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/ *(PI)*
- ☐ Human Subjects CITI Training 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:

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 Services Care 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.

- ☐ 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/
- ☐ 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/

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)