1. **Compliance Training Requirements:**
   - PIship Training (one time) [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 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

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](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)