Clinical Research Contract Execution Timeline

**SPA / DEPARTMENT**

- **Day 0**: Sponsor Provides Draft CDA to UTSW/PI
- **Day 3**: PI Submits to SPA
- **Day 5**: Master CDA in place
- **Day 5-14**:
  - SPA submits redline to sponsor by day 5
  - Sponsor returns to SPA by day 9 with initial comment
  - Day 9-12 finalize negotiation
  - Day 12-14 signatory routing
  - CDA execution by day 14 for Stand Alone
- **Day 25-90**:
  - SPA negotiates agreements with Sponsor
  - **Day 5-14**: SPA submits redline to sponsor by day 5
  - Sponsor returns to SPA by day 9 with initial comment
  - Day 9-12 finalize negotiation
  - Day 12-14 signatory routing
  - CDA execution by day 14 for Stand Alone
- **Day 15-24**:
  - Draft Clinical Trial Agreement (CTA)
  - Draft Coverage Analysis (CA)
  - Draft IRB Submission
  - Draft Budget
- **Day 15-45**:
  - Draft Clinical Trial Agreement (CTA)
  - Draft Coverage Analysis (CA)
  - Draft IRB Submission
  - Draft Budget
- **Day 15-30**:
  - Draft Statement of Work (SOW)
- **Day 15-45**:
  - Draft Statement of Work (SOW)
  - Draft Coverage Analysis (CA)
- **Day 15-60**:
  - Finalized Coverage Analysis (CA)
  - Submitted IRB
- **Day 15-90**:
  - Final Budget
- **Day 25-90**:
  - SPA sends final Agreement to PI for review and signature
  - SPA obtains all signatures and submits to Award Setup team
  - Final budget sent to SPA

**IRB Submission**

- Department and/or OCRP collaborates with regulatory to confirm draft Informed Consent (IC) aligns with budget
- PI submits application to IRB (or requests authorization from HRPP to use external IRB)
- IRB/HRPP submit approval; SPA verifies via direct access in eIRB

**SPA negotiates agreements with Sponsor**

- **Day 15-24**:
  - Review, negotiate, approve & execute CTA
  - Confirm consistency between CTA, including budget, and (IC)
- **Day 15-45**:
  - Review, negotiate, approve & execute CTA
  - Confirm consistency between CTA, including budget, and (IC)
- **Day 15-30**:
  - Review, negotiate, approve & execute CTA
  - Confirm consistency between CTA, including budget, and (IC)

**SPA Process Complete**