SOP #: I-M-4

SOP Area: Monitoring Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

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**Standard Operating Procedure**

 **Initial Monitoring Visit**

**1. PURPOSE**

To define procedures utilized to conduct an initial 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.

**2. 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.

**3. RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for assisting sponsors in the conduct of 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.

**4. PROCEDURES**

4.1 The initial monitoring visit will be conducted with the investigator and members of the research team on-site, by telephone or by web cast, after IRB approval is received and when possible, prior to subject enrollment.

4.2 The visit will be conducted to review the study protocol, documentation and implementation plan, and to identify the individual(s) responsible for protocol activities.

4.3 The sponsor/investigator will be provided with a checklist(s) outlining the responsibilities of the sponsor/investigator along with a copy or link to the University of Pittsburgh: Guidelines for Study Documentation in FDA Regulated Research and Clinical Trials.

**5.** **REFERENCES/ DOCUMENTATION**

University of Pittsburgh IDE Sponsor-Investigator Checklist

University of Pittsburgh IND Sponsor-Investigator Checklist