Center for **H**uman **P**henomic **S**cience	University of Pennsylvania Health System	**CHPS SOP 07**
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PURPOSE: To provide documentation that is pertinent, accurate, consistent, standardized, and relevant.

SCOPE: CHPS staff and Clinical Study Teams

PROCEDURE:

1. CHPS staff follows hospital policy regarding Documentation including:
   -General Documentation: HUP Policy 4A-02-01

2. Nurses may need to document on two separate sources. The source documents are the nursing worksheet for the clinical study team and EPIC.

3. EPIC documentation

   a. The following are required to be documented in EPIC:

      a. All vital signs

      b. Any invasive procedures including blood draws and IV placement

      c. The number of IV insertion attempts

      d. Medication checks

      e. Medication administration including Infusion start and stop times

      d. Communication with study team regarding abnormal vital signs, or other changes in clinical status

      e. Progress note on every patient.

   b. All studies use Beacon/EPIC orders for medication ordering so that nurses can document medication administration properly in EPIC.

c. All investigational medications need two nurses to Med Check in EPIC, whether or not the system prompts for a second nurse check.

d. Infusion administration requires start and end times documentation in EPIC.

e. The time of medication documentation in EPIC must match the time of administration on the worksheet.

f. Blood draw only appointments require LDA in EPIC, Progress Note, and CHPS billing worksheet.

4. Nursing Worksheets

a. It is both the CHPS and Clinical Study Team's responsibility to make sure all parts of the nursing worksheet are complete. It is best practice for both parties to review the nursing worksheet to ensure documentation is complete at the end of visit. This nursing worksheet is retained by the study team.

i. All blank spaces must be completed on the nursing worksheets. This includes initials, times, signatures and any other information needed for blank spaces.

ii. All CHPS staff that participated in the participant's care must sign the worksheet (except medication check in EPIC).

iii. On the worksheet signature table, if all CHPS staff have signed and there are empty lines, the CHPS RN must write "N/A" on those blank lines.

CHPS STAFF SIGNATURE

PRINTED NAME	SIGNATURE	INITIALS	DATE
Jane Doe	*Jane Doe*	JD	1/5/2022
NA	NA	NA	NA
NA	NA	NA	NA

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d. If the nursing worksheet includes multiple visits (ex. a 24-hour blood draw the next day), the worksheet can be kept on the CHPS unit in the Principal Investigator's designated folder at the CHPS nursing station until the last visit.

5. CHPS Chain of Custody

a. CHPS Chain of Custody will be completed by documenting medication checks on the MAR. The medication checks will serve as evidence that the investigational product (IP) was received on the CHPS unit and is no longer in the custody of the Investigational Drug Services (IDS).

b. Additional Chain of Custody documentation

i. CHPS Nurses may also be asked to sign a Chain of Custody paper document indicating that the IP was within the proper temperature range for the duration of transit from IDS to the CHPS unit. IDS will retain this document for their records.

ii. If an IP is picked up from the PCAM West pharmacy, you must additionally sign out the medication in the Chain of Custody log at PCAM West pharmacy.

6. Sponsor Databases

i. CHPS staff will not document or complete training in sponsor databases or Red Cap, this is the responsibility of the Clinical Study Team.

Supersedes Documentation, 10/2017

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