

Policies and Procedures

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|--|-------------------|--------------------------------------|
| SECTION: Human Research Protection Program | NUMBER: 111 | |
| CHAPTER: Institutional Review Board | ISSUED: 7/2010 | REVISED/REVIEWED: 3/2011; 11/2013 |
| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 1 OF 6 | |

1. PURPOSE

To ensure that the Investigator is fulfilling the role of “sponsor” (Sponsor-Investigator) when the Investigator holds his/her own Investigational New Drug (IND).

2. DEFINITIONS

- 2.1. Sponsor-Investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.
- 2.2. Investigational New Drug (IND): A drug permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

3. FDA REQUIREMENTS

- 3.1. A sponsor-investigator assumes all sponsor responsibilities required by the FDA as well as the investigator responsibilities, including those related to record keeping and prompt reporting of safety reports to the FDA. The responsibilities include:
 - 3.1.1. Selection of research staff qualified by training and experience
 - 3.1.2. Commitment to personally conduct or supervise the investigation according to the research plan
 - 3.1.3. Selection of study monitor(s) qualified to monitor the progress of the project
 - 3.1.4. Maintenance of adequate records showing the receipt, shipment, or other disposition of the investigational drug(s) and records of participants' case histories
 - 3.1.5. Completion of regulatory filings, including submission of amendments and annual and final reports

Policies and Procedures

| | | |
|--|-------------------|--------------------------------------|
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| CHAPTER: Institutional Review Board | ISSUED: 7/2010 | REVISED/REVIEWED: 3/2011; 11/2013 |
| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 2 OF 6 | |

- 3.1.6. Timely submission of reports to the FDA concerning adverse events and other unanticipated events occurring in the course of the study:
 - 3.1.6.1. Serious, unexpected adverse events associated with the use of the drug
 - 3.1.6.2. Written reports (no later than 15 days from observation)
 - 3.1.6.3. Telephone or facsimile reports (no later than seven days from observation if fatal or life-threatening event)
- 3.1.7. Any findings from tests in laboratory animals that suggest significant risk for human subjects
- 3.1.8. Other reports
- 3.1.9. Annual report (within 60 days of the anniversary date the IND went into effect)
- 3.2. There are certain cases in which investigators are exempt from obtaining an IND. They include the following:
 - 3.2.1. Exemption 1:
 - 3.2.1.1. The drug product is lawfully marketed in the United States.
 - 3.2.1.2. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication nor intended to be used to support any other significant change in the labeling for the drug.
 - 3.2.1.3. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.

Policies and Procedures

| | | |
|--|-------------------|--------------------------------------|
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| CHAPTER: Institutional Review Board | ISSUED: 7/2010 | REVISED/REVIEWED: 3/2011; 11/2013 |
| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 3 OF 6 | |

3.2.1.4. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

3.2.1.5. The investigation is conducted in compliance with 21 CFR 50 and 56.

3.2.1.6. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

3.2.2. Exemption 2

3.2.2.1. A clinical investigation is for an *in vitro* diagnostic biological product that involves one or more of the following:

3.2.2.1.1. Blood grouping serum

3.2.2.1.2. Reagent blood cells

3.2.2.1.3. Anti-human globulin

3.2.2.2. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established diagnostic product or procedure.

3.2.2.3. The diagnostic test is shipping in compliance with 21 CFR 312.160.

3.2.3. Exemption 3

3.2.3.1. A clinical investigation involving the use of placebo if the investigation does not otherwise require submission of an IND.

3.3. For further information on the FDA IND requirements, see [Title 21, Code of Federal Regulations, Part 312](#), particularly sections:

- 21 CFR 312.57: Recordkeeping and record retention

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| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 4 OF 6 | |

- 21 CFR 312.60: General responsibilities of investigators
- 21 CFR 312.62: Investigator recordkeeping and record retention
- 21 CFR 312.64: Investigator reports

4. IRB REQUIREMENTS

- 4.1. Prior to approving a protocol that involves a sponsor-investigator, the IRB shall be satisfied that the sponsor-investigator is knowledgeable about his/her responsibilities and has adequate policies and procedures in place to comply with the FDA regulatory requirements.
- 4.2. The IRB Chair or designee shall review the pre-review that shall be done by the Research and Compliance Quality Assurance Monitor before final approval of the project.
- 4.3. An on-site compliance audit, designed to evaluate compliance with the FDA regulatory requirements, shall be conducted on at least an annual basis and is a condition of continuing review approval by the IRB.

5. PROCEDURES (NEW PROTOCOLS)

- 5.1. The Investigator shall notify the IRB Office prior to submission to request a pre-review by the Research and Compliance Office. The Research and Compliance Quality Assurance Monitor shall then arrange a pre-review of the Investigator's area to review sponsor responsibilities. Upon completion of the visit, the Research and Compliance Quality Assurance Monitor shall submit a report to the IRB with the findings from the pre-review.
- 5.2. The visit shall cover the following areas for compliance and understanding:
 - 5.2.1. Documentation of the IND application and FDA correspondence (21 CFR 312.20)
 - 5.2.2. Plan to provide critical information/updates to researchers when applicable. (21 CFR 312.55)

Policies and Procedures

| | | |
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| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 5 OF 6 | |

- 5.2.3. Documentation of the IND application and FDA correspondence (21 CFR 312.20)
- 5.2.4. Plan to provide critical information/updates to researchers when applicable. (21 CFR 312.55)
- 5.2.5. Plan to select, supervise, and train personnel on an ongoing basis. (21 CFR 312.53)
- 5.2.6. Plan for monitoring of ongoing investigation. (21 CFR 312.56)
- 5.2.7. Plan for preparation, disposition, and destruction of investigational drug. (21 CFR 312.57, 312.59 and 312.62)
- 5.2.8. Plan to comply with reporting obligations. (21 CFR 312.32 and 312.33)
- 5.2.9. Plan for accurate drug tracking and record keeping. (21 CFR 312.57)

6. PROCEDURES (CONTINUING REVIEW)

- 6.1. Investigators shall be contacted by the Research and Compliance Office several months prior to the expiration of the protocol to arrange the compliance audit. Follow-up education shall be available if needed.
- 6.2. Compliance audit includes a review the following:
 - 6.2.1. Amendments to the IND (21 CFR 312.30 and 312.31)
 - 6.2.2. Safety records reported to the FDA (21 CFR 312.32 and 312.64)
 - 6.2.3. FDA Annual Report or plan for timely submission of report (21 CFR 312.33)
 - 6.2.4. Documentation of any unanticipated adverse events and reporting to the IRB and FDA (21 CFR 312.64)

Policies and Procedures

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|--|-------------------|--------------------------------------|
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| POLICY: Sponsor-Investigator Research Requirements (When a CU Investigator holds the IND) | PAGE 6 OF 6 | |

- 6.2.5. Changes to investigators and staff; qualifications of new staff (21 CFR 312.53)
- 6.2.6. Records of supervision and staff training (21 CFR 312.53 and 312.55)
- 6.2.7. Informed consent forms (ICF) and materials associated with informed consent (21 CFR 312.66)
- 6.2.8. Records of study monitoring (21 CFR 312.56)
- 6.2.9. Records of shipping, labeling, dispensing, and disposal of the drug (21 CFR 312.59 and 312.62)
- 6.2.10. Records of participant case histories (21 CFR 312.62)
- 6.2.11. Plan for long-term record retention (21 CFR 312.62)