DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Study Start Up	Policy #: CRP-1015
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DEPARTMENT: DHR Health Institute for Research & Development	OF: 3
	EFFECTIVE: 06/17
APPROVED BY: Sohail Rao, MD, D.Phil, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 06/17, 11/20, 01/21, 04/21, 05/21

Purpose:
The initiation of a clinical study marks the beginning of subject accrual. Prior to enrolling the first subject, all regulatory and institutional requirements must be met, and preparations for protocol procedures must be complete. In addition, the research staff and others involved in recruitment, selection of subjects and enrollment must receive appropriate training. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements of starting-up a 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 & 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.

Definition

A. Clinical Trial Agreement: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Policy:
This SOP describes the steps taken to organize and prepare DHR Health Institute for Research & Development for all clinical studies subject to regulations and requirements.

Procedures:

A. Determine facility readiness
    a. Financial Feasibility. Sponsor will send an initial budget offer, sometimes with an itemized breakdown of the protocol.
    b. The Research Coordinator will review the protocol, clinical trial agreement and budget and identify procedures to be itemized. The coordinator, under the supervision of the Vice President of Research, will identify the payer of each itemized procedure.
    c. Designated staff in the DHR Health Institute for Research & Development.

B. Budget & Contract Negotiation
    a. Sponsor will send a contract and an initial offer, sometimes with a breakdown of protocol procedures.
    b. The contract will be reviewed by the designated staff of the DHR Health Institute for Research & Development.

c. The Research Coordinator will ensure the breakdown has all required procedures accounted for, identify which procedures are paid by whom, ensure that the estimated time involvement for the project is covered by the budget and draft the first counter offer (***Protocol Coverage Analysis Template***).
d. Designated staff of the DHR Health Institute for Research & Development will review, edit and approve first counter offer of the budget.
e. Once the contract has been reviewed and edited designated staff of the DHR Health Institute for Research & Development will send both the contract and the budget to the sponsor.
f. Sponsor will counter offer, request edits, or approve the budget & contract.
g. This process will be repeated until a reasonable budget and contract have been approved by both parties. If not reasonable, then the protocol is not financially feasible for our institution.
h. Upon approval by both parties, the Principal Investigator will then need to present the protocol to the DHR Health Institute for Research & Development IRB committee. If approved, by DHR Health Institute for Research & Development IRB, the project may be commenced.

• DHR Health Institute for Research & Development	Ensure that the contract is executed. & Ensure that a final budget has been negotiated.
• Clinical Research Coordinator	Conduct in-service training for referring and (e.g., physicians, nurses, and lab technicians), others. Document content and attendance to inservice/training.

C. Establish site readiness

• Clinical Research Coordinator	Review regulatory files/binder for completeness. Establish the receipt of adequate investigational drug supplies. Inventory all related supplies. Develop or utilize sponsor- generated worksheets, checklists. Review study procedures with assigned research staff

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D. Initiate Recruitment

• PI • Clinical Research Coordinator	After receiving IRB approval, notify sponsor of launch date for recruitment activities. Assemble IRB approved recruitment materials. Activate recruitment plan.