DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Transportation of Ambient Investigational Medicinal Products	Policy #: CRP-1003
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DEPARTMENT: DHR Health Institute for Research & Development	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

Purpose:
It's extremely important to ensure the temperature stability and viability of Investigational Products at all times.

This SOP describes the steps to safely transfer Investigational Product (IP) from one facility to another or by a courier service.

This SOP applies to staff trained in the proper packing and shipping of IP.

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.

Procedure:

1. Packing:
   - Obtain an appropriate container to house the IP.
   - If there is any empty space that may cause IP to jostle around, place packing material in the box/container to prevent excessive movement.
2. In case packing instructions are provided by the sponsor follow those instructions to ensure appropriate handling.
3. Samples have to be labelled to prevent disclosure of PHI.
4. No PHI related documents must be enclosed with the samples.