DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Subject Management	Policy #: CRP-1027
	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:
To define the policies and procedures to follow with respect to study participant's expectations and rights when interacting with research staff during recruitment, enrollment, participation, and termination of a clinical research study.

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. Clinical Trial/Study:** Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
- **B. Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial, including risks, that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form. The subject is officially considered part of the study upon the moment they signed the informed consent form.
- **C. Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a potential subject to the subject's participation in the procedure(s) involved in the research.

Policy:
The Principal Investigator (PI) is responsible for ensuring that he/she and all study staff that interact with potential and actual study participants or their private health information follow guidelines concerning respect, safety, and confidentiality. The Clinical Research Study Coordinator must ensure that the patient is given identification of trial participation in the event of an adverse event.

DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Subject Management	Policy #: CRP-1027
	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

Procedure:
Research participants should expect that the Principal Investigator and the study staff will conduct a clinical research study and provide study-related care in accordance with federal, state and local law and regulations and with the institution's policies governing research. Clinical research will be conducted with concern for the participant, and the recognition of his/her dignity as a human being. Rights of a participant in a research study include the following:

1. The participant should be able to distinguish between patient care and research and understand that he/she is participating in a research study. The participant should be able to understand the study's purpose and expect to understand that there may be no therapeutic intent towards their condition or that the medication or device will be 100 percent effective. The subject must also be aware if the study is blinded and there is a possibility a placebo will be administered. Safety and efficacy of the treatment or device will be thoroughly explained to the participant at the onset of study through the signed informed consent process and throughout the duration of the study.
2. The participant has the right to decide to be in the research study and to make that decision in consultation with family, friends, or personal physicians and without undue influence or coercion from the research team.
3. The participant has the right to expect that the trial will be conducted ethically and the health and well-being of the participant is prioritized.
4. The participant has the right to have private health information treated confidentially to the extent described in the Informed Consent Document and HIPAA authorization.
5. The participant should expect continuity of care during the course of the study by the Principal Investigator and study personnel.
6. The participant has the right to expect the research team will provide a mechanism where he/she is informed of continuing health care requirements or other healthcare options outside of the study after termination of the study.
7. The participant has the right to at any given moment contact the Institutional Review Board should they feel compromised throughout the duration of the study.
8. The participant has the right to indicate he or she no longer wishes to participate in the indicated study with absolutely no recourse to his or her decision at any time throughout the duration of the study.