

# Workflow for Industry Sponsored\* Clinical Trials at USC

## Initial Communication

- Sponsor or Principal Investigator (PI) expresses interest in conducting a clinical trial at USC

## Confidential Disclosure Agreement (CDA)

- Sponsor sends CDA to investigator (CDA ensures secrecy of proprietary info)
- Investigator submits CDA to clinical trials office (CTO) thru OnCore
- CDA must be executed before sponsor will send additional information

## Protocol Acceptance

- Sponsor sends feasibility questionnaire to investigator (optional)
- Sponsor sends protocol to investigator
- Investigator/dept decide whether to accept the clinical trial

## Site Qualification Visit

- Sponsor determines site has facilities, staff, equipment and population necessary to complete the clinical trial

## Site Package

- Sponsor sends investigator protocol and documents needed for IRB submission
- Sponsor sends investigator initial contract and budget for submission to clinical trials office (CTO) thru OnCore

## Contract & Budget in OnCore

- Contract and budget submitted to CTO thru OnCore
- Study calendar built
- Medicare coverage analysis (MCA) conducted before budget and contract negotiation can begin
- Budget and contract must be complete for CTO to verify consistency between ICF and contract

## IRB Submission in ISTAR

- Investigator completes IRB submission including protocol, informed consent form (ICF) and HIPAA documents
- Changes to ICF must be reviewed by sponsor
- Approval letter issued by IRB
- ICF released by IRB when contract and budget are executed and ICF consistency has been verified

## Study Start

- CTO uploads final executed documents to OnCore: MCA, contract, budget and ROF
- Each new subject is enrolled in OnCore and a signed consent form and HIPAA uploaded for each subject
- Study calendars available in OnCore for tracking subject visits
- ClinCard must be arranged for subject compensation with University card services

\* Non-industry sponsored trials must be routed through Dept of Contracts and Grants

Post award billing is conducted by CTO