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

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

To track and maintain information regarding sponsor-investigator IND or IDE FDA filings and to assist those sponsor-investigators with compliance per FDA regulations.

Key Terms

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

ORRS: Mayo Clinic Office of Research Regulatory Support

IDE: Investigational Device Exemption. 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.

IND: Investigational New Drug. 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.

Sponsor-Investigator: an individual who both initiates and conducts an investigation, and under whose immediate direction: 1) the investigational drug is administered or dispensed, and/or 2) the investigational device is administered, dispensed, or used. The term does not include any person other than an individual.

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 ORRS or the Cancer Center Regulatory Affairs Unit within 30 calendar days. This IND or IDE information is maintained by ORRS and is 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 investigator must:

1. Complete educational requirements to become knowledgeable about the additional regulatory obligations they have as the sponsor-investigator of FDA-regulated research.
2. Maintain appropriate and up-to-date IND or IDE application documentation in his/her study regulatory files.
3. Provide ORRS staff or the Cancer Center Regulatory Affairs Unit with any additional FDA correspondence regarding his/her IND or IDE within 30 days after receipt.

The Office of Research Regulatory Support:

1. Tracks the IND or IDE information in the ORRS IND/IDE database.
2. Contacts the sponsor-investigator when annual FDA reports are due.
3. Directs sponsor-investigators to templates for sponsor-investigator annual FDA reports.
4. Provides educational content outlining sponsor-investigator regulatory responsibilities to sponsor-investigators.

Related Documents

Pathlore Training Module - IND-IDE Sponsor-Investigator Responsibilities

References

21 CFR 312: Investigational New Drug Application

21 CFR 812: Investigational Device Exemptions

Mayo Clinic Office of Research Regulatory Support website:
http://mayoweb.mayo.edu/research-regulatory-support/

Study File Management for Clinical Research Policy

Study File Management for Clinical Research Procedure

Effective Date

September 27, 2013