SOP #: I-M-6

SOP Area: Monitoring Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Close Out Visit**

1. **PURPOSE**

To define the procedures utilized to conduct a close out 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 a closeout monitoring visit 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. The close out visit will be conducted on-site, by telephone or web cast after all subjects have completed their final study visit and all documentation has been completed.

4.2 The close out visit will be conducted to:

* + 1. Formally document the termination of the study,
    2. Review remaining study documentation onsite or remotely,
    3. Complete final study product accountability (if applicable),
    4. Complete a final essential documents review (if applicable),
    5. Confirm resolution of data queries, and
    6. Verify that the investigator understands his/her post-study obligations.

1. **REFERENCES/DOCUMENTATION**

**NA**

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