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:

- IRB & OCTRI approvals obtained
- Study Calendar set-up in Epic (takes up to 10 business days)
- If the study involves medication(s) administered in the CTRC, have a Therapy Plan built in Epic by Investigational Pharmacy
- A study initiation meeting with CTRC staff (see below for details)

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

Sue Downs, R.N.
Nurse Manager
downss@ohsu.edu
503.494.6277

Ellen Pillow
Nursing Services Coordinator & Inpatient and infusion services
pillowe@ohsu.edu
p: 503-494-0163

Wendy Molinar, R.N.
Outpatient Clinic Supervisor & RN Research Educator
nicholsw@ohsu.edu
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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.

- The Physicians' orders, study calendar and infusion plan have been finalized
- The in-service held (preferably 1-2 weeks prior to the first visit)

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 utilized CTRC resources (under Ancillary Reviews and Notifications).

Building an Epic Therapy Plan

If the study also involves mediation(s), the study will need a Therapy built in Epic as follows:

1. Upload the CTRC Research Medication Template Form in the eCRIS pharmacy smart form and also send it to Research Pharmacy at INVDRUGS@OHSU.edu
2. Once the study coordinator receives a final CTRC Research Medication Template Form and Epic catalog request from Research Pharmacy, complete the online template submission and include both the 'CTRC Research Medication Template Form' and 'Epic Catalog' sheet.
3. The study coordinator Coordinates validation in Sandbox with all identified reviewers (PI, RPS, etc.) and compiles and submits via email all edits back to Pharmacy Informatics to build and indicates if revalidation is needed.
4. When the Therapy plan is complete, the Study Coordinator will receive an email from Pharmacy Informatics notifying them that the plan is complete.

Building an Epic Study Calendar

The Epic calendar for the study will be requested by the CTRC and built by the Epic Research team. Please note, however, that the build can take up to 1 week and the Epic Research account, which is created once the study is approve in eCRIS, is required to release the calendar for use in the study.

Study Initiation Meeting (required for any studies using RN services)

When you receive the OCTRI Approval email for your project you will be instructed to contact the CTRC to set up an initiation meeting. Attendees to the meeting should be a CTRC staff member, the PI and/or study coordinator(s).

The initiation meeting is a forum for an informal discussion on the procedures you are requesting from the CTRC nursing staff. Note that if the scope of services has changed from the time of the initial request to the time of implementation, then your Fee Agreement may need to be amended to reflect the procedures and costs accurately.

Topics covered at the initiation meeting include:

- Detail of procedures for each visit
- Timing and location of visits
- Specimen handling needs
- Research pharmacy involvement
- Bionutrition involvement

- Physician orders

Protocol-Specific Physician Orders

MD orders for research activities in the CTRC will be on paper. The CTRC will provide guidance regarding how to develop your orders in the study initiation meeting. All orders 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. For all OHSU clinical services completed for your protocol in the CTRC, you will need to place orders in Epic.

Our staff are available to work with you in developing the paper orders for your protocol. For information regarding how to set up your electronic orders in Epic, please see the user guide "Epic Order Entry for Research Staff".

You may also need to develop a summary of nursing procedures for the study. The CTRC has electronic templates available to assist you in the development of this summary.

In addition to the study procedures, orders must also include:

- Principal Investigator
- Covering medical staff
- Participant name, DOB, MRN/Subject ID (except for Standing orders)
- Date of visit (except Standing orders)
- Code status
- Allergies
- Diet
- Protocol number and title
- Participant diagnosis
- Procedure date(s)
- Medical staff original signature/date signed or Epic electronic signature

Internal Documents Utilized to Support your Protocol

Our staff will create documents which we use to help us prepare for and perform your protocol. We require a minimum of one full week to create the internal documents once your orders are finalized. These documents may include:

- Nursing flow sheets
- Protocol guide
- Lab requisitions
- Specimen and chart labels

We will need your finalized orders to prepare our flow sheets and other documents. These documents along with the Physician's Orders will be reviewed at the In-service

In-Service Meeting

1-2 weeks prior to the first scheduled study visit, an in-service will be conducted with the CTRC. Once a date is identified, the CTRC will send an In-service appointment request via email to the PI and study staff, the CTRC RN educator, lab staff, bionutrition staff and to the research pharmacy if needed. The PI is required to attend the in-service meeting. At the In-service, we cover the following:

- Study staff and CTRC introductions
- Study background, what you hope to learn, and details of the participant population
- Procedures of the study, orders and flow sheets
- Needs of the lab, bionutrition, research pharmacy, as appropriate
- Orientation to any special equipment, or special needs of the participant
- Q&A

Once the Epic Study Calendar and Therapy Plan, if applicable, are complete, participants can be seen in the CTRC.

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 eCRIS 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: octrisch@ohsu.edu. Please follow the guide found here for the format for participant scheduling requests.

- 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 1530.

- 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 protcol.

- 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 clinic desk at 503-494-0150 or the nurses' station at 503-494-7602**. If after hours, please leave a message.

Preparing for a Study Visit

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

1. Tubes, labels or other supplies provided by the study (if any).

2. Copy of the signed Informed Consent Form (see below), unless it is available to view in EPIC.

3. Physician's orders

Participant specific orders: Original paper orders signed by the PI/credentialed study staff, must be delivered to 10D 2 business days prior to the visit. If you are not able to deliver original orders to the unit within this time frame, please fax the signed originals to the unit and bring the originals at a later time, but no later than the start of the visit. Orders placed in Epic must be signed prior to the day of the visit.

Informed Consent Form

The Informed 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 seek confirmation from the participant that s/he has signed an Informed Consent Form prior to beginning any procedures.

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

Informed consent forms must be scanned into Epic. By having your participant consents scanned into EPIC, our staff will be able to view them prior to each visit. We suggest you send copies of the signed consent to HIS as soon as possible in order to simplify the consent verification process.

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 Therapy 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 the Research Pharmacy Services (RPS). All research participants are to arrive on the HRC10D unit between the hours of 8am and 3pm to ensure medication order identification and verification can be completed.

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.
- They will be sent to the OHSU Pharmacy for verification
- 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. Administration of these medications during the research visit must be coordinated with the nursing staff. 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. We will also need revised Physician's orders to reflect the changes, and may need to modify our internal documents as well. It is up to 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 (octrisch@ohsu.edu) when you confirm the visit.

OCTRI Core Laboratory

- M-F 0700-1700
- 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 those arrangements with the scheduler at the same time you schedule your participant visit. We will do our best to provide suitable accommodation 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 by 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: octrisch@ohsu.edu.

If less than 24 hour notice:

- *Outpatient side*: In addition to emailing OCTRI Scheduling: octrisch@ohsu.edu, 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 inform pharmacy of the cancellation to prevent mixing/preparing of the research study drug. Please email OCTRI Scheduling: octrisch@ohsu.edu. Nursing staff are NOT able to reschedule; this is done through OCTRI scheduling.

OTHER THINGS TO NOTE

Epic Usage in the CTRC

The CTRC is not yet fully transitioned to using EPIC for orders. We currently document the following in EPIC:

- Adult admission database
- Inpatient medication administration record
- Inpatient documentation flow sheet
- Inpatient plan of care
- Discharge from the inpatient unit
- Medication orders

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 given to study staff at each visit for you to maintain and file for your study records.
- Copies of all source documents are forwarded to HIS at the end of the study, ***unless you have made special arrangements with us to do otherwise.***
- All source documents can be viewed in Epic, OHSU's electronic medical record.
- Documents that are not part of the permanent medical record or that cannot be entered into the medical record due to IRB requirements will be provided to you directly.
- If you require copies of any documents, please let the nursing staff know.