1. PURPOSE

To define the procedures utilized to review test article accountability during a compliance activity.

2. SCOPE

This procedure applies to all compliance activities involving a test article performed by the Education and Compliance Office for Human Subject Research.

3. RESPONSIBILITIES

The Education and Compliance Coordinators may request the assistance of the Investigational Drug Service or may personally conduct the review of test article records at the investigator site.

4. PROCEDURES

4.1 The Education and Compliance Coordinators may assess the following information (depending on the nature of the study):

- Appropriate storage methods
- Physician dispensing orders written
- Test article administered or dispensed by a qualified person authorized according to the UPMC policies
- Inventory log maintained for the test article to include:
  - drug name
  - dosage form and strength
  - date and quantity of receipt
  - lot number
  - expiration date
  - quantity and date dispensed
  - identification of the study participant
  - date(s) and quantity returned by the study participant
  - date(s) and quantity returned to the sponsor/ or onsite destruction
  - amount transferred or wasted
  - name, address, and telephone number of the sponsor
- Inventory records are consistent with subject research records
- Test article preparation instructions available. Documentation of preparation of each drug administration including date and name of preparer.
4.2 If there is a problem or concern with the test article accountability managed by the Investigational Drug Service, the ECO staff may contact the IDS to clarify or address the problem.

5. REFERENCES/DOCUMENTATION

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