DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Suspensions and Terminations	Policy #: CRP-1046
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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:
During the conduct of human subject research, it may become necessary to suspend or terminate some or all research activities associated with an IRB approved protocol. Suspensions or terminations may be investigator/sponsor initiated or IRB initiated. In order to resume research activities, regardless of who initiated the suspension, a modification requesting re-initiation of the study must be submitted for IRB review.

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. Investigator/Sponsor-Initiated Termination or Suspension of a Research Protocol**: A determination made by the investigator or sponsor to voluntarily suspend or terminate some or all activities of an approved protocol.
- **B. IRB-Initiated suspension of approval**: A determination made by the DHR Health Institute for Research and Development IRB to temporarily withdraw University IRB approval for some or all activities of a currently approved research study.
- **C. IRB-Initiated termination of approval**: A determination made by the DHR Health Institute for Research and Development IRB to permanently withdraw IRB approval for some or all activities of a currently approved research study.

Investigator/Sponsor-Initiated Termination or Suspension of a Research Protocol:
An investigator may choose to voluntarily suspend or terminate some or all activities of an approved protocol. This should be reported to the IRB and is not considered to be a reportable event unless the IRB independently determines that suspension or termination has occurred because there was an unanticipated problem involving risks to subjects or others or there was an incident of serious or continuing non-compliance.

If a research project is being terminated or suspended by the principal investigator and/or the sponsor based on a change in the risk-to-benefit ratio of study participation, a report should be submitted through IRBNet within 1 working day of the receipt of the notice.

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If the reason for the termination or suspension is for administrative reasons, a report should be submitted through IRBNet within 10 working days of receipt of the notice. The termination report should include:

- the primary reason for the termination;
- the number of subjects enrolled to date;
- the plan for notifying currently enrolled subjects, if necessary;
- the procedures that will be undertaken to ensure the orderly and safe withdrawal of currently enrolled subjects, if necessary;
- whether there were any unanticipated problems involving risks to subjects or others that were not previously reported;
- whether subjects will be notified of the study results;
- whether the study had been monitored/reviewed/audited by an outside monitor, sponsor, or agency;
- whether the report has been sent to other agencies.

The suspension report should include:

- the primary reason for the suspension;
- the type of suspension (intervention only; all research activities)the number of subjects currently enrolled in the study;
- the procedure that will be undertaken to ensure the safe withdrawal of currently enrolled research subjects, if necessary;
- whether permission is being requested to continue research activities during the suspension period for the safety of currently enrolled subjects;
- whether subjects will be notified of the study suspension;
- whether the report has been sent to other agencies;
- a description of what must occur in order for a request for re-initiation of study activities can be submitted.

When a study is suspended in IRBNet, all listed investigators and research personnel are notified through the system.

For research protocols suspended due to unanticipated problems, including serious adverse events, IRB approval is required to re-initiate the research study. A modification should be submitted in order to request re-initiation. The information submitted should include:

- the outcome of investigations on the causality of the unanticipated problem;
- the frequency of occurrence of the unanticipated problem at internal and external sites, if applicable;
- changes to the protocol and/or informed consent document.

Human subjects currently participating in a research study may need to be notified of its termination or suspension. Upon review of the suspension or termination report, the IRB will make a determination about whether this is required as well as the best mechanism for the research team to utilize to make the notification.

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IRB-Initiated Termination or Suspension of a Research Protocol:
The DHR Health Institute for Research and Development IRB may suspend or terminate some or all research activities on a protocol if events are identified that represent serious or continuing noncompliance or unanticipated problems involving risk to subjects or others. The IRB may also suspend some or all of the research conducted by a principal investigator as a result of serious or continuing noncompliance with the research or if there are unanticipated problems involving risk to subjects or others.

This action is most often determined by a convened board. However, the IRB Chair has the authority to suspend some or all research activities if exceptional human subject safety issues are identified. This authority is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting. When this authority if exercised, it will be reported at the next convened IRB meeting.

The IRB Chair or Co-Chair will suspend or terminate the study within the IRBNet 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.

The IRB Chair or Vice Chair will ensure the report is distributed to all applicable parties. All applicable local, state, and federal regulations that pertain to reporting of suspensions and terminations will be followed.