ACTIVITY #7: Study Activation

7.1 Open Advance Account
If the sponsor agrees in writing (i.e., by e-mail) to provide funding for start up costs, the principal investigator can open an Advance Account. These accounts can be used to start recording your expenses early, prior to contract execution of the entire Clinical Trial Agreement. To set up the advance account, contact HS Contract-Clinical Trials Contracts. The Advance Account request form is located on the Health System Contracts webpage: http://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/requestforms.html

7.2 Open DaFIS Account
Upon receipt of IRB approval and execution of the Clinical Trial Contract by both UC Davis and the sponsor, a DaFIS account can be opened. The HS Contracts Office notifies Extramural Accounting to set up the extramural account. Once the DaFIS (Kuali) account is set up, the financial manager or CRC opens the Bulk Account.

7.3 Open Bulk Account
The Bulk Account is used to place clinical study specific charges for hospital and professional patient care services. Salaries and other expenses are posted directly to the DaFIS account. Use the Coverage Analysis Billing Grid as a tool to direct and review charges billed to the Bulk Account.

To open or close your Bulk Account or change information (e.g. end date or DaFIS#), email Patient Financial Services. The Bulk Account Application Form is located on the CTSC intraweb: http://intranet.ucdmc.ucdavis.edu/researchbudgeting/budgeting/index.shtml

For policy on establishing a Bulk Account see Hospital Policy and Procedures # 1815 http://intranet.ucdmc.ucdavis.edu/policies/hospital_policies_and_procedures/financial_management/1815.shtml

7.4 Post Information on clinicaltrials.gov
Clinicaltrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Title VIII of FDAAA, Public Law 110-85, amended the PHS Act by adding new section 402(j), 42 U.S.C. § 282(j). These provisions require that additional information be submitted to clinicaltrials.gov established by the National Institutes of Health (NIH)/National Library of Medicine (NLM). This includes expanded information on clinical trials and information regarding the results of clinical trials. This is a statutory requirement that applies to Investigational New Drug Applications (INDs), Biological License Applications (BLAs) and Investigational Device Exemptions.
(IDEs). The Sponsor or Sponsor-Investigator submits a certification (FDA Form 3674) attesting that the data will be submitted as available. Single patient, emergency use INDs do not fall under the referenced section, and therefore are not required to submit certification. Commercial IND/IDE sponsors are allowed to delay the data submission for commercialization purposes. Data submission by investigator-initiated studies is often dictated by the requirements of the scientific journal, where the investigator intends to publish.

Non-compliance with clinicaltrials.gov registration may result in fines up to $10,000/day.

For UC Davis-specific instructions on how to register a trial on clinicaltrials.gov, please reference [http://www.ucdm.ucdavis.edu/clinicaltrials/ClinicalTrialsGov/clinicaltrialsgov.html](http://www.ucdm.ucdavis.edu/clinicaltrials/ClinicalTrialsGov/clinicaltrialsgov.html)

Other Relevant Links


7.5 File paperwork into Study Binders
See Activity #11.8 for ideas on how to organize documentation.