How to Process an Amendment to 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 emails clinicaltrials@ucsf.edu with the following information:
   a. Subject Line: Award Number | iMedRIS Number | PI Name | Sponsor Name
   b. Attachments: Summary of Changes with PI’s preliminary billing determination

2. The DC uploads the following documents to OnCore as soon as they are available to the study team.
   a. Revised protocol
   b. Revised informed consent(s); the Sponsor’s draft is needed at first
   c. Revised contract, funding sheet, etc. with payments terms, including the Sponsor’s budget
   d. TO EXPEDITE YOUR PROJECT, upload an Excel spreadsheet of the study calendar listing new 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 new service is performed (building address is required)
   b. Who performs the service
   c. Whether the service is an APeX billable item
   d. How each procedure will be billed (research or patient’s insurance)
   e. 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 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 amendment timeline, 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 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.