1) **Admit to CTRC for Protocol # Visit #**

**Title:**

 **Location(select all that apply):** [x]  **Inpatient** [ ]  **Outpatient**

2) **Notify:** Study Coordinator of patient arrival to the unit.

 PI: Provider on Study: CRC:

 Cell #: Cell #: Cell #:

3) **Obtain: Vital Signs (VS) Height, Weight:** Obtain BP (record which ARM was used, and if multiple sets of vitals taken, use same arm each time), HR, Temp (c), SPO2, RR after participant rests in supine position for 5 minutes.

**-**Vital signs to be taken 45 mins prior to pre-dose

**-**Vitals sign to be taken immediately prior to infusion then every 15 (+ or – 5 minutes) for the first hour followed by every 30 minutes (+ or – 10 minutes) until 1 hour after the end of the infusion.

No shoes, empty pockets, no heavy coat/jacket

4) Verify Allergies

5) Verify Documents

 Consent Auth B H&P Central Venous Line access/flushing protocol.

6) **STAT orders/Special Considerations**: Withhold all antihypertensive treatments for 12 hours prior and throughout each

Ocrelizumab infusion

7) **Visit Parameters:**

Call MD for BP >180/100, <90/50, HR>110 <40, RR>20, <6, Glucose >250 <50 (Standard CTRC call orders)

8) **Diet: Patient to be fasted for >8hrs prior to infusion.**

9) **Activity:**

10) **Stop Criteria:** Infusion Reactions - Contact PI and MAIN STUDY COORDINATOR

* Sign and Symptoms
	+ Allergic reaction/hypersensitivity, Drug fever (>38C or >101F), Arthralgia, Bronchospasms, Cough, Dizziness, Dyspnea, Fatigue, Headache, Hypertension (SBP >160 or DBP >110), Hypotension (SBP <90 or DBP <60), Myalgia, Nausea, Pruritus, Rash/desquamation, Rigors/chills, Diaphoresis, Tachycardia (HR >110), Urticaria, vomiting

**Categorization of Infusion-Related Reactions**

* Mild - Infusion may be continued; if intervention is indicated it is minimal and additional treatment (other than acetaminophen for delayed reactions) is not required.
* Moderate- Requires treatment including more intensive therapy (e.g., IV fluids, nonsteroidal anti-inflammatory [NSAIDs] see medication order) in addition to infusion interruption but responds promptly to medication. Treatment is indicated for ≤24 hours.
* Severe- Not rapidly responsive to medication or to interruption of infusion; and/ or prolonged (treatment is indicated for >24 hours); recurrence of severe symptoms following initial improvement.

**Guidelines for Management of Infusion-Related Reactions**

Mild to moderate

* If the event that a patient experiences is a mild to moderate IRR (e.g. headache), the infusion rate should be reduced to half the rate at the time of the event.
* This reduced rate should be maintained for at least 30 minutes. If tolerated, the infusion rate may then be increased according to the patient’s initial infusion schedule.

Severe IRR (or complex of flushing, fever, and throat pain)

* Stop infusion and Call Infusion PI and PRA immediately
* If a patient experiences a severe IRR or a complex of flushing, fever, and throat pain symptoms, the infusion should be interrupted immediately and the patient should receive symptomatic treatment.
* The infusion should be re-started only after all symptoms have resolved.
* The initial infusion rate at restart should be half of the infusion rate at the time of onset of the reaction

Life-threatening or disabling IRR

* Stop infusion and Call Infusion PI and PRA immediately
* Immediately stop ocrelizumab if there are signs of a life-threatening or disabling IRR during an infusion, such as acute hypersensitivity or acute respiratory distress syndrome.
* The patient should receive appropriate treatment.
* Permanently discontinue ocrelizumab in these patients.

**End of Infusion**

The patient’s infusion site should be assessed for signs of any localized reaction during the infusion and for 30 minutes after the end of the infusion. The patient will remain at the study site for 1 hour following completion of dosing for observation and completion of assessments. **\*\***document any interruption or delay in infusion (delay type, time, duration, volume in bag at time of delay/interruption)\*\*

11) **Medication Orders:** [x] UCHealth IP Research Pharmacy or [ ] CU Anschutz OP Research Pharmacy (select one)

 **Predose:**

Methylprednisolone 100 mg IVP x 1 (slow IV) **Administer 30-45 mins prior to the start of infusion of study drug**

Benadryl 50mg IV x1 **Administer 60 minutes prior to start of infusion**

Tylenol 1000mg PO x1

* Record: Start Time (HH:MM) Stop Time (HH:MM), Amount Administered (mg), Volume (mL), Rate (mL/hr), Concentration (mg/mL) of Pre-Dose meds

**Study Drug:** Administer Ocrelizumab 300mg/250ml 0.9% NS (RO4964913) IV Infusion over approximately 150 minutes

* PRA to transport from pharmacy to CTRC
* Prepare infusion tubing (including filter) and all infusion procedures
* Start at 32 mL per hour, increase per the Infusion Rate Table below.

Maximum Infusion Rate: 194 mL per hour

* Infusion Nurse:

Record:

* 1. Start Time (HH:MM)
	2. Stop Time (HH:MM) (Stop time is when the flush is completed)
	3. Amount Administered (mg)
	4. Volume (mL) Record mL from pump at end of flush
	5. Rate (mL/hr)
	6. Concentration (mg/mL)
	7. Was there an infusion interruption? If yes, please document delay type, time, and duration

****

**PRN Meds: DO NOT GIVE ANY MEDS WITHOUT CALLING PI FIRST (route, dosing, frequency, and parameters to be determined by Dr. Alavrez or Dr. Vollmer)**

 Tylenol 1000mg PO Q 4-6 HR PRN for Pain or Temperature > 38

Benadryl 50 mg IV Q 8 HRS PRN for rash or itching

Compazine 5mg PO or IV Q6HRS PRN for nausea or vomiting

If systolic BP <90 please call for parameters and begin NSS IV for hypotension at 100cc/hr

**Special Medication Administration Instructions: Use of a 0.2 micron filter must be inserted within infusion line for all infusion visits.**

12) **Procedures for Protocol**

**A) Venous Access:** Insert 18-22 Gauge PIV for infusion, if unsuccessful after 3 attempts please call PRA. Insertion of a secondary 18-22ga PIV for blood collection post infusion.

**B) Labs (Blood/ Urine/other): COMPLETE LAB SECTION TABLES (only select as applicable)**

[x]  **Study Team to process and ship (no CTRC processing required)**

[ ]  **Tubes provided by CTRC (list all tubes needed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

[x]  **Tubes provided by Sponsor : Collect at pre-dose, EOI + 1 hour, EOI + 2hr**

[x]  **UCH Clinical Lab (if applicable)**

[ ]  **Collected on OP Unit– Use Beaker Build process (no need to complete the table below)**

[x]  **Collected on IP Unit – Complete the table below, reference** [**UCHealth Lab**](https://www.testmenu.com/universityhospital) **directory for lab codes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assay Name & Lab Code (required)** | **Timepoint(s)****(required)** | **Sample Type****(If known)** | **Tube/container type/color****(If known)** | **Collection Tube Size****(Lab Use Only)** |
| ***CBC with auto-diff LAB1748***  | ***Pre-dose*** | ***Plasma*** | ***Purple*** |  |
| ***CMP Lab17***  | ***Pre-dose, EOI, EOI + 3hr*** | ***Plasma*** | ***Green w/Gel*** |  |
| **Urinalysis LAB347** | **Pre-dose** | **Urine** | **Urin collection** |  |
|  |  |  |  |  |

[x]  **CTRC Research Core Lab (if applicable)**

[ ]  **Industry-initiated studies- Email lab manual to** **Core Lab** **-no need to complete table below**

[x]  **Investigator-initiated studies- Complete the table below**

**\*If identical labs to another study, list COMIRB# and Visit here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assay Name (required)** | **Timepoint(s)****(required)** | **Sample Type****(If known)** | **Tube/container type/color****(If known)** | **Collection Tube Size****(Lab Use Only)** |
| ***TSH***  | ***-10, 360*** | ***Serum*** | ***Red*** |  |
| ***Lipid +LDL***  | ***-10 ,0, 30, 60, 90***  | ***Plasma*** | ***Purple*** |  |
|  |  |  |  |  |
|  |  |  |  |  |

13) **Discharge Home:**

* Discontinue PIV if applicable
* De-access port if applicable

14) **Other: Urine collection for WOCBP: cup and test provided by study team, and test performed by CRC.**

|  |  |  |
| --- | --- | --- |
| MD Name (Printed or typed) | MD Signature | Date |
| Pharmacist Name (If applicable) (Printed or typed) | Pharmacist Signature | Date |
| Nursing Leadership Name Diane Branham, RN, BSN, MBA, CCRCORKyla Wulff, RN, BSN | Nurse Leadership Signature | Date |