

**Department of Medicine**  
**Clinical Research Coordinator Monthly Meeting**  
**October 30, 2007 – 2:00-3:00 PM, Laurel Height 430F**

**Present:** Karen Borovitz, Benjamin Brezler, Michele Carter, Fred Fishman, James Hong, Erik Kofler, Irina Gorodetskaya, Jennifer Spede, Suzanne Sutton, Joseph Wilson

**Guest:** Beth Davis

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**Challenges for Clinical Research Coordinators at UCSF**

Beth Davis, the Clinical Trials Manager in the Bone Marrow Transplant Clinical Research Unit of Hematology/Oncology, spoke about the challenges she has faced since joining UCSF a year ago. With over 40 years of clinical trial coordination experience in a community hospital setting, Beth is in a unique position to understand and approach the challenges of working as a CRC at UCSF.

*General*

Beth's extensive experience in both the community hospital and university setting gives her a unique perspective as a clinical trial coordinator. Unlike the community and private sector, UCSF cannot profit from clinical trials. This disparate financial motivation leads to extremely different approaches when negotiating funding and implementing trials. In Beth's experience, there is a bias on the part of industry sponsors to favor universities, which makes UCSF highly competitive in the award of new contracts.

One of the most significant differences Beth experienced when she transferred to UCSF was the amount of processing time it takes to begin a trial. Because it is necessary to obtain multiple committee approvals and signatures, the time to execution for contracts is at least twice as slow as industry. Due to Beth's diligence in streamlining the application process, she has been able to successfully open seventeen studies (two investigator-initiated, fifteen industry) within the past five months. From start-to-finish, it takes her group approximately eight weeks to obtain CHR approval.

Her group is able to accomplish this by submitting all paperwork simultaneously. The sponsor generally does not need the CHR approval letter to begin their side of the protocol set-up. They also do not rely on receiving the paper approval from CHR. They checked the website (RIO) constantly to print and send the approval to the sponsor. Beth saves additional time by drafting the CHR application for the PI. The information can be cut-and-pasted directly from the protocol. Hand-carrying documents to be routed for signature and to Office of Sponsored Research or CHR also expedites the process.

Her group utilizes a shared server to maintain all files. This ensures that items are accessible to all employees within the group, and are not lost due to employee turnover. Beth also created a spreadsheet that helps her track all active trials to ensure that they are within budget. The

spreadsheet notates how payment will be made, when, if the check has cleared, etc. Beth also requests from the sponsor a photocopy of all checks sent to UCSF so that she can work with the RSA to ensure the payments are posted by accounting.

Beth always reads the executed contracts for payment terms and determines upfront costs. A CRC should investigate in detail the budget during negotiations and monitor throughout the life of the trial. Ultimately, it is the CRCs responsibility to keep track of all financial data, and to ensure that everything is done properly. Questions about the budget (or any other aspect of the contract should be asked of the sponsors. They are the best equipped to answer them. In addition, utilizing an already executed contract from another UC campus for the same sponsor will expedite the contract negotiations at UCSF. The approved terminology can be used as a template. CRCs are not data monitors. They are research coordinators that should oversee all aspects of the trial.

Having a functional workspace is essential to working efficiently. Be sure your office does not become a storage space. Send old files to storage, request small shipments of supplies from the central lab, and request shelving/equipment that will maximize your working room and efficiency.

Post an erasable calendar and ask that patients schedule their own follow-up appointments.

Be sure that the content of a protocol initiation meeting is relevant and on topic to ensure that your PI's time is not wasted with administrative details.

Keep in mind that the Campus and Medical Center run on two completely different systems. Adjust internal administrative processes and timelines to account for this.

Always ask questions rather than trying to find the answer on your own. There are so many idiosyncrasies within the UC system that affect CRCs on a daily basis. It is impossible to know all of the answers. Make use of any resources offered to you (meetings, trainings, etc.), and don't be afraid to ask CRCs outside of your division for advice on how to find the right answer to your questions. If you do not have a direct supervisor who can be a mentor to you, find a mentor within the department. Although an introductory training course for CRCs in the Department will be offered in the future, the current absence of such a course means that we all need to feel comfortable approaching one another to find answers.

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*The next CRC Meeting is scheduled for Tuesday, January 29, 2008 from 2:00-3:00 PM at Laurel Heights in room 430F.*