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PURPOSE: To explain the responsibility of the principal investigators and/or covering providers on management of outpatient participants.

SCOPE: Principal Investigators and Clinical Study Teams

PROCEDURE:

1. The CHPS unit provides nursing coverage for participants seen on the CHPS unit. The study team is required to medically cover the participants. The CHPS unit does not provide medical coverage.
 - a. A provider must be on site and available for the duration of the time that the participant is on the CHPS unit.
 - i. A Principal Investigator can delegate a covering provider to provide this medical coverage to their participant.
 - ii. The provider must be on-site and available for as long as the participant is on the CHPS unit – even if the participant is on the unit longer than the provider’s normal hours.
 - b. The study team is responsible for communicating the coverage plan to the covering RN.
 - c. In the event of an emergency, the Rapid Response Team (RRT) is called to assist the CHPS staff. However, the RRT does not replace the need for covering provider.
 - d. After 19:30, any participant remaining on the CHPS PCAM outpatient unit will be transferred to the CHPS Dulles 1 unit. This does not mean that they have medical coverage on Dulles 1. The covering provider identified earlier in the shift must remain on-site and available.
3. If a participant’s treatment start time is delayed such that their infusion stop time will be past 19:30, the CHPS Nurse Manager needs to be contacted for approval to evaluate if appropriate nursing resources are staffed.
4. The following management algorithm then takes place in order to evaluate if the participant can be safely treated:

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- **Triaging of Provider coverage:** If the PI, treating investigator, or another authorized delegate available to stay onsite until treatment completion, in order to ensure the safety of the participant is not compromised. An agreement document (see below) will need electronic signature by the PI and Clinical Research Coordinator for long infusion/PK days.
- **Resource evaluation:** Are appropriate nursing resources already in place to safely execute the request.
- **Inpatient census:** If we have inpatients scheduled, do we have availability to utilize our outpatient (unlicensed) bed on Dulles 1 to transfer the patient to be monitored. If yes, a plan is worked out to transfer the outpatient on PCAM 4 to our unlicensed bed on Dulles 1 for monitoring after 19:30, utilizing our existing inpatient nursing staff, provided a covering provider is also available.
- **Clinical Judgment/Decision Making:** Based upon the above criteria, a decision will be made by CHPS Leadership (Nurse Manager and Charge RN) if we are safe to proceed with treatment/monitoring past outpatient hours of operation by utilizing our Dulles 1 unit.

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