

Standard Operating Procedure	Scattersite Participants	CHPS SOP
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INTRODUCTION: The Center for Human Phenomic Science (CHPS) staff can provide services to research participants who are admitted to non-CHPS inpatient units. These research participants are enrolled in clinical trials and are referred to as “Scattersite” patients (since they are “scattered” throughout the hospital). In these scenarios, CHPS services are performed in concert with standard inpatient nursing care. The CHPS team manages the research needs of the patient, while the inpatient team manages the standard medical needs of the patient.

PURPOSE: 1) To delineate responsibilities for Scattersite visits, 2) to provide guidance around communication between CHPS staff, non-CHPS clinical staff, and the clinical study team (CST), and 3) to provide guidance around Epic documentation for Scattersite visits.

SCOPE: CHPS staff, non-CHPS clinical staff, and Clinical Study Teams (CSTs).

RESOURCE: HUP & CPUP Policy_ [1-06-01 Inpatient and Outpatient Hospital Admissions and Transfers to HUP \(EMTALA\)](#)

PROCEDURE:

1. Delineation of Responsibilities

a. CHPS Staff Responsibilities

- (1) CHPS staff are responsible for all **research tasks** as described on the CHPS Nursing Worksheets or as directed by the CST. Tasks may include (list is non-exhaustive):
 1. Pre-medications
 2. Investigational Product administration
 3. EKGs required by the research protocol
 4. Blood draws required by the research protocol
 5. Vital signs required by the research protocol
 6. Other research activities

- b. Non-CHPS Clinical Staff Responsibilities
 - (1) Non-CHPS clinical staff are responsible for all **standard-of-care** activities. This includes (list is non-exhaustive):
 - 1. Admitting and Discharging procedures
 - 2. Standard-of-care medications unrelated to the research protocol (ex. daily Synthroid)
 - 3. Standard-of-care blood draws (ex. AM/Morning labs)
 - 4. Standard-of-care vital signs (ex. q4H vital signs per unit standard)
 - 5. Activities of Daily Living (ex. bathing, toileting, and ambulating)
- c. When there is lack of clarity around who should assume a certain task, a discussion should be had between CHPS staff, non-CHPS clinical staff, and the CST to determine the best course of action.
- d. **CHPS staff should complete all research tasks and they should not be delegated to the non-CHPS clinical staff.** Exceptions to this can be made if it was agreed upon with both the CST and clinical team ahead of time (in which case this would be noted on the CHPS Nursing Worksheet) or if necessary due to unforeseen staffing challenges. If CHPS staff need to unexpectedly delegate a research task to non-CHPS clinical staff, they must notify the CST prior to the task being performed and provide the non-CHPS clinical staff (including both the bedside RN and inpatient Charge RN) with education surrounding the task and the importance of exact timing in research.

2. Communication

- a. Communication principles
 - (1) Scattersite visits are inherently complex. Therefore, communication should be initiated early and occur throughout the day to ensure successful completed of the visit. **CHPS staff are responsible for taking the lead** on communication with all parties as they are the most familiar with this process.
- b. Secure Chat
 - (1) **Secure Chat conversations must be established** between the CHPS staff member, the non-CHPS clinical RN, and the CST **at the start of the day.**
- c. Communication with non-CHPS clinical staff
 - (1) The CHPS staff member assigned to the Scattersite should communicate as early as possible and often with the non-CHPS clinical staff. The following should be communicated (list is non-exhaustive):
 - 1. Introduce yourself
 - 2. Introduce what the CHPS unit is and does
 - 3. Explain the general delineation of roles between CHPS and non-CHPS clinical staff

4. Explain the unique research plan for the patient's day
5. Communicate what specific tasks will be performed and by who
6. Communicate anticipated side effects of treatment if known (ex. CRS)
7. Notify non-CHPS clinical staff when important timepoints are completed including:
 - a. When pre-medications are administered
 - b. When Investigational Product (IP) infusion is started or when IP is administered (if not an infusion)
 - c. When IP infusion is completed
 - d. If there are any changes in patient condition
 - e. When research tasks are completed for the day and CHPS staff is leaving the unit
- d. Communication with CST
 - (1) The CHPS staff member assigned to the Scattersite should initiate contact with the CST as early as possible.
 - (2) CHPS staff member should introduce themselves and ask the CST what type and frequency of communication they would like to receive over the course of the day.
 1. CHPS staff member should specifically ask if the CST would like to be notified of the timepoints listed above in section 2.c (1)7.a-e.

3. Documentation

- a. Epic Documentation
 - (1) **All documentation should occur in the inpatient encounter and *not* in the CHPS outpatient encounter.** This practice:
 1. Allows inpatient pharmacy to verify pre-medications or any patient-supplied investigational products. It is a requirement for inpatient pharmacy to verify any and all medications that patients take while admitted.
 2. Ensures that the inpatient team can view all patient activity which is important for patient safety. Standard inpatient provider practice is to only look at medications administered in the inpatient setting.
 3. Allows CHPS staff to use the inpatient wristband for bar-coded medication administration.
 4. Communicates the accurate delivery location for the investigational product (IP) to the Investigational Drug Services team. The delivery location can impact how the IP is stored prior to delivery and the chain of custody.
 5. Creates a standardized method for handling Scattersite visits: Non-oncology visits always have medication orders ordered directly

into the inpatient encounter, so this creates alignment between non-oncology and oncology visits.

(2) Medication Administration

1. If there is a Beacon plan (oncology studies):
 - a. Pre-medications, IP, and emergency medications should be released by the CHPS RN from the inpatient encounter. To do this, find the patient on the Unit Manager in Epic. Open their chart from the Unit Manager. Ask one of the inpatient staff members what the Epic login context is and change your login context to match it. Release only if 1) you are in the right login context and 2) you are in the right encounter.
2. If there is no Beacon plan (non-oncology studies):
 - a. Medications will be ordered directly into the inpatient encounter.

(2) Nursing Note

1. Should be documented in the inpatient encounter under the correct Login context. The CHPS SmartPhrase should be used to write the Nursing Note.

b. Billing Documentation

- (1) The assigned CHPS staff member must notify the CHPS front desk to update the sign in sheet with the time the CHPS staff member left the unit and the time they returned.
- (2) Complete a billing worksheet.

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