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

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| **SUBJECT:** Handling of Laboratory Results | Policy #: CRP-1038 |
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| **DEPARTMENT:** DHR Health Institute for Research & Development | 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:**
The purpose of this policy is to describe how the DHR Health Institute for Research & Development handles review, documentation, and counseling regarding laboratory results. This policy applies to all research institute staff including Principle Investigator, Sub-Investigators, study coordinators, study pharmacists and study nurse.

**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 Policy:**
This policy is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol that may deviate from this SOP.

**Procedure:**

A. Management of Lab Results
   a. The Principal Investigator or Investigator review lab results within 24 hours, initialing and dating the results to indicate review.
   b. Abnormal lab results that are not clinically significant (NCS) are initialed and dated by the Principal Investigator or Investigator. The clinical significance is noted on the lab report.
   c. Abnormal lab results that are clinically significant require prompt follow-up by Study Coordinator and/or Research Nurse. The Study Coordinator and/or Research Nurse report the abnormal lab value to the Principal Investigator or Investigator to the appropriate course of action.
   d. The Study Coordinator and/or Research Nurse contacts the participant, notifies the participant of the test results and the recommended course of action. When indicated, the Study Coordinator and/or Research Nurse attempts to contact the participant at least twice a day until contact are made. Attempts to contact the participant are documented in the progress notes.
   e. Research Nurse and/or Study Coordinator document the course of action recommended by Principal Investigator or Sub-Investigator due to the clinical significance of the abnormal lab result. This information will be documented by Principal Investigator or Investigator.
   f. The MOP for Expedited Reporting of Adverse Events is used by the Principal Investigator or Investigator to determine whether or not the abnormal lab result qualifies as an AE/SAE/EAE and takes appropriate action based on policy CRP- 1027, Adverse Event Management.
   g. Lab results are filed in the participant study files.

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B. Tracking Lab Results
   a. Specimen Collection and Shipping Logs
      i. Study Coordinator and/or Research Nurse tracks lab results by visiting the lab or phone calls to the laboratory daily.
      ii. If the expected lab results are not received within 2 days, the Study Coordinator and/or Research Nurse contact the lab to verify receipt of the specimen and request the results. The Study Coordinator and/or Research Nurse document this communication in the participant's study chart.

C. Training
   a. Each staff member receives or has direct access to applicable Standard Operating Procedures (SOPs).
   b. Each staff member reviews the applicable SOPs if there is any significant change.
   c. All SOP training is documented and tracked in the Training Record Log filed in the Regulatory Binder.
   d. New staff is trained on applicable SOPs within 10 business days of employment.
   e. Staff members whose duties fall within this SOP scope are retrained within 7 business days of the approval of each SOP revision.