

# RESCUE Newsletter

## RESearch Coordinators United in Excellence

*From the*  
Meeting on February 15th, 2008

### Announcements –

**OCIS - Kathy Miles announced the following staff changes:**

**Barbara Covington** is the new Team Leader for the OCIS Review Office

**Joan Holloway** is the new OCIS Project Manager and is in charge of tracking research contracts through the approval process

**Amy Claus** is leaving OCIS and MCG as she and her family are re-locating to Germany.

**OHRP - Kim Koss** announced on behalf of Christine Adams:

**1. The Office of Legal Affairs** has posted an updated version of *Individual Conflicts of Interest* policy, as well as a new administrative policy entitled, *Institutional Conflicts of Interest*.

Both policies may be accessed at <http://www.mcg.edu/policies/>. These policies affect all full-time and part-time MCG employees, including investigators, faculty and staff; and other representatives performing work on behalf of MCG, concerning any significant financial conflict of interest or other conflict of interest on his/her own or spouse and dependent children which arises during the course of his or her work.

Questions may be directed to the Office of Legal Affairs at 706 721 4018.

**2. Research Team Member Training Series** – Don't forget that OHRP is offering free WEBinars and Classroom Sessions (CE points are included).

These are scheduled between now and November 2008. For a list of sessions and to register, go to the OHRP training website at <http://www.mcg.edu/research/ohrp/training/> and select publications, then training catalog to view the different classes. Then, at the above web address, you can select the registration tab and register online.

### February Top Ten-

## **HAC Changes Based on the AAHRPP Site Visit and Response**

1. **Form 113** – Additional questions have been added that relate to amendments; the PI must sign the form for all amendments.  
<http://www.mcg.edu/research/ohrp/irb/hac/HACForm113Jan08.rtf>
2. **Form 101** – Revised to include new information about subject payment and waiver of consent.
3. **Form 110** – Unanticipated Problems: New information regarding reporting requirements. Adverse Events: New information regarding the types of adverse events that must be reported.  
<http://www.mcg.edu/research/ohrp/irb/hac/documents/rev11012.31.07.doc>
4. **Form 104** – New information regarding the responsibilities of PIs who are IND holders. PIs are also responsible for registering the studies in the Clinical Trials Registry.
5. **Form 105** – New information regarding the responsibilities of PIs who are IDE, HUD or HDE holders. PIs are also responsible for registering the studies in the Clinical Trials Registry.
6. **Form 100 (Research Screening Tool and Cover Sheet) New Form** - Tool to determine if the activity is “human research”; identifies all forms, support documents, required approvals and education requirements.

7. **Form 107** – Changes include additional reporting regarding: subjects' minority status; withdrawals; number of vulnerable subjects enrolled; unanticipated problems involving risks to subjects or others; subject complaints regarding their participation in the study; reports of recent relevant literature relating to the study.

8. **Form 107** – Additional study documents must be submitted with the continuation including: current advertisements and description of research proposal/protocol; relevant and recent literature that relates to the study.

9. **Revised HAC Policy on Waiver of Informed Consent** – The differences between “waiver of informed consent” and “waiver of the documentation of informed consent” are explained in greater detail.

10. **Revised VA Policies** – Clarifications on subject payment, enrolling non-veteran subjects, vulnerable populations, research related injuries, flagging the medical record, and amendments involving biological and radiation safety.

For all forms and policy information, please go to the links below:

Forms - [www.mcg.edu/research/ohrp/irb/hac/forms.html](http://www.mcg.edu/research/ohrp/irb/hac/forms.html)

HAC Policies - [www.mcg.edu/research/ohrp/irb/hac/policies.html](http://www.mcg.edu/research/ohrp/irb/hac/policies.html)

**RESCUE Presentation- HAC Forms Update (100 and 110 URAE/SAE)**

**By Ivy Tillman, Assistant Director of OHRP**

**HAC Form 100 – New Research Screening Tool and HAC Form**

**Identifies that the project meets the regulatory definition of research**

**Page One**

**Old HAC Form 100 and research team members complete the Sections A-C**

**Pages Two and Three**

**Research team members complete the Sections 1 and 2 and the HAC staff completes Section 3**

## **Pages 4 and 5**

This page describes the required documentation for attachments; research staff completes Sections I – IV

## **Pages 6 and 7**

Research staff completes Section F based on the type of research conducted and the required number of materials for each level of review

Place the documents in this order for the collated copies.

The effective date for form 100 is March 1, 2008.

## **Adverse Events - HAC Form 110URAE/SAE**

One form instead of two

Unexpected and Related Adverse Event (URE)/Serious Adverse Event (SAE)

### **Is the event unanticipated?**

- Not documented in the informed consent document or the protocol
- Not known in the specific population targeted by the study

### **Is the event related to the subject's participation in the study?**

- Would this event have happened even if they were not participating in the study?

## **Expected Adverse Event**

### **Expected Adverse Event that has increased in Frequency or Duration**

- Adverse Event that is listed in the ICD or protocol
- Example:
  - ICD states that the subject will have nausea and vomiting.
  - Increase would be that subject becomes dehydrated and requires fluids in the hospital setting.

## Serious Adverse Event – no changes in policy

### Protocol Revisions

#### Addition to the existing policy on Protocol Amendments:

- A revised DRP is required for all amendments which involve a protocol revision.

#### Why the Change?

- AAHRPP Standard. Element II.2.E
  - The Research Review Unit receives and considers the relevant information to evaluate proposed amendments to research studies.

The effective date for form 110URAE/SAE is March 1, 2008.

**Next RESCUE Meeting is March 21<sup>st</sup> Speaker and Topic – to be determined**