SOP #: I-A-8

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Review of Documentation of the Informed Consent Process**

**1. PURPOSE**

To define the procedures utilized to review documentation of the informed consent process for a compliance activity.

**2. SCOPE**

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

**3. RESPONSIBILITIES**

The ECS-HSR Coordinators are responsible for reviewing documentation of the informed consent process.

**4. PROCEDURES**

4.1 The consent document will be reviewedfor the presence of the following:

* + 1. The signature of the subject or the signature of the subject’s legally authorized representative
    2. Documentation of assent, if applicable
    3. The signature of the investigator. *If the study involves a drug, device or surgical procedure, the signature should be that of a physician investigator*
    4. Dates written adjacent to each signature, in the hand of the signatory
    5. Presence of the IRB approved and expires dates
    6. Utilization of the correct version of the IRB approved consent form
    7. Presence of any extemporaneous modification to the informed consent document
  1. Additional items to be assessed may include but are not limited to:

4.2.1 General adherence to the informed consent process outlined in the IRB approved electronic application

4.2.2 Narrative note in the case history regarding the informed consent process (Required for research regulated by the FDA and recommended for all research protocols.)

4.2.3 Determination that informed consent was obtained prior to the initiation of any research related procedures

**5. REFERENCES/DOCUMENTATION**

SampleConsent form data table (On ECS-HSR Website)

Sample Documentation of Informed Consent Process Form (On ECS-HSR Website)

Original: 8/1/01

Reviewed/Revised: 6/1/11

Reviewed: 10/5/12

Reviewed/ Revised: 7/8/15

Reviewed/Revised: 10/16/19

Reviewed/ Revised: 11/20/20