Department of Pharmacy Services

STANDARD OPERATING PROCEDURE (SOP): HANDLING OF QUARANTINED INVESTIGATIONAL PRODUCT (IP)

Policy: Investigational Drug Services (IDS) at the University of Virginia Health System (UVAHS) is responsible for establishing standard procedures for the appropriate control of investigational drugs and biologics used in human subject research. Standard procedures for the control of investigational agents comply with local, state, and federal regulations and requirements and are consistent with IRB standards, and practice standards of the American Society of Health-system Pharmacists (ASHP) and The Joint Commission.

Procedure:

A. Investigational product (IP) must be placed in quarantine when it is deemed potentially unfit for use.
    a. Reasons for being potentially unfit for use include, but are not limited to:
        i. Beyond expiration/retest date
        ii. Improper storage conditions (ie, temperature excursion)
        iii. Visible damage or contamination
        iv. Product recall
        v. Sponsor/monitor request
B. Quarantined product will be physically separated from viable inventory, and clearly labeled as “Quarantined.”
C. Quarantined product will be removed from active inventory in Vestigo and designated at “Quarantined.”
D. Quarantined product will remain in quarantine pending sponsor instructions.

Implemented: 05/2013
Revised: 11/2016