DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Roles and Responsibilities of Investigators and Research Staff	Policy #: CRP-1008
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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, 12/20, 04/21, 05/21, 03/22

Purpose:
The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the 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 and 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.

PI's leaving the health system are responsible for notifying the IRB well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

The following individuals may serve as PI:
- Principal investigators may be DHR physicians or full-time faculty at affiliated academic institutions.
- Fellows, residents, and students may not serve as principal investigators for their own research projects but may serve as sub-investigators.
    - Fellows, Residents, and medical students affiliated with the University of Texas Rio Grande Valley - School Of Medicine may serve as principal investigators for their own research projects provided they have the oversight of an assigned Faculty Advisor.

Note: The IRB reviews and holds student research projects to the same standards as human subject research conducted by faculty or staff. IRB approval or exemption must be obtained prior to initiating any research activity under IRB oversight. "Retroactive" IRB approval or exemption is not permitted under federal regulations and IRB policy. Failure to obtain IRB approval for research with human subjects may preclude the use of the previously collected data at the discretion of the IRB.

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General Responsibilities of Principal Investigators
As a general condition for the approval of a research study, the IRB holds the principal investigator of the study responsible for ensuring that:

- risks to research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
- 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 reasonably expected:
    - the DHR Health Institute for Research and Development IRB shall consider only those risks and benefits that may result from the research (as distinguished from the risk and benefits of therapies participants would receive even if not participating in the research).
    - The DHR Health Institute for Research and Development IRB shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks (such as possible effects of the research on public policy) that fall within the purview of its responsibility.
- selection of human subjects and patients for research participation is equitable – in making this assessment, the DHR Health Institute for Research and Development IRB will take into account:
    - the purpose of the research;
    - the setting in which the research will be conducted; and
    - special problems involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- individuals 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 will be obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required, by policies and federal regulations or appropriately waived as required by federal regulations and IRB policies;
- informed consent of human research subjects will be obtained in advance of research participation and appropriately documented or appropriately waived in accordance with, and to the extent required, by institutional policies and federal regulations;
- where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects;
- the privacy of human research subjects is protected and the confidentiality of data is maintained;
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Specific Responsibilities of Principal Investigators
The IRB holds the principal investigator of an approved research study responsible for:

- promptly responding to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB renewal;
- ensuring that adequate resources and facilities are available to carry out the proposed research study;
- abstaining from enrolling any individual in a research study (i) until such study is approved in writing, by the IRB; (ii) during any period when the IRB or sponsor/principal investigator has suspended study activities; or (iii) following IRB- or sponsor/principal investigator-directed termination of the study;
- ensuring that all associates, colleagues, and other personnel assisting in the conduct of the research study are appropriately informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) reportable new information requirements; and (v) data collection and record-keeping criteria;
- conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject;
- reporting of deviations that meet the definitions from the currently approved research protocol;
- requesting IRB approval of any proposed modification to the research protocol or informed consent documents prior to implementing such modifications;
- obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent documents (i.e., unless the IRB has granted a waiver of the consent process)
- maintaining adequate, current, and accurate records of research data, outcomes, and reportable new information to permit an ongoing assessment of the risk/benefit ratio of study participation;
- reporting promptly to the IRB (and, if applicable, the sponsor and FDA) any internal or external adverse event that is considered to be unexpected, serious, and possibly or definitely related to the study;
- reporting promptly to the IRB any significant changes in the risk/benefit of study participation;
- ensuring that, in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible;
- ensuring that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study;
- ensuring that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved and have completed the applicable required training modules;
- maintaining adequate and accurate research subject records to reflect adherence to protocol specific requirements.
- complying with additional requirements for federal agencies.

Responsibilities of investigators are further detailed in the references outlined below.

- FDA 1572 Statement of the Investigator
- 21 CFR 312.60: General Responsibilities of Investigators

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- 21 CFR312.60 – 312.70:: Responsibilities of Investigators: Biologics
- 21 CFR 812 Subpart E:: Responsibilities of Investigators: Devices
- DHHS: Office of Human Research Protections (OHRP): Frequently Asked Questions: Investigator Responsibilities

Sub-Investigators and Research Staff
Appropriately qualified sub-investigators and research staff may perform tasks as delegated by the Principal Investigator but they do not accept primary responsibility for the research study.

General Responsibilities of the Sub-Investigator and Research Staff
- Completing required institutional and protocol specific training;
- Adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants; and
- Assuring participant privacy and confidentiality according to HIPAA guidelines, institutional regulations, and HRPP policies and procedures.