SOP #: I-A-3

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Establishment of Date for Compliance Review**

**1. PURPOSE**

To define the procedure utilized to contact the Principal Investigator and establish a date for conducting a Research Investigator Start up Education (RISE) interviews, randomly selected audits, departmental QA and for-cause audits.

**2. SCOPE**

This procedure applies to RISE interviews, randomly selected audits, departmental QA and “for-cause” audits performed by the Education and Compliance Support for Human Subject Research (ECS-HSR) Division.

**3. RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for contacting the Principal Investigator to arrange for the compliance activity.

**4. PROCEDURES**

4.1. The principal investigator and research coordinator will be contacted to make arrangements for the compliance activity.

4.2 RISE interviews, randomly selected audits and departmental audits may be scheduled at a mutually agreeable time, preferably within one month of the audit notification.

 4.3Efforts should be made to schedule **for-cause** audits within two weeks of investigator receipt of the audit notification. If the investigator does not comply with the request to schedule the audit, the IRB Executive Committee will be notified of problems in scheduling the audit in a timely manner. If warranted, for-cause audits may be held without prior notice.

**5. REFERENCES/DOCUMENTATION**

NA

Original: 11/20/03

Reviewed: 9/3/04

Reviewed/Revised 1/17/06

Review/Revised: 12/15/10

Reviewed: 6/1/11

Reviewed: 10/5/12

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