# Clinical Trial (CTA) Lifecycle

HEALTH SCIENCES

1. **Initiation**
   - PI/Institution identifies the need for a clinical trial and submits a request for a CTA to the SPO
2. **Drafting/Review**
   - The initial draft of the CTA is prepared, outlining the terms/conditions, scope of work, budget, and compliance requirements
   - The draft CTA undergoes internal review by SPO, Legal (if necessary) and Privacy (if necessary) to ensure it meets institutional policies and legal standards
3. **Negotiation**
   - Both parties (the sponsor & institution) review the draft CTA and negotiate any necessary changes. This step ensures that the agreement is mutually acceptable and protects the interests of both parties
4. **Approval/Signing**
   - The final version of the CTA is reviewed and approved by authorized representatives from both institution, including an acknowledgement by the PI
   - The CTA is signed by the authorized signatories, making it legally binding
5. **Study Activation**
   - If necessary, the preaward spending accounts are set up to cover initial study costs
   - The study protocol is submitted to the IRB for ethical review and approval
6. **Conduct of the Trial**
   - The clinical trial begins, adhering strictly to the protocol and terms outlined in the CTA
   - Regular progress and financial reports are submitted to ensure compliance with the CTA terms
   - Both parties ensure ongoing compliance with the CTA and any applicable regulations
7. **Amendments**
   - Any necessary changes to the scope of work, budget, or duration are negotiated and documented through formal amendments to the CTA
8. **Closeout**
   - The PI/Accounting Office submits final technical and financial reports to the sponsor
   - The institution conducts a final review to ensure all terms and conditions of the CTA have been met
   - All required closeout documentation is completed, and the project is officially closed

**Contact HSC-Preaward@salud.unm.edu or 272-9383 w/questions**