SOP #: I-A-13

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

## Evaluation and Rating of Compliance Activity Reports

**1. PURPOSE**

To define the procedures utilized to evaluate and rate compliance activity reports.

**2. SCOPE**

This procedure applies to compliance activities performed by the Education and Compliance Support for Human Subject Research (ECS-HSR) Division.

**3. RESPONSIBILITIES**

The Director of the ECS-HSR and the Associate Director of the ECS-HSR or their designee are responsible for evaluating and rating compliance activity reports.

**4. PROCEDURES**

4.1 The complianceactivity report will be evaluated and rated in accordance with the following system. Ratings are recorded in the QA database.

A. No further action necessary, compliance activity complete – no possible serious non-compliance, continuing non-compliance or unanticipated problem involving risks to human subjects or others or no finding that would compromise the integrity of the research data.

B. Minor issues identified during the visit. The ECS-HSR Coordinator will correspond with the research team until all items are resolved - No serious non-compliance, continuing non- compliance or unanticipated problem involving risks to human subjects or others or no finding that would compromise the integrity of the research data

C.1 Item / medical issue identified in the report requires a response from the PI and review by the IRB Chair but does not need review by convened IRB Committee

C.2 Item / medical issue identified in the report requires a response from the PI, review by the IRB Chair and may require review by the convened IRB Committee. These findings may represent serious non- compliance, continuing non-compliance, an unanticipated problem involving risk to human subjects or others or the findings may compromise the integrity of the research data

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