DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Electronic Data Management Systems	Policy #: CRP - 1014
	PAGE: 1
DEPARTMENT: DHR Health Institute for Research & Development	OF: 6
	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, 3/21, 04/21, 05/21

Purpose:
This standard operating procedure (SOP) serves for general management of all clinical research data. We refer to this SOP for additional guidance concomitantly required when all or portions of the data that are required by an FDA predicate rule for a submission or inspection, are collected, managed and/or transmitted electronically, or include the use of electronic signatures in required records.

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. **Audit Trail**: means a secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.
B. **Biometrics**: means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.
C. **Certified Copy**: means a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.
D. **Computerized System**: means computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial.
E. **Digital Signature**: means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.
F. **Direct Entry**: means recording data where an electronic record is the original capture of the data. Examples are the keying by an individual of original observations into the system, or automatic recording by the system of the output of a balance that measures subject's body weight. In these cases, the electronic document is the source document.
G. **Electronic Case Report Form (e-CRF)**: means an auditable electronic record designed to record information required by the clinical trial protocol to be reported to the sponsor on each trial subject.

SUBJECT: Electronic Data Management Systems	Policy #: CRP - 1014
	PAGE: 2 OF: 6
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, 3/21, 04/21, 05/21

H. Electronic Patient Diary: means an electronic record into which a subject participating in a clinical trial directly enters observations or directly responds to an evaluation checklist.

I. Electronic Record: means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

J. Electronic Signature: means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

K. Predicate Rule: means an FDA regulation that requires the submission to and/or inspection by FDA, of certain data and information relevant to FDA-regulated investigational and/or marketed products. Examples include clinical trial data to support a New Drug Application or device Premarket Approval application.

Policy:
This SOP applies to electronic data management for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics, and investigational device (IDE) regulations for medical devices, during all investigational phases of development. This SOP does not apply to computerized medical devices, diagnostic laboratory devices or analytical laboratory devices that are used during a clinical trial. Nor does it apply to paper records that are transmitted electronically.

Procedure:

A. System setup, training, security and maintenance

1. Sponsor responsibilities (may vary pursuant to respective clinical trial agreement))

• *Sponsor*	*Retain primary responsibility for ensuring computerized systems used in clinical trial data management at this facility are in compliance with applicable regulations, as regards design and validation.*
	Train all clinical research team members on the proper use of all sponsor-provided electronic systems used to capture study data (electronic patient diary, e-CRF), and on the relevant regulatory requirements.
	Train the research manager and/or Research Coordinator/coordinator to conduct appropriate reviews of electronic data and audit trails at designated time periods.

2. Research sit › responsibilities

Identify which clinical	

SUBJECT: Electronic Data Management Systems	Policy #: CRP - 1014
	PAGE: 3
DEPARTMENT: DHR Health Institute for Research & Development	OF: 6
	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, 3/21, 04/21, 05/21

research team members are responsible: • Vice President of Research and Development	Work with sponsor to facilitate setup, implementation and maintenance of an FDA-compliant computerized system.
	Work with sponsor to ensure that computerized systems used in clinical trials have a logoff or comparable security function after a designated period of inactivity.
	Assign unique and secure User ID/password combination for each clinical research team member who has access to the computerized system(s).
	Invalidate stolen, lost or otherwise compromised User ID/password combinations and replace with a new combination.
	Ensure that proper computer system function is routinely monitored.
	Ensure that sponsor-provided computerized systems are used only for the purposes for which they were intended and validated.
	Ensure that computerized systems are securely stored when not in use.
• Principal Investigator (PI)	Login using his or her unique User ID/password combination or other electronic signature when preparing to perform computer data entry or management functions.
• All research team members	Do not divulge unique User ID/password combinations to anyone else for any purpose.
	Do not use anyone else's unique User ID/password combination or perform any required computer functions under anyone else's User ID/password combination.
	Log off when computer data entry/management activities are completed.

SUBJECT: Electronic Data Management Systems	Policy #: CRP - 1014
	PAGE: 4 OF: 6
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, 3/21, 04/21, 05/21

B. Collection of clinical research data

PI	*Ensure protocol identifies at which steps a computerized system will be used.*
• Research coordinator	Maintain a record listing the hardware and software that will be used for each clinical trial.

C. Transcription of the data to case report forms (CRFs), including remote data entry

• Research Coordinator	Ensure that sponsor-provided computerized systems are used only for the purposes for which they were intended and validated.
	Ensure the audit trail documents all changes to electronic records (who, when, why) and that the original entries are not overwritten.
	Ensure that all annotations to electronic records are attributable as to who and when (date, time) the annotations are made.
• Research Coordinator	Enter all required data into the appropriate fields of e-CRFs within the time frame indicated by the sponsor.
• Support Staff	Review and correct (or annotate) all data before transmitting the e-CRF to the sponsor.

D. Management of the data

• PI	Ensure that an original or certified copy of all electronic source documents and audit trail records are retained on file.
	With respect to an FDA audit, treat electronic records as you would paper records.
• Research Coordinator	Ensure that changed CRFs and eCRFs also display all prior information.
	Work with sponsor to ensure that audit trail reviews are

	performed and documented at defined intervals.
	Retain audit trail records according to regulatory and sponsor requirements.

E. Electronic Signatures

Electronic signatures from investigators or clinical trial personnel may be obtained using a 21 CFR Part 11 compliant system. However, in the absence of a Part 11 compliant system and in the circumstances where wet signatures cannot be obtained, Adobe Acrobat Self Sign may be utilized.

Documents with electronic signatures shall contain information associated with the signing that clearly indicates all of the following: The printed name of the signer; the date and time when the signature was executed; the meaning (such as review, approval, responsibility, or authorship) associated with the signature.

SUBJECT: Electronic Data Management Systems	Policy #: CRP - 1014
	PAGE: 6 OF: 6
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, 3/21, 04/21, 05/21

ATTACHMENT A

ELECTRONIC DATA MANAGEMENT LOG

Study Number:_____ Sponsor: _____

Study Title:_____ Site: _____

Hardware Used for Data Capture/Input

Item	ID#	Sponsor-Provided (Y/N)	Dedicated to Study (Y/N)*

Examples: Computer station, laptop computer

Accessory Items Used for Data Transmission

Item	ID#	Sponsor-Provided (Y/N)	Dedicated to Study (Y/N)*

Examples: Facsimile machine, Palm Pilot

Software

Item	Version	Sponsor-Provided (Y/N)	Off-the-Shelf (Y/N)

*Note: For computerized systems that are NOT dedicated to this study, provide explanation of how control is maintained over access to the system and its software