

CTRC Statement of Understanding
Scheduling Subjects in the CTRC (10/13/14)

As part of our move to the new location on Hatfield 10D, our scheduling processes have changed. The CTRC has begun scheduling all participant visits in Epic as of April 28, 2014. This change impacts CTRC visit scheduling in two ways:

1. We now require an OHSU medical record number (MRN) on all subjects
2. We now require that all subjects be linked in Epic to the study

Ideally, each subject will have both an MRN, as well as be linked to the study prior to the time of scheduling. To help facilitate understanding of our new processes we have created several informational documents:

- ✓ Additional Steps when Subjects are Scheduled at CTRC
- ✓ Instructions for Obtaining an OHSU MRN
- ✓ VA Study Patient Process
- ✓ Anonymous Patient Information

Steps when Subjects are Scheduled at CTRC

1. Study Staff -complete all steps below:

Submit the study to the IRB: When a new study is started in eIRB, it is important that to indicate in the IRQ that there will be clinical services performed if ANY of the services will be performed in the CTRC.(This is necessary to initiate the workflow within eCRIS that requests an industrial or zero charge account when the study receives all approvals and will necessitate the entry of a MRN for each subject enrolled.)

- a. Submit an OCTRI Resource Request form requesting CTRC services to the OCTRI Research Navigator
 - i. <https://octri.ohsu.edu/redcap/surveys/?s=jKxNzqKq3pm>
- b. If the study also involves medications, upload the CTRC medication order form in the eCRIS pharmacy smart form

- c. Access the CTRC Medication Template form on the OCTRI website. Send the request form to Research Pharmacy at INVDRUGS@OHSU.edu.

- i. <http://www.ohsu.edu/xd/research/centers-institutes/octri/resources/policies-forms/upload/CTRC-Research-Medication-Template-Form.pdf>

Note: We are utilizing Epic Therapy plan functionality for all medications that are given at CTRC (with the exception of take home medications). We need to start this process 6 weeks from when the subject will first be seen.

2. **CTRC** receives and reviews service request; provides cost estimate through OCTRI Navigator to study staff; sets up study initiation meeting (see CTRC Guide: Setting up a Study).
 - a. http://www.ohsu.edu/xd/research/centers-institutes/octri/working-with/accessing-resources/ctrc-guide-study-setup.cfm?WT_rank=1

3. Study Calendar in Epic

a. **CTRC**

- i. Completes the Excel template for the study calendar.
 1. Note - the IRB must be included and industrial account number, if available, to build the study calendar in Epic.
- ii. Email the completed form to the Epic research team at EpicResearchTeam@ohsu.edu
- iii. Please allow up to 10 business days for completion.

b. **Epic Research Team**

- i. Creates the Study Calendar in Epic and links it to the RSH Record when available
- ii. Replies to CTRC email to notify when the protocol is complete and available for use

If study involves medications:

4. **Research Pharmacy**

- a. Completes Epic Catalog Request form within 10 business days of receipt of completed CTRC Medication Template.

- b. Submits Epic Catalog Request form and order form documents to Pharmacy Informatics via Epic Help Desk

5. **Informatics Pharmacist**

- a. Configures build in Epic test environment
- b. Brings to CTRC Orders Committee for review (1st and 3rd Friday each month)
 - a. The Study Coordinator will be asked to attend and will receive an invitation to this meeting
 - b. Build is modified if applicable
- c. Release CTRC Therapy Plan within Epic Production and complete study specific order forms
- d. Email Invdrug@ohsu.edu, as well as the Study Coordinator, that the Therapy Plan is built and in Epic with a link to the final study specific orders.
 - a. Note: Study Coordinator still needs to follow through on the rest of the steps prior to the patient being seen.

6. **Study Staff** obtains IRB approval and receives Alias from SPA (Sponsored Project Administration) electronically through eCRIS, if applicable. Provides alias and FAID to OCTRI Navigator.

7. **Study Staff** receives an Industrial account electronically through eCRIS. Industrial account is created so we can link the patient to a study. There are two account types:

- a. Industrial account if charges are filed through Epic
- b. Zero charge industrial account (or dummy account) if there no billable services through Epic.

NOTE: As of July 2013, all studies start in eCRIS which will automatically process the correct account.

If study was not started in eCRIS and there is no industrial account assigned, Study Staff must contact the CRBO (crbo@ohsu.edu) to determine which account type is needed. CRBO will coordinate the account request through PBS.

8. **CRBO** populates the RSH record in Epic and forwards industrial account notification to Epic Research Team if necessary.
9. **CTRC & Study Staff** After OCTRI approval is received by CTRC and study staff (including study calendar build and Epic therapy plan build, if applicable), the study setup process for visits to CTRC may begin. Go to this link for details: <http://authoring.ohsu.edu/xd/research/centers-institutes/octri/working-with/accessing-resources/ctrc-guide-study-setup.cfm>
10. **Study Staff** starts identifying patients to participate on the study
11. **Study Staff** - before calling CTRC to schedule the patient for their first visit in CTRC:
 - a. Warm transfer the patient to OHSU Registration to get an MRN and current registration.
Note: This is a new process for those subjects being seen at CTRC; you will no longer be faxing an MRN Request form to HIM for these subjects.
 - b. If the study is not in eCRIS, request the CRBO to associate the patient to the Study in Epic by sending a study status change form to the CRBO.

- a. http://ozone.ohsu.edu/research/rates/RESEARCH_SUBJECT_STUDY_STATUS_CHANGE_FORM.docx
- c. Enter and enroll the patient in eCRIS. Epic will be updated with a nightly batch file with the research association.
- d. If 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 a study status change form (see link above) and sending it to CRBO.
 - a. NOTE: The study status change form must be completed and sent to CRBO in this instance regardless of if the study is in eCRIS.
- e. Confirm that the research flag has been created for the subject in Epic prior to sending a scheduling request.
 - a. NOTE: The CTRC cannot schedule a research subject until this flag is activated.

12. CTRC

- a. Scheduling is done thru the OCTRI Scheduling email address:
octrisch@ohsu.edu
- b. Adds the timeline to the patient the first time before scheduling
- c. Schedules the patient and links the patient to the Study Timeline

If medications are part of the visit:

13. Study Staff

- a. Ideally, if possible per the design protocol, before the first medication visit, but at a minimum prior to ordering medication (see below), Study Staff will obtain signed Informed Consent from the subject. Have signed Informed Consent form scanned into Epic

i. <https://ohsu.ellucid.com/documents/view/279>

- b. 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 faxing the medication orders. They should also add any study medications to the patient's medication list.

Note: Important - Pharmacy cannot apply the Therapy Plan or release the medications until this diagnosis is on the patient's Problem List.

14. Principle Investigator or LIP listed on the study will then order study medications using the final study specific CTRC medication orders, including medications approved to be continued from home on that patient and then fax the patient med orders to Research Pharmacy, if possible per the design of the protocol at least 2 business days prior to EACH visit at CTRC.

a. If you end up having to fax the orders on the day of the patient medication visit; once you know the patient will be coming in for their visit:

i. Fax the order form to Research Pharmacy

1. Research Pharmacist

- a. Applies the infusion plan to the patient
- b. Will let the CTRC Infusion Nurse know if meds need to be released prior to the patient arriving at CTRC by calling the CTRC Nurse Station at 4-7602 and asking them to tell the Infusion RN to immediately release the med orders.

ii. IMPORTANT NOTE: Once the medications have been prepared, the study is billed, whether or not the patient shows up.

b. Note: If the protocol design precludes advance ordering, please fax the medication orders as far in advance as possible.

- i. Note: some medications, due to preparation, may require longer than two days advanced notice.

15. **Note:** All investigational or EEG patients are to arrive on the HRC10D unit between the hours of 8am and 3pm to ensure medication order identification and verification can be completed.

16. CTRC Infusion Nurses

- a. Unless directed by Research Pharmacy and/or Study Coordinator to release the medications early, CTRC Infusion nurses will release medication orders when the patient arrives and is checked in through Cadence.

17. **Study Staff** may pick up medications from the Research Pharmacy prior to the patient's visit at CTRC or make arrangements to have medication delivered to CTRC prior to treatment.

Attachment 1

CTRC will be using some new Epic functionality to track study appointments that take place in the CTRC.

ONLY CTRC has access to this functionality at this time, but all users will see the changes.

Any study which includes patient visits in the CTRC will now have an associated CTRC Protocol. All CTRC outpatient and inpatient visits will be linked not just to the research study but ALSO to a specific point in the CTRC Protocol.

This CTRC Protocol and all encounters linked to it will now appear in the Research Studies activity alongside any other non-CTRC encounters that are linked to the study.

BEFORE:

Research Studies

Add a new study to list [Add](#) Show: R

Active

100097612 IRB 9333

Study Code: 100097612 Start Date: 10/15/2013
Principal Investigator: Joseph Quinn, MD

Study Description

Study Title: A Placebo-controlled, Double-blind, Parallel-group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study to Evaluate Safety and Efficacy of Donepezil in Subjects With Early Alzheimer's Disease. BAN2401-G000-201

Primary Contact: Monika Stanko x4-7615
Billing Indicator: All Services Paid
Research Industrial Account: 100097612
IRB #: 9333

Associated Encounters

09/24/2013	Appointment - Canceled	NEU AGING/ALZ CHH	Joseph Quinn, MD
10/15/2013	Research Encounter - Completed	NEU AGING/ALZ CHH	Joseph Quinn, MD
10/23/2013	HOV - Completed	RAD MRI HRC	
10/31/2013	Appointment - Canceled	NEU AGING/ALZ CHH	Joseph Quinn, MD
11/14/2013	Research Encounter - Completed	NEU AGING/ALZ CHH	Joseph Quinn, MD

AFTER:

Research Studies

Add a new study to list 

Show: In

Active

 100097612 IRB 9333 

Study Code: 100097612 Start Date: 10/15/2013
Principal Investigator: Joseph Quinn, MD

Study Description

Study Title: A Placebo-controlled, Double-blind, Parallel-group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study to Evaluate Safety of BAN2401 in Subjects With Early Alzheimer's Disease. BAN2401-G000-201

Primary Contact: Monika Stanko x4-7615
Billing Indicator: All Services Paid
Research Industrial Account: 100097612
IRB #: 9333

Patient Timeline and Associated Encounters

Display Options: By Patient Timeline By Encounter Date

 CTRC PROTOCOL 4281 (Ver. 2)  

Week 15-25

05/12/2014  Appointment - Scheduled CTRC INFUSION 10D HRC Ctrc Infusion

Week 15-25

05/27/2014  Appointment - Scheduled CTRC INFUSION 10D HRC Ctrc Infusion

Encounters Outside of Timeline

09/24/2013  Appointment - Canceled NEU AGINGIALZ CHH Joseph Quinn, MD

10/15/2013  Research Encounter - Completed NEU AGINGIALZ CHH Joseph Quinn, MD

10/23/2013  HOV - Completed RAD MRI HRC