

C enter for H uman P henomic S cience	University of Pennsylvania Health System	CHPS SOP 02
Standard Operating Procedure	Nursing Worksheets	Page 1 of 3

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 need to be provided on their nursing worksheets.

SCOPE: Principal Investigators and Clinical Trial Study Teams.

1. 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, if applicable
 - 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.
 - Number of IV access lines needing insertion and note for removal of access at end of visit. For IV insertion also include: Document peripheral IV time and location in EPIC under LDA. If port can be used for infusion and or bloods, please indicate this.
 - For clinical bloods 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 bloods that CHPS staff is drawing, state color, size and quantity of tubes needed. All research tubes need to be labeled by the study team prior to blood draw. All processing instructions need to be part of the nursing worksheet (the lab manual is not part of the nursing worksheet). We need specific instructions for the specific tubes CHPS staff is drawing. If study team picking labs up for processing elsewhere, state this on worksheet. Include timing of research bloods.
 - Instructions for medication administration including name, route, and infusion duration, if applicable, for all medications being given by CHPS staff. All medication orders need to be placed in EPIC.

C enter for H uman P henomic S cience	University of Pennsylvania Health System	CHPS SOP 02
Standard Operating Procedure	Nursing Worksheets	Page 2 of 3

Include specific tubing information if required (to accompany drug from pharmacy) 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.
- Medications for symptom management (i.e. hive—Diphenhydramine, Benadryl, anaphylaxis—epi).
- Numbering of each page
- Information on document must reflect what is ordered in EPIC (ie clinical labs, medications)
- One or two lines at end of worksheets for CHPS staff signatures.
- Document on worksheet if subject will be bringing in their own investigational medication to be taken during CHPS visit. For inpatients, this will be ordered as Patient Supplied.

2. 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.
3. A CHPS Training Document will need to be completed in addition to the nursing worksheets. This Training Document will be used as a guide by the clinical study team during the in-service to review protocol information.
4. When your nursing worksheet is complete, send to Kathlyn Schumacher @ kathlj@penn.medicine.upenn.edu. After review and approval, an in-service will be scheduled. At **least three weeks** are needed for nursing worksheet review and in-service scheduling.
5. After the in-service, a copy of your worksheet will be placed on CHPS SharePoint, however, it is in SharePoint for CHPS staff to use as a reference only, not to use for each subject's visit. The Training Document will also be placed on CHPS SharePoint.
6. For every study visit to CHPS, it is the Clinical Trial Study Team's responsibility to supply a copy of the appropriate nursing worksheet to the subject's visit.
7. 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 Kathlyn Schumacher. Depending on the complexity of additional study requirements, an updated in-service may need to be given.



C enter for H uman P henomic S cience	University of Pennsylvania Health System	CHPS SOP 02
Standard Operating Procedure	Nursing Worksheets	Page 3 of 3

Supersedes: Nursing Worksheets, 11/2017, 11/2018

Prepared by:	Kathlyn Schumacher, CRNP	Date: 11/01/2018 Edited: 6/13/2019
Checked by:	Paige Sinclair, RN MSN OCN	Date: 6/20/2019
Approved by:	Robert Tobin, RN BSN OCN <i>[Signature]</i>	Date: 7/18/19