Clinical Trial Agreement Processing Checklist -Department

☐ 1. Conduct a Feasibility assessment

☐ 2. Submit Contract to SPA to initiate contract review
   - Email to CRF@uth.tmc.edu
   - Include a copy of:
     - Draft agreement
     - Protocol
     - Draft ICF
     - Draft budget proposal

☐ 3. Submit protocol to IRB

☐ 4. Negotiate budget with sponsor
   - Include SPA Clinical Trial Administrator on the cc during the negotiations which will provide status updates (SPA is also required to have a copy of the final budget)

☐ 5. Coverage Analysis (CA) documentation
   - Complete all tabs within UTHealth Coverage analysis (CA) excel form
   - “Billing Attestation” form signed by PI
   - “Qualifying Trial Assessment” form completed and signed by PI
   - “Coverage analysis approval” email from CRF received

☐ 6. R&A form- submit to SPA

☐ 7. RCOI form for each member of the study team- submit to SPA

☐ 8. IRB Approval letter - submit to SPA

☐ 9. Route the final agreement for PI signature - submit to SPA

*Contract will not be submitted for institutional signature until items #5, #6, #7, and #8 above are received.*