CTSI Regulatory Specialist : Scope of Work
IRB Support Only

Start-up Phase (through initial IRB approval)

- **Listed as primary regulatory study contact in ETHOS**
- **Enter study in CTR Portal and OnCore**
- **Study Document Creation**
  - Draft local protocol addendum, if UMN IRB protocol template not used
  - Draft consent, assent, phone script, and HIPAA documents
  - CTSI Regulatory Specialist naming conventions will be used when assigning file names
- **Ancillary Reviews**
  - Assign and manage ETHOS Ancillary Reviews (e.g. HRPP Scientific Review, CMRR Pre-IRB Review, AURPC, Fairview)
- **ETHOS Navigation**
  - Enter study into ETHOS and route to PI for submission
  - Enter UMN IRB cede requests into ETHOS
- **UMN IRB Correspondence**
  - Draft response to stipulations for PI review, including applicable edits to non-protocol documents requested by IRB
- **Submit central IRB submissions to Advarra, wcgIRB or other institutional contact**
- **Regulatory Management**
  - Verify CITI and HIPAA training within ETHOS
  - Enter IRB review information in Oncore
- **Provide guidance on creating regulatory binder to study team**
- **Attend (remotely) regulatory portion of Study Initiation Visit upon study team request**

Ongoing Study Conduct

- **Regulatory Management**
  - Record local & central IRB correspondence in OnCore
  - Update OnCore staff list after IRB approval of personnel changes
  - Consult with study teams regarding management of regulatory binder
- **IRB Correspondence**
  - Complete local & central IRB Continuing reviews (with information provided by staff & PI)
  - Draft Modification submissions, including applicable non-protocol document edits and personnel changes
    - Verify CITI and HIPAA training for personnel changes
  - Upload amended documents from central IRB into ETHOS as External Updates
  - Draft and submit report forms (RNIs) with input from study team
  - Ensure responses to local & central IRB are submitted on time
- **Monitoring visits**
  - Assist study teams with IRB submissions needed following monitoring visits (i.e. reports, personnel changes)
- **Advise study team on regulatory issues**

Study Closeout

- **Complete study close out submission for IRB**
- **Enter study inactivation date in OnCore**

Not included:

Please note that CTSI Regulatory Specialists can provide guidance on what is listed below, but are not responsible for them directly. In most cases, we can refer you to experts who can help.

- **Document creation:**
  - Protocol writing/editing
  - Creation of recruitment materials
  - Transfer of approved ICF language into REDCap eConsent
- **Regulatory binder maintenance, study participant binder creation/maintenance**
- **OnCore:**
  - Entering minimal footprint into OnCore, establishing OnCore calendar
  - Registering subjects and subject visits/data into OnCore
- **Monitoring visits:**
  - Submission of monitoring reports to HRPP QA
  - Pre-monitor reg binders or study materials
  - File study specific training documentation
  - Resolving monitoring visit findings related to regulatory binders
  - Attend Internal Monitoring Visits (IMV) or sponsor monitoring visits (will be available by email/phone as needed to answer time-sensitive regulatory questions)
- **Federal level:**
  - clinicaltrials.gov submissions/ guidance
  - Consultation, reporting or documentation required fo IND/IDE submissions
- **Submit central IRB submissions directly to institutional IRB systems**
- **Other UMN institutional submissions:**
  - PARS Applications (CMRR)
  - IBC Submissions
  - Pre-clinical/animal research (i.e. IACUC applications)
- **Other sponsor requests:**
  - Local context forms (inc. patient population information, etc)
  - Data entry/system training for data systems
- **Budget/contract negotiation**
- **Assessment of system compliance (HIPAA, Part 11)**
- **Determining if an event meets requirements for prompt reporting**
  - It is the responsibility of the PI/study team to understand and reference the appropriate IRB of record's requirements for review of events that require notification of reporting to the assigned regulatory specialist.

Study Team Expectations:

- **Notify assigned regulatory specialist when any ETHOS changes are needed**
  - If a submission is urgent, add URGENT to the email subject line and provide timeline
- **Keep regulatory specialist updated on protocol amendments and other changes to approved documents (for ceded studies not in Advarra/wcgIRB)**
- **Update regulatory specialist of any staff changes, including sponsor contact(s)**
- **Include regulatory specialist on email chains related to ancillary reviews, IRB submissions, and regulatory documents**
- **Respond to requests (for information and updated training) from the regulatory specialist in a timely manner**
- **Minimize protocol changes while a protocol version is under IRB submission/review**