Accreditation Site Visit" by Ivy Tillman, Assistant Director of OHRP

What are the Changes?

- Revised HAC Forms 101, 104, 105, 107, 113
- Revised HAC Policy on Unanticipated Problems (UAP) and Adverse Events (AE) and HAC Form 110
- Revised HAC Policy on Waiver of Consent
- New Research Screening Tool and HAC Form 100
- Revised HAC Policy and Form for Continuing Review
- Revised Policy and Procedures for Research Conducted at the Charlie Norwood VA Medical Center

HAC Form 113

January 14th- Revised HAC Form 113

Changes:

- Additional questions that relate to amendments that affect VAMC BioSafety and Radiation Safety
- Additional questions regarding amendments that may affect a subject's willingness to continue in the study

- Additional questions regarding amendments that were implemented without prior HAC approval to reduce an apparent immediate hazard to subjects
- Additional question regarding revisions to the Informed Consent Document (ICD) that may have a financial impact on subjects
- PI is required to sign the form for all amendments

Everyone is required to use the form starting February 1st

UAPs and AEs

Revised HAC Policy on Unanticipated Problems (UAP) and HAC Form 110

Changes:

- Unanticipated Problems:
 - Detailed description of unanticipated problems that must be reported to the HAC
 - Specific examples included
 - Reporting requirements
 - Possible HAC actions upon review of UAPs
- Adverse Events
 - Unexpected and Related Adverse Events must be reported
- The policy regarding SAEs has not changed
- Revised HAC Form 110 URE/SAE

Waiver of Consent

- Revised HAC Policy on Waiver of Informed Consent (Process and Documentation)
 - Changes:
 - The differences between waiver of consent and waiver of the requirement to document the consent process is explained in greater detail
- Revised HAC Form 101
 - Changes:
 - Required to indicate if investigator is requesting waiver of consent or waiver of the requirement to document the consent process
 - Must include subject payment schedule and amount

HAC Form 104

- Revised HAC Form 104
 - Changes
 - If the Principal Investigator is the IND holder they are responsible for adhering to FDA regulations for sponsors (21 CFR 312, Subpart D) in addition to institution policies regarding devices. They are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).

HAC Form 105

- Revised HAC Form 105
 - Changes:

- If the Principal Investigator is the IDE, HUD, or HDE holder they are responsible for adhering to FDA regulations for sponsors (21 CFR 812.40, 21 CFR 812.110) in addition to institution policies regarding devices. They are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).
- If the device qualifies as exempt from IDE regulations, indicate the appropriate exemption criterion

Research Screening Tool and Cover Sheet

- New HAC Form 100 (Research Screening Tool and Cover Sheet)
 - Tool to determine if the activity is “human research” as defined by DHHS and FDA regulations
 - Clinical Document Cover Sheet:
 - Identifies all Forms, Support Documents, Required Approvals and Required Education

Continuing Review

- Revised Policy on Continuing Review and HAC Form 107
- Changes:
 - Additional reporting regarding:
 - Minority status of subjects
 - Subject withdrawals (withdrawal date and reason for withdrawal)
 - Number of vulnerable subjects enrolled in the study
 - Unanticipated problems involving risks to subjects or others
 - Subject complaints regarding their participation in the study
 - Reports of recent relevant literature that relates to the study (by the research team or others)
 - Additional study related documents must be submitted with the continuation
 - Current Advertisements
 - Current Description of Research Proposal/Protocol
 - Relevant and recent literature related to the study (by the research team or others)

VA Research

- Revised Policy Regarding Research Conducted at the Charlie Norwood VA Medical Center
 - Clarifications:
 - Subject payment for VA studies
 - Enrolling non-veteran subjects in VA studies
 - VA research involving vulnerable populations (pregnant women and children)
 - Research-related injuries
 - Flagging the medical record
 - Amendments that involve BioSafety and/or Radiation Safety issues

Human Research Protection Program

- Document will be posted on the OHRP web site
 - Defining non-compliance
 - Planned emergency research
 - Georgia law regarding minors in research, legally authorized representatives and guardians

When Are We Required to Comply with the Changes?

- Changes will be communicated weekly, via email, with the effective date for forms and policies included in the e-mail.
- If you are not listed in the HAC database and would like to receive the emails regarding changes to HAC forms and policies, please email Ivy Tillman at itillman@mcg.edu

Communicating Changes

- Weekly emails
- OHRP and HAC website
- OHRP Webinars and Classroom Seminars
- OHRP Tip of the Month
- HAC bulletin board in OHRP Office (CJ-2103)

Next RESCUE Meeting: February 15th
Topic: “New MCGHI Policy for Study Billing to Insurance”