



# RESCUE Newsletter

From the March 21, 2008 Meeting

## RESearch Coordinators United in Excellence

### Announcements

**OHRP** - Kim Koss asked for a show of hands who would be attending the ACRP Conference in April. For the May RESCUE meeting topic, the ACRP Conference attendees will have a panel discussion on Conference “highlights” and overview of sessions.

Also, just a reminder that Coordinator University is taking place April 21-25, from 8:00 am to 12:00 noon. If you know of any research team members who have started at MCG since last October/November timeframe, please encourage them to register for Coordinator University, or call/email Kim Koss.

**HAC** - Ivy Tillman announced that Lynnette Butler of the HAC Administrative Office was leaving to go to work at the Charlie Norwood VA Medical Center and said that Lynnette would be sorely missed.

Also, Ivy reminded everyone that the 100 Forms were being submitted incomplete, and to please make sure that the 100 Forms were filled out completely, or they would be sent back to be completed.

**Mary Anne Park** - Announced that Mary Bannan will be the new Vessl Coordinator for the Surgery Research Department.

**Angie Randazzo** - 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.

# RESCUE TOP TEN

## 10 Facts about Standard Operating Procedures (SOPs)

1. SOPs are simply “**how we get things done.**” They are written documents that contain step-by-step instructions for specific tasks, projects, work processes, etc.
2. SOPs serve as **training documents** for new employees, by walking them through processes and systems within their scope of responsibilities.
3. SOPs ensure **study consistency** (Processes are compliant, safe, efficient and also provide a level of quality control.)
4. **Departmental consistency** with SOPs (Procedures ensure that the department operates efficiently within itself, for all of the reasons stated in #3)
5. They are key to successful “**transitioning of responsibilities**” within department when **employees exit** and/or when **employees are “on leave”**, i.e. vacation, sick, maternity, etc.
6. SOPs provide a good **historical documentation of the processes** that have been used, and when modifications and/or revisions occurred. (Make sure you keep all previous SOPs.)
7. SOPs serve as a reliable tool and **checklist during the audit process.**
8. **SOPs are YOURS** – follow any format that works for your department.
9. SOPs **don’t have to be approved** by anyone outside of your department.
10. The Office of Human Research Protection’s (**OHRP**) **website has information on SOPs** and some existing SOPs that you can tailor for your department. You can find these on the OHRP website,

at <http://www.mcg.edu/research/ohrp/>

Select the tab on the left that says OHRP

Select OHRP Policies

Scroll down the page until you see Clinical Research SOPs

Or go directly to the link, at <http://www.mcg.edu/research/ohrp/training/sops.html>

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# An FDA Audit Experience

Speaker: Mary Anne Park, RN, MSN, CCR

Assistant Clinical Professor of Surgery, Director, Clinical Research Services

Department of Surgery, MCG

Mary Anne Park gave a great presentation on her experience with an FDA Audit that took place last year. **For a copy of this power point, please contact Kim Koss at [kkoss@mcg.edu](mailto:kkoss@mcg.edu), and it will be emailed to you in a PDF format.**

Here are a few excerpts from the presentation:

## Prior to the audit, the FDA Inspector asked:

How many actual subjects? How many hard copy charts?

What was plan to get her those not available?

When was our office open? Logistics of meeting with Dr. Lewis?

When could she meet with Pharmacy? Directions?

## What the department did to prepare:

Notified the Pediatric Urologist of his possible involvement (He had 50% of the patients.)

Set up Pharmacy appointment

Participated in a FDA Audit Preparation Review conference call with an Ethicon Compliance Officer

Exchanged emails with sponsor and CRO

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