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 (formerly known as CRISS)

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
    b. The DC reviews the calendar build in OnCore to ensure accuracy and releases it in OnCore 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)
    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.) Time assessments per service are collected when our office is developing your budget and building it in OnCore. If your department is not using OnCore for postaward invoicing, please note this in the comments of your submission to our office.

3. If you have not already submitted a study calendar in Excel with the required information, an Assistant Budget and Coverage Analyst (ABCA) will email an Excel calendar to the DC for trial data listed below:
    a. Where the service is performed (building address is required)
    b. Who performs the service
    c. How each procedure will be billed (research or patient's insurance)
    d. PI & staff time estimated for trial services (if the CTBSC is building your budget, this information is needed for labor calculations)

4. Once the Excel Calendar is completed and returned to the ABCA, missing or unclear information will need to be resolved before the project advances. The ABCA will call 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 4 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 our office, a Budget & Coverage Analyst (BCA) will begin a Coverage Analysis (CA). A first draft will be available within 5 business days. The BCA will:
    a. Verify billing designations
    b. Review medical procedures, rates & payments for compliance with federal/state regulations & UC policy
    c. If billing insurance, verify whether it can be billed under Medicare guidelines with justification added to the OnCore comments section.

6. It is highly recommended that the CTBSC negotiates trial payments directly with a sponsor or CRO.
    a. If the CTBSC is negotiating, then the DC reviews the initial counter offer & confirms agreement. The DC will be included in each subsequent counter offer.
    b. If the DC negotiates, the CTBSC will review the negotiated payments & terms for compliance. Any compliance issues will cause delays until resolved.

7. 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. A final CA is issued to the PI for agreement.