



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

Study Team Note: CTRC staff follow the study orders in Epic. CTRC staff *do not* read the study protocol. If the orders are incorrect or missing information, protocol deviations may occur. It is the study team's responsibility to ensure that the MD orders are congruent with the IRB approved study protocol.

IT IS AN EXPECTATION THE STUDY TEAM WILL:

- Understand the protocol for the scheduled visits and be able to answer *or find* the answer to questions the CTRC staff may have regarding protocol specific Information.
- Resolve missing or incorrect orders. It is not CTRC staff's responsibility to correct orders because we are not a part of the study team, not on the delegation log, and do not read the protocol, IB or lab manuals.
- Will contact the PI/study MD during a visit to place a Research Communication Order "need to collect this visit" missing, incorrect or last minute add on orders. The CTRC staff will not be able to complete a procedure or document correctly without a correct order.

The CTRC has 3 clinical environments:

- 1) An Outpatient Clinic (OPC) with 4 phlebotomy chairs and clinic exam rooms (Outpatient/Ambulatory setting)
- 2) An Infusion room (Outpatient setting) and
- 3) An Inpatient Unit (Inpatient setting).

The setting and CTRC services requested determine the type of order and where in the Epic environment (context) the study team created the study visit orders as follows:

ORDER TYPE 1

Outpatient Clinic study visits and Infusion Room study visits *without* Research Pharmacy dispensed study medication(s) to be administered by a CTRC RN.

Need to create orders in the Outpatient (Ambulatory) Epic environment (context).

****See Inpatient Unit CTRC Infusion Plan link in order type 2 section for studies with Research Pharmacy dispensed study medication(s) to be administered by a CTRC RN.**



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

Create Order(s) as a: (highly recommended)

1) Preference List (*study team created with specific name*):

- [Epic Order Preference List Personalization.docx \(ohsu.edu\)](#)

2) SmartSets (called “Order Sets” in Epic) *submit to Epic Research for creation*:

- [Howtorequestsmartset--1-.docx \(sharepoint.com\)](#)

3) Outpatient Research Communication Order (*see below*):

Common orders w/order number to include in order types 1 and 2 above:

- 1) (LAB101867) Research Venipuncture Only (Phlebotomy Draw): Use this order when research labs to be collected by CTRC staff or an OHSU Lab via venipuncture.
- 2) (LAB10187) Research Additional Tubes: Use when need to add additional research blood collections to a study visit.
- 3) (POC90000113) Hemocue (aka HGB (Hemoglobin): Use only if sending to OHSU Lab Central.
- 4) (Lab00680) Hemoglobin: Use only if sending to OHSU Lab Central.
- 5) (LAB00230) Hematocrit: Use only if sending to OHSU Lab Central.
- 6) (POC90000168) CAP Glucose, Point of Care (CBG): Use only if sending to OHSU Lab Central.
- 7) (POC90000171) Ua Dipstick 10 Dip Manual (Urinalysis): Use only if sending to OHSU Lab Central.
- 8) (POC90000003) HCG Urine Point of Care: Use only if sending to OHSU Lab Central. If not, create Research Communication Order with details.
- 9) (PULMLB00001) Sputum Induction
- 10) Other labs collected for processing by OHSU Central Lab: Select the specific lab from OHSU Epic list.
- 11) (RSRC01) Research Communication: Use for sample collections not processed by OHSU Lab Central and for procedures without a corresponding Outpatient Epic order e.g.:
 - a. Place a PIV and maintain through discharge vs collection.
 - b. Ok to remove and discharge once procedures are complete and vs stable.
 - c. 12 lead ECG not read by Cardiology with print out provided to study team.
- 12) (ECG00002) 12 lead ECG for cross location ancillaries.

Order details: For all orders, the specific study visit name listed on the CTRC Fee Agreement, procedure collection details, time-points, and study data to be documented in Epic will be described in the comment section of each order. *If a detail is not in the order, the RNs will not do it, and a protocol deviation may occur.*

Examples of Detailed Orders:

1) Visit weeks 2, 8, 12, 32 after a 3-minute rest period in semi-supine position collect BP, HR, RR, TEMP and immediately stand and collect after 2 minutes BP and HR. Document rest period start and stop times in Epic. All other visits after 3-min rest period in semi-supine position collect BP, HR, RR, TEMP.

2) All visits: Via PIV collect samples per study provided kit at 0-min (per study team instruction), 20-min, 1-hour, 2-hour. Study staff to process samples. Document all collection times in RN research note. RN to confirm with study coordinator study drink calculation using study provided dosing instructions and document total volume of drink in RN research note.



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

3) Upon study team instruction: After 10 min supine rest triplicate 12 lead ECG w/read 1 minute apart: not to exceed 5 minutes total for all 3. Document in RN Research Note supine position rest period start and stop time.

4) (PULMLB00001) Sputum Induction. In order *comment section*: use study provided 7% saline. Collect specimen in CTRC provided sterile specimen cup and give to study team upon collection. Collection time not to exceed 20 minutes.

Document in RN research note length of procedure time and sample collection time or state not collected in rn research note.

5) Perform finger prick with Mitra blood collection device provided by study staff.

6) Physical measurements: Height (cm), weight (kg), BMI, neck circumference (inches – 1" above shoulders at bottom of larynx to 1/4"), waist (inches – lower margin of the last palpable rib and the top of iliac crest. Hip (inches – widest portion of the buttocks with tape parallel to floor)

The following is an example of the research communication order to select for Outpatient (Ambulatory) Clinic and Infusion Room studies:

The screenshot displays the 'Order and SmartSet Search' window. At the top, there is a search bar with the word 'RESEARCH' entered. Below the search bar, there are tabs for 'Browse', 'Preference List', 'Facility List', and 'Database'. The 'Facility List' tab is selected. The main content area is divided into several sections:

- SmartSets, Panels, & Express Lanes**: This section contains a table with columns for Code, Name, Notes, and Type. It lists four items: 'RESEARCH ANESTHESIOLOGY', 'RESEARCH APHERESIS LABS IRB 16982', 'RESEARCH CEI CORNEA', and 'RESEARCH CEI GENETICS'. Each item has a corresponding note and is classified as a 'SmartSet'.
- Outpatient Medications**: This section shows '(No results found)'.
- Outpatient Procedures**: This section contains a table with columns for Code, Name, Type, and Pref List. It lists four items: 'RESEARCH VENIPUNCTURE ONLY (PHLEBOTOMY DRAW)', 'RESEARCH COMMUNICATION', 'RESEARCH COMMUNICATION', and 'RESEARCH DERM LAB'. The 'RESEARCH COMMUNICATION' row is highlighted in yellow.
- Inpatient Orders and Infusion Meds Medications**: This section shows '(No results found)'.
- Inpatient Orders and Infusion Meds Procedures**: This section contains a table with columns for Code, Name, Type, and Pref List. It lists four items: 'RESEARCH COMMUNICATION', 'RESEARCH VENIPUNCTURE ONLY (PHLEBOTOMY DRAW)', 'RESEARCH ADDITIONAL TUBES', and 'Research Communication #1 - Beacon'. The 'RESEARCH COMMUNICATION' row is highlighted in yellow.

At the bottom of the window, there are buttons for 'Broaden My Search', 'Select And Stay', 'Accept', and 'Cancel'.



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

The following is an example of a completed research communication order with protocol specific procedure details and instruction for study data to be documented in Epic. The research communication order may be used as a:

- One-time order
- A standing order
- Future order
- Order in a preference list or smartset

ORDER TYPE 2

Inpatient Unit study visits or Infusion Room study visits with CTRC Infusion Plan for Research Pharmacy dispensed and RN administered study medications.

Need to create orders in the Inpatient Epic Environment, Research Pharmacy will auto upload a CTRC Infusion Plan into the correct Environment.

Create Order(s) as a: CTRC Infusion Plan

- For study medications (all routes) dispensed by Research Pharmacy and administered by an RN or research pharmacy dispensed study medications for self-administered and study team administered medications (excludes study medications not dispensed from Research Pharmacy or dispensed from OHSU Outpatient Pharmacy for self-administered medications) [CTRC Infusion Plan Request Form](#)

Note: All CTRC orders need to be included in the CTRC Infusion Plan except: Procedures requiring an Epic Lab Order to complete such as labs going to OHSU Central Lab and 12 lead ECGs requiring Cardiology read. An order will need to be added to the CTRC Infusion Plan directing the RN to release the specified Epic order(s) or they may be missed due to requires the RN to navigate to a different Epic Environment which they won't know to do without instruction.



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

Research Pharmacy manages the CTRC Infusion Plan build. Once signed by study MD, Research Pharmacy will upload the CTRC Infusion Plan into the correct Epic Research Environment upon notification by the study team of a scheduled encounter. If modifications are required to the CTRC Infusion Plan, the study team will need to complete the CTRC Infusion Plan Request Form with the modification details. The study MD will need to re-sign the CTRC Infusion Plan modifications. A modified Infusion Plan will not be automatically uploaded to scheduled visits resulting in potential protocol deviations. Call Research Pharmacy to advise of the scheduled visits. Study teams can view the CTRC Infusion Plan prior to the first visit per instruction provided by Research Pharmacy.

2) PREFERENCE LIST**

or

3) SMARTSET**

***See links in Order Type 1 for instructions regarding these order types*

OHSU Lab central Epic orders may be incorporated into Preference List or Smartset. The following are the most common orders w/order # used in the CTRC. Additional orders may be found in the Epic Order Preference or Facility Catalog (found within Epic).

1. (POC90000001) CBG (aka Capillary Blood Glucose, POC)
2. (RAD102726) VAT: PIV w/US
3. (IPNUR677) Insert and Maintain IV access
4. (LAB101876) Research Venipuncture Only (phlebotomy Draw)
5. (Lab00680) Hemoglobin
6. (LAB00230) Hematocrit
7. (IPNUR185) Nurse Communication (also used BY RESEARCH PHARMACY in THE CTRC Infusion Plan)
8. (ipnur931) RESEARCH communication ORDER
9. Inpatient Bed only Admission order: (ADT66) Admit to Research
10. (CODE02) Full code
11. Inpatient Bed only Diet order: From Facility list diet orders, choose only from the options with code name DietXXX as these are for the inpatient environment
12. Inpatient Bed only Discharge Order: (ADT07) Discharge
13. ECG00002 12 Lead ECG for IP Facility Order

ORDER DETAILS: All orders to include the specific study visit names as stated on the OCTRI Fee Agreement, procedure collection details, time-points and study data to be documented in Epic. This information will need to be described in the comment section of each order. If a detail is not in the order, the RN's will not do it, and a protocol deviation may occur.

Examples of detailed orders:

1) Visits Weeks 2, 8, 12, 32 after 3 min rest period in semi-supine position collect BP, HR, RR, Temp, and immediately stand and collect after 2 minutes BP and HR. Document rest period. Start and stop times in Epic. All other visits after 3-minute rest period in semi-supine position collect BP, HR, RR, Temp.



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

- 2) Stop time of study medication infusion for post infusion procedures is stop time of study medication prior to flush start time. Document flush start, stop times and volume in Epic **or** study medication stop time is time of flush end. Document study medication plus flush volume in Epic. Do not document separate flush start/stop times.
- 3) Visits 1, 5, 9, 12, 15, 24, 28, 32: 1 hour post infusion end time see Epic for labs to OSHU Central Lab and collect research labs per kit provided by study team. Deliver to OCTRI Lab. All other visits pre-infusion collect research labs per kit and deliver to OCTRI Lab.
- 4) All visits: Collect BP, HR, RR, Temp, O2 SATS pre-infusion, every 15 minutes during infusion, at end of infusion and 30, 60, 90 minutes after end of flush. Flush time is end of infusion time. Document study med volume in MAR without flush. Document flush start and flush volume in MAR comment.
- 5) Study team to manage and document in Epic study medication administration via study pump. Study team to manage participant education for at home pump infusions. RN to teach participant butterfly SQ technique for at home infusions. RN to document teaching session in RN research note.



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

The following is an example of a rough draft of a study team completed [CTRC Infusion Plan Request Form](#) with protocol specific procedure details and instructions for the Epic study data documentation.

| Example Topics (insert additional rows for additional nursing communications. Delete rows that are not needed) | Communication (Must include visit #. Note the communication below will appear every visit) |
|---|--|
| Studies (EKG, ultrasound, etc.): timing and where the equipment is coming from | 12 lead ECG using CTRC machine at visits 16, 25. No specific instructions in the protocol for details for the procedure. pre-infusion |
| Peripheral IV: place PIV for collection of labs | Place PIV and maintain until discharge. |
| Lab instructions (central labs) | Visits 6,7,8,9,10,11,12,23,14,15,16,17,18,19,20, 22,24,25,26. pre-infusion: Draw blood per EPIC orders. Study coordinator will provide the tubes and collect them after the blood draw for processing. |
| Lab instructions (PK labs) (Pk labs usually fall under this category) | Visits 6,7,8,9,10,11,12,23,14,15,16,17,18,19,20, 22,24,25,26.post-infusion: Draw blood in tubes provided by the study coordinator one hour (+/- 15 minutes) after the end of the infusion, and return to study coordinator so that they may process and send out to central lab. |
| Post-dose observation period and discharge instruction | DC PIV when observation is complete. Patient may be discharged after being monitored for any signs of an infusion reaction 1-hour post-infusion |

Template last updated 2024 Apr 16

| | |
|---|---|
| (i.e. DC PIV when observation is complete. Patient may be discharged <u>1 hour</u> post-infusion if vital signs are stable) | |
| Tegoprunart Infusion | <p>20mg/kg IV infusion for 1 hour, should not be administered using an IV pump through a common IV line. Study data to be included is listed below:</p> <ul style="list-style-type: none">- Check the Use <u>By Date</u> and Time located on the label on the outside of the IV bag prior to starting the infusion to ensure the infusion end time will not exceed the Use By Date and Time.- Date of infusion- Infusion <u>start</u> and end time (total infusion time is not inclusive of the post-IP administration saline flush)- IV bag volume <u>infused</u>- Total dose <u>prescribed</u>- Total flush volume <u>infused</u>- If an infusion of AT-1501 is interrupted, record the reason for the <u>interruption</u> <p>Administration must be followed by a saline flush of at least 25 mL to ensure that any solution held <u>up</u> in the infusion bag / lines is also delivered</p> <p>End of Infusion Note - total infusion time is not inclusive of the post-IP administration saline flush. Participants should be monitored for any signs of an infusion reaction for 1 hour post infusion. Dispose of empty IV bags per site SOP at the end of the <u>1 hour</u> observation period. If for any reason an infusion is not completed, the remaining prepared IMP must be documented (remaining mL) and <u>then</u> destroyed per site practices.</p> |
| Nursing Communication | |

Per this Job Aid, the study team will need to add information to the following specific orders to avoid potential protocol deviations as follows:

- For an ECG order: Need to add if ECG to be uploaded into Epic for Cardiologist to read or printed only and provide to study team.
- For all research blood draws processed by study team (not going to a lab for processing), add instruction for RN to document in RN research note the times of all blood samples collected.
- Include instructions for specific study data documentation required in CRF (i.e., record time of last meal in RN note, record observation period start and stop times in RN note, record time of study medication administered by study team (time-point 0) in RN study note, record 24 hour urine collection start and stop



Research Orders in the CTRC Job Aid

Effective Date: 3/20/24

Next Review: 3/20/26

Owner: Research SPL

times and volume in Epic I&O flow sheet, record amount of flush in Epic in I&O flow sheet and volume of blood collected for each sample in flush comment box)...

Home Medications for Participants in an Inpatient Bed.

- Participants who will require the continuation of their home medications during an admission will require study team instruction to bring with them the medications they need to take *in the original medication bottles and only bring the number of doses they need during the admission to avoid an added pharmacy count charge*. If the home medications are not in the original medication bottles, OHSU pharmacy will not be able to verify the medications and, in this case, the medications will be supplied from OHSU pharmacy stock and billed to the research study industrial account number.
- Study MD will need to create an order with detailed administration instructions for each home medication to be administered during study admission.
- Upon admission, the CTRC RN will request OHSU Pharmacy to verify the home medications and label the bottles for RN administration.
- Home medications will be stored in a room assigned locked box in the unit medication room.
- The RN will administer the home medications as ordered and document the administration in the Epic MAR.
- Upon discharge, the home medication bottle(s) with any remaining doses will be returned to the participant.