

Department of Medicine
Clinical Research Coordinator Monthly Meeting
July 31, 2007 – 2:00-3:00, Parnassus S22

Present: Karen Borovitz, Michele Carter, Michele Downing, Lidia Espino, Fred Fishman, Irina Gorodetskaya, Ani Handajani, Natalie Jeha, Sarah Lee, Emily Little, Heather Logghe, Adrienne Moran, Marienna Murch, Patrycja Olszynski, Alex Rodas, Renuka Sippy, Jenny Spede, Suzanne Sutton, Erica Wong

Guest: Nina Feero

Medicare Clinical Research Policy (presented by Nina Feero)

Nina Feero, the Assistant Director of Health Plan Strategy and Contracting, spoke about the recent changes to clinical trial policy and the restructuring of procedures for setting up and executing clinical research.

General

Effective July 2007, Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) increased their oversight of clinical services performed during trials. These changes are intended to clarify the procedures for identifying, billing, and receiving payment for clinical services rendered to research patients. In addition to expanding the scope of research that will fall under these new policies, the Medical Center made the following significant procedural changes to ensure UCSF's compliance with CMS and OIG:

- 1) New reporting requirements that will help to facilitate a more thorough OIG auditing process in the future.
- 2) Mandatory utilization of a national site to register and track clinical trials (www.clinicaltrials.gov). Observational trials eventually may need to be registered as well. Registering is *essential* if the intent is to publish the research findings. 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.
- 3) Identification of all clinical services to be performed throughout the study prior to start of research.
- 4) Use of a QV modifier and diagnosis code V70.7 for all clinical trials any time a clinical service is provided to a patient covered by Medicare.
- 5) Use of a ZZ account for all research-related charges in all clinical trials. The ZZ account number will be included on all paperwork along with the visit number.

Services will be billed either to a ZZ account *or* to Medicare for standard-of-care services. Trial protocols should not consider the sponsor as the payer of last resort if Medicare covers the study's participants. All clinical services that will be rendered to research patients as part of the

research must be identified prior to the beginning of the study and must be documented in the budget. Standard pricing has been implemented for research services; if you are unsure of pricing for the trial, please contact Nina Feero. The Medical Center is still working to incorporate a protocol budget which distinguishes between research and standard-of-care services.

It is essential that all patients involved in clinical research be linked to the study in which they participate. This link is important for multiple reasons, but especially for patient safety and to maintain compliance. Therefore, an NCT number is now required when applying for a ZZ account. Jill Lezama (353-4446) is the UCSF administrator to contact for registering all investigator-initiated clinical trials to obtain an NCT number.

ZZ Accounts

The ZZ number is linked to the Regent's DPA/FUND number. There are currently two relevant Medical Record Numbers (MRNs): a unique, patient-specific MRN and a ZZ MRN/service number. The ZZ service number is not patient-specific; both MRNs must always be used. The NCT number that you receive when registering your clinical trial on the national site is now a mandatory data element on the "Clinical Research ZZ Medical Record/Visit Number Creation Request" form.

To gain access to a ZZ account, or to determine if there is already a ZZ account for the study, please contact Tim Arnold in the Medical Center's Patient Financial Services Department. As the ZZ account process is available only on paper, not electronically, Tim is the best resource for answering questions about ZZ accounts. ZZ accounts can be set up for a study without funds, so that patients can be tracked for care and complication information and reference.

QV Modifier

Using the QV modifier (to differentiate standard-of-care costs from research costs) can become confusing when patient visits incorporate both research and standard-of-care procedures. Most of these intermingled visits tend to be for inpatient services. Due to the high probability that patient visits will include both research and standard-of-care services, Tim Arnold automatically places a hold on any inpatient items. Once a hold has been placed, he will investigate the visit and will contact the relevant CRC if he is unable to clarify the charges.

The billing office should automatically parse out any patient visits that have been identified as not being for standard-of-care services.

CRCs are required to take the "Research Billing" training offered by the Medical Center. The content of this training is essential to ensure that CRCs are properly registering patients and are staying in compliance.

The next CRC Meeting is scheduled for Tuesday, August 28, 2007 from 2:00-3:00 PM in room LHTS 430F.