V. Sponsor-Investigator Responsibilities Training

Purpose

The purpose of the Sponsor-Investigator Responsibilities Training policy is to outline the process of educating Sponsor-Investigators of the additional responsibilities they hold as a sponsor of an IND or IDE.

All Sponsor-Investigators must meet with the EQuIP office for a Pre-Review Training prior to the release of IRB final approval.

Responsibility

Quality Improvement Specialist
Manager, EQuIP
Director, Clinical Research Compliance

Procedure

1. Identification of Sponsor-Investigators: the goal is to identify Sponsor-Investigators as early as possible in the protocol development and approval process. The IRB will notify any sponsor-investigator of the requirement to meet with the EQuIP office during the IRB protocol pre-review process. The Sponsor-PI will be informed at this time the training must be completed prior to release of IRB approval. However, the research community is continually educated about the pre-review requirement and encouraged to contact EQuIP as soon as possible; and all research entities try to refer sponsor-investigators to the EQuIP office prior to IRB submission if possible.

It is the responsibility of the Sponsor-Investigator to contact the EQuIP office to schedule the training meeting.

2. Sponsor-Investigator Training: the goal of this training is to ensure any investigator who also holds an IND or IDE understands the additional responsibilities required of a sponsor. The QI Specialist will go through the specific responsibilities with the Sponsor-Investigator, outlined in the EQuIP IND/IDE Sponsor-Investigator Checklists (IND, IDE Significant Risk, IDE Non-significant Risk), to ensure they have a clear understanding of the additional responsibilities.

Once the meeting is complete, the QI Specialist will enter the training into CHeRP to indicate the training has been completed.

References

- IND Sponsor-Investigator Responsibilities Checklist
- IDE SR Sponsor-Investigator Responsibilities Checklist
- IDE NSR Sponsor-Investigator Responsibilities Checklist