SOP #: I-M-3

SOP Area: Monitoring Activities

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Monitoring Plan Development**

1. **PURPOSE**

To define the procedures utilized in the development of a monitoring plan for clinical investigations that involve faculty sponsored Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications, 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 Coordinator/medical monitor is responsible for assisting sponsors in the development of a monitoring plan 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**

4.1 The ECS-HSR Coordinator will provide a template monitoring plan to the sponsor. The sponsor is responsible for development of a protocol specific monitoring plan.

4.2 Points to consider in the development of a monitoring plan include:

4.2.1. Summary of key points of the study including objectives, endpoints, recruitment goals, duration of recruitment and duration of the trial.

4.2.2. Frequency of monitoring visits.

4.2.3. Percentage of records to be reviewed.

4.2.4. Description of study documentation to be reviewed.

4.2.5. Procedures for investigational product accountability.

4.2.6. Methods for communication of monitoring results.

4.3 The ECS-HSR Coordinator will review the proposed monitoring plan with the sponsor and the ECSO-HSR Director and/or their designee. Once a consensus is met regarding proposed activities, all parties will sign off on the monitoring plan to indicate agreement. If changes to the monitoring plan are required throughout the course of the study, the sponsor will discuss with the ECO-HSR Coordinator and a revised monitoring plan will be implemented.

4.4 The medical monitor will be involved in this process as deemed necessary.

1. **REFERENCES/DOCUMENTATION**

Template Monitoring Plan

Original: 12/4/15

Revised: 3/8/16

Revised: 4/7/20

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