

| Center for Human Phenomic Science | University of Pennsylvania Health System | CHPS SOP 02 |
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INTRODUCTION: The nursing worksheet is a document dictating the study's step-by-step instruction for the CHPS nurses to follow during a visit. The CHPS unit deals with a considerable number of protocols with new ones starting consistently. This chronological documentation of each study's events helps ensure work is done correctly and in proper order for every study.

PURPOSE: To inform Principal Investigators and Clinical Study Teams about material that needs to be provided on their nursing worksheets.

SCOPE: Principal Investigators and Clinical Trial Study Teams.

- 1. Please find CHPS Nursing Worksheet templates on the CHPS website (www.med.upenn.edu/CHPS) under CHPS Core Services > Research Nursing Core > Nursing Tools > Training Document and Nursing Worksheet Template.
- 2. All medications orders need to be submitted within a Beacon treatment plan to the PennChart Beacon Team. For more information, please see the CHPS website under CHPS Core Services > Research Nursing Core > Epic Beacon Info. The CHPS Clinical Practice Lead should review the Beacon Request Form prior to submitting the ticket.
- 3. The nursing worksheet document needs to include, if applicable for the specific study:
 - > Full name of protocol, IRB #, CHPS #, PI and coordinator name and cell phones in header of first page.
 - ➤ Urine pregnancy testing is required for women of child-bearing potential (WOCBP) if: CHPS is administering investigational medications and/or chemotherapy or immunotherapy.
 - ➤ Height, Weight, Vital Signs and instructions of timing, if applicable.
 - For EKGs: note if a study-specific or CHPS machine will be used. If using the CHPS machine, document if the EKG is to be transmitted to EPIC or not. Transmission to EPIC ensures EKG will be read by cardiologist and is part of patient's electronic medical record. It needs to state on the worksheet if the EKG does or does not need to be read by PI/MD prior to drug administrant and/or discharge for post EKGs.
 - Number of IV access lines needing insertion and note for removal of access at end of visit. If port can be used for infusion and or blood draws, please indicate this. Include at the end of the worksheet: Remove IV(s) and document in EPIC.



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- ➤ For clinical blood draws going to Penn Medicine labs, state that orders are in EPIC and list labs needed.
- ➤ Indicate if clinical blood results need to be reviewed with Clinical Study Team prior to medication administration.
- For research specimens that CHPS staff is drawing, state color, size and quantity of tubes needed. All research tubes need to be supplied and labeled by the study team prior to blood draw. State on the worksheet if CHPS is or is not processing the research specimens. If CHPS is processing, include a separate document with the specific tubes CHPS is processing. If CHPS is not processing, state if tubes are to be kept on ice or not and where to keep them for study team to obtain if they will not be present during the draw. Include timing of research blood draws.
- ➤ Instructions for medication administration including name, route, and infusion duration, if applicable, for all medications (including pre-medications) being given by CHPS staff. All medication orders need to be placed in EPIC.
- ➤ Include specific medication tubing and filter information (if required) and specific flushing instructions for infusions. See SOP 14 for instructions on placing medication orders in EPIC.
- ➤ Clearly document if VS/study bloods/EKGs etc are to be drawn **post end or post start** of infusion.
- ➤ Include time frames and windows for all VS/bloods/EKGs. If there is not a specific time frame, other than pre or post, document "No Time Frame".
- Medications for symptom management (ex. hives—diphenhydramine, anaphylaxis—epinephrine).
- > Numbering of each page
- > Information on document must reflect what is ordered in EPIC (ex. clinical labs, medications)
- ➤ Include table for CHPS staff signatures at end of worksheet.
- > Document on worksheet if participant will be bringing in their own investigational medication to be taken during CHPS visit. For inpatients, this will be ordered as "Patient Supplied".



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- 4. If the study medication requires titration, the nursing worksheet must include an area for any math or rates that the nurses are doing to calculate for the titration. This math must be doubled checked by a second nurse, so 2 lines are needed for documentation of their initials.
- 5. A CHPS Training Document will need to be completed in addition to the nursing worksheets. This Training Document can be used as a guide by the clinical study team during the in-service to review protocol information and is a resource for the CHPS.
- 6. When your nursing worksheets are complete, send to the CHPS nurse practitioner (NP) for review. At **least three weeks** are needed for nursing worksheet review, which may include multiple revisions/edits if the CHPS Nursing Worksheet Template was not followed. The inservice is scheduled after the worksheets are finalized.
- 7. After the worksheets are finalized, a copy of your worksheet and training document will be placed on CHPS SharePoint. It is on SharePoint for CHPS staff to use as a reference only. Study teams are always required to bring a copy of the nursing worksheet to every visit.
- 8. For every study visit to CHPS, it is the Clinical Study Team's responsibility to supply a copy of the appropriate nursing worksheet to the participant's visit.
- 9. If the protocol changes and the nursing worksheet or EPIC orders need to be updated after the CHPS staff has been using it, please contact the CHPS nurse practitioner. Depending on the complexity of additional study requirements, an updated in-service may need to be given.

Supersedes: Nursing Worksheets, 11/2017, 11/2018, 6/20/2019, 4/5/2022

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