How To Start a Corporate Funded Clinical Trial

CTA Checklist

☐ Access UIRIS
☐ In UIRIS complete University of Iowa Proposal Routing Form….“Begin New Routing Form”
   - Complete all necessary fields
   - Submit and Print Form
   - Obtain signatures as required by your departmental policies
☐ Email the following documents to DSP at clinical-trials@uiowa.edu. Identify in the email: PI name, Sponsor name, Routing Form Number
   △ Copy of the CTA (Word Document Format)
   △ Budget
   △ Protocol
   △ CRO/Sponsor Contact Information
   △ Submission/shipping instructions from the sponsor
☐ DSP will send notification to research team that all materials have been received. KEEP THIS EMAIL. You will need to submit it with your IRB application.
   - Make note of the DSP Contract Administrator assigned to this project
   - Make note of the Sequence number that has been assigned; it is very useful in further communication with DSP.
☐ DSP Contract Administrator may meet with research team to discuss any special considerations
☐ Research team member prepares, negotiates and finalizes budget with CRO/Sponsor
☐ Check the DSP Contract Log for progress on the negotiation of CTA language
☐ Research team member emails completed budget to assigned DSP Contract Administrator
☐ If required, PI signs final version of CTA when received from DSP
   - Return contract to DSP for University signature. DSP will acquire sponsor’s signature, and then finalize the contract.
☐ IRB will release final approval documents to the research team once the DSP has notified the HSO there is a final signed contract with the sponsor
☐ DSP releases the agreement to the UI Grant Accounting Office (GAO). GAO will assign the MFK account number for the study and GAO will release the Award Activation Authorization Notice (AAAN)
☐ DSP will email copy of final signed CTA to research team member