|  |
| --- |
| **Directions to Study Team Creating Nursing Worksheet, please read before starting:** |
| Dear Study Team Staff,  We are looking forward to working with you as you create the nursing worksheets for this study. We understand translating the protocol information into a nursing worksheet can be challenging and it is important that you understand that finalizing the worksheets may take weeks to complete. Please keep in mind the following as you move through the worksheet:   1. You **must** use the CHPS nursing worksheet template. This ensures everything the CHPS staff needs is included, and we feel that using a consistent worksheet template improves patient safety and decreases protocol deviations. You can find the most up-to-date template at <https://www.itmat.upenn.edu/chps/research-nursing-core-rnc/> under “Nursing Tools.” 2. There are directions throughout this template in red to explain what exactly we are looking for. Please replace the red explanations with the requested information as indicated and change color to black. 3. List tasks in chronological order to help avoid deviations. For instance, do not place a 2-hour post blood draw after a 4-hour post EKG. 4. Do not number the steps of items needed. Items will occur as they are listed on worksheet. 5. If research tubes need to be processed immediately after collecting, put this on the worksheet as well on the processing instructions. 6. Please use track changes. **We recommend sending us the worksheet for the first CHPS visit** (for example, screening or C1D1 depending on the study) **for feedback before completing worksheets for other visits**. That way you do not need to apply changes to each visit’s worksheet. We will not accept more than 1 worksheet at a time for review. 7. Please email us with questions, we are happy to help. [Kathlyn.Schumacher@PennMedicine.upenn.edu](mailto:Kathlyn.Schumacher@PennMedicine.upenn.edu) and Bonnie.Falconer@pennmedicine.upenn.edu 8. Please delete these directions prior to worksheet finalization. 9. If your protocol changes, please revise the worksheets to reflect the most up-to-date study requirements and re-send to Kathlyn and Bonnie for review.   Thank you,  Kathlyn and Bonnie |

## **Study background: Patient population, investigational product**

|  |
| --- |
| **Study Population/Disease under Study** |
| - Summary of who will be enrolled, patient population, and total number to be enrolled  - Can discuss basics of disease here  -Study goal/science behind  (Keep this simple unless it is a rare disease. This section is to give more context to CHPS staff so they are able to provide the best care to patients.) |

|  |
| --- |
| **Investigational Product(s)** |
| - Basic pharmacology/mechanism of action  -Any known AE’s or reactions otherwise state if unknown. |

**Patient Trial ID #:** \_\_\_\_\_\_\_\_\_-\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_\_

mm dd yyyy

|  |  |  |
| --- | --- | --- |
| **Principal Investigator Contact:** | **Coordinator Contact Info:** | **Research Nurse Contact Info:** |
| name, M.D.  Cell – (xxx) xxx-xxx | Name  cell – (xxx)-xxx-xxxx | name, RN  Cell – (xxx)-xxx-xxxx |

Treating Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please contact treating physician/or covering NP (If applicable for your study) in the event of medical emergency.**

The signed consent form has been reviewed by CHPS staff. Initials: \_\_\_\_\_\_

If VS are not needed at this visit, the VS table can be deleted. VS upon arrival to CHPS is only required if treatment is being given.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Temperature** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **SpO2** | **Initials** |
|  |  |  |  |  |  |

Time: \_\_\_\_\_\_\_\_\_\_\_ Initials: \_\_\_\_\_\_\_\_\_

**12 Lead ECG**: (Delete if EKG not needed)

* Machine: State if a CHPS or study-supplied machine will be used.
  + If CHPS machine, state if the EKG is to be transmitted to EPIC or not. Please note that EKGs transmitted to Epic go into a pool to be read by a cardiologist and so there is an associated fee.
  + If study-sponsored machine is being used, specify that it is study-sponsored, put name of the machine on worksheet, and attach a laminated instruction sheet to the EKG machine.
* Clinical Significance: Specify if the EKG does or does not need to be read by provider prior to patient discharge. Must specify regardless of machine type used, see above.
  + If EKG does need to be read prior to discharge, specify how the provider will read the ECGs
    - Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver to provider to read

*EKG Time\_\_\_\_\_\_\_:\_\_\_\_\_\_\_ Initials*\_\_\_\_\_\_\_\_\_\_\_\_

Provider read post dose ECG(s) and confirmed OK to discharge patient when visit complete:    ⃝ Yes ⃝ No

Provider name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time approved: \_\_\_\_\_\_\_\_\_\_ CHPS RN Initials: \_\_\_\_\_\_\_\_\_

**Edit the table below for the specific labs your study needs:**

**List the tubes in order they are to be drawn.**

|  |
| --- |
| Collect blood samples in the following recommended order: |
| **Clinical bloods** (orders in EPIC): CMP*,* Amylase, Lipase, CBC, TSH, T3, T4  Or write “No Clinical bloods needed during this visit” |
| **Research Bloods:** Specify if CHPS will or will not be processing research bloods; provide processing instructions if CHPS is processing as a separate document.  If there are details in the processing instructions specific to how a sample is drawn, please provide that information with the specific tube (i.e. how the sample should be stored before processing) |
| Serum Biomarker Analyses (fasting sample)  *4mL Serum red top tube* |
| Plasma PK  *4mL lavender-top K2EDTA tube*  ***Once drawn, keep tube on ice prior to processing.*** |
| Genetics Analysis  *8.5ml Blood DNA tube* |
| RNA Analyses  *8.5ml Blood DNA tube* |

Time: \_\_\_\_\_\_\_\_\_\_\_\_ Initials: \_\_\_\_\_\_\_\_\_

**CHPS STAFF SIGNATURE**

|  |  |  |  |
| --- | --- | --- | --- |
| **PRINTED NAME** | **SIGNATURE** | **INITIALS** | **DATE** |
|  |  |  |  |
|  |  |  |  |