CTSI Regulatory Specialist : Scope of Work
Full Support

Start-up Phase

- **Listed as primary regulatory study contact in ETHOS**
- **Initial study registration 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
- **Ancillary Reviews**
  - Submit for 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
  - Complete 1572 and financial disclosure forms (FDF) and route for signature in eBinders
  - Draft initial DOA log / protocol training log based on staff list from PI and route for signature in eBinders
  - Enter IRB review information in OnCore
- **Create regulatory binder in Florence eBinders via OnCore annotation**
  - File according to **Electronic Regulatory Binder Template Sections**
- **Attend 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 and eBinders DOA log / protocol training log after IRB approval of personnel changes
  - Forward IND Safety Reports for PI sign-off in eBinders when necessary
  - Maintain most portions of eBinder --please see **Electronic Regulatory Binder Template Sections** for more
- **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
  - Ensure responses to local & central IRB are submitted on time
- **Monitoring visits**
  - Review monitor follow-up letters and address outstanding regulatory action items (i.e. missing IRB communications, protocols, consent forms, etc.)
  - Verify CITI and HIPAA training within ETHOS system, and print training tab for CITI and HIPAA documentation as needed
- **Advise study team on regulatory issues**

Study Closeout

- **Resolve outstanding eBinder tasks assigned to regulatory specialist**
- **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 (Only exception: RegSpec may update protocol versioning to ensure consistency!)
  - Creation of recruitment materials
  - Transfer of approved ICF language into REDCap eConsent
- **Regulatory binders:**
  - Please see **Electronic Regulatory Binder Template Sections (attached)** for more
  - Migrating existing documents into a new regulatory binder location
  - Filing in paper regulatory binders
  - Filing electronic regulatory binders in other systems
  - Filing electronic regulatory binders outside of our template structure
  - *If a department or group has an eBinders SuperUser, they will be responsible for training and access requests, and maintaining central binder documents. If no SuperUser is listed for the department, the CTSI Regulatory Specialist team can help for studies they support*
- **OnCore:**
  - Entering minimal footprint into OnCore
  - Requesting/assisting with completion of 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
  - 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 on IND/IDE
- **Other 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)**

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 regulatory binder location**
- **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)**
- **Follow up on pending Florence access and eLog signatures**
- **Include regulatory specialist on email chains related to ancillary reviews, IRB submissions, and regulatory documents**
- **Notify regulatory specialist of upcoming monitoring visits and audits**
- **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**
- **Batch personnel modifications whenever possible (no more than one personnel MOD per week)**