DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Clinical Research Process	Policy #: CRP-1001
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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, 1/21, 04/21, 05/21, 03/22

Purpose:
DHR Health Institute for Research & Development is participating in clinical research studies across various disease states to bring cutting-edge and innovative advanced clinical care to the people of the Rio Grande Valley. This document will help acquaint all interested parties with the policy and procedures to engage in clinical research investigations at DHR Health Institute for Research & Development.

The purpose of this document is to inform any potential research investigator of the process by which clinical research studies are initiated and approved at DHR Health Institute for Research & Development.

Potential research investigator includes but is not limited to any practicing physician employed by Renaissance Medical Foundation and affiliates, DHR Health and affiliates, or not employed DHR, any medical staff, allied health professional and any medical resident.

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, fellow, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; and 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:
All investigators must comply with both the Federal Drug Administration and Health Human Services codes of federal regulation indicating Human Subject Research Protection Regulations (45 CFR part 46).

Mandatory Regulatory Start-Up Documents:
1. Investigators must provide evidence of *successful* completion of a Human Subject Research Protection training, Conflict of Interest and/or the Good Clinical Practice training. All training modules may be obtained via the Collaborative Institutional Training Initiative (CITI) website.
    a. Step-by-step instructions will be provided by the DHR Health Institute for Research and Development.
    b. Certificates should be provided to the DHR Health Institute for Research and Development .
2. Investigators must provide an updated curriculum vitae (CV) with a clear affiliation with DHR Health.
    a. Investigator must sign and date first page of CV.
    b. An updated CV must be submitted every two years.

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3. A current medical license for each investigator (if applicable) will be obtained from the DHR Health Medical Staff office.
4. All documents will be stored at the DHR Health Institute for Research and Development office in study-specific binders.

Study Approval Process At Doctors Hospital At Renaissance:

1. Investigator will submit study to local DHR Health Institute for Research and Development Institutional Review Board (IRB) for approval or an acknowledgment to defer to a Central IRB.
2. Studies approved by the IRB will be presented to the DHR Health Medical Executive Committee and the DHR Health Board of Governors.

Procedure:

1. Upon identification of a research project, the study investigator is to contact the DHR Health Institute for Research and Development and meet with the Director or VP of Research and Development.

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2. Once the proposed study has been discussed with the Director or VP of Research and Development, the investigator will be directed to begin application to the DHR Health Institute for Research and Development Institutional Review Board (IRB) or their IRB of interest or record.
   a. Documents are sent to external Institutional Review Board by study coordinator or Investigator for review in parallel with internal review submission. IRB review fees will be incurred by initiating physician, or entity unless physician is employed by the Renaissance Medical Foundation at which point reimbursement will be made by the Renaissance Medical Foundation Board. Contact the DHR Health Institute for Research and Development for further information on IRB packet preparation and submission.