DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Monitoring Visits	Policy #: CRP-1017
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DEPARTMENT: DHR Health Institute for Research & Development	OF: 3
	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 establish a standard procedure for monitoring visits which are conducted to assure protection of rights and safety of human subjects, and quality integrity of clinical trials result. To ensure that necessary data for such monitoring is available, including designated space and responsible staff.

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. **Audit:** A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
B. **Case Report Form (CRF):** A printed, optical, or electronic document designed to record all of the protocol- required information to be reported to the sponsor on each trial subject
C. **Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.
D. **Monitoring:** The act of overseeing the progress of a clinical trial to ensure that: the rights and well-being of subjects are being protected; the data are accurate, complete, and verifiable; the trial is being conducted in compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.
E. **Monitoring Report:** A written report from the monitor to the sponsor after each monitoring visit summarizing what was reviewed including findings and actions recommended or taken to ensure compliance.
F. **Source Documents:** All information captured in original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico- technical departments involved in the clinical trial) of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

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Policy:
The Principal Investigator (PI) or designee will collaborate with the Sponsor (or designee) in scheduling the monitoring visit. The PI will assure that all staff involved with the clinical trial(s), including the Clinical Research Coordinator (CRC), research nurses, research pharmacist, and regulatory specialist are available to the monitor and present for the findings and debriefing at the end of the visit. The PI will assure that all data necessary to conduct a thorough clinical trials audit are available and centrally located for the monitor.

Responsibility:

A. Principal Investigator: The PI will assure that all necessary source documentation is available to demonstrate that the site and designated personnel have adequate qualifications and resources, including number of qualified staff and facilities, to safely and properly conduct (the) clinical trial(s). The PI will demonstrate via source documentation and regulatory files that the conduct of the trial is in accordance with protocol, Code of Federal Regulations, and Good Clinical Practice.

B. Clinical Research Coordinator: The CRC, also known as the Study Coordinator, will reserve adequate space, defined as a quiet space with table, for the monitor. The CRC will notify all involved study personnel of dates when the monitoring visit will be conducted. The CRCassures that subject study binders/research folder(s), original source documents and other study related documents are made available for source data verification

C. Regulatory Specialist: The clinical regulatory specialist will make available for review all essential/critical/regulatory documents pertaining to the study(ies) being monitored including but not limited to, site personnel CVs, medical license(s)/certificates, Financial Disclosure Forms (FDF),training log/history, delegation/responsibility log, form FDA 1572, letter of indemnification, IRB membership list, disclosure/confidentiality agreement letter, IRB assurance letter or compliance statement, IRB and sponsor correspondence, Investigator Brochure(s), protocol and amendments, copy(ies) of approved informed consent(s), IRB approvals and renewals, laboratory certification(s) and ranges, clinical supplies accountability and shipping forms, equipment calibration logs, and monitoring logs. The clinical regulatory specialist will assure that all forms are current, complete, accurate and organized.

Procedure:
Routine Monitoring Visits:
A. Scheduling the monitoring visit
- The sponsor monitor will contact the PI and lead coordinator to schedule the monitoring visit.
- The lead coordinator will work with the sponsor monitor and PI to schedule a mutually convenient date and time to conduct the monitoring visit.
- Upon confirmation from the sponsor monitor, the lead coordinator will reserve a designated room for the allotted time requested by the sponsor monitor.
- Have Wi-Fi passwords on hand if LAN connection is not available.
- Have available telephone if requested.

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- A monitoring visit letter from the sponsor monitor should be obtained and filed in the Regulatory Binder.

B. Preparing for the monitoring visit

- Ensure that all regulatory documentation and CRFs are complete and up to date and available for sponsor monitor review. If available, use sponsor provided tools such as the *Regulatory Binder Review Tool* and the *Subject Binder Review Tool* to ensure all aspects of the investigator file and subject binder is thoroughly reviewed and completed by the lead coordinator.
- Ensure all data queries received to date and pending open actions items have been resolved to the extent possible.
- Ensure that subject study materials, lab supplies, and Investigational Product (IP) have been inventoried accordingly.
- The appropriate patient medical records should be available for review at the time of the monitoring visit if applicable. All copied medical records or faxed medical records must be certified by delegated staff.
- Ensure all informed consent forms (ICF) are signed and dated, and that the original is in the subject's file unless otherwise instructed differently by the sponsor (i.e. file in Regulatory Binder).
- All CRFs and source documents must be complete, signed and dated as required.
- Up to date IRB approvals and copies must be appropriately filed in the Investigator site file/Regulatory Binder.
- File all study related correspondence/documents in the Regulatory Binder according to sponsor guidelines.

C. Managing the monitoring visit

- The monitor and delegated staff must sign the monitoring visit log at each monitoring occurrence.
- To ensure and protect patient privacy, sponsor monitors will not be allowed to roam freely about the facility unless escorted by the PI or CRC.
- Delegated site staff should be readily available for the sponsor monitor to answer questions and complete any open action items as they arise.
- Towards the conclusion of the visit, the PI or delegated staff (i.e. Sub-Investigator) should meet with the sponsor monitor to discuss any issues or trends that arose during the visit.
- The PI will also be advised by the sponsor monitor if needed.

D. Following up after the monitoring visit

- Upon receipt of the Monitoring Visit Follow up Letter, file letter accordingly in the Regulatory Binder.
- Delegated staff and/or PI should complete open action items/issues as soon as possible.
- Communicate to sponsor on the status of items/issues as they are completed.
- File correspondence with sponsor monitor accordingly in the regulatory binder.
- All open action items/issues must be resolved before the next monitoring visit.