DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Ethical and Regulatory Mandates to Protect Human Research Participants	Policy #: CRP-1039
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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:
DHR Health Institute for Research and Development have adopted all policies, procedures and guidelines that meet AAHRPP (link) accreditation mandates. This provides assurance to potential research subjects that the clinical investigation approved by the DHR Institute for Research and Development IRB meets the highest ethical standards identified by an external accrediting agency.

The DHR Health Institute for Research and Development is committed to ensuring that all human subject research1 in which it is engaged is conducted in accordance with the ethical principles stated in the Belmont Report. The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the ethical foundation for the federal regulations for the protection of human research subjects.

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.

Policy:
Respect for Persons
Individuals should be treated as autonomous agents afforded the right to make decisions for themselves. Those with diminished autonomy (e.g. minors, prisoners, persons who are mentally disabled) are entitled to additional protections. Application of this principle requires that human subjects are enrolled into research studies only under the conditions of effective informed consent. This involves a process in which participation in the research is acknowledged by the research subject (or by a legally authorized representative) as a voluntary act free from coercion or undue influence from the investigator or members of the research team. Exceptions to this informed consent requirement must be outlined in the federal regulations and subsequently approved by the DHR Health Institute for Research and Development

Beneficence
The research study must be designed and implemented so as to maximize possible benefits and minimize possible harms. Application of this principle involves a risk/benefit analysis in which the risks to subjects must be reasonable compared to the potential for benefit either to subjects directly or to society. Risk evaluation must include the consideration of both the probability and magnitude of harm, including psychological, physical, legal, social, and economic harm.

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Justice
The possibility for benefits and the potential burdens of the research should be equitably distributed among the potential research subjects. Application of this principle requires the close scrutiny of the enrollment process to ensure that particular classes (welfare patients, racial and ethnic minorities, or persons confined to institutions) are not selected for their compromised position or convenience to the research investigator.

Under the DHR Health Institute for Research and Development policies and procedures, an activity is human subject research if it is either (1) human research that is subject to FDA regulation or (2) human research that is subject to DHHS regulations. Activities are human research that are subject to FDA regulations when they meet the FDA definition of "clinical investigation" (21 CFR 50.3(c)) and involve one or more "human subjects" (21 CFR 50.3(g)) as defined in FDA regulations. Activities are human research that are subject to DHHS regulations when they meet the DHHS definition of "research" (45 CFR 46.102(l)) and involves one or more "human subjects" (45 CFR 46.102(e)(1)) as defined in DHHS regulations.

Regulatory Mandates
The IRB and the research community adhere to the following regulations and policies for human subject research activities:

- The Federal Policy regulations for the protection of human research subjects (45 CFR Part 46; Subpart A also known as the "Common Rule"), as well as all additional subparts outlined in 45 CFR Part 46. Equivalent protections will be applied all research reviewed under the jurisdiction of the IRB.

- When research involves articles subject to regulation by the FDA, the FDA regulations for the protection of human subjects (21 CFR Parts 50) and Institutional Review Boards (21 CFR Parts 56).

- When research is supported by other federal agencies, applicable regulatory requirements will be followed

- Where applicable, other state and local regulations regarding research involving human subjects.

- The provisions of the Federal Wide Assurance Agreement (FWA) for the DHR Health Institute for Research and Development (FWA # 00014304). (https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc)

When making determinations concerning the rights and welfare of human subjects participating in research studies, the IRB will also refer to current guidance available on OHRP and FDA websites; and to other interpretative directives, information, documents and guidance materials related to human subjects research.