SOP #: I-A-11

SOP Area: Investigator Compliance Activity

University of Pittsburgh

Education and Compliance Support for Human Subject Research

# Standard Operating Procedure

**Review of Test Article Accountability**

**1. PURPOSE**

To define the procedures utilized to review test article accountability during an Education and Compliance Support for Human Subject Research (ECS-HSR) Division compliance activity.

**2. SCOPE**

This procedure applies to compliance activities performed by the ECS-HSR that involve a test article.

**3. RESPONSIBILITIES**

For investigators that utilize the services of a University of Pittsburgh Medical Center (UPMC) Investigational Drug Services (IDS) or other infrastructure, e.g. internal laboratories for test article accountability, the Education and Compliance Coordinators may review test article accountability.

For investigators that do not utilize the services of a UPMC IDS for test article accountability, the ECS-HSR Coordinators may review test article accountability or request the IDS to perform a review of test article accountability.

**4. PROCEDURES**

4.1 A review of test article accountability performed by the ECS-HSR Coordinators will be conducted to verify, as applicable, the following:

* + 1. Test article storage conditions are adequate.
		2. Test article is supplied only to eligible subjects.
		3. Participants are provided necessary instruction regarding test article use.
		4. Receipt, use and return of test article are controlled and documented adequately.
		5. Lot #
		6. Expiration date

**5. REFERENCES/DOCUMENTATION**

 **NA**

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