WISPER – Clinical Trial Review

To facilitate the timing of negotiations of Clinical Trial Agreements, the following process may be used. Note: this process is to be used only with Clinical Trial Agreements funded on a per patient basis and not for Research Agreements.

I. Pre-Review
1. Create WISPER Record
   a. Submission Instructions must include:
      i. Sponsor contact name, phone, e-mail,
      ii. Special provisions (i.e., study is time-sensitive)
      iii. Indication if this is an investigator-initiated trial

2. Use APPROVAL function
   a. Use Clin Trial Pre-Review approval type
   b. Select Larry Westby as Approver
   c. Do NOT use Route function

3. RSP process:
   a. If Larry assigns the record to another RSP staff member, he will transfer the Approval
   b. Larry will assign the RSP staff who will negotiate on the SPO Action page.
   c. If information is missing or incorrect, RSP will contact the Campus Contact listed on
      the general tab of WISPER.
   d. The person working of the agreement will change the Status to 4.5.
   e. When the agreement is final, the RSP owner will notify the Campus Contact and
      upload a copy into WISPER.
   f. When Campus Contact is ready to route the WISPER record, they will ask the RSP
      owner to put it in status 1.

II. Final Routing (before RSP signature)
1. Campus Contact completes the WISPER record:
   a. Attach Budget
   b. Enter Protocol information
   c. Complete Project tab information
      (no effort is entered for clinical trials)
2. ROUTE to Division with PI signature and Chair approval
3. Division will forward to RSP using the Submit to SPO or Request Advance
   Award buttons as appropriate