SOP #: I-A-2

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Compliance Activity Notification**

**1. PURPOSE**

To define the procedure utilized for investigator notification of 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) Divsion.

**3. RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for providing written notification to investigators regarding upcoming compliance activities conducted on their protocols.

**4. PROCEDURES**

4.1.After a protocol is identified for a compliance activity, a written notification will be sent to the principal investigator by the ECS-HSR. Note “For Cause” audit notifications are only sent after the IRB Executive Committee/IRB Chair has notified the investigator of the audit.

4.2. Notification of a compliance activity will be sent via e-mail with a request for a delivery receipt. The notification will be sent to the e-mail address of the principal investigator and applicable research team members (designated research coordinator and mentor if applicable) listed in the IRB electronic application. The notification and the electronic delivery receipt will be saved in the ECS-HSR electronic file folder created specifically for each compliance activity.

 4.3 For “For Cause” Audits, the department chair will receive notification of the planned compliance activity.

 4.4 For departmental reviews, the dean or the department chair will receive notification of the planned compliance activity. The notification to the dean or department chair will permit the dean or department chair to request a compliance activity of a particular investigator in the respective area.

**5. REFERENCES/DOCUMENTATION**

NA

Original: 8/1/01

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