EPIC Tools for Clinical Research

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UIHC Healthcare Information Systems
Epic Research Study
Records

Epic Research Study Request Process

Clinical Orders

Study Medication Orders – IDS Pharmacy

Smart Set/Order Set – HCIS ESC

Treatment Plan – HCIS ESC

Billing, Record of Consent & Reporting

Research Study Record in Epic - ICTS ICART
Epic Research Study Records

- Epic Research Study Request Process
- Billing, Record of Consent & Reporting
- Research Study Record in Epic - ICTS ICART
Billing & Record of Consent

Request Build of Research Study Record

- To be able to associate patients to a research study in EPIC, you must first have a Research Study record created.
- Please submit your request via the I-CART system managed by ICTS

https://i-cart.icts.uiowa.edu
Billing & Record of Consent

Associate Patients to Your Study

• Once a research record has been created, you can associate your patient.
• You must be listed as part of the study team to complete this action. (Step in the ICART request process)
• Patients can be associated via the Research Studies Activity.
  o Search for your study by IRB Number
Billing & Record of Consent

Associate Patients to Your Study

- Complete Appropriate Fields
  1. Coordinator
  2. Status (required)
  3. Active Start Date (required)
  4. Comments
Billing & Record of Consent

View Research Study Details

• Utilize the Research Studies Activity to view current study association details
  1. View Study Description (Record of Consent Details) and Enrollment Comments
  2. See past updates

![Research Studies Activity](image.png)
Billing & Record of Consent

View Study Associations

- Utilize the **Research Studies Activity** to view past study association details
  - By default, the Research Studies Activity only displays “Active” associations. Utilize the “Show” boxes to see other associations.
Research

Epic's research support features assist in setting up and maintaining research studies at the UIHC including research study patient tracking, research billing, and other features related to BestPractice Advisories and reports. The Research Study Maintenance activity allows research coordinators to create a record for each study that includes a study description and the individuals working on the study. The Research Studies activity is used to link a patient to one or more studies and track the status of the patient for each study.

Resources

The following resources provide information on Research functionality.

- Add the Research Studies to Your Toolbar - (Handout v. 2017) To quickly find the Research Studies activity, add it to the Epic toolbar.
- Create a Study Report - (Handout v. 2017) Reporting Workbench can be used to display patients that are associated with research studies and their enrollment status.
- Epic Research Study Application Form - (Web Form) Submit this form to describe the research study and initiate the process for using Epic to enroll eligible participants for your study.
- Identify and Link Research Studies to Encounters - (Handout v. 2017) The Research Study section within Registration can be used to determine if an encounter is related to a clinical research study. Encounters can then be manually associated with research studies, or flagged if the correct research study is not listed.
- Prevent Draw Charges for Research Study Specimens - (Handout v. 2017) For outpatients in clinical care areas, draw charges are automatically generated when a blood specimen is received into the Specimen Control Laboratory. If a Research Team member is collecting a study-only specimen and sending it to the Specimen Control Laboratory for analysis, they must complete these steps in order to prevent a draw charge from posting to the patient’s account.
- Research Studies (RES901) - (Video: 15 min v. 2017) An overview of research studies functionality including if a patient is eligible for (or already connected with) a research study, accessing the Research Studies activity to view or edit a patient’s status, and using reports to gather data from studies in which a clinician is involved.
- Research Studies Activity - (Handout v. 2017) The Research Studies activity allows research coordinators to manage patients associated with one or more of their studies. An “active” status appears in the patient banner for enrolled or consented patients within the screening process.
- Review Record of Consent Details & Staff Contacts - (Handout v. 2017) Now that OnCore interfaces with Epic, staff will need to use one of the following options to locate Research Study staff contact information and Record of Consent details for Oncology clinical trials.
Clinical Orders

Order Types

- Medication Order
  - After Visit: Prescriptions; will show on medication list for Patient
  - During Visit: Given during a visit at UIHC; will show on MAR for Nurses

- Procedure Order
  - Procedure orders can also be After Visit or During Visit
  - UIHC Procedure Order: Completed with UIHC workflows & billing
  - Research Procedure order: Completed without UIHC workflows & billing
Clinical Orders

Study Medication Orders

• Any medication that is supplied by the study will need an investigational (INV) medication record created in EPIC.

• Investigational Drug Services (IDS) Pharmacy will complete the request for this build in Epic.

• Indicate the use of an INV medication record in all other Epic Build requests.
Clinical Orders

Procedure Orders

- Research specific procedure orders should be utilized when UIHC services are NOT involved in obtaining results.
- Research specific procedure orders can only be found in Smart Set RSH: Research Standard Orders
Clinical Orders

Order Tools

- **Smart Set/Order Set**
  - Grouping of medication and procedure orders
  - RSH: Research Standard Orders available for low accruing trials with few visits. Can only be utilized through CRU encounters.
  - *Custom smart sets/order sets can be created specifically for your study*
  - Epic demo

*Not all trials will qualify for custom smart set/order set creation*
Clinical Orders

Custom Smart Set/Order Set

- Best for studies with multiple visits or large accrual volume.
- Can be used for any visit at UIHC.
- Easily place multiple orders at once.
- Orders released when the patient checks into their appointment.
- Orders need to be placed prior to each appointment.
- Custom Smart Sets can be created for your study. Turnaround time is approximately 2-3 months.
Clinical Orders

**Custom Smart Set/Order Set**

- Submit an ESC request under “Epic Assistance” then “Orders”.
- The following information **must** be included in your ESC ticket:
  - IRB #
  - Research Study Name
  - Date trial is open for accrual
  - Number of patients expected to accrue at our site
  - Attach the research protocol to ESC ticket
  - Name of study team members who will be responsible for validating the Epic build
  - PI and coordinator names
  - Names of users who will be placing/signing the orders from this research order set
  - List of all orders needed including details with workflow (meds, nursing, labs, etc.)
    - What specific Epic orders should be used?
      - Nursing, RT, radiology, meds etc.
      - During visit or after visit order?
      - Should it be defaulted?
      - Should the orders be sign and held?
      - For non-med orders please include: priority, frequency, any comments
    - Do you have a study medication order from IDS pharmacy?
      - What is the dose, route, frequency, comments etc?
    - What other medications are needed?
      - Please include Epic medication order, dose, route, frequency and any comments or additional details needed.
Epic Research Study Records

- Epic Research Study Request Process
- Clinical Orders
  - Study Medication Orders – IDS Pharmacy
  - Smart Set/Order Set – HCIS ESC
  - Treatment Plan – HCIS ESC
Clinical Orders
Order Tools

- Treatment Plan/Infusion Plan
  - Grouping of medication and procedure orders
  - Created specifically for your study
  - Only used in CRU visits
  - Epic demo

[Infusion Suite Therapy image]

- **TP Height**: None
- **TP Weight**: 75 kg
- **TP ESA**: 1.5 m²

- **Day 1, Cycle 1 – Planned for 9/11/2018**

- **TREATMENT PLAN DEFAULT SETTINGS #1**
  - Patients should receive etepilens once every 7 days starting on Study Day 1. A window of 3 days from the scheduled dose is acceptable after the first infusion. Patients may not receive 2 separate doses of etepilens within the same 60-hour period.
  - Nursing staff may change "planned date" to match actual scheduled dates up to 3 days before or after the original planned date.

- **Dose Modifications**
  - **DOSAGE MODIFICATIONS #1**
    - There is no precision for dose alteration in this study. See protocol section 9.4.1 for details.

- **TREATMENT PLAN INSTRUCTIONS #1**
  - Patient is to be observed for 1 hour post end of infusion.
  - Nursing staff to record V (oral temp) at the following intervals:
    - 30 min prior to infusion
    - 5 min post end of infusion
    - 30 min post end of infusion
    - 60 min post end of infusion

- **TREATMENT PLAN INSTRUCTIONS #2**
  - INV etepilens dose is to be based on weights obtained every 4 weeks. (Weeks 1, 4, 8, 12, etc.)
  - INV etepilens: INV-450 (PROMO INV-450-301 STUDY) 2,250 mg in sodium chloride 0.9% 100 mL IV bag
  - 2,250 mg (10 mg/kg = 75 kg Treatment plan weight), Intravenous, Once, Starting when released, For 1 dose

- **Supportive Care**
  - **HEPArin (q1) 10 units, flush syringe 30 Units**
    - 30 Units, Intravenous, As Needed, Flush per policy, Starting when released
  - **HEPArin (q1) 100 units, flush syringe 500 Units**
    - 500 Units, Intravenous, As Needed, Flush per policy, Starting when released
  - **sodium chloride 0.9% continuous infusion**
    - at 30 mL/hr, Intravenous, Continuous, Starting when released
    - As needed TKO for line maintenance.
  - **DSM continuous infusion**
    - at 30 mL/hr, Intravenous, Continuous, Starting when released
    - As needed TKO for line maintenance.
  - **HEPArin (q1) 10 units, flush syringe 50 Units**
    - 50 Units, Intravenous, As Needed, Flush per policy, Starting when released
Clinical Orders

Treatment Plan/Infusion Plan

- Best for studies that have multiple timed treatment visits in the CRU.
- Set up an entire plan of therapy at one time.
- Customize per patient need by adding and deleting orders.
- **Must be custom created for each trial.** Turn around time is approximately 1 month.
- Submit a an ESC request under “Epic Assistance” then “Orders”. Please specify “Treatment Plan” in the request.
- Copy of the protocol will need to be sent to Shara Power (shara-power@uiowa.edu)
- Dedicated study team member is required for validation and maintenance.
- May require additional Epic education.
Clinical Orders

EPIC Education Resources Orders
https://hcis.healthcare.uiowa.edu/EpicSupport/resources/modules/orders/orders.html

Orders

Order Entry is a process of electronic entry of medical practitioner instructions for the treatment of a patient. Orders are used for many areas including pharmacy, laboratory, radiology, communication, and procedures. Orders can be placed individually or as part of a group known as Order Sets/SmartSets. The Manage Orders Activity is used for reviewing and placing inpatient orders.

Resources

The following resources provide information on Order Entry functionality.

Ordering Basics

- **LIP Add-On Ordering Workflow** - (Handout v. 2017) This document provides how to add orders to recently collected specimens. This new add-on feature allows providers to recognize and add orders to existing specimens that match the tube and specimen type of the new order.
- **Placing Orders Quick Reference Guide** - (Handout) Assists clinicians with determining type of order and different ordering workflows.

Ordering Efficiency

- **Associate Diagnoses While Signing Orders** - (Handout) While writing orders, you can associate your orders with diagnoses when you sign the orders, rather than before. You can also order new diagnoses at the same time.
- **Create an Order Preference List** - (Handout) Create preference lists to include orders that have been saved as favorites. This will decrease the time needed to place orders and increase efficiency.
- **Find Orders and Save Your Favorites** - (Handout) Efficiently finding and placing orders can help speed up your workflows. Add the orders you place most often to your preference list for quick access in the future.
- **Setting Multiple Orders** - (Handout v. 2017) Clinicians can set multiple orders to the same frequency more efficiently by editing them all at once. This is especially useful when editing the frequency of labs.
Clinical Orders

EPIC Education Resources for Treatment Plan
https://hcis.healthcare.uiowa.edu/EpicSupport/resources/modules/beacon/beacon.html

Beacon (Oncology)

Beacon is Epic’s medical oncology product and allows physicians to create treatment plans based on standard protocols and make treatment decisions guided by comprehensive decision support.

Resources

The following resources provide information on Beacon functionality.

- Treatment Plans from Orders/Notes Encounters: (Handout v. 2017) Some clinical staff are able to create and manage Infusion Plans from an Orders/Notes Encounter, providing them access to Infusion Plan functionality which they may not have within their Visit Navigators (assuming the staff member has sufficient security within EPIC such as Nurse or LIP / Provider access.)
Research Reporting in Epic

- Utilize Reporting Workbench reports customized to your study to find patient visits or monitor all enrolled patients.

- For assistance in creating a Reporting Workbench report for patients enrolled in your clinical trial, please submit an ESC request under “Epic Assistance” then “I Need A Report”.

- RWB reports are not appropriate for extracting large amounts of de-identified clinical data on study patients from EPIC. Those requests still need to be routed through ICTS workflows.
Additional Resources

Enterprise Service Center (ESC)

https://hcis.healthcare.uiowa.edu/selfservice