DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: SOP and Policy Development and Version Control	Policy #: CRP-1035
	PAGE: 1 OF: 2
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
This document describes how the DHR Health Institute for Research & Development manages Standard Operating Procedures (SOPs) and maintains version control.

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 References
Available upon Request

Policy:
This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol that may deviate from this SOP.

Procedure:
In clinical research, SOPs help define the group's (e.g., unit, division, department, institution, etc...) standard practices and daily processes conducted to assure execution of research tasks in accordance with institutional, state and federal requirements. SOPs should contain enough detail to guide research staff through a particular procedure and thereby establish uniformity in the everyday functions of the department. The SOP should have a specific aim but be written in a general format to allow for easy implementation across a broad set of venues and circumstances. The SOP however, should contain specifically defined procedures that can be followed without deviation.

1. Responsibility of the Principal Investigator: ultimately responsible for ensuring research procedures are performed according to SOPs and that the correct versions of SOPs are used.
2. Responsibility of the Study Coordinator: ensure, with the support of PI oversight, that all personnel involved in research comply with the SOPs.
3. Each version of an SOP will be numbered sequentially (1.0, 2.0, 3.0, etc.).
4. Version number and date should be added to the end of a file name and within the document.
5. At the beginning of each SOP, a revision history table will completed for documenting changes. Subsequent version number (1.0, 2.0, 3.0, etc), effective date, and description of changes should be included each time a SOP is changed.

SUBJECT: SOP and Policy Development and Version Control	Policy #: CRP-1035
	PAGE: 2 OF: 2
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

6. PI or designee will ensure that SOPs and any revised versions will be adequately disseminated and staff are appropriately trained.
7. PI and Study Coordinator will monitor adherence to SOPs.

Training

1. Each staff member receives or has direct access to applicable Standard Operating Procedures (SOPs).
2. Each staff member reviews the applicable SOP if there is significant change.
3. All SOP training is documented and tracked on the Training Record Log located in the Regulatory Binder.
4. New staff is trained on applicable SOPs within 14 business days of employment.
5. Staff members whose duties fall within this SOP scope are retrained within 7 business days of the approval of each SOP revision.