**10 Protocol Development Steps**

1. **Pre Development** – Pre LOI/RFP Submission point where the Sponsor Investigator has identified a research concept.
2. **Concept Development** – IST Research Proposal Form completed which is the transformation of the concept from Pre Development into a written document. The completion of the form marks Day 0 (Initiation of the Protocol Development Process).
3. **Grantor LOI / RFP Review** \*– Grantor review of the concept paired with a draft protocol document, demonstrating a commitment to the proposed project’s focus and expedited movement.
4. **Protocol Development** – Refinement of the Draft Protocol document toward a final submission-ready protocol.
5. **Grantor Review** \*– Grantor review of the concept review of the final protocol.
6. **Feasibility & RRC Review** – Prioritization and assessment of the protocol from a resource utilization, scientific value and catchment area perspective.
7. **FDA Review** – Food and Drug Administration review and issuance of an IND or IDE for those protocols required to be conducted under an IND or IDE per 21 CFR 312 or 21 CFR 812 respectively.
8. **IRB Review** – Institutional Review Board Review
9. **Study Start-Up** – CTRP and clinicaltrials.gov registration and confirmation that all elements required to activate have been adequately addressed concluding with an SIV meeting.
10. **Activation** – Post SIV assessment of required training and documentation followed by study activation and study status updates on CTRP and clinicaltrials.gov webpages.

\*While this process is outside of the protocol development process, the IST Program staff will track the Grantor process status and regularly pursue *(every 2 weeks)* a final decision from the Grantor; where applicable until such time that a terminal decision is made and the project is approved or rejected.