

## **GUIDELINE FOR OPENING A STUDY AT OCR**

### **Cooperative Group Protocol Submissions**

- Notify the Office of Clinical Research (OCR) that you are interested in opening a cooperative group protocol (at least 7-10 days prior to C.R.A.B.).
- The OCR will distribute copies of the protocol to 2-3 reviewers. (The PI may suggest reviewers.)
- PI presents protocol to C.R.A.B for feasibility, conflict, patient population, and general concerns
  - ✓ If accepted, the OCR will complete the initial submission packet and submit to the IRB.
  - ✓ If rejected, the protocol is finished.

### **Investigator Initiated Protocol Submissions**

- Principal Investigators must check with their departments for protocol development guidelines.
- Notify the Office of Clinical Research (OCR) that you are interested in opening an investigator initiated protocol (at least 7-10 days prior to C.R.A.B.).
- The OCR will distribute copies of the protocol to 2-3 reviewers. (The PI may suggest reviewers)
- PI presents protocol to C.R.A.B for feasibility, conflict, patient population, and general concerns.
  - ✓ If accepted, the protocol is then presented to the Scientific Review Committee (SRC).
  - ✓ If rejected, the protocol goes back to the investigator.
- Once accepted by the SRC, the investigator needs to submit the following to the Office of Clinical Research:
  - 1 copy of the Protocol
  - 1 copy of the Agreement/Contract
  - 1 copy of the Investigator's Brochure
  - 1 copy of Advertisement (if applicable)
  - 1 copy of Diary Cards, patient's Questionnaires (if applicable)
  - 1 copy of IND number (if applicable)
  - 1 copy of the Consent Form (The OCR will put into Tulane format and include HIPAA statement)
  - 1 copy of the Biospecimen Collection Consent Form (if applicable)
- The OCR will complete the initial submission packet and submit to the IRB.

### **Pharmaceutical Protocol Submissions**

- Principal Investigators review the protocol and start budgeting and contracting process.
- Notify the Office of Clinical Research (OCR) that you are interested in opening an industry sponsored protocol (at least 7-10 days prior to C.R.A.B.).
- Contact the OCR for cost analysis and OCR fees.

- The OCR will distribute copies of the protocol to 2-3 reviewers. (The PI may suggest reviewers.)
- PI presents protocol to C.R.A.B for feasibility, conflict, patient population, and general concerns.
- Once approved by C.R.A.B. the investigator needs to submit the following to the Office of Clinical Research:
  - 1 copy of the Protocol
  - 1 copy of the Agreement/Contract
  - 1 copy of the Investigator's Brochure
  - 1 copy of Advertisement (if applicable)
  - 1 copy of Diary Cards, Patient's Questionnaires (if applicable)
  - 1 copy of the Sample Consent Form (the OCR will put into Tulane format and include HIPAA statement)
- The OCR will complete the initial submission packet and submit to the IRB.