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| --- | --- |
| **Study Team Contacts** | **Biospecimen Team Contacts Delete if n/a** |
| *Principal Investigator*: Name and cell # | Name and cell # |
| *Research RN*: Name and cell # | Name and cell # |
| *Study Coordinator*: Name and cell # | Name and cell # |

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| **Visit 1** | Subject Initials: | Subject ID: |
| Date of Visit: | Randomization Date:  |

Weight\_\_\_\_\_\_\_\_\_\_\_\_\_kg

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| **Pre-Dose Assessments** |
| Obtain vital signs: Specify timing of VS if protocol mandates limited window or No Time Frame. |
| Temperature | Pulse | Oxygen Sat | Respiratory Rate | Blood Pressure | *Time:* | *Initials:* |
| C |  |  |  | \_\_\_\_\_\_\_\_\_ mmHg |  |  |

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

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| 1. Insert IV(s) If Applicable: If patient has an available central line, please use it; state if central line can be used for bloods or infusion
 | *Time:* | *Initials:* |

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| 1. Collect Pre-Dose biospecimen samples in the following recommended order:

-Specify timing of Pre-Dose labs if protocol mandates limited window OR No Time Frame. -Specify if CHPS will or will not be processing bloods; provide processing instructions if CHPS is processing as a separate document.  | *Time:* | *Initials:* |
| Clinical Bloods: (Orders in EPIC) List **exactly as name or abbreviation appear in EPIC** CMP*, Phosphorus, Uric Acid, Amylase, Lipase, CBC PLT, TSH, Urinalysis (Micro and Dipstick), T3 and Free T3.* |  |  |
| 1. Research Bloods: Research team provides labelled tubes. Pre-Dose biospecimen samples in the following recommended order OR *may be collected in any order as long as it is pre-*dose
 |  |  |
| Serum Biomarker Analyses (fasting sample)*collected in a 4mL Serum red top tube* |  |  |
|  Plasma PK*collected in a 4mL lavender-top K2EDTA tube* |  |  |
| Genetics Analysis*collected in a 8.5ml Blood DNA tube* |  |  |
| RNA Analyses*collected in a 8.5ml Blood DNA tube* |  |  |
| Urine for Genetic Analysis |  |  |

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

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| Obtain Pre-Dose ECG-specify timing of Pre-Dose EKG if protocol mandates limited window or put No Time Frame. Also state if we are using CHPS machine or study-sponsored machine. If CHPS machine, state if the EKG is to be transmitted to EPIC or not. If study-sponsored machine, specify that it is study-sponsored and put name of the machine. Attach a laminated instruction sheet to the EKG machine.  | *Time:* | *Initials:* |

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| 1. **Pre-Meds**
 |  |  |
| Please administer 30 to 60 minutes before name of study drug | *Time:* | *Initials:* |
| **Premedication** | **Dose**  | **Route**  |  |  |
| Acetaminophen  |  650 mg  | Oral |  |  |
| Diphenhydramine  | 25 mg | Oral  |  |  |
| Famotidine | 20mg | IV |  |  |

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| **Dosing**  |
| 1. Dosing with Investigational Products (put name of IP) and route
 | *Time:* | *Initials:* |
|  |  |  |  |
| **Study Drug name here with route and how long if infusion**  | START Infusion |  If infusion  |  |
| END infusion | If infusion |  |

**Example:**

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| **Flush with 30 ml NS *Specific flush needs to be part of Beacon orders*** | Flush Start |  |  |
| End of Infusion is the End of Flush.  | Flush End |  |  |

**State if EOI is the end of medication or the end of flush.**

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

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| **Assessments During infusion**.  |

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| 7. Time Point after start of Infusion | **Scheduled Time** | **Actual Time** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **Oral Temperature C°** |
| **15 minutes** |  |  |  |  |  |  |
| **30 minutes** |  |  |  |  |  |  |
| **45 minutes** |  |  |  |  |  |  |
| **60 minutes** |  |  |  |  |  |  |

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| **Post-Dose Assessments**For infusions, state if post assessments are post **start or** post **end** of infusion.  |

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| 7**. VS** Time Point after EOI | **Scheduled Time** | **Actual Time** | **Blood Pressure** | **Heart Rate** | **Respiratory Rate** | **Oral Temperature C°** |
| **15 minutes** |  |  |  |  |  |  |
| **30 minutes** |  |  |  |  |  |  |
| **60 minutes** |  |  |  |  |  |  |
| **1 hour** |  |  |  |  |  |  |
| **2 hour** |  |  |  |  |  |  |
| **4 hour** |  |  |  |  |  |  |

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| 1. Post-Dose PKs and EKGs Time Point after EOI
 | *Scheduled Time:* | *Actual**Time:* | *Initials:* |
| **1 hour** ± 10 minutes **PK***collected in a 4mL lavender-top K2EDTA tube* |  |  |  |
| **2 hour**  ± 15 minutes **ECG***(If using CHPS machine, state if transmitting to EPIC or not.)**(ECG should be performed prior to the PK sample blood draw if both are scheduled at the same nominal planned time point)* |  |  |  |
| **2 hours**  ± 10 minutes **PK***collected in a 4mL lavender-top K2EDTA tube* |  |  |  |
| **4-10 hour** **PK***collected in a 4mL lavender-top K2EDTA tube* |  |  |  |

Document PIV removal in EPIC.

Comments:

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**CHPS STAFF SIGNATURE**

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