THE UNIVERSITY OF ARIZONA | COLLEGE OF MEDICINE

Research Office
University of Arizona
College of Medicine – Tucson
1501 N. Campbell Ave.
PO Box 245016
Tucson, AZ 85724-5016

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)

IRB

- IRB Submission – preparing documents (PAF, ICF, IB, etc.)
- Responding to IRB questions, obtaining and submitting other documents required by the IRB
- University of Arizona IRB Fee [Web]
- Central IRB submission fees [Web]

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