DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Education & Training	Policy #: CRP-1006
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DEPARTMENT: DHR Health Institute for Research & Development	OF: 3
	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:
It is policy of the DHR Health Institute for Research and Development IRB that all involved in the review, conduct and oversight of human subject research (investigators, research staff, key personnel, mentors, IRB members, IRB chairs and IRB staff) must complete initial and continuing education in human research protections.

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.

General Initial Training and Education Requirements
The DHR Health Institute for Research and Development utilizes CITI (Collaborative Institutional Training Institute) as its human subjects training program. Individuals engaged in human subjects research, as well as faculty mentors, are required to complete the following courses:

- Human Subject Research – Biomedical Research
- Conflict of Interest

In addition, all investigators and research team members who are engaged in the conduct, oversight or management of clinical trials (as defined by the NIH) are required to complete the CITI GCP training course regardless of funding before participating in any research activities. There are four GCP training courses available: Good Clinical Practice, GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus), GCP for Clinical Investigations of Devices and GCP – Social and Behavioral Research Best Practices for Clinical Research. HRPO considers research to be FDA-regulated if it falls under one of the following sections of the Federal Food, Drug, and Cosmetic Act: section 505 (New Drug Application) or 520 (Devices intended for human use). Clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products are also considered to be FDA-regulated research.

Any physician who is engaged in the conduct, oversight or management of Humanitarian Use Devices (as defined by the FDA) are also required to complete the CITI Humanitarian Use Devices training course.

All investigators and research team members must renew CITI training prior to the expiration date listed on completion certificates.

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Continuing Education Requirements
In order to meet Continuing Education Requirements, individuals engaged in human subjects research, as well as faculty mentors, must complete the CITI Refresher Course at least every four years. In addition, it is recommended that three hours of continuing education credit related to human subjects protection or ethical considerations in the conduct of human subject research be completed over a four year period. Examples of available programs include:

- Designated IRB-sponsored programs
- Other Modules through CITI
- Research Coordinator Orientation program
- Participation in a Research Investigator Start-up Education (RISE) Interview
- FDA Training Continuing Education Courses
- Attendance at IRB-approved bioethics programs
- Attendance at programs sponsored by PRIM&R or its affiliates on human subjects protections

IRB Committee Members

A. In-house orientation
All prospective IRB Committee members are required to complete an initial orientation session prior to serving on the IRB. The orientation session is conducted by the IRB Coordinator. All new members are provided the following information and complete the CITI IRB member module in addition to those noted above:

- IRB Policy and Procedure Manual;
- DHHS regulations (45 CFR 46), FDA regulations (21 CFR 50 and 56);
- Belmont Report;
- Declaration of Helsinki;
- Nuremberg Code;
- DHR Health Institute for Research and Development Conflict of Interest Policy;
- DHR Health Institute for Research and Development policies pertaining to IRB Memberership and IRB procedures
- Relevant IRB Forms

B. Observation of IRB Meeting
All new IRB Committee members are required to observe at least one IRB committee meeting prior to functioning as a voting member.

C. IRBNet Training
All new IRB Committee members will be trained the use of IRBNet, the electronic submission system. This training includes how to review electronic applications, post reviewer notes, and access checklists and other supporting documentation.

Investigator and Research Personnel
There are also several other modules that can be used as resources for the research community. The modules can be accessed through the CITI program.

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The Office of Human Research Protection Program provides guidance documents to assist in navigating the IRB process and adhering to federal regulations as well as IRB policies and procedures related to human research protections.