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

## Compliance Training Requirements:

* PIship Training (one time) [*http://www.stanford.edu/dept/DoR/PIship/*](http://www.stanford.edu/dept/DoR/PIship/) (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*](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 Care Services 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.
* 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/*](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

## 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*](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)