## **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. 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. You can find the most up-to-date template at <https://www.med.upenn.edu/chps/research-nursing-core-rnc.html> 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.
3. Please list tasks in chronological order.
4. 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.
5. 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.
6. Please email us with questions, we are happy to help. kathlj@pennmedicine.upenn.edu and jessica.diamond@pennmedicine.upenn.edu
7. Please delete these directions prior to worksheet finalization.
8. If your protocol changes, please revise the worksheets to reflect the most up-to-date study requirements and re-send to Kathlyn and Jess.

Thank you,Kathlyn and Jess |

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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 are able to provide the best care to patients.) |

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| **Investigational Product(s)** |
| - Basic pharmacology/mechanism of action-Any known AE’s 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 | Namecell – xxx-xxx-xxxx | name, RNCell – (xxx xxx-xxxx |

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

**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 add No Food Restrictions.

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

.

[ ]  Clinical Urinalysis (order in EPIC) Document 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\_***\_\_\_\_\_\_\_\_\_\_\_**

**Weight \_\_\_\_\_\_\_\_\_\_\_\_\_**kg *Initials***\_\_\_\_\_\_\_\_\_\_\_\_**

**VS upon arrival to CHPS**\* CHPS required; if pre-dose VS has no time frame, VS do not need to be repeated pre-dose and you may remove the pre-dose VS table from page 4.

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

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

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

 **Insert IV(s)** ⬜ **IV access:** insert peripheral IV, access port-a-cath, or use PICC lumen for lab draws

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 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

|  |  |
| --- | --- |
| **Type** | **Tubes to Draw** |
| Plasma for Pre-Dose PK | 2 mL K3EDTA Tube: Lavender |
| Whole Blood for PBMC | 6 mL EDTA Tube Lavender |
| PD Biomarker: Cell Pellet | Two 8.0 mL CPT Sodium Citrate Tube: Black/Blue |
| 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 ECG**:

* Timing: Specify timing of EKG if protocol mandates limited window prior to drug administration, or No Time Frame.
	+ If triplicate ECG, 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.
	+ 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 ECGs
		- Options: Sent from CHPS RN to provider via Secure Chat, study team to hand deliver

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

Provider read pre-dose ECG 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

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

## **Pre-Meds**

Specify timeframe premeds must be given in relation to study drug dosing, the exact medications, and dosages & routes for each.

|  |  |  |
| --- | --- | --- |
| Please administer \_\_\_\_ to \_\_\_\_ minutes before \_\_\_\_\_\_\_\_. (List name of IP)  | **Time** | **Initials**  |
| **Pre-medication** | **Dose**  | **Route**  |  |  |
| Acetaminophen  |  650 mg  | Oral |  |  |
| Diphenhydramine  | 25 mg  | Oral  |  |  |
| Famotidine | 20mg | IV bolus |  |  |

*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 thorugh 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 doubled 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.  | *Time:* |
| Name of drug and duration.  | START Infusion |  |
| Post drug assessments are after END of \_\_\_\_\_\_\_\_\_\_\_\_ (name of drug) Infusion time. | END of Infusion |   |

Administer flush: ⃝ Given

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: |
| Obinutuzumab or rituximab (blinded) | 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:**

## **Assessments duRing infusion**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Time Point after start of Infusion**(+/- \_\_ minutes)Specify Time Window or state “No Window” | **Scheduled Time** | **Actual Time** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **Oral Temperature C°** |
| **15 minutes** |  |  |  |  |  |  |
| **30 minutes** |  |  |  |  |  |  |
| **45 minutes** |  |  |  |  |  |  |
| **60 minutes** |  |  |  |  |  |  |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Time Point**(+/- \_\_ minutes)Specify Time Window or state “NoWindow” | **Scheduled Time** | **Actual Time** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **Oral Temperature C°** |
| **15 minutes** |  |  |  |  |  |  |
| **30 minutes** |  |  |  |  |  |  |
| **60 minutes** |  |  |  |  |  |  |
| **1 hour** |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- |
| **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 |

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

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

* Timing: Specify timing of EKG if protocol mandates limited window prior to drug administration, or No Time Frame.
	+ If triplicate ECG, 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.
	+ 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 If

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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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VS at Discharge (Required by CHPS, not needed on Screening or Non-Treatment visits)

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

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

**CHPS STAFF SIGNATURE**

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