PI connects Sponsor with OSP

OSP negotiates and executes Confidentiality Agreement (CDA)

PI reviews protocol and feasibility to determine Yale’s participation

PI/Dept provides the following to OSP:
- Transum
- Yale Informed Consent Form (ICF)
- Contact information
- Draft Agreements
- Protocol

OSP reviews ICF and discusses with research coordinator and sponsor

PI submits application to IRB

Upon IRB approval PI notifies OSP

OSP responsibilities for Clinical Trial Agreement (CTA)
- Review, negotiate, approve and execute
- Ensure budget consistency
- Confirm consistency with ICF and protocol

Simultaneous Process

Simultaneous Process

Simultaneous Process

OSP sends final CTA to PI for review and signature

OSP obtains all signatures and submits to Award Set Up (ASU)

OSP Process Complete

Department or YCCI initiates budget discussion

Dept/YCCI collaborates with OSP to align budget, payment terms and CTA terms

Budget negotiated and finalized with industry sponsor

Yale University
Office of Sponsored Projects, Clinical Agreements

INDUSTRY-SPONSORED CLINICAL TRIAL PROCESS