Opening a trial with the Clinical Trials Business Support Center (CTBSC)

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

1. The DC establishes the trial in OnCore with CRISS. http://hub.ucsf.edu/oncore
    a. The DC enters required information directly into OnCore (recommended) after receiving training from CRISS (contact oncore@ucsf.edu) **or** completes the REDCap survey on our web page. https://redcap.ucsfopenresearch.org/surveys/?s=Q7RI6J
    b. The DC reviews the calendar build in OnCore (or as an Excel spreadsheet, if not trained in OnCore yet) to ensure accuracy.

2. An Assistant Budget & Coverage Analyst (ABCA) collects documents and detailed information from the DC (via OnCore or email). For intake questions, please contact Catherine.Savangsy@ucsf.edu.
    a. The DC submits the following trial documents to the CTBSC:
        i. Draft protocol or scope of work including a study calendar or Schedule of Events
        ii. Draft informed consent(s)
        iii. Draft contract with payments terms, including the Sponsor's budget
        iv. Other documents, depending on the type of trial (e.g. Lab Manual, FDA letter, etc.)
    b. The DC is responsible for confirming the participation of all entities providing services to the trial including reaching agreement on remuneration (i.e. DCs work directly with other depts. & vendors to set up services for their trials). The DC initiates, collects, verifies, & corrects quotes for services & submits them to the CTBSC along with the Excel calendar issued by an Assistant BCA containing columns for collecting trial data listed below.
        i. Where the service is performed (building address is required)
        ii. Who performs the service
        iii. Procedure rates, if known.
        iv. How each procedure will be billed (research or insurance)
        v. PI & staff time estimated for trial services
    c. If billing to insurance, the DC should be able to identify evidence-based clinical practice guidelines followed for SOC. (e.g. UpToDate®, medical textbooks, or guidelines.gov)

3. Once all required information is received, a Budget & Coverage Analyst (BCA) will begin a Coverage Analysis (CA) in OnCore & the PI confirms agreement.
    a. Performs verification of billing designations based on the PI's plan (i.e. Step #2)
    b. Reviews rates & payments for compliance with federal/state regulations & UC policy
    c. Reviews medical procedures for applicable indirects based on location & provider information
    d. If billing insurance, verifies whether it can be billed under Medicare guidelines and documents justification.

4. For fixed price contracts, the CTBSC (or DC) will negotiate trial payments 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 reviews the negotiated payment terms, medical procedure rates, and budget for compliance with UC policies & federal/state regulations.

5. Once funding is secured, the CTBSC will configure a budget in OnCore based on final award documents.

6. To expedite the final award, the DC should email the IRB-approved consent to the CTBSC Analyst so s/he can finalize the CA. A final version of the CA is issued to the PI for agreement in OnCore (or via email).

7. The award will be processed only after the CTBSC has received all required information and reviewed all trial documents for consistency and billing compliance.