Department of Pharmacy Services

STANDARD OPERATING PROCEDURE (SOP): MANAGEMENT OF INVESTIGATIONAL PRODUCTS (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) managed by IDS will be received per protocol
    a. IP will be electronically logged into Vestigo and any other systems (eg, IVRS) as required immediately upon receipt
    b. IP will be immediately placed in appropriate storage conditions
    c. Shipping/packing slips will be stored in the pharmacy for the duration of the study and will be available upon request
        i. Temperature monitoring devices will be discarded following documentation of shipping conditions
B. IP managed by IDS will be stored in compliance with the protocol, local, state, and federal regulations, and practice standards of the American Society of Health-system Pharmacists (ASHP) and The Joint Commission
C. Further detail regarding handling of IP may be found in situation-specific SOPs, listed below

Related SOPs:

A. Expiration date management of investigational drug product
B. Handling of quarantined investigational product
C. Out-of-range temperatures in investigational drug pharmacies
D. Dispensing and labeling of investigational drug products from IDS
E. Destruction or disposition of investigational drug products in investigational drug pharmacy
F. Transporting investigational agents from main campus IDS pharmacist to locations within the Medical Center
G. Transporting investigational agents from main campus IDS pharmacist to off-grounds clinics

Applicable Regulations & Guidelines:

Joint Commission Standard MM.06.01.05
21 CFR 312.59 – Disposition of unused supply of investigational drug.

21 CFR 312.62(a) – Investigator recordkeeping and record retention.
ICH GCP 4.6.3
ICH GCP 5.14.3
ICH GCP 5.14.4(b,d)

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