DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Reporting of IRB Determinations	Policy #: CRP-1045
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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:
It is the policy of the IRB to comply with all applicable local, state, and federal regulations that require the following to be reported:

- Unanticipated problems involving risks to human subjects or others;
- IRB initiated suspension or termination of IRB approval;
- Serious or continuing noncompliance with federal regulations or the policies of the DHR Health Institute for Research and Development IRB.

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 and Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research and 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.

Time Frame for Communicating IRB Decisions:
Reports are issued within 10 working days of the receipt of the final written report by the IRB committee to the applicable parties as outlined below.

Contents of the Report of IRB Findings:
At a minimum, the following information should be included in the report of IRB findings:

- Name of the institution conducting the research;
- Title of the associated research project and/or grant proposal;
- Name of the principal investigator on the corresponding research protocol;
- Number assigned by the IRB to the research project and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the report;
- Actions taken by the institution to address the reported issue.

Parties Responsible for Preparation and Distribution of Correspondence
SERIOUS OR CONTINUING NON-COMPLIANCE AND UNANTICIPATED PROBLEMS INVOLVING RISKS TO HUMAN SUBJECTS OR OTHERS
Correspondence related to determinations of serious or continuing non-compliance or that involve risk to subjects related to compliance report activities will be prepared by the Human Research Protection Program Administrator for approval by the IRB Chair and Associate Legal Counsel.

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Correspondence related to determinations of serious or continuing non-compliance or that involve risks to human subjects or others related to unanticipated problems will be drafted by the Human Research Protection Program Administrator for approval by the IRB Chair and Associate Legal Counsel.

After review and comment by the above parties, the Authorized Institutional Official will review, approve and sign the report and ensure the report is distributed to all applicable parties. For non-federally funded and non-FDA regulated studies, the correspondence is signed by the IRB Chair and distributed to all applicable parties.

Study Termination or Suspension by the IRB
For studies in IRBNet, the IRB Coordinator will suspend or terminate the study within the system. Correspondence is sent to the Principal Investigator as well as to all listed co-investigators and research staff. The study moves to a “suspended” or “terminated” state and the consent documents are no longer accessible.

Compliance Activity Reports
Correspondence related to Compliance Activity Reports where the study remains active and no serious or continuing non-compliance were identified or protocol modifications were required will be prepared by the Human Research Protection Program Administrator for signature by the IRB Chair.

Correspondence related to a Compliance Activity Report which resulted in a determination of serious or continuing non-compliance; an unanticipated problem involving risks to human subjects or others; or study termination or suspension will be performed in the same manner as other determinations of this kind.

When a protocol modification is necessary as the Compliance Activity Report, the correspondence associated with the protocol modification will be drafted by the Human Research Protection Program Administrator for signature by the IRB Chair or Co-Chair.

Recipients of the IRB Correspondence / Reports

Investigator Correspondence
The IRB Chair or Co-Chair communicates the IRB’s determinations to the principal investigator. If the IRB’s decision requires immediate action on the part of the principal investigator, the decision will be communicated verbally to the principal investigator as soon as possible and followed up with written notification by the IRB Chair or Co-Chair within 10 working days of the decision.

A date for the investigator response is specified in the written notification. Failure to comply with this date, in the absence of a suitable justification, will be handled in accordance with IRB policies involving the reporting and handling of other unanticipated problems.

Compliance of the principal investigator with the directed actions specified by the IRB committee are reviewed and approved by the IRB Chair or Co-Chair unless full board review of the principal investigator’s response/actions is determined to be required.

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If the principal investigator has additional information that may be relevant to the situation at hand, it will be brought to the attention of the IRB committee for consideration.

Institutional Official, Regulatory Agencies, Sponsors and Others
In addition to the IRB correspondence sent to the investigator, reports of any unanticipated problems involving risks to human subjects or others, any serious or continuing non-compliance, any suspension or termination of IRB approval will be sent to all applicable parties, which may include:

- The Office for Human Research Protections – for research funded by any agency that is a signatory to the "Common Rule" at 45 CFR 46;
- The Food and Drug Administration – for research that is subject to the FDA regulations at 21 CFR 50 and 56;
- The federal or non-federal external funding agency
    - For DOD funded research, the letter will be sent to the attention of the Director, Defense Research and Engineering.