DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Maintenance of all study-related documents	Policy #: CRP-1026
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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
Federal regulations require documentation of all study-related activities. The regulatory files and subject records, which are periodically reviewed by the sponsor and upon request by the FDA, serve as the site's record of compliance with good clinical practice (GCP).

This policy describes the steps for fulfilling all regulatory, and clinical requirements for collecting, filing and storing study-related documents and records.

Implementation of Good Regulatory Practice is essential in ensuring compliance and communication with regulatory authorities.

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.

Definition:
Good Regulatory Practice (GRP) is defined as the appropriate and effective management of regulatory documentation maintaining compliance and communication with regulatory authorities.

Policy:
This policy applies to the activities involved in maintaining the regulatory and subject records for all clinical studies conducted at this investigative site subject to applicable local, state, and federal regulations for drugs, devices, and biologics during all phases of development.

Procedure:

Maintaining Files:

- For each study, create a series of file folders or start a binder for documents collected during the study (e.g., Regulatory Files Checklist, Subject File Checklist).
- Maintain and update the file folders or binders as necessary, adding appropriate documents as they are generated or received. Logs of document changes and/or additions should be kept to maintain organization (e.g., IRB approval documents, informed consent versions log)
- Retain copies of <u>all</u> original and revised documents (e.g., protocol, investigator's brochure, informed consent form).

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- Ensure that subject records and regulatory files are kept confidential and are stored in a secure, limited-access location.
- Prior to appointments scheduled by monitors, auditors, and subjects, review contents of files for completeness.
- When the study close out visit has been completed, prepare files for archive by obtaining appropriate storage container and location.

File Archive:

- Archive regulatory files and subject records as per institution or sponsor specifications.
- Label any records/films with label advising they are research records and date allowed to be destroyed.
- Label storage boxes clearly and completely as Research Records.
- Store all records in a secure location for at least 15 years unless otherwise instructed by sponsor or other regulatory authorities.

File Destruction:

- Verify documentation from sponsor or regulatory authority of authorization to destroy documentation.
- File authorization to destroy in appropriate location. This document will not be destroyed for at least 15 years.
- Documents will be destroyed on site by shredding or as specified by specific study sponsor.