After it has been determined to move forward with an industry sponsored clinical study. The first step is to receive the “startup” package from sponsor. This includes protocol, draft, Contract draft, budget draft, IB, regulatory docs such as 1572, etc.) Once this has been received, you have the needed information to begin start up activities.

***This checklist was created to help department staff ensure all items required to be submitted to SPA for CTA projects have been completed.***

Submit protocol to IRB

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* This initiates the coverage analysis build process in SPA.

Submit new START Agreement record to SPA. Submit the contract via START by creating a New Agreement record. (Select type “Clinical Trial Agreement”)

* + Complete Agreement Information Form
  + Upload a copy of the draft agreement provided by sponsor
  + Upload a copy of Protocol
    - *NOTE- SPA gives the highest priority to those agreements in which the proposal record has been submitted. This ensures SPA prioritization is in line with departmental priorities*

Billing Coverage analysis has been completed (SPA staff or START will send notification when CA is completed and uploaded into START. (See Coverage analysis process here [Link](https://www.uth.edu/sponsored-projects-administration/plan-propose/clinical-trials-research/coverage-analysis) )

Internal budget/cost analysis has been completed by department staff (see CAIB tool guidance document under “Tools and Resources> Form &Templates [Link](https://www.uth.edu/sponsored-projects-administration/tools-resources/forms-templates)- Clinical Research Finance section.)

Budget negotiations with Sponsor have been completed by the PI/Study team. (see CAIB tool guidance document under “Tools and Resources> Form &Templates [Link](https://www.uth.edu/sponsored-projects-administration/tools-resources/forms-templates)- Clinical Research Finance section.)

Submit a Proposal Development (PD) Record to SPA for budget review and approval

* See START guidance document “Clinical Trials-PD  [Link](https://www.uth.edu/sponsored-projects-administration/tools-resources/system-access-guides/uthealth-start) This document provides step by step instructions.
* Upload required documents. The PD record must be completed accurately and data entered into all tabs. The following documents must be uploaded under the attachments tab:

1. Copy of Final budget with sponsor
2. Copy of the CAIB tool with completed internal budget information
   1. *The above 2 documents are required for budget approval*
3. Copy of IRB approval(s) and Approved ICF
4. RCOI form signed for everyone listed as members of the study team on the R&A form
   1. The above 4 documents are required to be uploaded for proposal record finalization- routing contract for approval.