**DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT**
**POLICY AND PROCEDURE**

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| **SUBJECT:** Protocol Implementation | Policy #: CRP-1023 |
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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 |

**Purpose:**
To ensure appropriate review of a protocol prior to implementation.

**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.

**Definitions**

A. **Approval:** The affirmative decision of the IRB (IRB defined below) that the clinical trial has been reviewed and may be conducted at the institution's site within the constraints set forth by the IRB, the Institution, Good Clinical Practice (GCP [defined below]), and the applicable regulatory requirements.
B. **Clinical Trial/Study:** Any investigation in human subjects intended to discover, prevent, control, diagnose or treat illness, including: verify clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
C. **Multi-Center Trial:** A research trial conducted according to a single protocol at more than one site, and, therefore, with more than one site Investigator.
D. **Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a clinical trial. The protocol usually also gives the background and rationale for the clinical trial, but these could be provided in other protocol referenced documents.
E. **Protocol Amendment:** A written description of a change(s) to a protocol or formal clarification of a protocol.
F. **Subject/Trial Subject:** An individual who participates in a clinical trial and has signed approved informed consent form.
G. **Trial Site:** The location(s) where trial-related activities are actually conducted that has previously been approved by the sponsor, and if applicable indicated in the Form FDA 1572.
H. **Clarification Memo:** A memo designed to clarify a specific part of the protocol. A clarification memo does not officially change the protocol (see protocol amendment).
I. **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

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J. **Institutional Review Board (IRB):** Independent bodies constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The primary review of clinical trials rests with the IRB.

K. **Investigational Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Policy:**
The Principal Investigator and delegated research staff involved with the performance of a protocol are responsible for reading and implementing the clinical research protocols once approved by all necessary regulatory authorities [the Sponsor, IRB a Central Institutional Review Board (if applicable), IEC, and any other required regulatory officials], in accordance with Federal, International, Sponsor and DHR Health Institute for Research & Development Policies.

**Responsibility:**
The Principal Investigator and delegated research personnel involved with the execution of the research trial.

**Procedure:**
1. **READING THE PROTOCOL: The Principal Investigator and Clinical Research Coordinator will be** responsible for reading the assigned research protocol in its entirety including but not limited to the schema, study design, study treatment, inclusion/exclusion criteria, required evaluations, laboratory tests/procedures, toxicity management, clinical/laboratory endpoints, the schedule of events, appendices and the informed consent.
2. **INFORMED CONSENT DOCUMENT: The Principal Investigator and clinical research coordinator will** be responsible for reading and understanding the informed consent document prior to reviewing it with a potential study candidate. Clinical research coordinator must ensure required language for patient population of informed consent document is available and adorns the proper IRB approval stamp.
3. **CHECKLISTS:** The clinical research coordinator will ensure all protocol procedures are completed by providing visit checklists prior to study/trial implementation.
4. **SOURCE DATA/CASE REPORT FORMS:** The clinical research coordinator will develop visit case report forms to ensure all proper data points are obtained per protocol requirements prior to study/trial implementation. Case report forms should contain information requested on Electronic Data Capture system and any information considered relevant.
5. **DATA ENTRY:** The Clinical Research Coordinator must input visit data within three (3) days post visit into the sponsor/Clinical Research Organization assigned Electronic Data Capture (EDC) clinical trial management system (CTMS).

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6. **TRAINING:** Principal Investigator must ensure all delegated staff has appropriate training to fulfill their assigned duties to the protocol. All training material must be in regulatory binder at all times.
7. **ACCOUNTABILITY:** It is ultimately the responsibility of the Principal Investigator to delegate and ensure all Investigational Product is accounted for. Delegated staff must ensure to document dispensation and return of all Investigational Product.
8. **PROTOCOL AMENDMENTS:** The Principal Investigator must ensure all delegated staff is trained on the new protocol amendment prior to conducting protocol amendment procedures. Appropriated delegated staff must ensure the protocol amendment is filled in the Investigator Site File along with the training log.
9. **CORRESPONDENCE:** Appropriately delegated staff will be responsible for reviewing all communication/correspondence, ensuring review by principal investigator and filing it appropriately in the Investigator Site File.