OREGON CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE

Guide to Accessing CTRC Nursing Services

The OCTRI Clinical and Translational Research Center (CTRC) is committed to facilitating interdisciplinary clinical investigation and provision of holistic, specialized nursing care within an environment that patients, families, and investigators recognize as exceptional.

WHO CAN BENEFIT FROM THIS GUIDE?

This guide was developed for study coordinators, investigators, and research staff who are utilizing CTRC Nursing Services for a clinical research protocol.

WHAT TYPES OF INFORMATION DOES THE GUIDE CONTAIN?

This guide contains detailed information about how to set up an inpatient or outpatient research protocol with the OCTRI CTRC.

CTRC GUIDE TO IMPLEMENTING YOUR PROTOCOL

Setting up a Study Prior to Scheduling Participant

Prior to scheduling participants on your study in the CTRC, we need to review your protocol and request for services to prepare an OCTRI Fee Agreement and ensure that we can meet your needs. If you have questions about how to submit a request for services please contact the OCTRI Navigator (octri@ohsu.edu). Once you submit a request for services, an OCTRI project number will be assigned to your protocol. Please reference this number in all correspondence regarding your study.

Prior to scheduling visits for your study, your project must go through the following steps:

- Signed Fee Agreement and IRB & OCTRI approvals obtained
- Study Calendar Build: See below
- Study Orders: See below
- Complete Study Research Guide: See below
- Complete a Study Initiation Meeting with the CTRC (preferably 1-2 weeks prior to the first visit). A Protocol Synopsis, Study Orders, Fee Agreement, Research Guide and Scheduling Guidelines will be reviewed during this meeting. See below.

CONTACT OCTRI CTRC

This is the best single point of access to CTRC nursing services in the 10D Hatfield Research Unit:

octrisch@ohsu.edu

This account is monitored by CTRC research staff Monday – Friday from 7:00 a.m. to 3:30 p.m.

PERSONNEL

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503.494.6277

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RNs on 10D

For questions/issues concerning currently admitted participants:

p: 503-494-7602

CTRC OPERATING HOURS

OUTPATIENT CLINIC
7:00 a.m. – 3:30 p.m.

INPATIENT CLINIC
24 hrs/7days a week

Please inquire about any scheduling needs that are outside of these standard hours to see if they can be accommodated.

Submitting a Study Using the CTRC to the IRB

When a new study utilizing the CTRC is started in the eIRB, you must indicate in the IRQ that there will be clinical services performed if ANY of the clinical services will be performed in the CTRC. You must also indicate that your study will utilize CTRC resources (under Ancillary Reviews and Notifications).

Building an Epic Study Calendar

The Epic calendar, a list of the study visits contracted in the fee agreement and assigned to each scheduled CTRC encounter, will be requested by the CTRC Navigators and built by the Epic Research team. Please note, the build can take up to 10 days and the Epic Research account, which is created once the study is approved in eCRIS, is required to release the calendar for use in the study.

Protocol-Specific Physician Orders

MD orders for research procedures completed by CTRC staff are required. Orders are created by the study team and must be signed by the PI or co-PI with privileges to practice medicine at OHSU. In the event the PI is not an MD/DO, an MD/DO or equivalent with privileges to practice medicine at OHSU and listed as personnel on the IRB approved study submission must sign all orders. The type of order created will be determined by the CTRC setting utilized. MD order types include: Preference List/Smartset (for studies without medications) or CTRC Infusion Plans (for studies with medications). Refer to the CTRC Research Job Aid and OCTRI Training and Education for Clinical Research Staff.

CTRC Outpatient Clinic: If study visits are scheduled in our Outpatient Clinic (OPC), the study team will create a Preference List (study team created and managed) or Smartset (built upon study team request by Epic Research). If an OPC study visit also includes a CTRC RN administered medication or treatment, see Infusion Room/Inpatient Unit orders below.

- Orders to include the specific study procedures completed by the CTRC staff for each visit as described in the study Fee Agreement. CTRC staff will document the procedure specific data collected.
- Orders to describe ancillary study specific documentation to be completed in the medical record by CTRC staff. The ancillary documentation requested should match the documentation requested in the CRF.
- Visit name(s) in the orders need to be the same names listed in the Fee Agreement.
- Include collection instruction for all lab samples.
- Send the CTRC a copy of the finalized orders prior to the Study Initiation Meeting (described below).
- Refer to the CTRC Research Job Aid noted above for guidance in the study order process.

Infusion Room or Inpatient Unit: If the study visit(s) include a medication(s), a medication administration visit will be scheduled in our Infusion room or Inpatient unit (as contracted in the Fee Agreement) and will require a CTRC Infusion Plan.

If the study visit does not include a medication(s) administration and does include CTRC RN only procedures (excluding aerosol generating procedures), the visit will be scheduled in our Infusion Room or Inpatient Unit (as described in the Fee Agreement) and will require a Preference List of Orders or a Smartset Order.

- Orders to incude the specific study procedures completed by the CTRC staff for each visit as described in the study Fee Agreement. CTRC staff will document the procedure specific data collected.
- Orders to describe ancillary study specific documentation to be completed in the medical record by CTRC staff. The ancillary documentation requested should match the documentation requested in the CRF.
- Visit name(s) in the orders need to be the same names listed in the Fee Agreement.
- Include collection instructions for all lab samples.
- Send the CTRC a copy of the finalized orders prior to the Study Initiation Meeting (described below).
- Refer to the CTRC Research Job Aid noted above for guidance in the Study Order process.

Please see the Epic Research page to access tips and toolkits for entering research orders into Epic

Study Specific Research Guide

The Research Guide is a document of pertinent information for the CTRC completed by the study team. CTRC staff do not read the Protocol, lab manuals or IBs.

CTRC staff follows MD study orders and utilizes the Research Guide as a resource during the study visits. The CTRC will provide the template once the Study Initiation Meeting has been requested by the study team. The study team will manage updates to this guide as needed and provide the updated versions to the CTRC.

The Research Guide includes the following information:

- OCTRI Protocol Number
- IRB Number
- Protocol Title
- Protocol synopsis
- Study Medication Information
- Study Medication known side effects
- Study Team information and contact numbers
- Key Study Information
- Lab information
- Diet information

*Send the CTRC a copy of the completed Research Guide prior to the scheduled Study Initiation Visit.

Study Initiation Meeting

Once the study has received IRB and OCTRI final approvals and prior to scheduling the first study visit, the study team will need to schedule with the CTRC a Study Initiation Meeting. Dependent upon the CTRC setting used for the study visits. The CTRC Specialty Practice Leader, Outpatient Clinic SRA(s) and the Unit Manager may attend the meeting. The PI is not required to attend the meeting, although their attendance is highly recommended.

RN's are invited to listen in and ask questions during these meetings.

The study initiation meetings will be recorded for staff to watch at a later time.

The following will be reviewed during this initiation meeting.

- Study staff and CTRC introductions
- Study background, what you hope to learn, and details of the participant population
- Procedures of the study
- Review of the MD orders, Fee Agreement, Research Guide, Scheduling Guidelines
- Lab instructions as needed
- Orientation to any special equipment, or special needs of the participant. Study supplied equipment to be utilized by CTRC staff will require an additional training meeting with study staff and the CTRC Research SPL, Resarch United Based Educator (UBE) and/or Outpatient Clinic SRA(s).
- Q&A

*Once all of the above requirements are completed, the study team can begin to schedule study visits.

Scheduling Participants & Preparing A Study Visit

Pre-Scheduling Requirements:

- Before scheduling a patient for their first visit in the CTRC all participants must be registered by OHSU. Registration to get an Medical Record Number (MRN).
- Additionally all participants must be enrolled in the OHSU Clinical Trial Management system (CTMS) prior to scheduling their appointment at the CTRC.
- Epic will be updated with a nightly batch file with the research association.
- If a patient has not yet signed an informed consent form, the Study Staff should request that a Pre-Consent status is applied to the patient in Epic by the CRBO (note: this links the patient to the study in a pre-active status) by completing and sending a Research Subject Pre-Consent Status form to the CRBO. Confirm that the research flag has been created for the subject in Epic prior to sending a request to schedule, as the CTRC cannot schedule a research subject until this flag is activated.

How to Schedule a Visit:

Once you have completed the above, to schedule a study visit, **send email requests** to OCTRI Scheduling.

- Please schedule your participants as far in advance as possible, since all visits are subject to staff and space availability.

- Scheduling staff will respond to your requests as soon as possible, please allow for up to 48 hours. If you need a more immediate response, please send your message "high importance" and we will respond the same day, or next business day if you inquire after 1550.

- For studies that demonstrate a need, holds may be placed on the schedule to ensure availability of space and staff for a specific visit.

- Holds will be lifted 3 weeks prior to use date unless we have a participant name confirmation from study staff. This timing may be flexed if required by the protocol.

- If you are not able to make your appointment with less than a 24 hour M-F notice, in addition to emailing OCTRI Scheduling. Please also call the CTRC Outpatient Clinic at 503-494-0150 (if after hours please leave a message). Or the CTRC Inpatient Nurses' Station at 503-494-7602 as appropriate for the appointment setting.

Preparing for a Study Visit

Once you have a study visit confirmed in the CTRC, please complete the following:

1. Tubes, labels or other supplies provided by the study (if any). We request the supplies be provided to the CTRC at least 2 days ahead of an Infusion Room or Inpatient study visit and the day of a visit in the Outpatient Clinic.

2. For Infusion Room and Inpatient Visits - Informed Consent Forms in Epic. See details below.

3. Epic orders must be signed prior to the day of the visit to avoid delays.

Informed Consent Form

The Informed Consent Form (consent form) must be signed by all required parties prior to the start of any study procedures.

You may also schedule participants for the consenting visit in our areas, but our staff may not begin the admission process or the study procedures until the consenting process is complete.

For minimally-invasive procedures, our staff will verbally confirm that the participant has signed a consent form prior to beginning any procedures.

For any procedures more than minimally invasive, our staff must first view the signed consent form. If your study has multiple visits, our staff is required to view the consent form for each visit.

Per OHSU policy, research consent forms are to be scanned into Epic. By having your participant consent forms scanned into EPIC, our staff will be able to view them prior to each visit. You will be asked to provide the consent form prior to our staff initiating study procedures if it is not filed in Epic.

Medical Staff Coverage Considerations

A medical staff person who is listed on the IRB Submission must be available by phone or pager anytime a participant is in the CTRC. For some studies, based on risk of the intervention, the medical staff must be on campus to respond to a medical emergency during the participant visits. We will assess the need for such requirements on a study by study basis.

MEDICATION CONSIDERATIONS

Study Medications

If the visit involves medications, make sure the diagnosis v70.7 (Examination of participant in clinical trial) is listed on the patient's Problem List. If not, have someone associated with the protocol (Principal/co-Investigator, or other LIP listed on the study) add the diagnosis to the patient record prior to placing medication orders. They should also add any study medications to the patient's medication list. Pharmacy cannot apply the CTRC Infusion Plan or release the medications until this diagnosis is on the patient's Problem List.

Study medications for participants are delivered to our unit by either a member of the study team or by Research Pharmacy Services (RPS) as arranged by the study team.

Medications Brought From Home

Inpatient

- When a participant is to be admitted as an Inpatient, there are special OHSU-mandated procedures for any medications they take while admitted. Please refer to OHSU Healthcare Policy Patient's Personal Medication when Admitted for Research (HC-MMM-171-POL).
- The medications must come to the unit in their original and labeled containers.
- Instruct your participants to bring only the amount of each home medication needed for the admission to avoid an OHSU pharmacy pill count charge.
- All home medications will be verified by an OHSU Pharmacist.
- Powders, liquids and inhalers must be in new sealed containers (otherwise, they cannot be verified).
- No narcotics, or any schedule 2 or 3 medications are allowed to come from home. They must be ordered for the participant from the OHSU Pharmacy. Please provide our staff with a valid Industrial account number to cover the cost of these medications.

Outpatient

Outpatients may bring medications from home. These medications do not require pharmacy verification.

DURING THE CONDUCT OF YOUR STUDY

Protocol Modifications

If there are IRB approved modifications to your protocol that affect nursing staff activities in caring for your participants, we will need to meet with you briefly to discuss them. The MD may also need a modification to the fee agreement to reflect the changes and we may need to modify our internal documents as well. It is the responsibility of the study staff to alert CTRC staff of these changes and the date when they are to be effective.

Lab Specimen Handling Considerations

The three labs most commonly used by OCTRI Clinical Research Studies are listed below with their hours of operation and methods of specimen delivery.

For specimen-processing needs after hours and on weekends, please alert OCTRI Scheduling when you confirm the visit.

OCTRI Core Laboratory

- M-F 0700-1600
- Hand deliver to lab

OHSU Clinical Pathology

- All days All hours
- Pneumatic tube

OHSU Lipid Lab

- M-F 0930-1730
- Hospital Transportation, Pneumatic tube

CAREGIVERS, FAMILY MEMBERS, AND VISITORS

Caregivers

For participants who need to come to 10D with caregivers, please make arrangements with the scheduler at the same time you schedule your participant visit. We will do our best to provide suitable accommodations for the caregiver.

Visitors

As a general rule, a participant may have visitors during their study visit on 10D. Visitors may not stay overnight, and are expected to leave the unit by 2300. Food is not provided to visitors, but there are many food service areas on the OHSU campus where they may purchase meals and snacks. Pediatric visitors present special concerns to our unit in terms of their safety. We require children to be closely attended at all times, be escorted if they leave the unit, and leave the unit by 2300.

The CTRC staff may exclude a visitor at their discretion if the visitor's presence interferes with study procedures.

CANCELLATION POLICY

Greater than 24 hour notice:

- Please email OCTRI Scheduling:

If less than 24 hour notice:

- Outpatient side: In addition to emailing OCTRI Scheduling, please also call the clinic desk at 503-494-0150. If after hours, please leave a message.
- Inpatient, Infusion Services, and Day Patients with RN services: Please call the nursing station at 503-494-7602. If given enough notice, we can also, upon request, inform the pharmacy of the cancellation to prevent mixing/ preparing of the research study drug. Please email OCTRI Scheduling. Nursing staff are NOT able to cancel or reschedule study visits.

OTHER THINGS TO NOTE

Epic Usage in the CTRC

EPIC currently does not support the documentation of the following information: for orders.

- Research labs collected and processed by OCTRI Lab, Lipid lab or study staff
- Certain types of study meal information

The CTRC will create a lab requisition or other source documentation to capture information not applicable to Epic documentation. This will be discussed during the Study Initiation Meeting.

Post-Study Flow Sheet & Document Handling

Any health information that is created or received by OHSU is considered Protected Health Information (PHI) and is stored electronically in a secure environment by OHSU Health Information Services (HIS).

- All original source documents will be recorded in Epic in the scheduled encounter for Infusion Room and Inpatient study visits. Exception: 1) research labs processed by OCTRI Research Lab will be recorded on a CTRC generated OCTRI Lab Requisition document for Infusion Room and Inpatient study visits. 2) OPC may utilize paper flowsheets for study visit data documentations, including lab sample collection information, which will be provided to the study coordinator at the end of a study visit.
- The original OCTRI Research Lab Requisition will be sent to the OCTRI lab with the final samples collected at each study visit. A copy of the Requisition will be sent to HIS by the CTRC RN.
- A study team copy of an OCTRI Lab Requisition may be acquired from the participant Epic record in the Media tab or requested from OCTRI Research Lab.
- Study staff may view CTRC documented study data in the participant Epic chart encounter. Contact Epic help desk for assistance in viewing.
- Documents that are not part of the permanent medical record or that cannot be entered into the medical record will be provided to you directly. Printed ECG's not submitted for cardiology read via Epic are an example of this document type.