DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Clinical Data Management	Policy #: CRP-1013
	PAGE: 1
DEPARTMENT: DHR Health Institute for Research & Development	OF: 4
	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 standard operating procedure (SOP) describes the processes followed at the DHR Health Institute for Research & Development Institute for the collection of clinical research data, transcription of the data to case report forms (CRFs), and the management of the data, including procedures for:

- Quality control
- Data query resolution
- Record retention and archiving

Research data shall be collected, recorded and managed in accordance with the principles of Good Clinical Practice (GCP), International Council for Harmonization and the Health Insurance Portability and Accountability Act.

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:

A. **Case Report Form (CRF):** A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.
B. **Confidentiality:** Prevention of disclosure, to anyone other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.
C. **Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.
D. **Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
E. **Quality Assurance (QA):** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).
F. **Source Data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

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	PAGE: 2 OF: 4
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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 data management for all clinical studies subject to applicable local, state, and federal regulations for drugs, devices and biologics during all investigational phases of development.

Procedure:

A. Collection of clinical research data

• Principal Investigator • Research Coordinator	• The Investigator is responsible for accurate and complete collection, support, and storage of the data generated during a clinical study. • The Investigator is responsible for the clinical review and interpretation of the clinical data. • The Investigator is responsible for the secure collection and maintenance of all electronic records in accordance with applicable regulations (as applicable). • The Clinical Research Coordinator is responsible for collecting accurate and complete clinical study data, and for maintaining the source documentation and Case Report Forms (CRFs) during a clinical study.

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	PAGE: 3 OF: 4
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B. Transcription of the data to case report forms (CRFs), including remote data entry

• Research Coordinator • Support staff	Record all documentation in black ball point pen. Complete all fields in the CRFs according to sponsor specifications. Correct errors by striking through the error, dating and initialing it, and making the correction. Ensure the original entry is not obliterated. If necessary, note an explanation in the right margin. Ensure that data for the CRFs are transcribed promptly from the source documentation.
• Research Coordinator • Support staff	If the sponsor requires remote data entry, ensure that data are entered by computer according to sponsor specifications promptly from the source documentation.

C. Management of the data

• Research Coordinator	Ensure that the first sets of completed CRFs are entered into electronic CRFs and reviewed by sponsor data management team.
• Research Coordinator	Request a copy of the sponsor's SOPs for making changes or corrections to the CRFs. Collect any discrepancies noted at the sponsor's monitoring visit and note any clarification generating a Note to File. Note to File to be signed and dated by delegated staff. Ensure that the Note to Files are kept with the other study records in the regulatory files for this study. Correct errors to the CRFs noted at the monitoring visit by using the procedures described above.
• Research Coordinator • Support staff	At the conclusion of the study, ensure that data are retained according to regulatory and sponsor requirements. Inform the sponsor of the study in writing and obtain approval prior to destroying any study-related data.

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	PAGE: 4 OF: 4
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Attachment A

SOURCE DOCUMENTATION REQUIREMENTS

For each study, source documentation to support case report form data should include the following:

1. Date of entry into the study, sponsor's protocol number, and subject number.
2. Note that written informed consent was obtained; consent form dated and signed by subject (or subject's representative).
3. Record any current medications and medications discontinued within the last month (or longer, as specified by the protocol).
4. Record subject's diagnosis and status prior to treatment, including documentation of medical history, particularly that relevant for the disease or condition being treated.
5. Record names of possible study drugs and dosing times.
6. Document the dates and the results evaluations and procedures required by the study; note any deviations from the protocol and provide an explanation.
7. Record any reported complaints or adverse events that occurred during the treatment period and for a period specified by the sponsor following the last dose of study drug. Record any treatment administered and/or recommended.
8. Record subject's condition during and/or after treatment.
9. Document final disposition of the subject and subject status at time of study termination.