

Standard Operating Procedure	Management of Late Outpatient Participants	CHPS SOP
------------------------------------	---	-------------

PURPOSE: To clarify the medical coverage responsibilities and disposition for patients that have study visits that extend past CHPS-PCAM business hours.

SCOPE: PIs, Clinical Study Teams (CSTs), CHPS Staff

RESOURCES: CHPS SOP_Medical Coverage

PROCEDURE:

1. The CHPS-PCAM unit is open Monday-Thursday until 7pm and on Friday until 5pm. “Late” is defined as after these business hours.
2. The RRT located in PCAM is not available after 7pm. If an RRT is called, the RRT will come from the hospital, which can take longer to arrive at PCAM because of the distance that must be travelled.
3. Medical coverage requirements for late PCAM outpatients:
 - a. The following requires **on-site** medical coverage:
 - i. Medication administration. Examples include:
 1. Actively infusing investigational product
 2. Chemotherapy administration
 - ii. Infusion reaction management
 1. Either real or anticipated.
 2. This may require ED transfer.
 - iii. Other unexpected/unrelated medical concern
 1. This may require ED transfer.
 - iv. Protocol-required safety monitoring
 - b. The following requires **remote** medical coverage:

Standard Operating Procedure	Management of Late Outpatient Participants	CHPS SOP
------------------------------------	---	-------------

- i. Research tasks without safety monitoring
 - c. The CHPS Leadership can decide that a circumstance warrants on-site coverage even if not specified above.
- 4. Disposition for late CHPS-PCAM outpatients:
 - a. **Study visit that is planned to extend past CHPS-PCAM business hours**
 - i. CSTs must reach out to CHPS prior to scheduling the appointment to inquire about whether this will be feasible to accommodate.
 - 1. An email request needs to be sent to Kathlyn Schumacher and Yael Malul specifying 1) the desired date 2) the anticipated length of the visit, 3) the research activities that will take place after business hours and 4) the medical coverage plan. Either Kathlyn or Yael will confirm whether this can be accommodated on the selected day and whether the medical coverage plan is appropriate.
 - ii. Patients will be transferred proactively to Ravdin 6NE prior to the end of business hours at PCAM.
 - b. **Study visit that is planned to occur within CHPS-PCAM business hours, but unexpectedly extends past business hours due to:**
 - i. Delay in treatment leading to research tasks needing to be collected past business hours
 - 1. Assessment of CHPS staffing will be performed to determine whether the additional research tasks can be completed.
 - 2. Patients will remain on **PCAM** to complete protocol-required research tasks, if there is no safety monitoring component and staffing allows. The patient may need to be transferred to Ravdin if staffing is only available at that location.
 - ii. Infusion reaction, other medical concern, or additional safety monitoring.
 - 1. Assessment will be performed which will determine whether the correct disposition is to 1) remain on **PCAM** 2) move to **Ravdin 6NE** or 3) transfer to **ED**.

Standard Operating Procedure	Management of Late Outpatient Participants	CHPS SOP
------------------------------------	---	---------------------

Prepared by:	Paige Sinclair, RN MSN OCN Amanda Brock, MSN, MBE, RN, OCN Yael Malul MSN, RN, OCN, AGACNP-BC	Date: 12.26.18 Revised: 3.15.22 Revised: 8.19.24
Approved by:	Amanda Brock, MSN, MBE, RN Caitlin O'Neill DNP, RN, OCN, NEA-BC Lorri Schieri, MBA	Date: 9.26.24