DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Inventory/Investigational Product Management	Policy #: CRP-016
DEPARTMENT: DHR Health Institute for Research & Development	PAGE: 1 OF: 5
	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21, 03/22

Purpose:
This Standard Operating Procedure (SOP) describes the processes DHR Health Institute for Research Development conducts for the receipt, storage, dispensing, reconciliation and return or authorized destruction of the Investigational drug.

Applies To
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

Definitions:

A. **Blinding/Masking:** A procedure in which one or more parties to the trial are kept blinded of the treatment assignment(s). Single blinding usually refers to the subject(s) being blinded, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).
B. **Investigational Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. In this SOP, the term Investigational Product (IP) will refer to the investigational drug, study drug or device.
C. **Randomization:** The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
D. **Source Documents:** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Policy:
This SOP applies to all procedures related to all clinical studies subject to Investigational New Drug (IND) and non-IND regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all investigational phases of development. It describes the steps monitored by DHR Health Institute for Research and Development from the time the investigational product is received on-site until it is either returned to the designated location in the protocol or destroyed on-site.

SUBJECT: Inventory/Investigational Product Management	Policy #: CRP-016
	PAGE: 2 OF: 5
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Investigator Responsibilities:
For IND and non-IND studies alike and unless otherwise specified, the Investigator is responsible, unless otherwise stated in the respective clinical trial agreement, for the overall managing and documenting all of the following: ordering, receiving, inventory, storing, dispensing, return, destruction and labeling if applicable before dispensing according to protocol and Good Manufacturing Practices (GMP). A subset of these responsibilities can be delegated to a research staff member or pharmacist.

Procedure:
Inventory/IP Management:

A. Receipt of Inventory/IP

Immediately upon receipt, IP must be checked against any shipment/packing list to ensure that what has been received corresponds with what is listed. The following checks should be made:

a) Ensure supplies are correctly addressed
b) Ensure all packaging intact
c) Ensure that the quantity, batch/serial numbers, correspond with shipment list.

The delegated staff receiving the shipment should sign and date all forms once confirmation is made and filed in the Site Study Binder. Copy of forms will be forwarded to sponsor/vender if required. If required by sponsor/vendor, inventory will be managed by means of Interactive Voice Response System (IVRS) or Interactive Web Response System (IWRS). At a minimal, a confirmation report of the transaction should be filed in Site Study Binder.

B. Storage of Inventory/IP

Immediately after checking the IP/supplies received at site they should be stored in appropriate conditions/containers as specified by the sponsor/vendor. All IP should be separated by sponsor study and labelled accordingly. No commercial medication/drugs (i.e. drug samples) are to be stored in same area.

The drug storage area/room should be secure and double-locked at all times with limited access to personnel involved in the study only.

The temperature of the storage area should be monitored and recorded (manually or electronically) according to sponsor/vendor instructions.

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	PAGE: 3 OF: 5
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C. Dispensing Inventory/IP

1. Ensure that each time IP is dispensed the appropriate Drug Accountability Record (DAR) is completed or copy of confirmation of transaction if IVRS/IWRS is used. Documentation will include:
   - Amount (and lot number, if appropriate) dispensed,
   - Name of individual dispensing study drug,
   - Subject's number,
   - Subject's initials, if appropriate
   - Date (and time, if appropriate) of dispensing,
   - Date and time, if appropriate, amount of study drug returned,
   - Amount of study drug returned.
2. After use by the study subject, return all used containers/units, if appropriate, to the study staff/pharmacist. If any containers/units are missing, document the reasons.
3. Note any discrepancies between amounts used by subjects and amounts expected to be returned and document the reasons.
4. Ensure that study supplies are adequate and within an appropriate expiration date.
5. If automatic re-supply of IP is not available, inform sponsor/vendor per their instructions.
6. Only if emergency breaking of the study drug blind is medically necessary to determine treatment will this be allowed. Emergency breaking of the blind (unblinding) should be documented and the sponsor informed at the earliest time. In all other circumstances, the site will follow sponsor guidelines for unblinding.

D. Return/destruction of Inventory/IP

Return of Disposed Inventory/Investigational Product

1. After the study has been completed, a comprehensive inventory of the product / devices is completed before returning them to the Sponsor. (ONLY at the instruction (if possible, written instruction) of the Sponsor should any IP be destroyed). Any discrepancies in the beginning and ending inventory are noted and explained. A copy of the post-study inventory and all study subject dispensing logs will be kept in the study files at DHRH-IR&D. A copy, if required, will be included in the box of IP being returned to the Sponsor.
2. The manner of shipment of used or unused IP must be defined by the Sponsor and followed by site personnel. Returned IP must be packed and shipped with the documentation provided by Sponsor. The manner of shipment must have mechanism of being traced.

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	PAGE: 4 OF: 5
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Disposal of Used Inventory/Investigational Product

1. All IP used and unused must be accounted for by the Study Monitor. Disposal of used or unused IP must be initiated only after the written instruction from the Sponsor/Study Monitor had been obtained.
2. Once accounted for, if the sponsor does not request that drugs need to be returned, then the products may be disposed of. The procedure for destroying used study drugs is as follows:

   A. Environmental Services must be contacted (phone #956-362-7917) to arrange for pickup of used or unused IP for disposal as biomedical waste.
   B. Prepare accounted drug and place them in a biohazard bag. Secure and tape the bag closed.
   C. Keep bag with investigational product locked at site until it may be released to biomedical waste management personnel.
   D. Document that drugs were disposed of according to policy.

3. Documentation shall be maintained concerning the disposal of the Investigational Product which shall contain:
   - The quantity of the Investigational Product disposed of;
   - The date and manner of disposal;
   - The staff member who conducted the disposal;
4. A copy of this documentation shall be sent to the sponsor and kept with the research records.

E. Inventory/IP Issues

Temperature Excursion

Temperature Excursions can happen for many reasons, it is important to document the excursion as appropriate and follow the procedures below to ensure the IP is safe for use.

1. Remove all affected IP from excursion area and place in an appropriate temperature location (quarantine).
2. Inventory all affected IP on the Sponsor provided form.
3. Document temperature ranges, MAX and MIN, and how long the IP was exposed to the temperature excursion on the Sponsor provided form.
4. Do not dose or dispense affected IP to any subjects. Document inability to dose accordingly in source documents.
5. Notify all Sponsors, whose IP was affected, of the excursion as per Sponsor protocol.
6. Do not use IP until written approval for use is received from sponsor and remove from quarantine.
   a) If deemed unusable, follow sponsor protocol for destruction of IP or destroy as per DHR Health Institute for Research & Development policy

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7. Label affected IP appropriately in *IP Accountability log* and sponsor IVRS/IWRS.
8. File all Sponsor Correspondence and documentation accordingly in Investigator Site File or subject chart.

Damaged Inventory/IP

Investigational Product may be damaged in transit or damaged during dosing. Follow procedure below:

1. Inventory all affected IP on the Sponsor provided form or DAR.
2. Follow sponsor protocol/instructions for removal/disposal/destruction of IP.
3. Do not dose or dispense affected IP to any subjects. Document inability to dose accordingly in source documents.
4. Notify all Sponsors whose IP was affected.
5. When replacement is obtained, dose or dispense to subject.
6. File all Sponsor Correspondence and documentation accordingly in Investigator Site File and subject chart.