## CLINICAL TRIAL START-UP FEES

STUDY START-UP COSTS MAY INCLUDE ANY OR ALL OF THE FOLLOWING ITEMS

### MEETINGS
- Attendance at Investigator meetings
- Site evaluation visit (SEV)
- Site initiation visit (SIV)

### BUDGET & FINANCIAL
- Budget development
- Budget/contract negotiation
- Setting up study financial accounts
- Building financial tracking calendar

### REGULATORY
- Feasibility questionnaires
- Preparing of regulatory documents (CDA, 1572, updated CV & Med. licenses, lab licenses, financial disclosure, delegation of authority)
- Setting up study regulatory binder and updating database
- Submitting documents for committee approvals (Site Review Authority, Radiation, Biosafety, Conflict of Interest)

### TRAINING
- Reviewing CRF and attending training
- Sponsor training of their data system (Interlink, CPAC)

### CLINICAL PREP WORK
- Preparation of study clinical package/binder
- Developing study fact sheet, protocol worksheet, and orders
- QA/QC monitoring tools, insurance authorization form etc.
- Receiving sponsor supplies and equipment

### ADMINISTRATIVE
- Addressing all communications from sponsor/CRO
- Protocol registration (CT.gov & CTRP)
- Setting up study specific meeting/training with screening team, treatment staff & pharmacy

### OTHER
- Principal Investigator fee
- Scientific Review Committee fee
- HIPAA Authorization
- Setting up Pharmacy Service
- Initial protocol review

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[University of Arizona IRB Fee](Web)

[Central IRB submission fees](Web)