

## **INDUSTRY-SPONSORED RESEARCH**

OUHSC Office of Research Administration: Clinical Trials Division

### **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