## **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.  Office – (215) xxx-xxxx  Cell – (xxx) xxx-xxx | Name  cell – xxx-xxx-xxxx | name, RN  Office – (xxx) xxx-xxxx  Cell – (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:

POC Urine Pregnancy Test: Urine pregnancy test: □ Positive □ Negative □ N/A Please note: CHPS does not perform study-sponsored Urine Pregnancy Tests and cannot accept results from a study-supplied test. If a pregnancy test is needed, CHPS needs to perform our supplied tests.

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

Pre-Dose Research Urine for PK (indicate if CHPS will be processing or not)

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

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

**Pre-Treatment Vital Signs\*:** *Time***\_\_\_\_\_\_\_:\_\_\_\_\_\_\_**

Specify timing of VS if protocol mandates limited window or No Time Frame.

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

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

**Insert IV(s)**

**State here is subject has port that can be used for infusion or blood draws**

**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.

|  |  |
| --- | --- |
| **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**: -Specify timing of EKG if protocol mandates limited window prior to drug administration or No Time Frame.

-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.

-Document if the EKG does or does not need to be read by PI/MD prior to study drug administration.

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

## **Pre-Meds**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Please administer 30 to 60 minutes before name of study drug. | | | **Time** | **Initials** |
| **Pre-medication** | **Dose** | **Route** |  |  |
| Acetaminophen | 650 mg | Oral |  |  |
| Diphenhydramine | 25 mg | Oral |  |  |
| Famotidine | 20mg | IV bolus |  |  |

## **Study Drug Administration:**

**Study Drug Administration: name of drug dose, 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

|  |  |  |
| --- | --- | --- |
| 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 **Drug**  Infusion time. | END of Infusion |  |

Flush given:     ⃝ Yes        ⃝ No

Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## **Assessments duing infusion**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Time Point after start of Infusion  (+/- 5 minutes) | **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:**

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| --- | --- | --- | --- | --- | --- | --- |
| **Time Point**  (+/- 5 minutes) | **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** | **Tubes Needed** | **Scheduled Time** | **Actual Time** | **Initials** |
| **1.5 h Post-Dose:**  PK (+/- 5 min) | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
|
|
| **2.0 Post Dose:**  PK (+/-10min) | 2.0 mL K3EDTA Tube Lavender | **\_\_\_\_\_:\_\_\_\_\_** | **\_\_\_\_\_:\_\_\_\_\_** |  |
| **2.0 Post Dose** Plasma for ADMA/SDMA and Biomarkers  (+/- 10 min) | 6.0 mL EDTA Tube Lavender |
| **2.0 Post Dose** WB for PBMC  (+/- 10 min) | 6.0 mL EDTA Tube Lavender |
| **2.0 Post Dose** PD Biomarker:  Cell Pellet  (+/- 10 min) | Two 8.0 mL CPT Sodium Citrate Tube: Black/Blue |
| **2.0 Post Dose** WB for Biomarker Analysis (+10 min ) | 2.5 mL PAX gene: Red Top |

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| --- | --- | --- | --- | --- | --- | --- |
| **VS Time Point**  (+/- 5 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**:

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 and put name of the machine. Attach a laminated instruction sheet to the EKG machine.

Document if the EKG does or does not need to be read by PI/MD prior to discharge.

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

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

VS at Discharge: (Not needed on Screening or Non-Treatment visits)

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

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

## **Adverse Event Documentation:**

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Any supportive medications given?  Yes  No

*If yes, what?* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Initials***\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CHPS STAFF SIGNATURE**

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