INDIANA UNIVERSITY
MELVIN AND BREN SIMON
COMPREHENSIVE CANCER CENTER

IUSCCC Protocol Development Levels of Service

Level 1: Basic (retrospective, non-CTO, non therapeutic studies, observational studies)

Allow average 2-6 weeks from initial review to SRC submission

1. Protocol Development

    - Protocol Review/Drafts and revisions
    - Consent Draft/Revisions (as required)
    - Draft SRC documents (provide templates if necessary)
    - SRC submission (includes request for exemption for retrospective trials only) and assistance with approval as required

2. Amendments- support as requested (no support for non-CTO trials)
3. Study Procedure Manual (SPM) or Protocol Supporting Document (i.e. recruitment materials)- no support
4. CT.GOV- support on request

Level 2: Moderate (correlative studies, non-drug interventional studies, radiation oncology studies etc.)

Allow average 6-8 weeks from initial review to SRC submission

1. Protocol Development

    - Protocol Review/Drafts and revisions
    - Consent Draft Review/Revisions
    - Draft and review SRC documents (provide templates if necessary)
    - SRC submission and assistance with approval
    - Assist with IRB and Post-SRC required modifications to study documents as needed
    - Basic study start up project management services (i.e. coordinating with finance, Biostats, basic science collaborators, study team etc.)

2. Amendments-
    - CTO- full support
    - Non-CTO- support if requested/ SRC required Amendments

3. Study Procedure Manual (SPM)/ Protocol Supporting Documents
    - CTO- full support
    - Non-CTO- support if requested

4. CT.GOV
   - CTO- full ct.gov services (registration, maintaining record, assist in managing results reporting, etc.)
   - NON-CTO: support if requested (will not assist with results reporting)

5. IND Exempt Initial Submission Support
   - CTO: full support
   - NON-CTO: no IND support

Level 3: High (phase 1, therapeutic trials that require an IND, multicenter studies etc.)

Allow average 8-12 weeks+ from initial review to SRC submission

1. Protocol Development

   - Protocol Review/Drafts and revisions
   - Consent Draft Review/Revisions
     - Incorporating IB/PI risks and pharma template language as required
   - Draft and review SRC documents (provide templates if necessary)
   - SRC submission and assistance with full approval
   - Assist with IRB and Post-SRC required modifications to study documents as needed
   - Study start up project management services (i.e. coordinating with finance, Biostats, basic science collaborators, study team, funders, pharma companies, multicenter, IDS, etc.)
   - Collaborate with pharma funders on protocol development approval and incorporating required template language (as required)
   - Attend and assist with required start up meetings including pre-SRC, database and site initiation visit (SIV) meetings

2. Amendments- full support including SRC, FDA, and pharma funder submissions as needed

3. Study Procedure Manual (SPM)/ Protocol Supporting Documents – full support

4. CT.GOV
   - NON-CTO: support if requested (will not assist with results reporting)
   - CTO- full ct.gov services (registration, maintaining record, amendment and status changes, assist in managing results reporting, etc.)
5. IND
   - NON-CTO: no IND support
   - CTO- full support
     a. IND services include:
        i. Preparing initial IND application documents for FDA submission
           - Form FDA 1571
           - Introductory statement
           - General investigational plan
           - Manufacturer's package insert/IB; IB creation if IU is manufacturing facility
           - Study protocol
           - Investigator data, facilities data, IRB data (FDA 1572)
           - Chemistry, manufacturing, and control data; collaborate with IU staff if manufacturing at IU (i.e. Brown Center)
           - Pharmacology and toxicology data
           - Previous human experience
           - Letters authorizing cross-reference (from pharma funder) and/or Drug Master Files (only apply if manufacturing at IU)

- Certificate of compliance with clinicaltrials.gov (FDA form 3674)
- Curricula vitae of the sponsor-investigator and clinical sub investigators and necessary staff (i.e. CRNs, MDs, PAs, NPs, and CRPS)

ii. Assisting with FDA clinical deficiencies, comments and revisions required for FDA study may proceed letter

iii. Maintenance of IND including
- Submission of IND Annual Reports within +/- 60-day window of "approval" date
- Submission of qualifying Amendments (PI change, major amendments, request for FDA correspondence etc.) within 30 days of IRB approval
- Submission of new protocols under existing INDs

iv. Submission of Serious Adverse events that meet IND Safety Reporting Requirements within either the 7 or 14 calendars from event

v. Submission of IND withdraws at time of study termination, or as otherwise requested