SOP #: I-A-10

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Review of Regulatory Documents**

**1. PURPOSE**

To define the procedures utilized to review regulatory documents during 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 regulatory documents.

**4. PROCEDURES**

4.1The ECS-HSR Coordinators may review regulatory documents for research studies selected for a compliance activity. Review will be based on the type of study. The following is a list of documents that investigators are to maintain, as applicable, in a regulatory binder or electronic file system:

4.1.1 Protocol

4.1.2 Informed Consent Document

4.1.3 IRB Correspondence

4.1.4 IRB Documentation

4.1.5 Investigators Brochure

4.1.6 Report of Prior Investigations

4.1.7 Qualification Documentation

4.1.8 Financial Interest Forms

4.1.9 Conflict of Interest Management Plan and email Notifications of Significant Financial Interest

4.1.10 Signature and Delegation of Authority Log

4.1.11 Training

4.1.12 Form FDA 1572 or Investigator’s Agreement

4.1.13 Investigational Drug and Investigational Device Exemption Support (IIS) Correspondence

4.1.14 FDA Correspondence

4.1.15 Enrollment Log

4.1.16 Lab Certifications and Normal Ranges

4.1.17 Accountability Records

4.1.18 Specimen Tracking Log

4.1.19 Serious Adverse Events or Unanticipated Adverse Device Effects

4.1.20 Reportable New Information/Protocol deviation logs

4.1.21 Monitoring Visit Reports/Logs

4.1.22 Sponsor Correspondence

4.1.23 Data Safety and Monitoring Documents

4.1.24 Case Report Form Templates

4.1.25 Federal Wide Assurance Agreement (FWA)

4.1.26 IRB Roster

4.1.27 SOPs/MOPS

**5. REFERENCES/DOCUMENTATION**

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

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