SOP #: I-A-6

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Development of Compliance Activity Worksheets/Spreadsheets**

**1. PURPOSE**

To define the procedures utilized to prepare protocol specific worksheets/spreadsheets 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 preparing protocol specific worksheets/spreadsheets for compliance activities.

**4. PROCEDURES**

4.1Prior to conducting the compliance activity, the ECS-HSR Coordinator will develop worksheets/ spreadsheets specific to the research protocol. These worksheets/spreadsheets will include data points outlined in the IRB approved protocol, which are deemed to be pertinent to the conduct of the study such as:

* + 1. Eligibility criteria
    2. Screening procedures
    3. Study procedures
    4. Follow-up procedure

The lead ECS-HSR Coordinator may also inquire as to whether the research team has developed study specific data collection forms. The ECS-HSR Coordinator may make recommendations to enhance study documentation.

**5. REFERENCES/DOCUMENTATION**

Sample Eligibility Checklist

Original: 8/1/01

Reviewed/Revised: 11/20/03

Reviewed: 9/3/04

Reviewed/revised: 12/15/10

Reviewed/revised: 6/1/11

Reviewed/ Revised: 7/8/15

Reviewed/Revised: 10/16/19

Reviewed/Revised: 11/20/20