

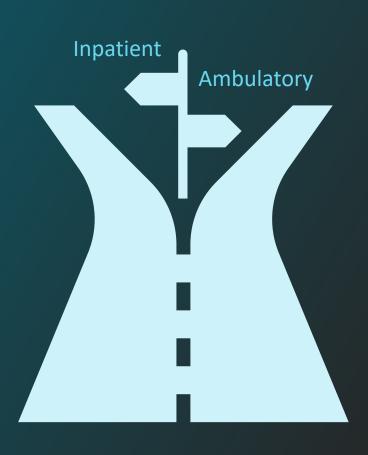


MD Orders on the CTRC

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This is a multipart training



- Start here
 - The first training "Research Orders on the CTRC" covers general principles and examples of writing MD orders for the CTRC.
- Next, complete either or both of the following trainings based on the types of study visits you plan to conduct on the CTRC:
 - Ambulatory Orders on the CTRC
 - Inpatient Orders on the CTRC

Research Orders on the CTRC Outline



Purpose of Research Orders



Content of MD Orders



Study Team Responsibilities



EPIC Environments (Inpatient, Ambulatory)

Purpose of MD Orders on the CTRC

 Communicate the research and medical (if applicable) care that a patient will receive during a visit/admission.

Orders are Critical for Safety and Study Quality

Participant Safety

 Orders must clearly outline all safety procedures and who to alert if adverse events occur.

Compliance

 Must clearly indicate which procedures are being done for research and for regular patient care.

Quality Study Data

- Clearly written orders support procedures conducted consistently and completely.
- Orders with errors will lead to protocol deviations and potentially adverse events.

- OHSU has several policies that outline requirements for the content of Research Orders in Epic
 - Content of the Integrated Health Record
 - Investigational Medication Dispensed to Research Subjects
 - Research Medication and Study Management Policy
 - Designated Record Set

Content of Research Orders

Research Order Content on the CTRC

If it isn't in the MD orders, it won't be done!

- Epic Orders are required for all study visits conducted on the CTRC.
 - Exception room only visits in the Outpatient Clinical Exam Rooms
- Orders must be clear, detailed, and congruent with the study protocol.
- Include all procedures you want the CTRC to complete:
 - Tests (e.g. ECG, labs, VS, sputum induction, etc.)
 - Medications to be administered/dispensed (investigational and other)
 - Treatments
 - Any other instructions relevant to the care of the participant
 - Specific documentation requirements (e.g. start and stop times of a vital sign rest period)

Research Orders Must be Complete and Understandable

If it isn't in the MD orders, it won't be done!

- CTRC RNs do not read your study protocol.
- Therefore, orders must describe all procedures in detail.
 - Orders including "tests as outlined in protocol" or "repeat" are not acceptable

Details of Research Order Content



The orders should be limited to the procedures you want the CTRC RNs to complete.

You may mention tasks completed by others if they impact the timing or sequence of CTRC procedures

"Study team will collect ECG at the end of infusion, then CTRC RN will collect the PK sample."



If procedures must be conducted in a specific way to comply with the protocol these details must be included in the orders.

Consider details such as handling of samples, timing of procedures, meal content/timing,

"opaque blinding to the entire study drug set during administration."

Research Orders CTRC Requirements

- Orders must be signed by an <u>IRB approved</u>, OHSU credentialed/privileged Principal Investigator or Co-Investigator.
- Order name should match the OCTRI Fee Agreement Visit name.
 - Required for billing accuracy and study set up

Examples of Bad CTRC Orders: Pax Gene Tube Draw

- "Draw the Paxgene tube per the protocol instructions then send to CTRC core lab."
 - Why is this unacceptable?
 - References instruction in materials outside of the MD order
 - Lacks Paxgene handling
 - Lacks visit information (visit name, etc.)

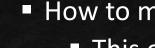
Good Example: Pax Gene Tubes

- Patient Name OCTRI visit name study protocol title, IRB#
- Draw samples after vitals are taken. Coordinator will provide labeled tubes. Collect red top tube first then PAXgene tube. Ensure the PAXgene Blood RNA tube is at room temperature prior to the blood draw. PAXgene tubes contain a chemical additive that can be harmful to the patient, so it is important to avoid possible backflow from the tube.
 - Draw a small amount of blood into a "discard tube" prior to drawing blood into the PAXgene Blood RNA Tube.
 - Hold the PAXgene Blood RNA tube vertically below the participant's arm during the blood collection.
- Allow at least 10 seconds for a complete blood draw and ensure the blood has stopped flowing into the tube before removing the tube from the venipuncture holder. swirl the tube 8-10 times to disperse the anticoagulant evenly through the sample.
- Observe collection site for irritation and call the study team (4-XXXX) to report any adverse reactions. CTRC staff will manage tubes post draw. PAXgene tube must be stored upright at room temperature for a minimum of 2 hours prior to storing in -20 freezer in CTRC Core Lab.

Examples of Bad Orders: Out of Scope Orders



- "Titrate infusion to maximum rate of 8mg/kg/hour"
 - Why is this bad?
 - It is out of scope for CTRC RNs to determine how and when to titrate an infusion.



- How to make this order acceptable?
 - This order should specify the number of titrations and calculated titrated rate and time-point each titration to occur.



- "Hypersensitivity Order #1-Guidelines for Ordering"
 - Why is this bad?
 - It is out of scope for CTRC RNs to determine what should be ordered.



- How to make this order acceptable?
 - A "Guidelines for Ordering" Order should be selected and include the specific guidelines.

Examples of Bad Orders: Missing Key Details

- "Visit 1 Collect 12 lead ECG, local read, print for coordinator"
 - Why is this bad?
 - No details on when the ECG should be done.
 - What ECG machine? Is this done on a CTRC machine or a study provided machine?
 - How to make this acceptable?
 - Include the following in the ECG Comment Section....

Visit 1 Collect 12 lead ECG using the CTRC ECG Machine. Collect ECG after patient has rested supine for 5 minutes (document rest time in the EHR). ECG to be read by cardiology; however, call Dr. Doctor 4-XXXX if the ECG output show abnormal results.

Note: If a professional read is requested CTRC cannot provide a copy of the ECG. The ECG will be available in Epic after the read.

Epic Environment Considerations:

 Orders are often available in both Ambulatory (outpatient) and Inpatient "environments" of Epic.

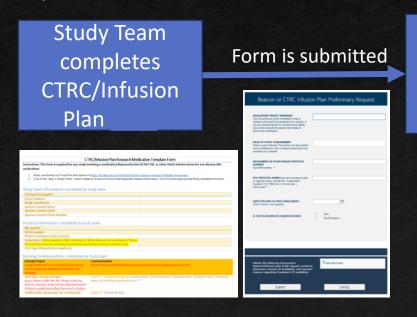


- Orders are not visible or transferable between Epic environments, so it is <u>critically important</u> that orders are entered in the same environment as the scheduled CTRC appointment.
 - For example, the CTRC RN would not be able to see ambulatory infusion orders if the patient was schedule in an inpatient chair/room.
- When scheduling on the CTRC confirm with the schedulers if the area you are requesting is Ambulatory or Inpatient to avoid significant study visit delays.

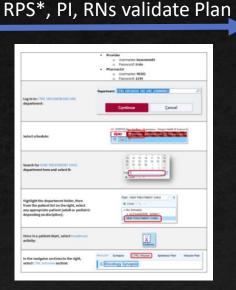
In this training we use "environment" to differentiate between inpatient and outpatient views (a.k.a, applications) of Epic.

Medication Orders and the CTRC- Infusion Plans

- The <u>CTRC Infusion plan</u> is used in Ambulatory and Inpatient areas for <u>all</u> routes of study medication administration, *not just infusions*.
- Infusion plan workflow:



RPS Reviews
Informatics
Builds Infusion
Plan



Informatics incorporates edits and releases Plan

^{*} Research Pharmacy Services (RPS)

Medication Orders and the CTRC- Infusion Plans

- CTRC RNs can only administer medications dispensed by Research Pharmacy and included on the Epic MAR (Medication Administration Record).
- Confirm all medications CTRC RNs will administer are included in the orders.
 - If the order isn't present and clear, RNs must request an MD verification of the medication order.

Medication Orders and the CTRC Self Administered Medications

- For Medications self-administered by the participant or administered by the study team, study teams should work with Research Pharmacy and CTRC to determine if an <u>Infusion Plan</u> is needed.
- Nursing Communication Orders should describe self-administered medications.
- Epic MAR (Medication Administration Record) are not created for non-RN administered medications on the CTRC.
 - CTRC RNs will not document self-administered or study team managed medications unless the order includes instruction to document the administration in the RN note.

- An IRB approved provider must review and sign research orders.
 - The provider is responsible for verifying the orders match the IRB approved protocol.
- If orders are inadequate, or include errors, the study team must update orders and have them resigned <u>before</u> study procedures begin.
 - CTRC staff must have a signed order <u>before</u> they can provide services.
- To avoid problems:
 - Take the appropriate Epic for Research Trainings.
 - Have Epic access to place orders in the appropriate Epic environment.

Study Team Responsibilities

Study Team Responsibilities, Continued

- To avoid delays and protocol deviations, study teams must:
 - Provide orders to the CTRC 48 hours prior to a visit.
 - This allows the CTRC staff to prepare for visits, review orders and ask for clarification prior to the participant arriving
 - If you randomize participants the same day as the first dose of study medication, call the CTRC Nurse Station <u>ASAP</u> after randomization.
 - An Epic hard stop prevents the CTRC RNs from releasing the order until they confirm randomization
 - Scan consent forms into Epic or show them to the CTRC staff before the study visit.
 - RNs must verify consent was obtained before study procedures begin

Streamlining Ordering

- Study teams can request <u>Epic for Research built Smartsets</u> (outpatient)/Ordersets (inpatient).
- Smartsets/Ordersets serve as a one stop "shopping list" of orders, procedures, diagnostics, medications, etc. that can be selected and signed all from on one screen.
- Providers can build their own Order Preference Lists .

Ad Hoc Orders

- Research Communication is an order that can be used for procedures that are not in the Epic catalogue.
 - Also used for Ad Hoc requests such as extra labs to be processed by OCTRI lab.
 - Prior CTRC approval is required for requests outside the CTRC fee agreement.



- The Research Communication should be added to the appropriate Ambulatory or Inpatient environment.
- Procedures in the Epic catalogue such as OHSU central labs or 12 lead
 ECG should be entered as usual in Epic
 - Inform the CTRC staff of any additional orders that were not included in the original request (e.g. not on fee agreement and/or visit calendar)

CTRC has:

- An Outpatient Clinic with exam rooms
- Infusion room (inpatient and outpatient)
- Inpatient unit



- Know which Epic environment your study visits will occur in (inpatient/ambulatory).
 - There are different documentation requirements based on the Epic environment

Epic Environments and Research Orders

CTRC Epic Environments



Inpatient

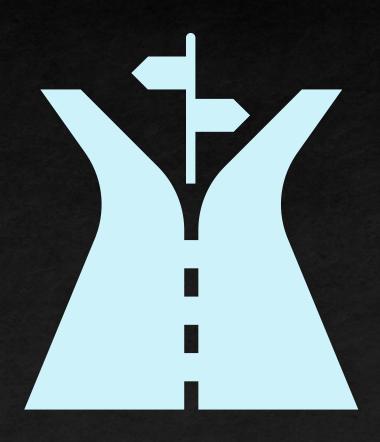
Generally, includes overnight and day patients.



Ambulatory (outpatient)

Generally, includes short procedures on the CTRC.

Research Orders in Epic Environments



- Confirm whether your visit will be scheduled in an ambulatory or inpatient environment
 - contact <u>octrisch@ohsu.edu</u> to confirm
- If orders are placed in the wrong environment, the CTRC nursing staff will not be able to see the orders
 - If this happens you need to enter new orders as they cannot be transferred across Epic environments
 - This will delay your study visits

Your Next Trainings

For more training and tips on the different Research Orders click below:

- Inpatient
 This link will take you to the training for CTRC Inpatient Orders.
- Ambulatory: This link will take you to the training for CTRC Ambulatory (outpatient) orders.

Be sure to take the Epic trainings and refer to their tip sheets along with these trainings.

Inpatient Orders

- In this training we will cover <u>CTRC</u> Inpatient Orders
- Inpatient Orders can come from CTRC Infusion Plans, Ordersets, or Order Preference Lists.
- Take the Epic trainings in Compass and refer to the tip sheets if you need more information
 - Placing Research Orders
 - CTRC Dept Research Orders
 - CTRC Dept Infusion Orders

Inpatient Orders – where to start

- Review Epic for Research guidance documents.
 - Placing Research Orders
 - CTRC Dept Research Orders
 - CTRC Dept Infusion Orders
- Request a <u>CTRC Infusion Plan</u> for any medication administered by the CTRC Staff
 - Research staff must know which environment each visit will occur (inpatient or ambulatory).
 - You need to speak to both the CTRC <u>and</u> Pharmacy staff to determine which is appropriate!
- You may need Infusion Plan orders and additional orders from an Orderset or preference list.
- Sticky notes are not an order and will not be accepted as an order.
- Orders for clinical procedures should follow the inpatient order instructions.

Inpatient Orders – what to include



- Inpatient orders require:
 - Research Admission order
 - Code Status
 - Diet orders from OHSU Food and Nutrition servicesOR
 - A Research Communication order for OCTRI Bionutrition meals or other non-OHSU Food and Nutrition services meals
 - Discharge order
 - Note: Research admissions do not require a study MD signed Discharge Summary. For more information see OHSU DRS policy

Inpatient Order Content

- Orders must be clear, detailed, and congruent with the study protocol.
- Include all procedures you want the CTRC to complete (tests, medications, treatments) and any other instructions relevant to the care of the participant.
 - Use a Research Communication order for all in unit Point of Care (POC) CBG, UPT, UA or Hematocrit/Hemacue/Hemaglobin procedures.
- CTRC RNs do not read your protocol; therefore, you must include any protocol specified documentation requirements in the orders.

Protocol Specific Details

- Include protocol specific requirements in the orders, for example:
 - "Collect blood from the arm opposite to the peripheral IV."
 - State if study provided or CTRC equipment will be used "Collect 12 lead ECG using the CTRC ECG Machine."

Protocol Specific Details

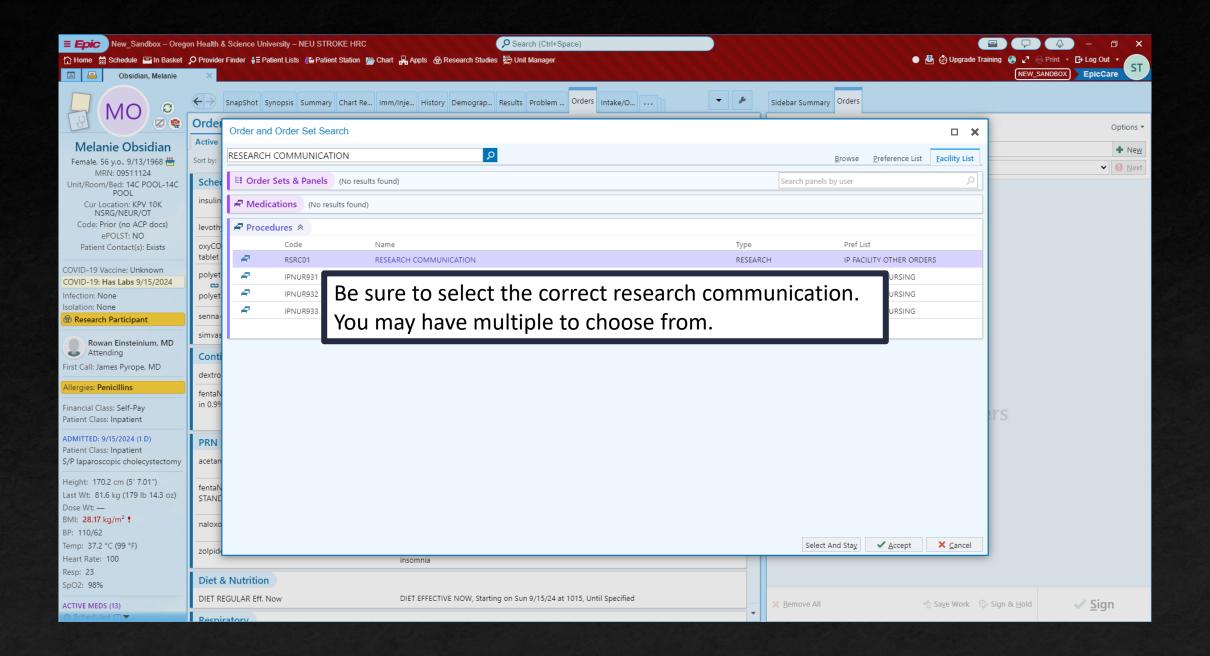
- If timing is important in your study, include the timing and the documentation requirements, for example:
 - "Participant must rest for at least 10 minutes prior to 6 minute walk test. Document rest start and stop time. During this rest period document blood pressure, heart rate, oxygen saturation, and any complaints of baseline dyspnea and fatigue"
 - "After the infusion, draw blood samples for pharmacokinetic testing every 8 hours +/- 30 minutes. Record collection times in RN note."
 - "A 30 day supply of study drug will be dispensed to participant prior to arrival on CTRC. The study team provided instruction on taking this oral medication. Document the time the study drug is taken"

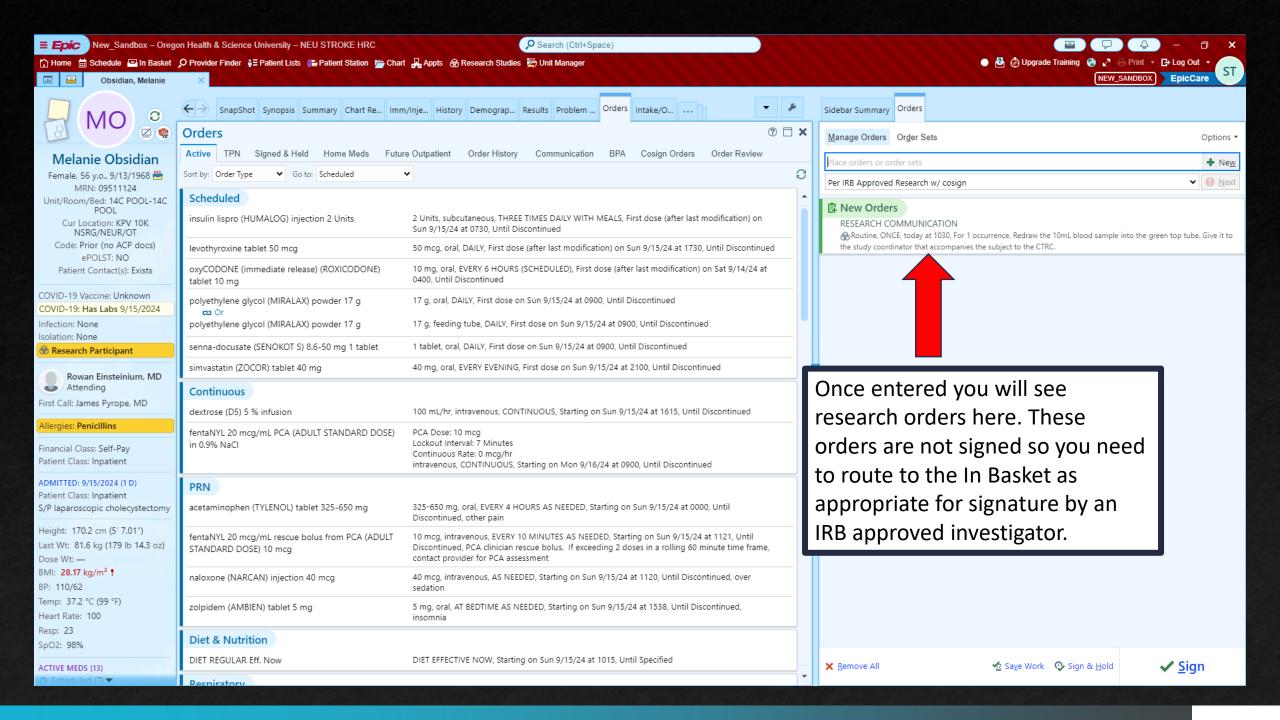
Patient Care Details

- Include an order for peripheral IV placement if there will be infusions or multiple blood draws
- •Include any instructions for flush start time, stop time and volume for study medication infusions
 - "flush the peripheral IV every 8 hours"
 - Note: Peripheral intravenous line flush is a standard procedure not included in the Epic MAR for RN documentation.

Research Communication Orders

- Research Communication orders are required for the following:
 - Point of Care (POC) testing:
 - Capillary Blood Glucose, Urine Pregnancy Test, Urinalysis or Hematocrit/Hemacue/Hemaglobin procedures
 - Additional information not otherwise included in the Epic orders
 - "Perform HGC urine test for women of childbearing potential. If positive, stop procedures and contact study team 4-XXXX"
 - "After blood is drawn the study team will need an exam room for about 1 hour to interview the patient"
 - Instructions for sample handling (e.g. OCTRI lab or processed by study team) and timing of draws if needed
 - "Draw 7.5mL EDTA and 10 mL Lithium Heparin vacutainers. Transfer blood to study coordinator for transport and processing." Please provide directions that include who is responsible for managing tubes, or which lab will process the samples.





Ambulatory (outpatient) Orders

- In this training we will cover <u>CTRC</u>
 Outpatient Orders
- Be sure to take the EPIC trainings and refer to their tip sheets along with this training
 - Placing Research Orders
 - CTRC Dept Research Orders
 - CTRC Dept Infusion Orders
 Pend & Send Ordering *new

Ambulatory Orders – where to start

- Review Epic for Research guidance documents
 - Placing Research Orders
 - CTRC Dept Research Orders
 - CTRC Dept Infusion Orders
- Request a <u>CTRC Infusion Plan</u> for any medication administered by the CTRC Staff (if needed)
 - Research staff must know which environment each visit will occur (inpatient, ambulatory)
 - You need to speak to both the CTRC <u>and</u> Pharmacy staff to determine which is appropriate!
- Complete an <u>online request form</u> to have the Epic for Research Team build you for a SmartSet
- Review Epic for Research Pend & Send Ordering *new
 - Do Not use for medication or inpatient orders

Ambulatory Orders – what to include

- Orders must be clear, detailed, and congruent with the study protocol.
- Include all procedures you want the CTRC to complete (tests, medications, treatments) and any other instructions relevant to the care of the participant
 - Use a Research Communication order for all Point of Care (POC) CBG, UPT, UA or Hematocrit/Hemacue/Hemaglobin procedures
- CTRC RNs <u>do not</u> read your protocol; therefore, you must include any protocol specified documentation requirements in the orders



Protocol Specific Details

- Include protocol specific requirements in the orders, for example:
 - "Confirm patient fasted and refrained from alcohol and caffeine for 12 hours prior to specimen collection. If participant has eaten food, consumed alcohol or caffeine, contact the study staff."
 - State if study provided or CTRC equipment will be used "Collect 12 lead ECG using the CTRC ECG machine."

Protocol Specific Details

- If timing is important in your study, include the timing and the documentation requirements, for example:
 - "Participant must rest for at least 10 minutes prior to 6 minute walk test. Document rest start and stop time. During this rest period collect blood pressure, heart rate, and oxygen saturation, and any complaints of baseline dyspnea and fatigue"
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 - Instructions for sample handling (e.g. OCTRI lab or processed by study team) and timing of draws if needed
 - "Draw 7.5mL EDTA and 10 mL Lithium Heparin vacutainers. Transfer blood to study coordinator for transport and processing." Please provide directions that include who is responsible for managing tubes, or which lab will process the samples.
 - Include timepoints for research labs as appropriate

