**GENERAL INFORMATION**

<table>
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<tr>
<th>Principal Investigator:</th>
<th>Protocol Number:</th>
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<td>Protocol Title:</td>
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**PROTOCOL/IND STATUS**

1. MMC/IRB Review:  
   - [ ] Approved  
   - [ ] Pending, status: ___________________  
   - [ ] Not Submitted

2. SEQuR Meeting Date: ___________________

3. SEQuR Representative: ___________________

**MEETING NOTES**

__________________________________________________________________________
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__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

**SIGNATURES: SEQuR REPRESENTATIVE AND SPONSOR INVESTIGATOR**

The responsibilities required by FDA regulations and MMC policies for a Sponsor-Investigator of an investigational drug in a clinical research trial, were provided to and reviewed with the Sponsor-Investigator of this proposed research trial. The responsibilities and information provided to and reviewed with the Sponsor-Investigator are checked / marked in the attached forms.

SEQuR Representative: ___________________ Date: __________

The undersigned understands and accepts the responsibilities of the FDA regulations and MMC policies required of the Sponsor-Investigator of an investigational device clinical research study, as provided by and reviewed with the SEQuR Representative.

Sponsor-Investigator: ___________________ Date: __________
## Sponsor Responsibilities and Required Documents

### General Responsibilities of Sponsors

The Sponsor is responsible for:

- Maintaining an effective IND with respect to the investigations
- Submitting annual reports on the progress of the investigation to the FDA
- Report in an “information amendment” essential information on the IND that is not within the scope of a protocol amendment, IND safety reports, or annual report, such as new toxicology, chemistry or technical information.
- Submitting a protocol amendment to describe any change(s) in a:
  - Phase 1 protocol that significantly affects the safety of subjects, or
  - Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation or the scientific quality of the study.
- Selecting only qualified investigators by training and experience as appropriate experts to investigate the drug.
- Providing each participating investigator with all information required to conduct the study properly.
- Obtaining the following information from each participating investigator before permitting them to begin any activity on the investigation:
  - Signed and completed investigator statement(s) – Form FDA 1572.
  - Curriculum Vitae or other statements of qualification on file for all investigators
  - Clinical Protocol
  - Financial Disclosure Information (as described under part 54)

### Managing Conflicts of Interests: Financial Disclosures

The Sponsor is responsible for:

- Maintaining current, complete and accurate records documenting the financial interests of all participating clinical investigators, including sponsor payments, for the duration of their participation in any covered studies under the IND, plus 1 year following the completion of the study.

  → Note: sponsors are responsible for developing a method (e.g. form/letter) to ensure adequate disclosure of participating clinical investigators’ financial disclosure.

  → Note: many sponsors obtain financial disclosures from participating investigators at the start of the study, and require updates annually during the study and again before data is ‘locked’.

  This documentation of on-going financial disclosure for each clinical investigator will be required when submitting the application for marketing.
### Monitoring and Selection of Study Monitors

**The Sponsor is responsible for:**

- Monitoring the progress of all clinical investigations being conducted under its IND, to ensure that the investigation is conducted in accordance with approved investigational plan and protocol covered by the IND and in compliance with the signed FDA form 1572.
  
  - 312.50
  - 312.56

- Selecting a monitor qualified by training and experience to monitor the progress of all clinical investigations conducted under its IND.
  
  - 312.53(d)
  - 312.56(a-d)

### Transfer of Obligations to a Contract Research Organization

- A sponsor may transfer responsibilities to a contract research organization (CRO). Such transfers shall be described in detailed in writing.
  
  - 312.52

### Study Management

**The Sponsor is responsible to:**

- Provide all participating investigators with the Investigational Brochure.
  
  - 312.23(a)(5)

- Notify the FDA and all participating investigators in written IND safety reports, of adverse events related to the drug that is both serious and unexpected, and/or findings in laboratory animals that suggests a significant risk for humans
  
  - 312.32

- Ship investigational new drugs only to investigators participating in the investigation
  
  - 312.53(b)

- Inform all participating investigators of new observations discovered by or reported to the sponsor about the drug
  
  - 312.23(a)(5)

- Ensure compliance from all participating investigators, or discontinue shipment of investigational drugs. See Principal Investigator Responsibilities.
  
  - 312.56

- Review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from participating investigators, and report serious and unexpected adverse events to FDA
  
  - 312.56

- If the sponsor determines that the investigational drug presents unreasonable and significant risk to subjects, discontinue those investigations and notify the FDA, all IRBs, and all investigators who have at any time participated in the investigation. This should occur as soon as possible, and in no event later than 5 working days after making the determination.
  
  - 312.56

- Ensure the FDA and all participating investigators are promptly informed of significant new adverse events or risks with respect to the drug. This should occur as soon as possible, and in no event later than 5 working days after making the determination.
  
  - 312.50
### Electronic Systems

The Sponsor is responsible for:

- Ensuring any electronic data and source documentation meets the same fundamental elements of data quality that are expected of paper records

  > Reference 21 CFR Part 11

  > Note: Sponsor-investigators planning to implement software and electronic systems to collect and maintain study data are recommended to contact the HIM.

### Receipt, Storage, Disposition, and Return of Investigational Drug

**The Sponsor is responsible to:**

- Maintain adequate records showing receipt, shipment, or other disposition of the investigational drug.

  These records must include the name of the investigator to whom the drug is shipped, and the date, quantity, and the batch or code mark of each such shipment.

- Ensure the return of all unused supplies/investigational drug from each participating investigator, and maintain adequate records of proper return/disposal of all investigational drug

### Current Good Manufacturing Practices: cGMPs

**The Sponsor is responsible for:**

- Ensuring the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals in compliance with the requirements of § 501(a)(2)(B) of the FD&C Act.

### Labeling and Representation of Investigational New Drug

- Immediate packaging of the IND intended for human use bears a label with the statement, “Caution: New Drug – Limited by Federal (or United States) law to investigational use”.

- The IND drug label does not bear any statement that is false or misleading, and does not represent the IND as safe or effective for the purpose it is being investigated.

- The sponsor or investigator must not represent the IND as safe or effective for the purposes for which it is under investigation.
Principal Investigator Responsibilities and Required Documents

Each participating investigator is responsible to:

- Obtain informed consent from all human subjects receiving investigational drug 312.60
- Properly administer drug to enrolled subjects (only the PI or authorized Co-PI may administer investigational drug) 312.61
- Maintain records of drug disposition, including dates, quantity and use by all subjects. 312.62(a)
- Return all unused investigational drug to the sponsor, or dispose of the drug properly as instructed by the sponsor. 312.62(a)
- Maintain adequate and accurate case histories for each subject, including the following: 312.62(b)
  - Case Report Forms and Supporting Data (Source Documents), such as:
  - Signed and Dated Informed Consent Forms
  - Medical Records (e.g. physicians/nurses’ progress notes, individual’s hospital chart)
- Submit Progress Reports, Safety Reports, Final Report, and Financial Disclosure Reports to the sponsor. 312.64
- Report and document all study changes to the IRB, and must not implement changes prior to IRB approval. 312.66
- Report all unanticipated problems involving risk to human subjects to the IRB 312.66

For Further Information


Available References/Handouts upon Request

- FDA Annual Report: guidance/template
- Regulatory Study Binder
- FDA Form 1572: Statement of Investigator: outlining/highlighting investigator responsibilities
- Financial Disclosure Requirements

Investigational New Drug Application (IND)
The application filed with the FDA informing them of the sponsor’s intent to test a new pharmaceutical product in humans

Investigator’s Brochure
A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects
Protocol
A document that describes the objectives, design, methodology, statistical considerations, and organization of a trial.

Standard Operating Procedures (SOPs)
Detailed, written instructions to achieve uniformity of the performance of a specific function

Sponsor
An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial, but who does not actually conduct the investigation.

Sponsor-Investigator
An individual who both initiates and conducts a clinical trial. This term does not include any person other than an individual.

Investigator
A person responsible for the conduct of the clinical trial at a trial site

Sub-Investigator
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g. associates, residents, fellows)

Contract Research Organization (CRO)
A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor’s trial-related duties and functions.

Multi-center Trial
A clinical trial conducted according to a single protocol but at more than one site/investigator

Monitoring
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), GCPs, and the applicable regulatory requirements

Monitoring Report
A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor’s standard operating procedures (SOPs).

Case Report Form (CRF)
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject

Source Document
The record or location where study data/information is first recorded. This may include original results, certified copies of results, observations or other means to reconstruct and evaluate a study as needed.