Clinical Trial Checklist

Determine if the project is a clinical trial and type of sponsor

**Non-Industry Sponsored Clinical Trial**
- Create CRMS record.
- Submit CDA to in the Industry Contracting Office through CRMS. (note: CRMS still has the OCT listed and not the Industry Contracting).
- Industry Office notifies of fully executed CDA.
- Conduct feasibility assessment.
- Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- Submit to IRB.
- Create IPF.
- PI certifies IPF.
- OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks
- Once all compliance checks completed and agreement executed, PS project ID assigned

**Solicited or Unsolicited Full Proposals**
- Create and submit IPF.
- PI certifies.
- OSR review.
- Create CRMS record.
- Conduct feasibility assessment.
- Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- Submit to IRB.
- OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks
- Once all compliance checks completed and agreement executed, PS project ID assigned

**Industry Sponsored Clinical Trial**
- Create CRMS record.
- Submit CDA to in the Industry Contracting Office through CRMS. (note: CRMS still has the OCT listed and not the Industry Contracting).
- Industry Office notifies of fully executed CDA.
- Regulatory packet received from sponsor.
- Conduct feasibility assessment.
- Submit CTA to the Industry Contracting Office for negotiation, PI certifies submission
- Create BCA
- Submit to the Scientific Review Committee or Protocol Review committee as applicable.
- Submit to IRB.
- Create IPF.
- PI certifies IPF.
- OSR will confirm PI Eligibility
- Once all compliance checks completed and agreement executed, PS project ID assigned.
OCT Compliance Checks Include

☐ Confirmation of IRB approval
☐ Review of subject injury and cost language in the approved ICF against the fully executed CTA for congruency.
☐ Confirm GCP training for all personnel listed on the IRB application is current.
☐ Confirm COI training, disclosure and review is current and complete for both those personnel listed on the IRB application and the RAMSeS IPF.
☐ BCA is complete through all steps and PI has certified.