



# Investigator-Initiated Clinical Trial Start-up Checklist for PIs and Study Coordinators

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## 1. Compliance Training Requirements:

- Plship Training (one time) <http://www.stanford.edu/dept/DoR/Plship/> (PI)
- Human Subjects CITI Training [http://humansubjects.stanford.edu/resources/req\\_tutorial.html](http://humansubjects.stanford.edu/resources/req_tutorial.html) (All budgeted Staff)

## 2. Contract and Budget Process Initiation Requirements: (Study Coordinator/PI)

Please send the following items to [rmg\\_ct\\_intake@stanford.edu](mailto:rmg_ct_intake@stanford.edu):

### For The Budget Process

- Completed SHC/LPCH Budget and Billing Workbook: <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:
  - o Completed Research Participants Services (RPS) form and Routine Care Services form
  - o All research items on RPS form must include CPT/Service Codes (if applicable)
  - o For Complex Procedures/Surgeries: Actual patient bills of similar procedures may be required to estimate pricing. Meetings with hospital service units may be required.
- Proposal/Scope of work
- Schedule of Events (recommended)
- Sponsor's Contact Information for the budget (if applicable)
- IND/IDE Application to the FDA (if applicable)

### For Studies utilizing CTRU services:

- The study must be registered with Study Navigator: <http://spectrum.stanford.edu/studynavigator/>
- The CTRU has a new CTRU Budget Planner that is **required for the budget**. The Budget Planner can only be accessed through Study Navigator.

### For The Contract Process (Initiated once the Proposal is approved)

- Sponsor's Contact Information for the contract

## 3. Additional Requirements (Study Coordinator/PI)

### 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>

***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)