

How to Open a 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
 - i. **OR** (if not trained in OnCore yet) complete the REDCap survey on our web page <https://redcap.ucsfopenresearch.org/surveys/?s=Q7RI6J> Be aware that our REDCap survey will not be available after June 30, 2014, so plan to be trained in OnCore by then.
 - b. The DC reviews the calendar build in OnCore (or as an Excel spreadsheet, if not trained in OnCore yet) to ensure accuracy.
2. The DC uploads the following documents to OnCore (**or**, if not trained in OnCore yet, emails them to clinicaltrials@ucsf.edu) **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 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. Direct submissions by Depts. are no longer accepted by the APeX team.
3. Once the OnCore calendar has been checked for accuracy by the DC and released, 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
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. Once OnCore is populated with required trial data by the DC and ABCA, a Budget & Coverage Analyst (BCA) will begin a Coverage Analysis (CA) in OnCore.
 - a. Verification of billing designations
 - b. Review of medical procedures, rates & payments for compliance with federal/state regulations & UC policy
 - c. If billing insurance, verification of 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 budget from the CTBSC should be used. 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 in OnCore. (If not trained in OnCore yet, an alternative approval method via email will be used.)