Issuing Department: Human Subjects Protection Program
Policy Number: 2011-022.1
Policy Title: Investigational Drug Studies

Purpose

The purpose of this policy is to describe the obligation of investigators, sponsors and the Institutional Review Board when conducting or reviewing studies involving the use of investigational new drugs.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Clinical Investigation | Investigational New Drug

Policy

Unless criteria for an exemption are met, clinical investigations in which a drug is administered to human subjects must be conducted under an IND as required in 21 CFR part 312 when research involves the use of a drug other than the use of a marketed drug in the course of medical practice.

The IND goes into effect 30 days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA.

Investigators will be responsible for conducting the investigation in accordance with the signed investigator statement, the investigational plan, and applicable regulations and policies; and for protecting the rights, safety and welfare of subjects in their care. Investigators are also responsible for the following:

- controlling of drugs under investigation;
- administering the drug only to subjects under the investigator's personal supervision or under the supervision of a co-investigator responsible to the investigator;
- supplying the drug only to persons authorized to receive it;
- maintaining adequate records for the disposition of the drug (dates, quantity, and use by subjects);
- returning unused supplies to the sponsor or otherwise providing for the disposition in accordance with the direction of the sponsor;
- maintaining adequate and accurate case histories on each individual receiving the drug or employed as a control (all observations and other data pertinent to the investigation including case report forms and supporting data, e.g. signed and dated consent forms, medical records including progress notes, hospital charts and nurses notes);
- retaining records for 2 years after either the date a marketing application is approved for the drug for the indication under investigation, or, if no application is to be filed or if the application is not approved, until 2 years after the investigation is discontinued and FDA is notified;
- submitting progress reports and safety reports to the sponsor and IRB;
- providing financial disclosures to the sponsor and the IRB;
- storing drugs properly and securely;

- obtaining IRB and FDA review and approval prior to initiating the research (including the consent process); and
- permitting authorized individuals (HSPP or IRB staff, FDA staff) to have access to and to copy relevant records.

The names of subjects do not have to be disclosed unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

In the event that a UConn Health PI is also the sponsor of the IND, the PI must make arrangements with a Research Compliance Monitor to schedule a pre-approval-audit to ensure that procedures are in place to fulfill the additional obligations of the sponsor.

Exemptions: The IRB may determine that a clinical investigation of a lawfully marketed drug(s) is exempt from the investigational new drug regulation if all of the following conditions apply:

- the investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- if the drug is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- 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 risk (or decreases the acceptability of the risk) associated with the use of the drug product;
- the investigation is conducted in accordance with the requirements of institutional review and informed consent as set forth in FDA regulations
- the investigation is conducted in compliance with requirements regarding the promotion and charging for investigational drugs.

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

A clinical investigation involving an in vitro diagnostic biological product (blood grouping serum; reagent red blood cells; and anti-human globulin) is exempt if it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with the requirements set forth in regulations.

Procedure

In the course of preparing a submission to the IRB the Principal Investigator must respond to a series of questions regarding the need for an IND.

- If an IND is required the PI must include the submission material proof that the FDA has granted the IND.
- If the IRB has questions as to whether an exemption can be granted the IRB may require the PI to provide proof that the FDA has determined that the use of the drug qualifies for exemption.

The IRB conducts its review according to standard practice.

When the PI is also the sponsor of the IND, the PI must arrange for an audit with a Research Compliance Monitor prior to the submission of the IRB application and the results of the audit must be submitted with the IRB application.

Related Policies

2009-005 – Monitoring of IRB Approved Studies
2011-007.0 – Definitions Applied to Policies
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

21 CFR 312
21 CFR 50
21 CFR 56

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Reviewed and Approved By:

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