

Reporting Requirements for Sponsor-Investigators Conducting Investigational New Drug (IND) or Investigational Device Exemption (IDE) Research Policy

Scope

Applies to Sponsor-Investigators when their research involves IND or IDE as required by Mayo Clinic Human Research Protection Program.

Purpose

To state the reporting requirements to track and maintain information regarding sponsor-investigator IND or IDE Food and Drug Administration (FDA) submissions and to assist those sponsor-investigators with compliance per FDA regulations.

Policy

- Mayo Clinic researchers acting as sponsor-investigators and who have an IND or IDE from the FDA must submit relevant documentation of the IND or IDE to the Mayo Clinic Office of Research Regulatory Support (ORRS) or the Cancer Center Compliance Office within 30 calendar days of the IND or IDE effective date. This IND or IDE information is maintained by the ORRS and is to be used to prompt sponsor-investigators of their reporting obligations to the FDA.
- The sponsor-investigator must fulfill additional education requirements to become knowledgeable about his/her additional regulatory obligations as the sponsor of the FDA regulated research. ORRS provides [this](#) educational content.

Responsibilities

The sponsor-investigator must:

- Complete educational requirements to become knowledgeable about the additional regulatory obligations they have as the sponsor-investigator of FDA-regulated research.
- Maintain appropriate and up-to-date IND or IDE application documentation in his/her study regulatory files.
- Provide ORRS or the Cancer Center Compliance Office with any additional FDA correspondence regarding his/her IND or IDE within 30 days after receipt.
- Provide a study initiation meeting for the study team before enrolling participants.

The Office of Research Regulatory Support or the Cancer Center Compliance Office:

- Tracks the IND or IDE information in the ORRS IND/IDE database.

- Contacts the sponsor-investigator when annual FDA reports are due.
- Directs sponsor-investigators to templates for sponsor-investigator annual FDA reports.
- Assists the sponsor-investigator with study initiation meetings and provides agenda content.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

[ORRS: Sponsor-Investigator Responsibilities Module: IND-IDE Sponsor-Investigator Responsibilities](#)

[Mayo Clinic Office of Research Regulatory Support website](#)

[Study File Management for Clinical Research Policy](#)

[Study File Management for Clinical Research Procedure](#)

Definitions

Food and Drug Administration (FDA): The regulatory authority in the United States (U.S) that oversees the pharmaceutical and medical device industries. The FDA is responsible for ensuring that the drugs and medical devices marketed in the U.S. are safe and have a greater benefit than risk when used according to manufacturer's directions.

Investigational Device Exemption (IDE): Application document submitted to the FDA proposing human clinical research to study an unapproved significant risk device, or a cleared/approved device for use other than its approved indication or intent.

Investigational New Drug (IND): Application document submitted to the FDA proposing human clinical research to study an unapproved drug, or an approved product for a new indication or in a new patient population in a research study.

ORRS: Mayo Clinic Office of Research Regulatory Support

Sponsor-Investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction:

- The investigational drug is administered or dispensed, and or
- The investigational device is administered, dispensed or used. The term does not include any person other than an individual.

References

[21 CFR 312: Investigational New Drug Application](#)

[21 CFR 812: Investigational Device Exemptions](#)

Owner

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Contact

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Revision History

Date	Synopsis of Change
08/02/2021	Scheduled review. Updated Owner and Contact. Link for educational resource and definitions updated.
09/21/2017	Minor review. Updated the following definitions per Glossary review: Food and Drug Administration (FDA); and Sponsor-Investigator.
08/22/2017	Scheduled Review - updated to new template - Spelled out ORRS to - Office of Research Regulatory Support. Updated the Cancer Center Regulatory Affairs Unit to Cancer Center Compliance Office. Added: The Sponsor- Investigator must provide a study initiation meeting for the study team prior to enrollment of participants. Added: ORRS to assists the sponsor-investigator with study initiation meetings and provides agenda content. Updated the Owner of document to Karen Hartman with Tammy Neseth as the Contact/reviewer.

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