Clinical Trial Start-up Checklist for PIs and Study Coordinators

1. Compliance Training Requirements:
   - PIship Training (one time) [http://www.stanford.edu/dept/DoR/PIship/](http://www.stanford.edu/dept/DoR/PIship/) (PI)

2. Contract and Budget Process Initiation Requirements: (Study Coordinator/PI)
   Please send the following items to rmg_ct_intake@stanford.edu:
   - For The Budget Process
     - Completed SHC/LPCH Budget and Billing Workbook: [https://spectrum.stanford.edu/accordions/set-up-study](https://spectrum.stanford.edu/accordions/set-up-study). Click on the Log In link located at the top right corner of the website. Enter your SUNet ID and password. Click on Complete the SHC/LPCH Budget and Billing Workbook link located in the center of the page.
       - Please include:
         - Completed Research Participants Services (RPS) form and Routine Services Care form
         - All research items on RPS form must include CPT/Service Codes (if applicable)
         - For Complex Procedures/Surgeries: Actual patient bills of similar procedures may be required to estimate pricing. Meetings with hospital service units may be required.
     - Protocol (can be sent directly to rmg_ct_intake@stanford.edu or via IRB application in eProtocol)
       The Protocol is required for the Contract Process as well.
     - Sponsor’s Contact Information for the budget (if applicable)
   - For Studies utilizing CTRU services:
     - The study must be registered with Study Navigator: [http://spectrum.stanford.edu/studynavigator/](http://spectrum.stanford.edu/studynavigator/)
     - The CTRU has a new Budget Planner that is required for the budget. The Budget Planner can only be accessed through Study Navigator.
   - For The Contract Process
     - Sponsor’s Contract and Payment schedule
     - Sponsor’s Contact Information for the contract

3. Additional Requirements (Study Coordinator/PI)
   - For All Studies:
     - IRB application: [https://eprotocol.stanford.edu/](https://eprotocol.stanford.edu/)
   - For Child Health Studies:
     - All Child Health investigators are required to enter their new studies into the Study Navigator beginning January 1, 2011. [http://spectrumchildhealth.stanford.edu/services/study-navigator.html](http://spectrumchildhealth.stanford.edu/services/study-navigator.html)
For Device Studies:

- Medicare Pre-Authorization must be obtained for those under IDE. This may take up to 8 weeks. The CTRPM will provide the Coordinator with the application forms and instructions.
- If the device will be purchased by Stanford, SHC will have to establish appropriate records to be compliant with Medicare billing regulations. The coordinator will collaborate with Spectrum to complete a ‘charge code template’ form. This should be initiated very early and the process may be complex. The CTRPM will notify Spectrum.
- Sponsor’s Medicare Reimbursement Guide (if available)