Subject Legal Name:

D.O.B.: Age:

Medical Record #:

Gender:

Ethnicity:

Race:

**Visit Information**

**Date of Visit**:

**Time of Visit**:

**Consent form**: Signed prior to arrival?/at visit?

**Visit Information:** V1 V2 V3 V4

**Type of orders**: Outpatient

**Location of study**: ACC/CTH/CTC

**Protocol Information**

**Protocol Title**:

**Principal Investigator:**

**IRB Protocol #:**

**IRB Expiration date:**

**Purpose**

The purpose of this study is to...

**Dietary**

* Dietary Services? Y N

If Y, please list dietary services:

* Is subject fasting? Y N

**Pharmacy – NURSING TO COMPLETE THIS SECTION**

1. **ID-**

Instructions:

* If weight based: screening weight used for dosing (date) ? Weight used for dosing (date)
* Volume:
* Rate:
* Tubing:
* Filter:

1. Flush 0.9% NaCl 50ml bag provided by CCI \_?\_\_provided by IDS

* Enter flush instructions. Is addtl flush needed? Or are we flushing tubing only to ensure entire volume of study drug administered?

1. ID-Allergic Reaction Emergency Kit Panel- Do not dispense. Use CCI floor stock.

Study coordinator is responsible for picking up study medication(s) at IDS and bringing to outpatient center. Study coordinator should be at outpatient center with drug and patient ready at appointment time. Study coordinator will return unused medication (if necessary) to IDS after visit.

**Medical Information**

Diagnosis: *List ALL diagnoses*

Allergies:

Medications taken at home:

**CCI Technician** not needed

1. Obtain VS (T, HR, RR, BP, O2) Call MD for T> 100.0, HR ≤60 or ≥100, SBP ≤90 or ≥160, DBP ≤50 or ≥100, RR> 20, SaO2 <95%)
2. Obtain EKG. CCI machine Study Machine (CCI can place leads. Study team to transmit)

Insert special instructions

EKG must be read by study LIP prior to drug administration *(to be discussed at IM)*

1. Obtain bloods per **lab chart** (venipuncture).

**CCI LIP (NP, PA)** not needed

1. Perform targeted complete physical exam.

Insert any special instructions

**Nursing**

**Pre-Dose**

1. **Female Subjects:**  The study team/PI is responsible for obtaining pre-dose urine pregnancy testing. The PI MD has appointed the study staff to document the results of this test on the CCI study visit worksheet. OK for CCI staff to proceed with visit if negative.

Pregnancy test not needed

1. Obtain VS (T, HR, RR, BP, O2). Call MD for T> 100.0, HR ≤60 or ≥100, SBP ≤90 or ≥160, DBP ≤50 or ≥100, RR> 20, SaO2 <95%)
2. Confirm medication list with subject. Contact MD if discrepancies.
3. Place IV for infusion. Draw pre-dose bloods. See **lab chart.**
4. If subject will be self-administering any home medications during the visit, they need to be noted on these orders. *For example: “Subject may self administer ABC 10mg PO x 1 after baseline blood draw.”*

**Dosing**

1. Administer ID- ? /Placebo at? mg/kg/0mg at ? ml/hr.
2. Enter frequency of vital signs during infusion. See parameters above.
3. Enter anything else that is done during infusion

**Post-Dose/Monitoring**

1. When infusion is complete, convert IV to saline lock?
2. Obtain VS (T, HR, RR, BP, O2) after \*\*\*\* following infusion. See parameters above.
3. Post dose bloods?
4. Subject may be discharged if they feel well and VS are stable.

**In Case of Emergency:**

**In the event of a drug reaction, and upon confirmation from MD/LIP:**

* Administer Diphenhydramine 50 mg IM/ IV push. If administering by IV push, give over 1-2 minutes.
* Administer Acetaminophen 325-650 mg PO x 1
* Administer Hydrocortisone 100 mg IM/IV. If administering by IV push, give over 1-3 minutes.

**In the event of anaphylaxis:**

* Administer Epinephrine 0.3 mg IM to lateral mid-thigh
* Call CODE / 911 if at ACC
* Call study MD

**(Labs will be written as “refer to lab chart” (bold).)**

**LAB CHART**

Tubes provided by study team Tubes provided by CCI (BWH labs-provided by CCI)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Test** | **Tube** | **Volume (mL)** | **Special Instructions**  **Or Comments** |
| **Pre-Dose** | | | | |
|  |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **Post-Dose** | | | | |
|  |  |  |  |  |
|  |  |  |  |
| CCI ADMIN | **Lab chart approved by lab tech. Date:** | | | |

MD Signature: Date:

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contact Information**

|  |  |  |
| --- | --- | --- |
|  | **Name** | **Pager/Cell Phone** |
| Primary Medical Contact: |  |  |
| Secondary Contact: |  |  |
| Study Coordinator Contact(s): |  |  |

***These orders must be signed, scanned and e-mailed to*** [***cciadvancedoutptservices@partners.org***](mailto:cciadvancedoutptservices@partners.org) ***72 hrs in advance of visit***