Control of Investigational Devices

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

To provide compliant and consistent control of investigational devices used in clinical research.

Key Terms

Clinical Research: Research conducted with human subjects (or on material of human origin, such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects.

Investigational Device: An investigational medical device is one that that does not have FDA approval for its clinical indication or for its proposed use in the study, and its use is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. This policy applies to investigational devices whether they are determined to be significant risk or non-significant risk.

Medical Device: A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes (21 U.S.C. 321(h)).

Policy

The principal investigator is responsible for the control of investigational devices. In appropriate circumstances, a principal investigator may delegate implementation of this policy to a qualified member of the research study team.

Qualified investigators (or their delegates) who have an approved IRB research project have the authority to distribute investigational devices.

FDA regulations for the control of investigational devices require the maintenance of accurate device tracking documentation by the investigator.

Responsibilities

The investigator (or his/her delegate) will:

- 1. Ensure that an investigational device is used only in accordance with the study protocol approved by the IRB.
- 2. Distribute the investigational device only to subjects enrolled per the IRB-approved protocol.
- 3. Manage investigational device accountability or delegate duties for investigational device accountability to qualified site personnel when necessary.
- 4. Maintain accurate and up-to-date tracking records of device shipment, receipt, inventory at the site, usage and final disposition including return or other type of disposal if applicable.
- 5. Document pertinent information assigned to the investigational device (e.g., date, quantity, batch or serial number, expiration date and unique code number, as applicable).
- 6. Store the investigational device according to the manufacturer's recommendations with respect to temperature, humidity, lighting, and any other environmental considerations.
- 7. Store the device in a secure area with limited access that is in accordance with applicable institutional and regulatory requirements.
- 8. Retain all study-related documents and all versions (electronic or hardcopy) of each with the study regulatory records.
- 9. Maintain records for the appropriate length of time per applicable institutional and regulatory requirements.

Compliance

The Research Compliance Office, IRB and any other appropriate research management personnel address failures to comply with this policy.

References

21 CFR Part 812: Investigational Device Exemptions

Effective Date

June 3, 2015