

Department of Medicine
Clinical Research Coordinator Monthly Meeting
August 28, 2007 – 2:00-3:00 PM, Laurel Height 430F

Present: Karen Borovitz, Michele Carter, Vivian Chang, Ian Jones, Elizabeth Steinfield, Suzanne Sutton

Guest: Fred Fishman

The CTSI Clinical Research Center or CCRC (presented by Fred Fishman)

Fred Fishman is a clinical research coordinator (CRC) for Joel Palefsky, the Director of the CCRC (formerly the GCRC) under the Clinical and Translational Science Institute (CTSI). He spoke about the structure and organization of the CCRC.

General

The CTSI Clinical Research Center (CCRC) is funded by the National Institutes of Health (NIH) and was created, in its current iteration, in 2002. The CCRC began as the GCRC, or General Clinical Research Center; while the term GCRC is being phased out, the terms GCRC and CCRC are used interchangeably. The GCRC began in 1959, when Congress mandated that the NIH establish a standardized network of clinical research centers connected by a common administrative structure. In 2002, the NIH introduced a revised strategy for the GCRC and introduced the CTSI award. The significant funds given to the CCRC by this award are utilized both by the Biostatistics Research Ethics and Design (BREAD) Program and by the various CCRC locations. The BREAD Program assists principle investigators (PIs) and research service analysts (RSAs) or CRCs design studies, requisition funding, and organize the set-up of clinical trials. The CCRC incorporates various facilities, which offer an array of services, including specimen collection and laboratory work.

The CCRC provides researchers with a “one-stop shop” for their clinical research studies, where recruited patients can be intaked, assessed, and provided all study clinical procedures in one location. The CCRC has its own nurses and inpatient beds that are dedicated to the clinical studies that are enrolled. The CRC will set up the protocol, recruit and register patients, and document patient consent. Once the patients are registered, the CRC will provide the CCRC staff involved in the trial with the protocol list. The CRC may also be responsible for some data analysis and collection. Prior to the patients being seen, the CCRC will hold an “in-service” for all CCRC staff participating in the study. During the in-service, physicians’ orders and protocol specifics will be finalized.

The CCRC has multiple advisory committees to review applications for clinical research. Protocols are reviewed for scientific merit, patient safety, and the study’s need for CCRC

services. Although these committees will not give their final approval until the trial has been approved by the Committee on Human Research (CHR), protocols may be reviewed by the CCRC and CHR simultaneously to expedite the approval process.

The CHR application should be submitted as soon as the trial protocol is finalized. Patients can be seen prior to contract approval providing that CHR approval has already been granted and that the Division or PI has accepted financial responsibility for the trial if it is not funded. Once the CCRC is given the finalized protocol, nursing staff working with the trial will complete the step-by-step protocol list. For an additional fee, the Biostatistics and Epidemiology group can handle the data recording.

Whether or not it is ideal to utilize the CCRC for a particular study depends on variables unique to each study and PI. If the infrastructure of the CCRC is not compatible with the particulars of a study, the services of the CCRC should not be used.

Billing

One significant aspect of the service the CCRC offers is linking the patient to the study. Although the CRC is responsible for creating the study's ZZ account, the CCRC will complete all other phases of patient linking. Other particularly helpful services that the CCRC offers are phlebotomist support, patient care, and clean-up for procedures.

Keep in mind that each patient, even those registered anonymously in a study, must have an MRN linked to their data. Anonymous studies may register patients under an alias to shield the patient's protected health information (PHI); studies in which patient anonymity is desired must present compelling arguments to the CTSI Advisory Committee prior to the protocol's acceptance by the CCRC.

Because the ZZ account number creates a link between subjects and the study, it is essential that every clinical trial have a corresponding ZZ number. This precaution is necessary for many reasons and must be completed for all clinical trials, even if there is no funding source and no charges ever will be made on that account. Subjects may be linked to several studies, but each visit is attached only to the ZZ account that should be charged for that visit.

The next CRC Meeting is scheduled for Tuesday, September 25, 2007 from 2:00-3:00 PM at Parnassus in room N 527.