CLINICAL TRIALS – REGULATORY START-UP PROCESSES

Revised May 31, 2024

OVERVIEW – REGULATORY PACKAGE

- **Description**: The regulatory package from sponsor consists of important documents necessary to initiate study start-up. These documents include, but are not limited to, the following: protocol, 1572, protocol signature page, IB, etc.
    - These documents describe the study procedures, the investigational drug/devices, location of research, and drug/safety composition.
- **When Can You Expect to Receive a Regulatory Package**:
    - Receive Site-selection letter (SSL) from Sponsor, which signifies that the PI and site has been approved by the sponsor to start the research study at your site location. Send sponsor Regulatory Document Request Form to send to Sponsor
        - In cases where sponsor does not provide a complete regulatory package, best practice is to follow up within 5 business days.
- **Timeline**
    - It is recommended to return the completed documents in the regulatory package to sponsor within 5 business days.
        - NOTE: If you must access these documents only through sponsor's external portal, it may take an additional 1-2 days to return these documents (as you will need to gain access to the sponsor portal first).

ACTION ITEMS

1. Once the Site-selection letter (SSL) is received, email sponsor the Regulatory Document Request Form and begin generating regulatory documents:
    a. Once you begin receiving documents from the regulatory package, start to generate a study binder to organize your electronic files in your hard drive (ex: protocol, IB)
    b. Once study is submitted to BruinIRB, and created in Oncore, you can start to generate regulatory e-binder, via Florence eBinder.
        i. Log into OnCore and find the study. Under "document" section, click "Update", and select "Interface to eBinders."
        ii. Log into Florence eBinder portal.
        iii. More information coming soon.
2. Regulatory Coordinator will send sponsor required regulatory documents via email
    a. PI/Sub-I's CV (to be collected from each MD)
        i. Signed + dated first page (best practice is DocuSign Compliant or a wet ink signature and date).
    b. PI/Sub-I's Medical License (ML)
    c. PI/Sub-I's GCP CITI Certification
    d. Lab normal values (if local labs are involved):
        i. Local labs: labs that are processed by the local (UCLA) pathology – information obtained from completed Regulatory Document Request Form.
            1. Local lab information is needed to complete the CPRS application
        ii. If sponsor requires lab ranges, send this link: https://www.testmenu.com/UCLA.
        iii. Lab Director CV and ML
3. Populate sponsor's regulatory documents for signature (via DocuSign). Once signed, copies will be internally filed, and also sent to study sponsor.
    a. 1572 (regulatory to complete form and obtain PI signature):
        i. Please confirm with study team the locations where research will occur.

   b. Sponsor Financial Disclosure Form (FDF): this form will disclose if PI/Sub-I has a financial interest with the study sponsor. This must be disclosed (regulatory to complete form and obtain PI/sub-I signature).
      i. Please confirm if PI and Sub-I's) have any positive disclosure(s)
   c. Protocol signature page (obtain PI signature): This confirms that PI has familiarized themselves with the study protocol.
   d. IB signature page (obtain PI signature): This confirms that the PI has reviewed clinical data about the investigational study product.
   e. Any other document as needed by sponsor (e.g. Document Receipt/Training Forms)
4. Once the regulatory package has been received, send the Notification to FM form to the Fund Manager for the study.

CONTACT/RESOURCE

- UCLA DOM CTP (DOMCTP@mednet.ucla.edu) for further guidance and training, if necessary.