

### **SPA's Procedure for Processing Pharmaceutical Clinical Trials:**

1. Administrator and/or PI enters a complete\* proposal into eProp and routes it through the pipeline to SPA.
2. Once received via eProp, the Contract Administration team within SPA will review the complete proposal and send the contract and affirmation memo to the Office of General Counsel (OGC) within 2 business days. We will contact the PI and/or Administrator if there are problems with the proposal.
  - a. If the contract comes back NOT APPROVED by OGC:
    - i. SPA will handle all contract negotiations. SPA will email the sponsor with the requested changes. The PI and/or Administrator will be copied on the correspondence with the sponsor.
    - ii. Once SPA receives a response to the requested changes from the sponsor, SPA will review the contract, get input from the PI or Administrator if necessary, and return the updated contract back to OGC for review. If the contract has further requested changes, SPA will continue the negotiation process until we receive an approved contract.
  - b. If the contract comes back APPROVED by OGC and:
    - i. The proposal is complete - SPA will request and obtain the necessary signatures and mail the contract back to the sponsor. A copy of the contract will also be emailed to the PI and/or Administrator.
    - ii. The proposal is not complete - SPA will contact the PI and Administrator to remind them of what is still needed. Once the proposal is complete, SPA will request and obtain the necessary signatures and mail the contract back to the sponsor. A copy of the contract will also be emailed to the PI and/or Administrator.
3. Once the University has signed off on the contract and HIC is approved, the proposal will be turned over to the Grant and Contract Officer for an index establishment as an Internal Tentative (if the contract is partially executed) or an Active award (if the contract is fully executed).
4. The index number and fully executed contract will be sent to Clinical Financial Services (CFS) for billing purposes.

\* A complete proposal consists of a complete eProp submission as well as the following included as attachments to the proposal: 1) the clinical trial agreement, 2) an affirmation memo signed by the PI 3) the internal budget, 4) the study protocol, and 5) the sponsor contact information