Control of Investigational Devices Policy

Scope

Applies to Mayo Clinic Human Research Protection Program when using Investigational Devices in Clinical Research for which Mayo Clinic is the Institutional Review Board (IRB) of Record.

Purpose

To provide consistent control of Investigational Devices used in Clinical Research to be in compliance with Federal and institutional requirements.

Policy

- The Principal Investigator (PI) is responsible for the control of Investigational Devices. In appropriate circumstances, the PI 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.
- Food and Drug Administration (FDA) regulations for the control of Investigational Devices require the maintenance of accurate device tracking documentation by the investigator.

Responsibilities

The PI or his/her delegate will:

- Ensure that an Investigational Device is used only in accordance with the study protocol approved by the IRB.
- Distribute the Investigational Device only to subjects enrolled per the IRB-approved protocol.
- Manage Investigational Device accountability or delegate duties for Investigational Device accountability to qualified site personnel when necessary.
- 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.
- Document pertinent information assigned to the Investigational Device (e.g., date, quantity, batch or serial number, expiration date and unique code number, as applicable).
- Store the Investigational Device according to the manufacturer's recommendations with respect to temperature, humidity, lighting, and any other environmental considerations.
- Store the device in a secure area with limited access that is in accordance with applicable institutional and regulatory requirements.
- Retain all study-related documents and all versions (electronic or hardcopy) of each with the study regulatory records.
- 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 must address failures to comply with this policy.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

N/A

Definitions

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 a significant risk or non-significant risk to patients.

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:

- Listed in the online FDA database.
- 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 (Classification of Products as Drugs and Devices and Additional Product Classification Issues).

References

21 CFR Part 812: Investigational Device Exemptions

Classification of Products as Drugs and Devices and Additional Product Classification Issues

Online FDA database

Owner

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Contact

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Revision History

Date	Synopsis of Change
06/10/2021	Updated Owner and Contact. Updates to Scope and Purpose.
09/01/2017	Minor revision. Updated the following definitions per Glossary review: Medical Devices.
08/04/2016	Reformatted to Policy and Procedure System Management template and minor edits

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