SOP #: I-M-2

SOP Area: Monitoring Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Monitoring Activity Notification**

1. **PURPOSE**

To define the procedures utilized for notification of monitoring activities 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 Coordinators are responsible for providing written notification regarding upcoming monitoring activities.

1. **PROCEDURES**

* 1. Notifications will be sent via e-mail with a request for a delivery receipt.
	2. Notifications will be saved in the O3IS/IIS monitoring electronic file folder.

**5. REFERENCES/DOCUMENTATION**

NA

Original: 11/13/15

Revised: 4/7/20

Revised 12/7/20