DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Clinical Quality Management Plans	Policy #: CRP-1034
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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:
The purpose of the policy is to describe the minimum requirements for the development, implementation, and evaluation of a Clinical Quality Management Plan (CQMP) for clinical research sites to ensure that the rights and safety of participants are protected and that data collected is accurate and complete.

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.

Scope:
This policy applies to all clinical research sites conducting or participating in clinical research at DHR Health Institute for Research & Development or through one of its affiliated outpatient clinics. This policy refers to CQMPs that address clinical and regulatory activities at the clinical research site. Refer to DHR's Policies and Procedures for guidance and policies for quality management requirements for laboratory and/or pharmacy activities.

Background:
The CQMP is a "living document" that should be updated/changed as procedures are streamlined and new areas of focus are identified. Quality Management (QM) is part of a system of oversight required for the conduct of clinical research. Each clinical research will develop, implement and evaluate a CQMP. QM activities will allow planning for effective protocol implementation, assure compliance with sponsor and applicable regulatory requirements, identify areas in need of corrective action, verify data accuracy, and assure a constant state of readiness for an external audit or monitoring visit.

A QM system includes both Quality Control (QC) and Quality Assurance (QA). QC is the real time, on-going (day-to-day) operational techniques and activities that are undertaken to verify the requirements for quality trial-related activities. QA is a retrospective, objective, systematic, and periodic review of trial-related activities to ensure that the trial is performed and the data are generated, documented and reported in compliance with Good Clinical Practice (GCP) and any applicable regulatory requirements.

Responsibilities:
Principal Investigator (PI), Clinical Research Site (CRC) Coordinator, and/or designee. The PI, CRC and/or designee is responsible for the development, implementation, and evaluation of a CQMP.

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Policy:
Clinical research sites conducting clinical trials will develop, implement, and evaluate a CQMP.

A CQMP should include the following:

A) Description of the person(s) responsible for the development, implementation, and evaluation of the CQMP.

B) At a minimum, inclusion of the following key indicators (as applicable) for QA/QC review:

1. Informed consent form and process. All written informed consent forms should be provided in both English and Spanish.
2. Eligibility criteria
3. Scheduled tests and procedures as per study protocol specifications
4. Missed visits, tests, or procedures
5. Concomitant/prohibited medications
6. Study product administration/dosing
7. Clinical endpoint identification
8. Identification and reporting of Serious Adverse Events (SAE), Expedited Adverse Events (EAE) and Adverse Events (AE)
9. Identification and reporting of Unanticipated Problems (UP).

C) Description of Quality Management (QM) activities

1) Quality Control (QC)
Description of QC activities, including the scope (number and type) of QC activities. QC is typically performed on 100% of Case Report Forms (CRFs) prior to entry into the database and on other trial related forms. For example: Verification that all headers, required fields, and dates are completed correctly on case report forms (CRFs).

2) Quality Assurance (QA)
A description of the frequency of review for each type of research record during a defined period of time. For example, staff may evaluate key elements of source documentation and compare them to completed CRFs for agreement weekly.

D) Designation of a minimum percent of records for QA review in the CQMP based on, but not limited to, high risk protocols, higher accruing protocols, initial enrollments in new protocols, and protocol visits conducted by new or less experienced staff members. A minimum required percent of records for QA review for a particular study or clinical research site may be set.

E) Description of QA and QC activities to be performed in order to ensure that the contents of regulatory files are complete and up-to-date.

F) Description of tools or checklists to be used in the QA and QC processes. Examples may include, but are not limited to, the following: visit reminder checklists; data entry, query and error reports from the data management center; clinical site monitoring reports; chart review tools

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G) Documentation of QM activities
   1) Documentation of QM activities should include the following:
      i. Name of the reviewer
      ii. Date of the review
      iii. Participant identification numbers of items reviewed where indicated
      iv. Specific items that were reviewed
      v. Time period covered by the review
      vi. Findings/results of review

H) Description of CQMP Evaluation
   1) Description of frequency and types of QC and QA activities that will be evaluated and how they will be communicated to appropriate staff.
   2) A Summary of Activities Tool should include identification of problems, identification of possible causes, and any corrective actions taken.
   3) The CQMP should describe how the findings from annual CQMP review, or more frequently as needed, are evaluated and communicated to appropriate staff. Annual Summary Review Reports should include identification of problems, identification of possible causes, and any corrective actions taken.

I) Description of Reporting Requirements
   1) QM findings must be reported to DHR Health Institute for Research & Development per established DHR Health Institute for Research & Development and protocol requirements. For example: If an unreported serious adverse event is uncovered during QM activities, report the event per protocol, DHR, and site or institutional requirements.
   2) All AE, SAE, UP are reported to the DHR Health Institute for Research & Development Institutional Review Board and sponsoring company and/or collaborator.
   3) On an annual basis, clinical research sites must prepare an evaluation of the CQMP and related activities.

J) Review of the CQMP
   CQMP shall be reviewed prior to its implementation. The clinical research site may be required to submit revisions of the CQMP to DHR Health Institute for Research & Development