SOP #: I-A-5

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Review of IRB Electronic Application in Preparation for a** **Compliance Activity**

1. **PURPOSE**

To define the procedures utilized to review the IRB electronic application in preparation for a compliance activity.

**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 ECS-HSR Coordinators are responsible for reviewing the IRB electronic application in preparation for Compliance Activities.

**4. PROCEDURES**

4.1Prior to conducting the compliance activity, the ECS-HSR Coordinators will review the IRB electronic application. During the review, the ECS-HSR Coordinators will assess:

* + 1. Dates of initial protocol review and approval by the IRB
		2. Nature and dates of any modifications to the IRB approved protocol, e.g. changes in entrance criteria, study procedures, drug administration, consent form changes
		3. Dates of renewal approvals granted by the IRB
		4. Lapse of IRB Approval
		5. Relevant IRB meeting minutes
		6. Reportable Events
		7. IRB approved exceptions

This information will be used as a source of reference during the course of the compliance activity.

4.2Issues of significant concern noted with the IRB review of the study will be brought to the attention of the Director of the ECS-HSR who will forward the issue to IRB leadership as needed.

**5. REFERENCES/DOCUMENTATION**

NA

Original: 8/1/01

Reviewed/Revised: 11/20/03

Reviewed: 9/3/04

Reviewed/Revised: 12/15/2010

Reviewed/Revised: 6/1/11

Reviewed/Revised: 7/8/2015

Reviewed/ Revised: 10/16/19

Reviewed/ Revised: 11/20/20