CLINICAL TRIALS BUSINESS SUPPORT CENTER (CTBSC)

How to Open a New Clinical Study/Trial

DC = Dept. Contact = the PI or a study team member (e.g. clinical research coordinator or RN)  TI = Translational Informatics

1. The DC establishes the trial in OnCore with TI. [http://hub.ucsf.edu/oncore]
   a. Enter required information directly into OnCore. For training from TI contact oncore@ucsf.edu
   i. For observational studies that do not need a calendar build, according to the Coverage Analysis Matrix, please skip to Step 2 and upload drafts of the protocol, consent, and contract (if you have it); email clinicaltrials@ucsf.edu so the Assistants know the OnCore record is ready for processing. A Coverage Analyst will review the OnCore record and fill out the QCT checklist to complete UCSF documentation for your clinical project.
   b. The DC reviews the calendar build in OnCore to ensure accuracy and signs off on it when correct.

2. The DC uploads the following documents to OnCore for a new study as soon as they are available to the study team.
   a. Draft protocol or scope of work including a study calendar or Schedule of Events
   b. Draft informed consent(s); the Sponsor’s draft is needed at first
   c. Draft contract, funding sheet, etc. with payments terms, including the Sponsor’s budget
   d. Case Report Forms (CRFs) for UCSF PI-sponsored studies
   e. Other documents, depending on the type of trial (e.g. Lab Manual, FDA letter, etc.)
   f. Completed APeX set-up form except the procedure code pages. The CTBSC will verify data and send it directly for APeX study builds.
   g. TO EXPEDITE YOUR PROJECT, upload an Excel spreadsheet of the study calendar listing all required services with the PI’s billing determination, service provider name and address (see the example template posted on our web page.)

3. If you have not already submitted a study calendar in Excel with the required information, an Assistant Coverage Analyst (ACA) will email an Excel calendar to the DC for trial data listed below. NOTE that if you are using the CTSI CRS, they require the same trial data before they will issue a quote for services.
   a. Where the service is performed (building address is required)
   b. Who performs the service
   c. Whether the service is an APeX billable item
   d. Who is paying for each procedure (research or patient’s insurance)
   e. If the CTBSC is building your industry budget, PI & staff time estimated for trial services

4. Once the Excel Calendar is completed and returned to an Assistant, missing or unclear information will need to be resolved before the project advances. An Assistant will contact the DC and establish a plan for resolving unclear information and collecting service quotes and CPT codes.

In order to stay on track for a 90-day activation, Steps 1 - 4 should be completed within 2 weeks of the study team knowing they want to proceed, so do not delay your interaction with our office.

5. After required documents and information have been submitted via OnCore to the CTBSC office, a Coverage Analyst will begin a Coverage Analysis (CA). The CA may be done by a consulting group or an internal Coverage Analyst and a draft should be available in OnCore within 10 business days. A Coverage Analyst will:
   a. Verify that the study is a Qualifying Clinical Trial according to Medicare rules.
   b. Verify whether procedures may be billed to a subject with justification added to the OnCore comments section.
   c. Verify that study information is accurate in all clinical trial documentation.
   d. Verify that financial disclosure information in informed consent(s) meets guidelines.
   e. Add CPT codes in OnCore for items billed to the Research fund.

6. Once an IRB-approved consent is available, it should be uploaded to OnCore and a notification sent to clinicaltrials@ucsf.edu. The award will not be made until the CA is finalized, a final review of all trial data for compliance. The coverage analyst will sign-off on the CA in OnCore. The department confirms agreement by releasing the OnCore calendar.

Questions? Email clinicaltrials@ucsf.edu

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