



RESCUE Newsletter

April 18, 2008

RESEARCH Coordinators United in Excellence

Announcements

OHRP - Kim Koss reminded everyone that, for those who are attending the ACRP Conference in Boston, they would be asked to serve on a panel discussion at the May RESCUE to update everyone on ACRP news, educational information, etc. Kim said that she would reach out to the ACRP Conference attendees by email once they had returned.

Finally, Kim reminded everyone 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.

Michelle Christiano - Michelle wanted to commend Robin Dobbins, Nurse Clinician/Study coordinator, Cancer Research Center, for receiving a commendation letter from Novartis. Michelle said that, as far as sponsors go, letters of commendation are few and far between. She wanted to stress that, for Novartis to take the time to send Dr. Jillella a complimentary letter regarding Robin's exceptional performance, she must be doing a stellar job, and should be given a "pat on the back" for her efforts.

OCIS - Kathy Miles said that, regarding EMR access: a process is in place for NEW studies only. You must wait until HAC approval, and have the HAC approval #. The form is located on the OCIS website

Brenda Rosson - Introduced Raji Ponnala, MS, as the new Charlie Norwood VA Medical Center Urology Coordinator.

Continued, page 2

RESCUE TOP TEN

10 Facts about *Continuing Review*

1. **Continuing review**, simply put, is a report to the HAC on the progress of a study.
2. The request for continuing review **applies to all studies, regardless of review level**. Although federal regulations don't require continuing review for exempt studies, **MCG's HAC does require an annual submission for exempt studies**. Why? Because this is a way to ensure that our studies are providing the maximum protection for human subjects and/or human derived materials.
3. It is the **investigator's responsibility to seek continuing review**, however, as a courtesy, the HAC Administrative Office will mail the HAC Form 107 Clinical Study Status Report to the PI or designee approximately 60 days prior to the approval expiration date.
4. The HAC Form 107 is the only form that you can't print out from our website; you have to request this through the HAC Administrative Office. Why? Because the Form 107 Clinical Study Status Report is generated by entering data specific to your protocol. If wrong numbers or missing information, etc. is entered, the report will be incorrect, and will delay your continuation. Therefore, the HAC Administration Office generates this report for you, to ensure that your information is accurate.
5. Deadlines for continuing review submissions are the following:

The **first business day of the month prior to your month of expiration** (you can find this information at the top of the HAC Form 107.)

For example, if your approval expires April 14, 2008, then you must submit by the first business day of March 2008.

Please note: **if the form is not returned to the HAC Administrative Office by the due date on the form, the protocol approval terminates.**

6. Study Progress—the statement “**Study is proceeding as planned**” is not an adequate report regarding the study progress. Unanticipated problems or unanticipated benefits must be entered here, as well as any complaints by the subjects. If a progress report was made to the sponsoring agency, then it should be submitted with the HAC Form 107

7. Other documents that must be submitted with the Form 107:
 - Informed Consent Document** or **Children's' Assent Document** for studies that are still actively enrolling subjects.
 - Advertisements** and/or **recruitment plans**

8. Always **keep a copy of your completed HAC Form 107 and any support documentation** that goes along with it (ICDs, advertisements, etc.) in your regulatory binder.

9. The HAC Administrative Office performs the **initial review** of the HAC Form 107. If the form is incomplete, the PI will be contacted. If the form is complete, the HAC Administrative Office will forward the HAC Form 107 to the HAC chairperson or his/her designee to review.

10. **Information regarding the continuing review process** can be found on the **OHRP website**, under “Institutional Review Boards”, then “Human Assurance Committee” then “Policies and Procedures”.

The direct link is <http://www.mcg.edu/research/ohrp/irb/hac/documents/PP39.pdf>

“Update on Study Scheduling and Billing”

Speaker: Kathy Miles, NHA, BS, CCRP

Operations Manager, Office of Clinical Investigative Services, MCG

For a copy of this power point, please contact Kim Koss at kkoss@mcg.edu, and it will be emailed to you in a PDF format.