

Guidance for Emory Sponsors and Sponsor-Investigators

Background

When using a drug or device for research, a principal investigator should consider if the drug or device is FDA approved for the proposed use. If not, the use of the drug or device for research may need a special FDA authorization called an Investigational New Drug (IND) or Investigational Device Exemption (IDE), respectively.

An IND is required if a drug (or biologic) is not FDA approved and an IND may be needed if approved for a different indication or in a different patient population. For more information, please consult the FDA website at this [link](#).

An IDE is required if a device is not FDA approved and an IDE may be needed if approved for a different indication or in a different patient population. A device which is determined to be a non-significant risk device generally does not need an IDE submission to the FDA, but it is considered to have an abbreviated IDE once the protocol and risk assessment are approved by the IRB. For more information, consult the FDA website at this [link](#).

Investigators who hold an IND or IDE are considered to be Sponsor-Investigators (S-I) and have responsibilities both as the investigator and as the sponsor. In particular S-Is have additional FDA regulatory, record keeping and safety reporting requirements.

The IRB works closely with the Office of Research Compliance (ORC) to ensure that Emory S-Is are compliant with federal regulations and Emory IRB requirements. ORC provides educational resources and is available to assist investigators in determining which regulations apply to their research.

When the IRB identifies a study as one having an Emory investigator as S-I, the S-I will be referred to ORC for training about specific S-I responsibilities. The S-I will be requested to complete Emory S-I IDE or IND Responsibility Forms. The [ORC website](#) contains Emory S-I IDE or IND Responsibility Forms and other important information about IDE or IND submissions:

[Drug Studies](#)

[Device Studies](#)

Submitting a S-I study to the IRB

The Emory IRB requires SIs to provide the IRB with the following:

- IND or IDE number assigned by the FDA and FDA IND or IDE 'may proceed' letter or documentation that establishes that the drug is exempt from IND requirements or that the device is non-significant risk or exempt from IDE requirements. A study can be submitted to the IRB before the IND or IDE review is completed, but full IRB approval cannot be granted until the IRB receives documentation of FDA review.
- Completion of S-I training

- Completion of [IND](#) or [IDE](#) S-I responsibility form,
- Protocol with adequate Data and Safety Monitoring Plan (DSMP) and site monitoring (more details below).
- Other study requirements per current Emory policies and procedures.

Data Safety Monitoring Plan (DSMP) and Study Monitoring

All studies need a DSMP. If a research protocol involves an increased level of risk, a Data and Safety Monitoring Board (DSMB) may be required to ensure that subjects are protected, reporting requirements are met, and that the data is kept confidential. For more information about DSMBs, follow this [link](#).

Sponsors and S-I's are responsible for site monitoring to ensure that the investigation is conducted according to the investigational plan & protocol. Site monitoring is an essential part of study oversight and is not done by a DSMB. Monitoring demonstrates that the S-I is taking steps to ensure *the adequate protection of the rights, welfare, and safety of human subjects and the quality of the clinical trial data submitted to FDA*¹. The IRB will review the DSMP and site monitoring plan and may consider a monitoring plan which utilizes self-monitoring adequate for a study conducted only at Emory.

Multi-site Studies

If the S-I has more than one site (making him/her a sponsor at an external site), a CRO or other monitoring alternatives may be required before IRB approval. For an overview of monitoring methods and more information, please go this [FDA guidance](#). ORC is available to provide assistance with development of a monitoring plan.

After IRB submission

When all S-I requirements are met, the study will be placed on a Full Board Meeting agenda for review.

Continuing Review

At continuing review, the IRB will request that the Sponsor/S-I complete the appropriate Emory Sponsor-Investigator Responsibility Form Continuing Review Update and forward to the ORC. ORC will make the IRB aware of significant concerns with S-I processes.

Amendments to add non-Emory study sites or change sponsor and/or S-I

Amendments may require that the Sponsor/S-I complete S-I training, the appropriate Emory Sponsor-Investigator Responsibility Form (if changing Investigator or Sponsor) and/or Multi-Site trials information form(s) (if adding a non-Emory site).

¹ From "[Guidance for Industry: Oversight of Clinical Investigations, A Risk-Based Approach to Monitoring](#)".