SOP #: I-M-1

SOP Area: Monitoring Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

 **Facilitating Initial Monitoring Activities**

**1. PURPOSE**

To define the procedures utilized to facilitate initial 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.

**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 Investigational Drug and Investigational Device Support Staff (IIS) will notify the ECS-HSR Director of protocols involving investigator-sponsored INDs or IDEs. Protocols will be assigned to a designated ECS-HSR Coordinator, who will facilitate the monitoring process.

**4. PROCEDURES**

* 1. The ECS-HSR Coordinator will complete the following activities:

* + 1. Assignment of monitoring number
		2. Establishment of an electronic monitoring file in the O3IS/IIS shared drive
		3. Review of the IIS paper and electronic file for pertinent FDA communication
		4. Review of the PittPRO or OSIRIS application and attachments
		5. Development of protocol specific monitoring tools
		6. Contact of the study team to facilitate an initial monitoring visit

**5. REFERENCES/DOCUMENTATION**

 NA

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