DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Protecting Confidential Information	Policy #: CRP-1031
	PAGE: 1 OF: 3
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:
The objective of this policy is to describe the responsibilities of the Principal Investigator (PI) and clinical study staff at the clinical trial site with regards to sponsor and patient confidentiality. The policy details the procedures to ensure confidentiality.

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. Confidentiality: Methods for protecting data that is collected in association of a clinical research study. Confidentiality includes ensuring the protection of research subjects' privacy from disclosure of their personal, sensitive or private information to unauthorized persons.

B. Individually identifiable: Individually identifiable includes information about an individual that could lead to the identification of that individual by either the research staff or general public.

C. Identifying characteristics: HIPAA defines the following attributes as identifying characteristics:

- Full name or last name and initial(s)
- Geographical identifiers smaller than a state, except the initial three digits of a zip code, provided the combination of all zip codes starting with those three digits. When the initial three digits of a zip code contains 20,000 or fewer people it is changed to 000
- Dates directly related to an individual, other than year
- Phone Numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health insurance beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers
- Device identifiers and serial numbers;
- Web Uniform Resource Locators (URLs)
- IP addresses

SUBJECT: Protecting Confidential Information	Policy #: CRP-1031
	PAGE: 2 OF: 3
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

- Biometric identifiers, including finger, retinal and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data

D. Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. Additionally, private information includes information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record.) Private information must be individually identifiable information about living individuals to constitute research involving human subjects. All patient health information is considered private information.

Policy:
DHR Health Institute for Research & Development follows the guidelines set forth in the Good Clinical Practice Confidentiality Guidelines (GCP ICH-E6) and Title 45 Code of Federal Regulations (CFR) Part 46. These guidelines set standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials and studies. These guidelines provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of study participants is protected. In addition to these guidelines, DHR Health is compliant with 45 CFR 46 Subpart A also known as The Common Rule.

Procedure:
The Principal Investigator (PI) and designated staff of the DHR Health Institute for Research & Development are responsible for oversight of this policy, and for ensuring that patient and Sponsor confidentiality are maintained at all times. Clinical Research staff are responsible for maintaining confidentiality and adhering to this policy. Discussion of a patient's participation in a clinical study will be limited to the PI, Clinical Research and support staff providing direct patient care, as needed and will be done in a private room. Disclosure of a research subject/patient's private information shall be governed by the Informed Consent and HIPAA Authorization document signed by the patient/research subject

Responsibility:
This policy applies to those members of the clinical research team involved in conducting clinical trials at this research site. This includes the following:

- Principal investigator
- Sub-investigator
- Designated staff of the DHR Health Institute for Research & Development
- Research Coordinator
- Support staff

Process Overview:

- All protected health information (PHI), such as patient's names and data obtained from patient medical records is kept confidential in accordance to DHR Health HIPAA authorization policy.

SUBJECT: Protecting Confidential Information	Policy #: CRP-1031
	PAGE: 3 OF: 3
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

- When providing copies of source documents to the sponsor all patient identifying characteristics will be removed and/or blinded
- All protected health information (PHI), such as patient's names and data obtained from patient medical records is kept confidential in accordance to DHR Health HIPAA authorization policy.
- When providing copies of source documents to the sponsor all patients identifying characteristics will be blinded.

Applicable Regulations and Guidelines

21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 812 Subpart E	Responsibilities of Investigators
21 CFR 812 Subpart G	Records and Reports
45 CFR 160 Subpart A & E	Privacy Rule
45 CFR 164	Privacy Rule