G. Sponsor-Investigator Pre-Review

Purpose

The purpose of the Sponsor-Investigator Pre-Review Standard Operating Procedure (SOP) 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 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 CCI/IRB will notify any sponsor-investigator of the requirement to meet with the EQuIP office prior to release of IRB approval during the review process. 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 a pre-review meeting.

2. Sponsor-Investigator Pre-Review: the goal of this pre-review 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**, to ensure they have a clear understanding of the additional responsibilities.

   Once the meeting is complete, the QI Specialist and the Sponsor-Investigator will both sign the appropriate pre-review checklist which will be submitted to the IRB. A copy will be given to the Sponsor-Investigator.

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