



Research Coordinators United in Excellence (RESCUE) Newsletter

November 16, 2007

No Announcements were made at this meeting.

Top Ten List for Researchers: **“Checklist Items to Do if Your PI Leaves”**

Although the below checklist items are the responsibility of the PI, he/she may delegate these duties to the Study Coordinator. Regardless of the manner in which they are executed, the below items have to be completed:

1. Prior to leaving and in writing, notify the IRB. This will be the Human Assurance Committee (HAC) or Chesapeake Research Review, Inc. (CRRRI) whichever is applicable.
2. Prior to leaving and in writing, notify the Division of Sponsored Program Administration (SPA).
3. Prior to leaving, compile a list of all active studies (by title and IRB file #) and submit to the IRB and SPA, with a request to either terminate the study or designate a new PI.
4. If a new PI is designated, submit a revised written Informed Consent Document(s) (ICD) and/or a revised Children's Assent Document(s) (CAD) to the IRB. This must be submitted and approved by the IRB before the transfer of the study.
5. If study is being terminated, the following forms are needed: For HAC studies, Form 111 Final Report, or HAC Form 107 Clinical Study Status Report (if at the same time as continuing review would occur) or if the IRB is Chesapeake Research Review Inc., then go to the www.cirbi.net for instructions.

6. If study is being transferred with the PI to his/her new location, check with SPA before transferring to determine sponsor requirements and contact the HAC as they must put the study on hold so that the study will not be without IRB approval.
7. If data (tissue, samples, records, etc.) is to be transferred, contact the Office of Technology Transfer and Economic Development, as you may need a Material Transfer Agreement (MTA). Also, add the Division of Environmental Health and Safety as another contact that you will need to add to your checklist, if applicable.
8. Revised Documents – check for any/all documents that need to be revised. These may include Informed Consent Documents, Children's Assent Documents, FDA form 1572, advertisements, budgets, contracts, etc.
9. Don't forget to contact OHRP, HAC or Chesapeake, the sponsor (if applicable), the Division of Sponsored Programs Administration (SPA) and the subjects.
10. Find out the PI's new contact information (forwarding address, new phone #s) for any future audits, legal issues, etc.

Topic: **"The AAHRPP Site Visit Experience"**

Panel Group Discussion

Ivy Tillman, MSM, CCRC Assistant Director of OHRP

Joanne Rogalsky-Nacca, RN Nurse Research Assistant in Neurology

Ivy and Joanne discussed their experience with the AAHRPP (Association for the Accreditation of Human Research Protection Programs) accreditation site reviewers from the previous week. From a research coordinator's position, Joanne was interviewed by AAHRPP. She was asked several questions during her interview, with a portion of the questions focusing on the informed consent process. Here are a few questions:

Regarding the informed consent process: Who obtains it?

How do you involve the patient in the consent process?

Do you re-consent after the patient is awake? Is there follow up?

What is the process when you have changes to the consent?

Tell us about revised informed consent.

Does the IRB provide study coordinators information?

Joanne said that, after her interview, it really made her review her processes and take a self assessment to ensure that she was taking all of the right steps in her consent process.

Ivy was interviewed as well by the AAHRPP site reviewers regarding her former role as OHRP Training Coordinator. Kim Koss, the new OHRP Training Coordinator was also interviewed. With Ivy and Kim, the site reviewers were more interested in the training process. Their questions were along the lines of:

How do you provide training for new study coordinators?

Do you provide training for PIs?

Do you train new HAC members?

How do you handle subsequent and continual training for Study Coordinators, PIs and HAC members?

Is any of this training mandatory?

How do you measure the efficacy of the training?

The AAHRP site reviewers seemed pleased with the training that was provided to our research staff, and added that "Coordinator University" should be used as a model for other medical universities and research divisions across the entire nation.

Michelle Christiano added that there would be several changes in the near future (processes, etc.) as a result of the AAHRPP site visit and subsequent feedback, and that OHRP would keep everyone informed and educated as the changes were executed.

Next Meeting:

December 21st, 12:30 pm to 1:30 pm

Topic – Cookie Swap and Holiday Hangin' with Friends

Everyone bring some cookies to share at the RESCUE Meeting. OHRP will provide drinks and holiday music!