SOP #: I-M-5

SOP Area: Monitoring Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Interim Monitoring Visit**

1. **PURPOSE**

To define the procedures utilized to conduct an interim monitoring visit for clinical investigations that involve an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application, in which the sponsor of the IND/IDE is utilizing the services of the Education and Compliance Support for Human Subject Research (ECS-HSR) Division to assist them in fulfilling their responsibility to monitor the progress of the clinical investigation.

1. **SCOPE**

This procedure applies to clinical investigations that involve an IND or IDE in which the sponsor is utilizing the services of the ECS-HSR Division to assist the sponsor with fulfilling the sponsor’s responsibility to monitor the progress of the clinical investigation.

1. **RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for assisting sponsors in the conduct of interim monitoring visits for clinical investigations that involve an IND or IDE in which the sponsor is utilizing the services of the ECS-HSR Division to assist the sponsor with fulfilling the sponsor’s responsibility to monitor the progress of the clinical investigation.

1. **PROCEDURES**
	1. Interim monitoring visits will be conducted to review the ongoing progress of the study.
	2. The interim monitoring visits will be conducted to confirm that the investigative site is meeting the following requirements:
		1. The rights and well-being of human subjects are protected.
		2. Original source documentation is maintained for research participants.
		3. The study is conducted in accordance with the protocol and applicable regulatory requirements.
		4. There is accurate and timely recording and reporting of adverse events and serious adverse events.
		5. Protocol deviations are properly recorded and reported.
		6. A regulatory binder is maintained and contains up-to-date essential documents.
		7. Study product storage is appropriate and the study product accountability records are accurate, as applicable.
2. **REFERENCES/DOCUMENTATION**

**NA**

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