SOP #: I-A-9

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Review of Research Participant Records**

**1. PURPOSE**

To define the procedures utilized to review research participant records maintained by the investigator 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 conducting reviews of research participant records maintained by the investigator.

**4. PROCEDURES**

* 1. The ECS-HSR Coordinators will review the research participant records to:
		1. Evaluate the investigator’s methods of documenting research data.
		2. Verify that the source documentation substantiates the existence of subjects and adherence to eligibility criteria and study procedures.
		3. Confirm the proper evaluation, follow-up and reporting of adverse events and reportable new information.
		4. Identify any instances of non-compliance or unanticipated problems.

**5. REFERENCES/DOCUMENTATION**

 University of Pittsburgh Guidelines: Study Documentation for FDA Regulated Research and Clinical Trials (On ECS-HSR Website)

Original: 8/1/01

Reviewed/Revised: 11/20/03

Reviewed 9/3/04

Reviewed/Revised: 12/15/10

Reviewed/Revised: 6/1/11

Reviewed: 10/5/12

Reviewed/Revised: 7/9/15

Reviewed/Revised: 10/16/19

Reviewed/Revised: 11/20/20