Department of Medicine
Clinical Research Coordinator Monthly Meeting
September 25, 2007 – 2:00-3:00, Parnassus N527

Present: Michele Carter, Vivian Chang, Fred Fishman, Monique Koenigsberg, Jenny Spede, Suzanne Sutton

Presenter: Irina Gorodetskaya

Clinical Research Billing Updates

With the help of Tim Arnold, we clarified a number of points that were made at Nina Feero’s presentation on the new Medical Center’s Protocol for Clinical Studies at our July CRC meeting.

New federal policies require that all clinical trials be registered and tracked at the national site www.clinicaltrials.gov. The NCT number received upon successful registration of a trial is now required prior to the start of any research for new studies and for all active studies as of July 1, 2007.

A QV modifier and diagnosis code V70.7 must be utilized for all clinical trials any time a clinical service is provided to a patient covered by Medicare.

Patients should never be de-linked from the ZZ account to which they were assigned. To prevent Medicare billable standard of care costs from being charged to the study, a budget should be provided to Tim Arnold at the start of the trial. He will allocate the appropriate charges to the study and to Medicare for each encounter form submitted based on the budget. Ensure that all encounter forms are routed to Tim Arnold within seven business days. Encounters are automatically charged against the ZZ number after the seventh business day, which requires additional research and time of Tim and the CRC to transfer costs off.

Successes and Challenges of Clinical Research Practice at UCSF

Irina Gorodetskaya, a clinical research coordinator in the Division of Nephrology, spoke about her experiences dealing with challenges at UCSF and ways she sees such challenges may be resolved.

Having worked with the University for almost 10 years, Irina has extensive experience working with both industry and federal research administratively. She also compares this experience to her time as a Co-PI in Russia.
UCSF’s is a leading university that defines the field of advanced biomedical research, which creates an exciting and inspirational working environment for employees. However, the complex matrix of academic medicine and administrative structure of the university also creates a fast-paced, often confusing and convoluted network of departments that can hinder communication and efficiency for coordinators.

Ideally, the existing research administration network (including Accounting, the Committee on Human Research, Contracts & Grants, Human Resources, and the Medical Center) within the University is to exist solely to assist the PI and CRC in facilitating research. However, the reality is that one of the primary objectives of the network is to ensure that the University remains in compliance, which may create additional steps and time delays for the PI and CRC.

The Research Administration unit in the Department of Medicine provides infrastructure, grant management, and assistance in research related matters. The team of Research Services Analysts (RSAs) is available to assist CRCs with certain aspects of pre-award set-up and with grant management. The RSA is also to function as a liaison between their division and Office of Sponsored Research. If there is an issue and the CRC is unable to receive a timely response from their division’s RSA(s), the CRC should bring the issue to their Division Administrator or to Suzanne, who will help facilitate resolution of the issue.

If a CRC is having trouble getting a response from an employee in a central campus department, it is advised that the CRC approach either that individual’s supervisor, or speak with their DA or with Suzanne to help facilitate resolution. Keep in mind that the employees in these departments are likely very busy and are dealing with the same fluctuating day-to-day priorities that all UCSF employees face. Assume that the issue is not being ignored, but has fallen off their radar. Oftentimes, taking the issue to their supervisor is an effective method of initiating a re-evaluation of the request on the employee’s priority list.

One of the constant challenges of the CRCs work is that, often times, deadlines require that paperwork be completed immediately, which is not often possible with the campus’ units. This means that CRCs must often anticipate that something must be done even before they are to know about it.

Ultimately, it is important to utilize the network of clinical research coordinators as a resource for information and conflict resolution.

There was discussion in creating a core training course that would be mandatory for all Department of Medicine CRCs to ensure that every CRC is exposed to important regulations and information in a standardized format, possibly using the Cancer Center program as a guideline. Although the necessary framework is not currently in place to fulfill this request, it is being taken into consideration. In the meantime, please direct questions or concerns about policy and resources to Suzanne Sutton, via Michele Carter at mcarter@medicine.ucsf.edu.
The next CRC Meeting is scheduled for Tuesday, October 30, 2007 from 2:00-3:00 PM at Laurel Heights in room 430F.