Principal Investigator/Study Coordinator Responsibilities:

Confidential Disclosure Agreements (CDA)
- Sponsor sends CDA to Principal Investigator (PI)
- PI sends CDA to ORA with routing form for authorized signature
- Upon execution of CDA, PI receives Protocol from Sponsor
- PI informs Sponsor and ORA if he/she decides to (or not to) participate in Clinical Study

Clinical Trial Agreements (CTA)
- Sponsor sends CTA to PI or ORA
- PI submits required applications/forms to University and OUMC offices
  - ORA routing form
  - IRB and IBC applications and Exhibit A/B, if required
  - Risk Assessment form, if requested by ORA
- PI negotiates budget with Sponsor, including required overhead costs, IRB fees ($2,000)
- PI confirms compliance with specific contract terms, as requested by ORA
- PI reads and signs CTA in acknowledgement of terms when ORA has finalized negotiations
- Clinical Study can begin after contract is fully executed and IRB approval obtained

Office of Research Administration Responsibilities

COM Goal: Confidentiality (3 days) and Clinical Trials Agreements (3 wks)
- Pre-reviews contract for legal and university compliance
- Obtains Legal review from OUHSC Legal Counsel
- Negotiates required modifications with Sponsor, if necessary
- Coordinates consistency in language between contract IC & HIPAA authorization forms
- Prepares Risk Assessment packet, if required; communicates with APIC, if required
- Obtains PI approval of certain terms, as necessary
- Verifies IRB approval
- Obtains fully executed contract (authorized signatures from OUHSC and Sponsor)
- Notifies IRB when contract is fully executed so IRB approval letter can be released
- Requests establishment of C account from Grants and Contracts Accounting
- Post-award administrative responsibilities
  - Prepares & negotiates sub-agreements, as needed
  - Processes no-cost extension requests
  - Process contract amendments