

09-Sponsor and Investigator Responsibilities and Training

Expanded Access Standard Practices and Procedures

Scope: All Expanded Access



1. PURPOSE

To define the process for educating and training physicians participating in Expanded Access on the roles and responsibilities of being a sponsor, investigator, or sponsor-investigator.

2. FEDERAL REQUIREMENTS

2.1 Expanded Access to Investigational Drugs

2.1.1 Sponsor Responsibilities

2.1.1.1 Physicians that sponsor an expanded access Investigational New Drug (IND) application are required to fulfill sponsor responsibilities as stated in [21 CFR Part 312, Subpart D—Responsibilities of Sponsor and Investigators](#).

2.1.1.2 Sponsor responsibilities apply to all expanded access applications whether they are for individual patients or intermediate-size patient populations.

2.1.2 Investigator Responsibilities

2.1.2.1 Physicians participating as an investigator on an expanded access protocol being run under an IND are required to fulfill investigator responsibilities as stated in [21 CFR Part 312, Subpart D—Responsibilities of Sponsor and Investigators](#).

2.1.3 Sponsor-Investigator Responsibilities

2.1.3.1 If the same physician both sponsors an expanded access IND and administers the investigational drug to patients, the physician will be considered a sponsor-investigator. Sponsor-investigators are required to fulfill sponsor and investigator responsibilities as stated in [21 CFR Part 312, Subpart D—Responsibilities of Sponsor and Investigators](#).

2.2 Expanded Access to Investigational Medical Devices

2.2.1 Sponsor Responsibilities

2.2.1.1 Physicians that sponsor an expanded access Investigational Device Exemption (IDE) (i.e., Treatment IDE) are required to fulfill sponsor responsibilities as stated in [21 CFR Part 812, Subpart C—Responsibilities of Sponsors](#).

2.2.1.2 Sponsor responsibilities apply to all expanded access applications whether they are for individual patients or intermediate-size patient populations.

2.2.2 Investigator Responsibilities

2.2.2.1 Physicians participating as an investigator on an expanded access protocol being run under an IDE are required to fulfill investigator responsibilities as stated in [21 CFR Part 812, Subpart C—Responsibilities of Investigators](#).

2.2.3 Sponsor-Investigator Responsibilities

2.2.3.1 If the same physician both sponsors an expanded access IDE and administers the investigational device to patients, the physician will be considered a sponsor-investigator. Sponsor-investigators are required to fulfill sponsor and investigator responsibilities as stated in [21 CFR Part 812, Subpart C—Responsibilities of Sponsors](#) and [21 CFR Part 812, Subpart C—Responsibilities of Investigators](#).

3. TRAINING RESOURCES

3.1 It is critical to train physicians on the roles and responsibilities of sponsoring or participating as an investigator on an expanded access application. There are a number of non-research

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physicians who participate as sponsors or investigators on expanded access programs, and they may be unfamiliar with regulatory requirements. Lack of understanding can result in non-compliance with federal regulations and reporting.

3.2 Training should minimally cover the responsibilities required by regulation and can be performed a number of ways:

- Physicians can participate in existing training required of regulatory sponsors at the institution.
- Institutions can develop or use a pre-recorded trainings with a learning assessment such as the [IND or IDE Sponsor and Investigator Training Modules](#) created by Duke University and ReGARDD.
- Institutions can perform in person 1:1 training with individual physicians.
- Institutions can email summaries of regulatory responsibilities to physicians and require that the physician review and attest that they understand their requirements.