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

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| **SUBJECT:** Study Closeout Visit | Policy #: CRP-1020 |
| **DEPARTMENT:** DHR Health Institute for Research & Development | PAGE: 1 OF: 2 |
| | 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:**
This describes the steps followed by DHR Health Institute for Research & Development from the time the Study Termination Visit is scheduled until all follow-up activities associated with the visit have been completed.

A Study Termination Visit is a final monitoring visit conducted after all subjects have completed the study and all data are recorded in case report forms (CRFs). The purposes of the visit are:

- to ensure that all investigational product has been administered according to the protocol, accounted for, and the remaining product returned to the Sponsor or destroyed;
- to ensure that all documents regarding investigational product accountability are accurate, complete, and legible;
- to complete monitoring at the study site and return all completed CRFs to the Sponsor;
- to confirm the return (or final disposition) as per Sponsor's instructions of all study-related materials (including forms, blank CRFs, etc.);
- to ensure that all regulatory documents are on file at the investigational site;
- to review with the Investigator his/her responsibilities after termination activities have been completed

**Policy:**
Study closeout activities are performed to confirm that DHR Health Institute for Research & Development study obligations have been met and post study obligations are understood.

**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. **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. **Clinical Trial/Study Report:** A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report.

C. **Monitoring:** The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).
D. **Source Documents:** 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).

**Procedure:**
**Study Closeout Visit:**
Inform sponsor/CRO promptly if notified by FDA of impending inspection.

Provide copies of all FDA documentation (Form FDA 483, letters) generated as a result of the inspection.
- The PI and research coordinator must ensure that the documentation is complete, accurate, and ready for review for the monitor's termination visit.
- The PI and research coordinator verify that all outstanding issues, queries/action items from prior communications have been resolved.
- The Investigator and/or appropriately delegated staff, prepares the final report for Institutional Review Board (IRB), notifying them that the study is closed. A copy of the report is sent to the Sponsor and filed in the regulatory documentation binder.
- The Clinical Research Coordinator reviews the regulatory documentation binder and recovers any missing documents. If documents cannot be found, the Sponsor is notified and a memorandum will be placed in the regulatory documentation binder.
- The Clinical Research Coordinator arranges for secure storage of the CRFs, source documents, and regulatory documentation binder, and informs the Sponsor of the storage location.
- If the trial is terminated prematurely or suspended for any reason, the investigator and research staff will promptly inform the subjects via phone call or in person. If these attempts fail, then an attempt will be made with a certified letter.
- If the trial is terminated prematurely by the sponsor for any reason, the Investigator and research coordinator will inform the institution and IRB.
- If the IRB terminates, suspends or places the study on enrollment hold, the PI will inform the sponsor and provide a copy of the IRB notice/determination.