DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Specimen Collection, Labeling & Handling	Policy #: CRP-019
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DEPARTMENT: DHR Health Institute for Research & Development	OF: 2
	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:
The proper collection and processing of specimens obtained from study subjects is an important factor impacting the integrity of data collected in a clinical study and protecting against the spread of infection at DHR Health as well as during transport to and arrival at off-site locations.

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 and Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research and 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.

Definition:
A. **Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments.
B. **Subject/Trial Subject:** An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Policy:
To ensure accurate data, specimens must be collected in specified tubes, quantities, and at the specified time points. In addition, specimens must be processed, possibly preserved, and shipped as per study protocol. Research, laboratory, and ancillary staff must adhere to appropriate lab practices when collecting, processing, and arranging for shipment of the specimens. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in specimen collection and handling.

Procedure:
<u>Specimen Collection and Handling</u>:

A. Collecting the specimens
a. Collect the appropriate specimens identified in the study protocol.
b. In the subject's record, note the date and time of the collection as well as any other relevant information pertaining to the subject's status at the time of the procedure.
c. Label the test tubes or other containers with the subject identifier, date, time, and any other information required by the study protocol.

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B. Processing the specimens

a. Process the specimens according to the processing procedures defined in the study protocol.
b. Spin, separate and transfer the specimens to the appropriate transport tube(s) as required by the study protocol.
c. Ensure all study-specific test tubes and containers are labeled appropriately as defined in the study protocol.
d. Complete lab requisition slip
    i. One copy with the specimens being shipped
    ii. One copy for the subject's record.

C. Preparing the specimens for shipment to the testing laboratory

a. Ensure all personnel packaging/shipping specimens have completed Dangerous Goods Training within the past 24 months.
b. Prepare and package the specimens according to the shipping instructions specified in the study protocol and/or laboratory procedure manual
c. Retain a copy of the shipping receipt and file with the subject's record.