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

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| **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 most up-to-date CHPS nursing worksheet template. This ensures everything the CHPS staff needs is included. You can find the most up-to-date template at <https://www.itmat.upenn.edu/chps/nursing-tools.html>. 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 after a 4-hour post EKG. 4. Do not number the tasks on the worksheet. The order in which tasks are listed is the order they will get done in. 5. Not applicable sections may be removed, such as pre-dose ECG. However, if there is a pre-dose ECG per protocol, all directions in red under pre-dose ECG must be addressed even if the answers are not found in the protocol. This likely will require additional communication with sponsor and/or PI. 6. If research tubes need immediate processing or immediate placement on ice after collecting, please state this on both the worksheet as well as on the processing instructions. 7. Please use track changes. 8. We will not accept more than 1 worksheet at a time for review. **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. 9. 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 10. Please delete these directions prior to worksheet finalization. 11. If your protocol changes, please revise the worksheets to reflect the most up-to-date study requirements and re-send to Kathlyn and Bonnie.   Thank you,  Kathlyn and Bonnie |

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| **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 nurses, so they can provide the best care to patients.) |

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

**Cycle 1, Day 8 OR study visit day**

**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 |

Covering Provider \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**Please refer to EPIC for lab orders and Beacon for treatment plan and nursing instructions.**

## **Perform the following prior to Drug Administration:**

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

* Add any necessary fasting if applicable ie: No food intake will be allowed for 2 hours before and 1 hour after dosing or write “No Food Restrictions” in this spot.

POC Urine Pregnancy Test: □ Positive □ Negative □ N/A

Clinical Urinalysis (order in EPIC) Write if Clinical U/A result needs review prior to IP administration.

Pre-Dose Research Urine Indicate if CHPS will be processing or not.

Urine Collection *Time:* **\_\_\_\_\_\_:\_\_\_\_\_\_**  *Initials* **\_\_\_\_\_\_\_\_\_\_\_**

**Height\_\_\_\_\_\_\_\_\_\_\_\_\_cm Weight \_\_\_\_\_\_\_\_\_\_\_\_\_**kg *Initials***\_\_\_\_\_\_\_\_\_\_\_\_**

**VS upon arrival to CHPS**\* CHPS required; if pre-dose VS have no time frame: VS do not need to be repeated pre-dose and you may remove the pre-dose VS table from page 5 and put “No Time Frame” here.

\**Performed in supine or semi-recumbent position* after a 5-min resting period.

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

*Time***\_\_\_\_\_\_\_: \_\_\_\_\_\_\_**

⬜ **Insert IV(s) or access central line**

Some IPs have infusion restrictions and may be infused only through a central line, others only through a peripheral IV. Please specify if this IP can be infused through central line and/or peripheral IV so CHPS staff is aware of any restrictions.

**Pre-Dose Clinical Lab Collection: (orders in EPIC)**

**Indicate here if clinical blood results do or do not need to be reviewed prior to dosing.**

* CMP, Amylase, Lipase, and Bilirubin, Direct.
* Complete Blood Count with Auto Diff (CBC)
* Prothrombin Time with INR (PT), PTT

List lab exactly as name or abbreviation appear in EPIC

**Pre-Dose Research Labs:**

* Specify timing of Pre-Dose Research labs if protocol mandates limited window (i.e. to be drawn within 30 minutes of dosing) or No Time Frame
* Specify if CHPS will or will not be processing bloods; include processing instructions on a separate document if CHPS is processing
* See below for a sample, adjust as needed to fit protocol requirements
* List tubes in order they are to be drawn for all research bloods, including post dose.
* 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)

|  |  |
| --- | --- |
| **Type** | **Tubes to Draw** |
| PD Biomarker: Cell Pellet | Two 8.0 mL CPT Sodium Citrate Tube: Black/Blue |
| Plasma for Pre-Dose PK | 2 mL K3EDTA Tube: Lavender |
| Whole Blood for PBMC | 6 mL EDTA Tube Lavender |
| Whole Blood for Bio Marker Analysis | 2.5 mL PAX gene: Red Top  \*A butterfly/winged collection or venflon **MUST** be used for this tube.  **MUST** be **LAST** tube drawn.  ***Tube must be kept upright at room temp for 2h prior to freezing.*** |

*Blood Draw Time:* **\_\_\_\_\_\_\_: \_\_\_\_\_** *Initials\_***\_\_\_\_\_\_\_\_\_\_\_**

**Pre-Dose 12 Lead EKG**:

* Timing: Specify timing of EKG if protocol mandates limited window prior to drug administration, or No Time Frame.
  + If triplicate EKG, specify timing per protocol, (example: rapid succession within 3 minutes, each 2 minutes apart)
* 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 study drug administration. Must specify regardless of machine type used, see above.
  + If EKG does need to be read prior to dosing, specify how the provider will read the EKGs
    - Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver EKG to provider to read

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

Provider read pre-dose EKG and confirmed OK to dose patient:    ⃝ Yes ⃝ No

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

**Pre-Dose Vital Signs if time frame is required (specify timeframe):** *Time***\_\_\_\_\_\_\_:\_\_\_\_\_\_\_**

\**Performed in supine or semi-recumbent position* after a 5-min resting period

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

## **Pre-MEDS -- See EPic orders for dose and route**

Specify timeframe premeds must be given in relation to study drug dosing.

Please administer \_\_\_\_\_\_ to\_\_\_\_\_\_ minutes before \_\_\_\_\_\_\_\_\_\_\_\_\_\_. (List name of IP)

|  |  |  |
| --- | --- | --- |
| **Pre-medication** | **Time** | **Initials** |
| Acetaminophen |  |  |
| Diphenhydramine |  |  |
| Famotidine |  |  |

*Or specify there are not any pre- meds:*

## **There are not any pre-medications**

## **Study Drug Administration: Repeat here if IP has infusion restrictions about being infused only through central line and/or PIV.**

**Study Drug Administration: Specify name of drug, route**

If the study medication requires titration, include an area for any math or rates that the nurses are doing to calculate for the titration. This math must be double checked by a second nurse, so 2 lines are needed for documentation of their initials. (See titration table example below; delete if not needed)

|  |  |  |
| --- | --- | --- |
| Indicate if Investigational Medication to be or not to be supplied by IDS. See EPIC order for dose. | | *Time:* |
| Name of drug and duration. | START Infusion |  |

Put any assessments (examples: vital signs, blood draws, EKGs) that occur during the medication administration here.

Please note we do not record multiple Stop and Start times on the worksheet; they will be recorded in EPIC if needed.

|  |  |  |
| --- | --- | --- |
| Post drug assessments are after END of \_\_\_\_\_\_\_\_\_\_\_\_ (name of drug) Infusion time. | END of Infusion |  |
|  |  |  |

Administer flush: ⃝ Given

**Example if Titration is needed:**

Administer at 50mg/hr. Infusion rate can be escalated in 50mg/hr increments every 30 min to maximum of 400mg/hr.

|  |  |  |
| --- | --- | --- |
| Investigational drug supplied by IDS. | | Time: |
| Name of drug | START Infusion |  |

**Titration Table example:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Infusion rate**  **(mg/hr)** | **Infusion rate (ml/hr)** | **Scheduled Time** | **Actual Time** | **RN #1 Initials** | **RN #2 Initials** |
| 50 mg/hr |  |  |  |  |  |
| 100 mg/hr |  |  |  |  |  |
| 150 mg/hr |  |  |  |  |  |
| 200 mg/hr |  |  |  |  |  |
| 250 mg/hr |  |  |  |  |  |
| 300 mg/hr |  |  |  |  |  |
| 350 mg/hr |  |  |  |  |  |
| 400 mg/hr |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Post drug assessments are after END of \_\_\_\_\_\_\_\_\_\_\_\_ (name of drug) Infusion time. | END of Infusion |  |

Administer flush: ⃝ Given

**Space for math:**

If Study Drug is oral, please include any specific instructions**.**

|  |  |  |  |
| --- | --- | --- | --- |
| Investigation drug supplied by IDS | | Time: | Initials: |
| XYZ123 Oral Medication  Take XYZ123 capsules with 8 ounces (240 ml) of water at least 1 hour before eating or 2 hours after eating | Oral Administration |  |  |

\*\*Participant must remain fasting for 1 hour post study drug administration

## **Collect the following Post administration:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Time Point**  (+/- \_\_ minutes)  Specify Time Window or state “No Window” | **Scheduled Time** | **Actual Time** | **Temperature** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **SpO2** |
| **15 minutes** |  |  |  |  |  |  |  |
| **30 minutes** |  |  |  |  |  |  |  |
| **60 minutes** |  |  |  |  |  |  |  |
| **1 hour** |  |  |  |  |  |  |  |

**Put if CHPS or study team is processing all post dose research bloods.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time Point**  Specify Time Window for each draw or state “No Window” | **Tubes Needed** | **Scheduled Time** | **Actual Time** | **Initials** |
| **1.5 h Post-Dose:**  PK (+/- \_\_ min) | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
|
|
| **2.0 Post Dose:**  PK (+/- \_\_ min) | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
| **2.0 Post Dose** Plasma for ADMA/SDMA and Biomarkers  (+/- \_\_ min) | 6.0 mL EDTA Tube Lavender |
| **2.0 Post Dose** WB for PBMC  (+/- \_\_ min) | 6.0 mL EDTA Tube Lavender |
| **2.0 Post Dose** PD Biomarker:  Cell Pellet  (+/- \_\_ min) | Two 8.0 mL CPT Sodium Citrate Tube: Black/Blue |
| **2.0 Post Dose** WB for Biomarker Analysis  (+/- \_\_ min ) | 2.5 mL PAX gene: Red Top |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **VS Time Point**  Specify Time Window for each draw or state “No Window”  (+/- \_ minutes) | **Scheduled Time** | **Actual Time** | **Temperature** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **SpO2** |
| **2 hour** |  |  |  |  |  |  |  |
| **4 hour** |  |  |  |  |  |  |  |

**4-hour Post Dose 12 Lead EKG**:

* Timing: Specify timing of EKG if protocol mandates a particular +/- window, or write No Window.
  + If triplicate EKG, specify timing per protocol, (example: rapid succession within 3 minutes, each 2 minutes apart). If triplicate EKGs, scheduled time below will be for first EKG only.
* 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.
  + 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 EKGs
    - Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver to provider for review

*Scheduled EKG time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Actual EKG Time\_\_\_\_\_\_\_:\_\_\_\_\_\_\_ Initials*\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs: Scheduled Time of First EKG: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs, actual EKG times:

EKG #1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #3: : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time Point** | **Tubes Needed** | **Scheduled Time** | **Actual Time** | **Initials** |
| **8 H Post-Dose:**  PK (+/- 30 min**)** | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
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**8-hour Post Dose 12 Lead EKG**:

* Timing: Specify timing of EKG if protocol mandates a particular +/- window, or write No Window.
  + If triplicate EKG, specify timing per protocol, (example: rapid succession within 3 minutes, each 2 minutes apart). If triplicate EKGs, scheduled time below will be for first EKG only.
* 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.
  + 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 EKGs
    - Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver to provider for review

*Scheduled EKG time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Actual EKG Time\_\_\_\_\_\_\_:\_\_\_\_\_\_\_ Initials*\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs: Scheduled Time of First EKG: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs, actual EKG times:

EKG #1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #3: : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time Point**  Specify Time Window for each draw or state “No Window” | **Tubes Needed** | **Scheduled Time** | **Actual Time** | **Initials** |
| **10 h Post-Dose:**  PK (+/- \_\_ min) | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
|
|

**10-hour Post Dose 12 Lead EKG**:

* Timing: Specify timing of EKG if protocol mandates a particular +/- window or write No Window.
  + If triplicate EKG, specify timing per protocol, (example: rapid succession within 3 minutes, each 2 minutes apart). If triplicate EKGs, time below will be for first EKG only.
* 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.
  + 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 EKGs
    - Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver to provider for review

*Scheduled EKG time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Actual EKG Time\_\_\_\_\_\_\_:\_\_\_\_\_\_\_ Initials*\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs: Scheduled Time of First EKG: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If triplicate EKGs, actual EKG times:

EKG #1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ EKG #3: : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

VS at Discharge required by CHPS if not done within 30 minutes prior to discharge (Required by CHPS, not needed on Screening or Non-Treatment visits)

* N/A. Vital signs done within 30 minutes of discharge; see vitals documented above.

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

*Time***\_\_\_\_\_\_\_: \_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Discontinue Peripheral IV, or De-Access Portacath and document in EPIC**. | *Time:* | *Initials:* |

**CHPS STAFF SIGNATURE Put “n/a” on blank lines below.**

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

For CHPS Staff:

-Please review worksheet prior to filing or handing to study team.

-Complete any blank spaces or mark “N/A” if not applicable.

-Please indicate on the sheet if a circumstance prevented a time point from being met (for example: participant was in the restroom, hard stick that took multiple attempts, etc.)