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Standard Operating Procedure	Management of the Acutely Ill Clinical Research Subject	Page 1 of 2

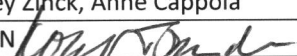
PURPOSE: To inform CHPS staff, PCAM staff and clinical research study teams utilizing CHPS services of the appropriate process for managing clinical research participants who become acutely ill or need supportive standard of care treatment.

SCOPE: All staff utilizing the CHPS department for research services.

PROCEDURE:

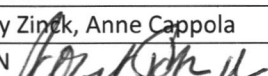
1. Subjects with a CHPS approved protocol and 4 digit CHPS number that have a confirmed appointment in CHPS can be safely managed in our unit if they meet the following *inclusion criteria*:
 - a. Patient is receiving an investigational infusion/treatment and experiences a reaction/anaphylaxis.
 - i. CHPS staff will work with Rapid Response Services and the Principal Investigator/study team to manage patient reaction.
 - b. Patient is receiving an investigational infusion/treatment and their CBC comes back with low platelets and/or hemoglobin.
 - i. If we have the availability in our schedule and the nursing resources to extend the treatment duration, we can add a blood transfusion or platelets onto the existing infusion appointment.
 - ii. Refer to CHPS_SOP4_Scheduling Subjects for further guidance in this scenario.

2. Patients that are not appropriate to stay in the CHPS unit for management (due to safety, resources and billing concerns) are outlined below in the *exclusion criteria*:

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Approved by:	Robert Tobin, RN BSN OCN 	Date: 7/8/2019

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Standard Operating Procedure	Management of the Acutely Ill Clinical Research Subject	Page 2 of 2

- a. Patient is scheduled for a blood draw only or space utilization (no treatment appointment)
 - i. These patients should be instructed to go to the emergency department (or alternate location as decided by the MD/APP) if clinically relevant.
 - b. Patient needs physical exam performed by APP/MD frequently, and the provider is unavailable to stay in the CHPS unit with their patient.
 - c. Inpatients/Outpatients whose medical conditions are not being controlled on their home medications, such as uncontrolled hypertension or diabetes, and are symptomatic. The patient will be discharged from Dulles One or CHPS 4 south and brought to emergency department.
 - d. Patient presents to the CHPS unit for their research protocol, but is identified as sick prior to starting therapy.
 - i. Patient should be seen and evaluated by Provider, and based on clinical treatment plan, sent to PCAM Infusion Suite for supportive care, or Oncology Evaluation Center (OEC)/Symptom Management Services (SMS), if they meet inclusion criteria
 1. If patient does not meet inclusion criteria for supportive care in PCAM Infusion, or treatment in the OEC/SMS, they should be sent to emergency department (or call rapid response) for appropriate follow-up.
3. Any further feasibility questions may always be reviewed with the CHPS Nurse Manager.

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