

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

SUBJECT: Providing Emergency Medical Care to Clinical Trial Participants	Policy #: CRP-1012
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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, 11/20, 01/21, 04/21, 05/21

Purpose:

The purpose of this policy is to demonstrate the policy and procedure in providing emergency medical care to the clinical research subjects. Patients requiring medical treatment, as the result of a change in condition, will be managed accordingly and when necessary, transferred to the appropriate level of care.

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. Emergency medical condition:** acute injury or illness that poses an immediate risk to a person's health.
- B. Basic Life support:** Provision of resuscitation and management in assessment of life threatening conditions.

All DHR Health Institute for Research & Development staff is certified in Basic Life Support (BLS) procedures.

Policy:

This standard operating procedure (SOP) describes the responsibilities of the research team in the event of a subject emergency.

Procedure:

When a patient has experienced a change in status requiring emergency medical attention:

- The staff will follow basic life support procedures, notify the attending physician on site, contact 911 and instruct the ambulance services to transport the patient to the emergency department (ED) at DHR Health Institute for Research & Development or, the ED of their choice if applicable.
- The staff should communicate the subject status to the ambulance service in order to facilitate the transfer within an acceptable amount of time.
- If transfer is imminent, the staff should provide the receiving emergency personnel with clinical data and recent vital signs, if available.

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- The staff should remain with the patient until the transfer is complete and he / she are no longer required to assist.
- If the subject is a child or adolescent, Basic Life Support procedures are conducted in accordance with age specifications and family will be notified