

Services of the Clinical Research Administration Division

MARKETING

- Marketing to pharmaceutical companies
- Marketing to contract research organizations
- Establish relationships with sponsors in order to recruit new trials as a result of previous studies
- Recruit studies from sponsors on behalf of individual investigators
- Maintain a file of physician interests
- Receive notification of new studies and recruit investigators

PRE-INITIATION

- Attend site evaluation visits to answer institutional questions study processing and activation time
- Serve as centralized sponsor contact point for the Medical Center
- Provide protocol development services for investigators
- Prepare consent form for investigator's review
- Secure Human Subjects Committee approval of protocol and consent form
- File regulatory documents required by FDA and sponsor
- Submit research administration checklist to Office of Sponsored Programs
- Prepare and negotiate trial budgets
- Request discounts for hospital and clinical services
- Apply for study billing number
- Coordinate confidentiality agreement and contract approval with Contracts Division of the Research Institute
- Notify investigator and sponsor of final HSC approval
- Prepare and submit initial IND documents, amendment and annual progress reports for IND

POST-INITIATION

- Secure HSC approval of protocol revisions and revised consent forms
- Obtain HSC approval for print or media advertising
- Process internal adverse events and IND safety reports for HSC submission and approval
- Provide status reports of each investigator's trials as requested
- Submit reports to HSC for annual re-certification of trials
- Coordinate ongoing communication between sponsor and investigator

STUDY CLOSURE

- Process study closure for trial termination

QUALITY IMPROVEMENT FOR CLINICAL RESEARCH

- In conjunction with the Office of Compliance, conduct quality improvement visits [QIV]

EDUCATION OPPORTUNITIES

- Host and organize Clinical Trial Education Lecture (CTEL) series on a monthly basis
- Provide training workshops (CTEC) for investigators and study coordinators
- Meet with physicians and study coordinators to review Research Institute services
- Provide new study coordinator/research nurse orientation
- Facilitate coordinator certification, networking and educational opportunities