DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Reliance Mechanisms	Policy #: CRP-1049
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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:
Relevant guidance from OHRP states that multiple institutions engaged in the same non-exempt human participant research may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort. Similarly, FDA regulations permit a sponsor to utilize a single, central IRB for review of multicenter clinical trials.

The purpose of this policy is to define the procedures and standards the DHR Health Institute for Research and Development Office of Human Research Protection (OHRPP) follows for determining when to accept the review of another IRB for non-exempt human-participant research in which DHR Health Institute for Research and Development faculty, staff or students are engaged, and when to permit another institution or an unaffiliated researcher to rely upon the review of a non-exempt human-participant protocol by the DHR Health Institute for Research and Development IRB.

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 Statement:
When non-exempt human participant research is being conducted in collaboration with other institutions or with collaborating individual investigators, each collaborating institution and/or collaborating individual investigator engaged in the research must obtain IRB approval from an appropriately authorized IRB. The OHRP guidance document, Guidance on Engagement of Institutions in Human Subjects Research and the listed Jurisdiction criteria found in CRP-1040 will be used as the basis for determining whether the duties contemplated by an investigator constitute engagement in human participant research. Such determinations will be made in collaboration and consultation with authorized representatives of the collaborating institution and/or the collaborating individual investigators, as applicable.

In an effort to streamline IRB reviews for multicenter trials, OHRPP will consider requests to either rely on another institution's IRB or to serve as the central IRB for other collaborating sites engaged in the trial under the conditions set forth in this policy. The Institutional Official (IO), in consultation with the OHRPP, has the authority to execute Institutional Authorization Agreements (IAAs) or Reliance Agreements (RAs) on behalf of the DHR Health Institute for Research and Development. All determinations to rely upon, or to permit another institution to rely upon the DHR Health Institute for Research and Development IRB, shall be documented in an IAA or RA.

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Procedures

DHR Health Institute for Research and Development IRB Reliance on Another IRB:

Investigators considering requesting reliance on another IRB should contact the OHRPP office early in the research proposal process. Decisions about whether to permit reliance on another IRB shall be determined by the IO, after review and recommendation by the OHRPP. The DHR Health Institute for Research and Development may rely on another appropriately constituted IRB for the review of cooperative research projects under the conditions set forth below.

In deciding whether or not to rely on another IRB, the IO will consider the following criteria:

- Whether the use of a Central IRB mechanism has been mandated by the study sponsor;
- The number of proposed studies involved in the collaboration;
- The anticipated level of risk associated with proposed studies;
- The terms and conditions of the proposed IAA or RA;
- Whether the reviewing IRB's policies and procedures meet the DHR Health Institute for Research and Development standards. If the other IRB is AAHRPP accredited, then it will be presumed that the DHR Health Institute for Research and Development standards are being met; however, accredited status does not in itself necessarily suffice as a basis for the IO's decision.
- The location where the interventional human research activities will take place.
- The capacity of the other institution and its IRB to sufficiently be informed about the DHR Health Institute for Research and Development local research context and applicable laws and regulations.

The OHRPP Administrator will ensure that the finalized agreement is appropriately signed by the IOs for the involved institutions. Copies of all agreements will be maintained in the OHRPP.

- In order to maintain an accurate record of studies being done at the institution, as well as to manage required ancillary reviews, investigators are required to create an IRBNet application utilizing the application for deferment for studies that are reviewed by another IRB. Updates to the IRBNet package are only required 1) at the time of continuing review,2) if there is a change in PI, or 3) if there is a change that affects any of the required ancillary reviews (except fiscal) 4) at the time of study closure.

Another Institution's Reliance on the DHR Health Institute for Research and Development IRB:

The DHR Health Institute for Research and Development may serve as the IRB of record for review of human participant research for another institution with appropriately executed IRB Authorization or Reliance Agreements.

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In deciding whether to provide IRB review for another institution, the IO will consult with the OHRPP, and make a determination based on the following criteria:

- The number of studies being proposed under the agreement;
- The number of sites engaged in the research;
- The risk level of the study;
- Whether the study is being conducted under an investigator-initiated IND or IDE;
- The location where the interventional human research activities will take place;
- Whether the use of a Central IRB has been mandated by the sponsor;
- Whether adequate funding is provided to cover the additional costs associated with managing the approval and necessary IRB oversight at the other sites;
- The capacity of DHR Health Institute for Research and Development to be sufficiently informed about the other institution's local research context and local applicable laws and rules.

The DHR Health Institute for Research and Development will facilitate communication with the relying institution about IRB actions on the human subject research that is the subject of the Agreement, in accordance with its specific provisions of the Reliance Agreement.