DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Purpose of the office of Human Research Protection program and Institutional Review Board	Policy #: CRP-1041
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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, 03/22

Purpose:
The mission of the DHR Health Institute for Research and Development Office of Human Research Protection Program (HRPP) is to protect the rights and welfare of research subjects who participate in research consistent with ethical principles and federal, state and local regulations.

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.

Office of Human Research Protection Program (HRPP):
In the process of executing its mission, the HRPP is responsible for the following key components:

- Institutional Review Board
- Compliance
- Ethical Management of Grants
- Delivery of Educational Programs
- Regulatory Oversight of Research Pharmacy
- Conflict of Interest
- Investigators and Research Staff

The Office of Human Research Protection Program is committed to providing support and guidance to the research community, as well as ongoing support and advice on issues that arise during the conduct of research.

Institutional Review Board (IRB):
The primary purpose of the IRB is to protect the rights and welfare of human subjects involved in research activities being conducted under its authority. In so doing, the IRB shall ensure adherence to the criteria for IRB approval as listed in 45 CFR 46.111 and 21 CFR 56.111 i.e., that:

- The risks to human research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk, and whenever appropriate, by using procedures already being performed on subjects for diagnosis or treatment purposes.

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- The risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
    - For the purpose of IRB consideration, "benefit" is defined as a valued or desired outcome; an advantage.
    - For the purpose of IRB consideration, "risk" is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study.
    - In evaluating risk, the IRB is to consider the conditions that make the situation dangerous, per se (i.e., as opposed to those chances that specific individuals are willing to undertake for some desired goals). In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (i.e., as distinguished from risks and benefits of treatments or procedures that the patient would undergo if not participating in the research).
    - In evaluating risks and benefits, the IRB does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of research on public policy).
- The selection of human subjects for research participation is equitable.
    - In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
    - The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, (e.g., children, prisoners, individuals with impaired decision-making capacity or economically or educationally disadvantaged persons).
- Human research subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent is obtained from each prospective human research subject, or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulations and IRB policies.
- Informed consent of human research subjects is obtained in advance of research participation or appropriately waived to the extent required by federal regulations and IRB policies and appropriately documented or appropriately waived in accordance with, and to the extent required by federal regulations and IRB policies.
- The research protocol, when appropriate, makes adequate provisions for monitoring the data collected to ensure the safety of human research subjects.
- There are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.
- Appropriate additional safeguards have been included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

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The criteria at 45 CFR 46.111(a)(8) will not be utilized as broad consent will not be implemented.

As a secondary purpose, the IRB must seek to ensure that the DHR Health Institute for Research and Development, affiliate institutions, and the investigators that it serves are compliant with the ethical standards and regulations governing human subject research. The IRB and IRB Office also serve to assist investigators in the design of ethical and regulatory compliant human subject research studies.