



REsearch **C**oordinators **U**nited in **E**xcellence

From the February 20th RESCUE Meeting

Announcements

Kim Koss, OHRP - Announced the dates of Coordinator University , which are April 20-24, 2009. Anyone who is new, or who would like a “refresher” is welcome to attend. Registration forms can be found on the OHRP website, under Education and Training.

Kathy Miles, OCIS—Kathy Miles discussed Study Contract Amendments and Billing Language. See pages **two and three** of this newsletter for a complete overview of Kathy’s hand-outs and announcements.

Ivy Tillman, HAC— Introduced Michelle Harper to the group, as the new IRB Specialist for OHRP and the HAC. Also, Ivy announced that the previous positions of Office Specialists for the HAC had been upgraded. Therefore, Christy Wise and Michelle Harper each received a promotion to IRB Specialists.

Additionally, Ivy discussed **eProtocol**. She noted the following:

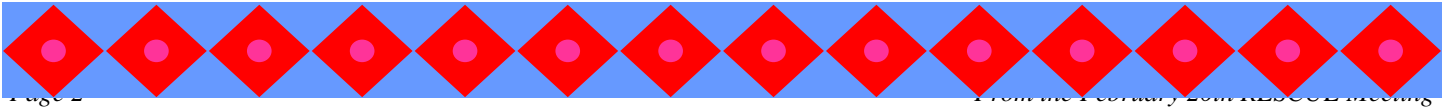
- eProtocol is an online submission software program
- Paper submissions will be “going away”
- The phases for eProtocol will be

Phase I, March 2, 2009—HAC Office Specialists and OHRP staff

Phase II, April 2009—HAC members and “Pilot Group”

Phase III, July 1, 2009—Investigators and Research Team Members

Ivy stressed that everyone will be trained on eProtocol; there would be ample opportunities for classes, webinars, etc. And finally, she said to expect some “bumps in the road”. With this being a new system, there are bound to be some kinks. But we will work together to get eProtocol up and running



Billing Language for Treatment Studies

Purpose: To provide consistent language when insurance or Medicare is going to be billed for routine procedures required by the Study Scope of Work. This language needs to be in the clinical trial agreement and the informed consent document.

For all studies except Cooperative Group studies

For the Clinical Trial Agreement

PAYMENT TERMS

Routine care procedures outlined in the study scope of work and not paid for by the study will be billed to the subject's insurance or Medicare if applicable. The sponsor will pay the institution for any study scope of work that is denied or the amount not covered by insurance or Medicare.

For the Informed Consent Document

COSTS OF PARTICIPATION

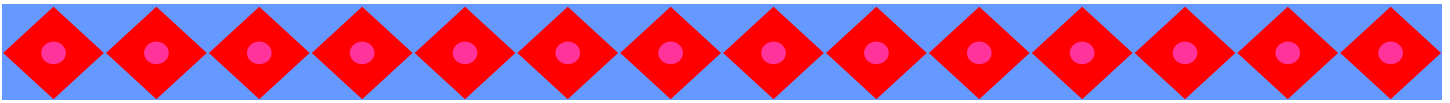
This is a treatment study. Routine care procedures not paid for by the sponsor will be charged to your insurance or Medicare if applicable. You are responsible for all co-pays. It is possible that Medicare or insurance will not pay for routine care charges that take place within a research study. If this happens, the sponsor will be responsible for the charges. Please feel free to discuss any financial concerns that you may have with the research staff.

For Cooperative Group Studies

Informed Consent Document

COSTS OF PARTICIPATION

This is a treatment study. Routine care procedures not paid for by the sponsor will be charged to your insurance or Medicare if applicable. You are responsible for all co-pays. It is possible that Medicare or insurance will not pay for routine charges that take place within a research study. If this happens, you will be responsible for any denied claims or the amount not covered by Medicare or insurance. Please feel free to discuss any financial concerns that you may have with the research staff.



Study Contract Amendments that Require Review and MCG Health Inc. Approval

Criteria

The Principal Investigator (PI) or their designated research staff are required to submit to the OCIS Review Office any study contract amendment that **increases** the utilization of hospital resources. Examples include an increased number of subjects, increased number of procedures or the addition of new procedures, tests and hospital charges.

The new or additional items will need to be budgeted at the current MCG Health Inc. research rate. Research sites should negotiate with the sponsor for additional funds to cover any additional charges resulting from a contract amendment.

Rationale

The study budget approved by MCG Health Inc. serves as a contractual agreement for hospital services.

Process

The research site sends to the OCIS Review Office:

A new extramural routing form and MCG Health Inc. budget. Only the **new or additional** costs are listed on the MCG Health Inc. budget.

The study contract amendment.

The current approved MCG Health Inc. budget for the study.

Upon review and sign off, the OCIS takes the budget packet to MCG Health Inc. administration with a cover sheet.

After approval, the research site is contacted for pick-up. The research site obtains the signature of the PI on the extramural routing form and sends it with the contract amendment and the approved budget to Sponsored Programs Administration.

NOTE: Only the signature of the PI is required on the extramural routing form for study contract amendments.

Next Meeting: March 20th RESCUE on the ROAD at GPI. Kim Koss will send out emails with the details. Plan on going straight to GPI, and you will be sent instructions on where to meet, etc.