FDA Investigational New Drug and Investigational Device Exemption

Working Guidelines

Version Date: *11/11/2024*

1. PURPOSE / SCOPE

To outline processes for IND and IDE application preparation, submission, and management at the University of Utah.

2. Types of Submissions

- Pre IND or Pre IDE Meetings
- IND Applications
- IDE Applications
- IND or IDE Amendments
- Serious Adverse Event Reporting
- IND or IDE Annual Reports
- Study Closures

3. RESPONSIBLE PARTIES

Sponsor-Investigator requesting an IND or IDE

IND/IDE Specialist: Jonna Davis with Clinical Research Support Office (CRSO) at the University of Utah

4. PROCESS OVERVIEW

A. Procedures
    a. IND/IDE Support Request
    b. Contact Information
    c. Consultation
B. Responsibilities
    a. Sponsor-Investigator Responsibilities
        i. Documents to Collect
        ii. Documents to Develop
        iii. Other Responsibilities
    b. IND/IDE Specialist Responsibilities
        i. Initial Application
        ii. IND Management
            1. Adverse Events
            2. Amendments
            3. Annual Reports

4. Study Closure
5. Audit and Monitoring Support

C. Queue and Submission Timelines
D. Document Retention
E. Submission Review
F. Helpful Links

5. PROCEDURES

A. IND/IDE Support Request

a. Sponsor-Investigator gathers general information for Support request such as:

i. Sponsor-Investigator name and department
ii. Name of investigational product
iii. Name of pharmaceutical or device company
iv. Target date for FDA Submission

b. Contact IND/IDE Support Specialist

i. jonna.lee.davis@hsc.utah.edu
ii. CRSO.FDAsupport@hsc.utah.edu
iii. ProTracks (The Clinical and Translational Science Institute's REDCap Intake Form)- can be accessed at the top of the CRSO webpage: https://ctsi.utah.edu/crso

c. Consultation

IND/IDE Specialist will coordinate meeting with Sponsor-Investigator to discuss study FDA pathway, document requirements, submission timing, and submission process.

B. Responsibilities

Sponsor-Investigator Responsibilities:

The following documents must be developed or collected and sent to the IND/IDE Specialist for FDA submission preparation.

a. Documents to collect:

i. Investigator Brochure or Package Insert
ii. Names of clinical sites and investigators - list sub-investigator(s) so the Principal Investigator will have backup should it be needed.

iii. CVs of investigators
iv. Letter of Authorization to reference a manufacturer IND or IDE if applicable.

b. Sponsor-Investigator Documents to develop and provide:

i. Protocol
ii. Informed Consent Document

c. Other Responsibilities

i. Sign documents prepared by IND/IDE Specialist required for submissions.
ii. Be available to answer FDA questions and comments during FDA reviews.
iii. Respond to IND/IDE Specialist with requested information for any FDA comments and Information Requests.
iv. Notify IND/IDE Specialist of any SAEs, changes to the study or study documents, changes to investigators and sites, and study closure. Provide information and documents listed below to the IND/IDE Specialist for ongoing IND or IDE submissions.

IND/IDE Specialist Responsibilities:

a. Initial Application

Prepare and submit FDA submissions and coordinate all FDA communication during review, IND/IDE Specialist will sign FDA Form 1571 as the Sponsor-Investigator's Authorized Representative for the purposes of managing the IND or IDE.

b. IND Management

Manage all submissions required over the course of the IND including:

i. Reporting of reportable serious adverse events

Required documents from Sponsor-Investigator include a copy of the SAE report containing description of event, relatedness, and any actions taken related to the event.

ii. Amendment submissions of revised protocols, consent and study documents, and investigator and site changes.

Required documents from the Sponsor-Investigator include a tracked version of the updated protocol and consent documents, and a summary of all changes with

rationale for changes. CVs will be provided for additional investigators or site information for sites added to the study.

iii. Submission of annual progress reports

IND/IDE Specialist tracks Annual Report due dates and will email Sponsor-Investigator prior to the due date requesting study specific information required for the annual report submission.

Required documents from Sponsor-Investigator include a cumulative Adverse Event log and log of reported SAEs since study opened.

iv. IND or IDE Close out

Sponsor Investigator will notify IND/IDE Specialist when study is closed and provide final study results and final Adverse Event and SAE logs for the closure submission.

v. Provides IND or IDE information to study monitors/auditors.

C. Queue and Submission Timelines

Following initial consultation, prospective studies are added to an FDA tracking spreadsheet. Once all the required documents have been received, the study is moved into a queue. Submissions in the queue are completed in the order that all the required documents were received. Sponsor-Investigator will be notified of anticipated submission date. Emergency Use requests and submissions with specified FDA deadlines take priority.

D. Document Retention

a. A master file including all FDA submissions and FDA communications and responses is maintained by the IND/IDE Specialist for each IND and IDE. Sponsor-Investigators are provided with a letter stating the location of FDA files for regulatory records.

b. Sponsor-Investigator will be notified of all FDA communications. FDA notifications of study approval will be sent to the Sponsor-Investigator to be included in the IRB submission.

E. Submission Review

For Sponsor-Investigators who choose not to utilize CRSO services, it is required that the CRSO reiew documents prior to FDA submission.

F. Helpful Links

i. CRSO IND/IDE Specilist Webpage: https://ctsi.utah.edu/crso/ind-ide

ii. IND SOP: https://qualitycompliance.research.utah.edu/sop-library/uu-sop-11.php

iii. IDE SOP https://qualitycompliance.research.utah.edu/sop-library/uu-sop-12.php