

Department of Medicine
Clinical Research Coordinator Monthly Meeting
May 29, 2007 – 2:00-3:00, Parnassus S170

Present: Karen Borovitz, Michele Carter, Fred Fishman, Irina Gorodetskaya, Yelena Idomsky, Win Kryda, Emily Little, Heather Logghe, Kristine Partovi, Jenny Spede, Joseph Wilson, Elisabeth Zurlinden

Guest: Beth Davis

Set-Up and Functioning of Clinical Trials (presented by Beth Davis)

Beth Davis, Manager of the Hematology/Bone Marrow Transplant Clinical Research team at the Comprehensive Cancer Center, outlined the process that she and her team follow when preparing for set-up and maintenance of Clinical Trials.

General

Always plan ahead when beginning the study.

Always keep detailed copies of *any and all* paperwork pertaining to your study on file. Be particularly aware of email correspondence – although this is saved on a computer, there may be situations which prohibit access to this information. It is always best to have a physical paper copy of email correspondence in addition to what is saved on your server. If it is not documented, dated, and signed, it didn't happen. **Always** document that patient consent has been obtained.

Industry trials will provide the CRC/PI with all of the information that both the funding agency and UCSF will need.

It is invaluablely helpful to always keep current copies of licenses, CV's, and Committee on Human Research (CHR) approval list for all of the PIs you work with on hand *at all times* – this information is essentially 1/3 of all of the paperwork you will need to submit in order to begin the set-up process.

Keep a pre-filled 1572 Template on hand at all times – when a new trial needs to be set-up, simply add the new study title and save.

Fully complete one blank Financial Disclosure form and print; then go back, revise PI name, and print (etc.)

For Investigator-initiated trials, create regulatory binders in which to file copies of *any and all* study-related documents; keep these binders up-to-date. Utilize your sponsor contact to help with IND forms/paperwork – get them involved in the process, if necessary. Try to obtain a grant from the sponsor to support the work.

In multi-center studies, keep in mind that UCSF will not allow classification as a “site” – UCSF will not ship medications/materials to other sites. Drugs must be sent directly by the sponsor agency to the other sites.

Pilots, Phase I and II, and some Phase III are the types of trials which should be done within the University setting. Phase IV trials generally do not make enough budgetary provisions to be financially viable in the University setting, and are therefore more appropriate for private or community hospitals.

Complete your data entry as soon as each patient is treated – this will allow you to close your database (and, ultimately, the study) faster.

Specific items (specialized equipment, etc.) that are necessary for the study should be paid for by the sponsor. Having the sponsor provide the equipment will also cut down on time and cost spent coordinating for these tests with the patients and the various different departments that may have the equipment available. If you cannot requisition the equipment you will need yourself and do need to coordinate with other departments, make sure that this is done prior to the beginning of the trial.

If the necessary tests are considered to be standard-of-care, they can be billed to the patient’s insurance *as long as* the proper code is used. (A V-code on billing paperwork tells the insurance company that the patient is enrolled in a clinical trial.) Many of the tests that are necessary during trials are considered to be standard-of-care, as they would be done regardless of trial enrollment to help treat the patient.

Most studies will require online data and data entry as a trial component. Keep this in mind when thinking about the type and amount of equipment you will need.

For Industry trials, the FDA requires sponsors to keep a complete log of every patient they are asked to see, and all of that patient’s pertinent information. You must keep this on file whether the patient is enrolled in the study or not; and, if not, why they were not enrolled.

Create sample orders (for treatment, blood work, etc.) for the trial during the lag time while waiting for CHR approval and contract processing. CRCs may write the orders, but PIs need to sign them.

Create a study calendar, both for yourself and for the patients, detailing which steps of the trial will occur when.

When recruiting for patients for your study, make contact with local physicians to alert them to your target audience and objectives. It is not necessary to obtain CHR approval to let other physicians know about your study.

Budget

As a CRC, one of your integral responsibilities is formulating the budget. It is extremely important that you make sure to keep your PI on a realistic budget. Make sure that the budget is realistic prior to the start of the study. A copy of the budget should be obtained by yourself and the PI as soon as the PI agrees to do the study.

To formulate a realistic budget, keep in mind the number of visits per patient and the data collection required at each visit. Is the overall per-patient fee listed in the budget realistically enough to cover the time spent by yourself and the PI? Will it cover the costs of the required tests? Will there be lifetime follow-up?

To facilitate creating a realistic budget, create a cheat-sheet documenting all of the possible tests that could be utilized within the study and their costs. If the GCRC is being used, consolidate fees rather than looking at individual fees, and create a blanket-fee charge based on the GCRC per-hour charge.

Once you have reached a budget you are comfortable with, send it out to your financial contact within UC – they can help you to work out any internal cost issues or issues with determining effort distribution if you are involved with multiple studies. As there is generally a 3-4 month lag-time in waiting for budget approval, send this information out concurrently with CHR application.

Look carefully at the contract to determine how much of the funding will be front-loaded, and how much will be back-loaded (i.e. withheld until your data is submitted.) 10% is a reasonable amount to be back-loaded, but much more than this is not.

Build non-refundable start-up fees (e.g. the cost of your time, the PIs time, overhead, etc.) into the contract – this will help to give you a realistic budget, and help discourage too much back-loading. A good starting point for determining these fees is to estimate the per-patient fee for the entire life of the trial. Also, be sure to add 22% of the overall projected cost (UC's Industry overhead.)

The next CRC Meeting is scheduled for Tuesday, July 31st, 2007 from 2:00-3:00 PM in room PAR S170.

