

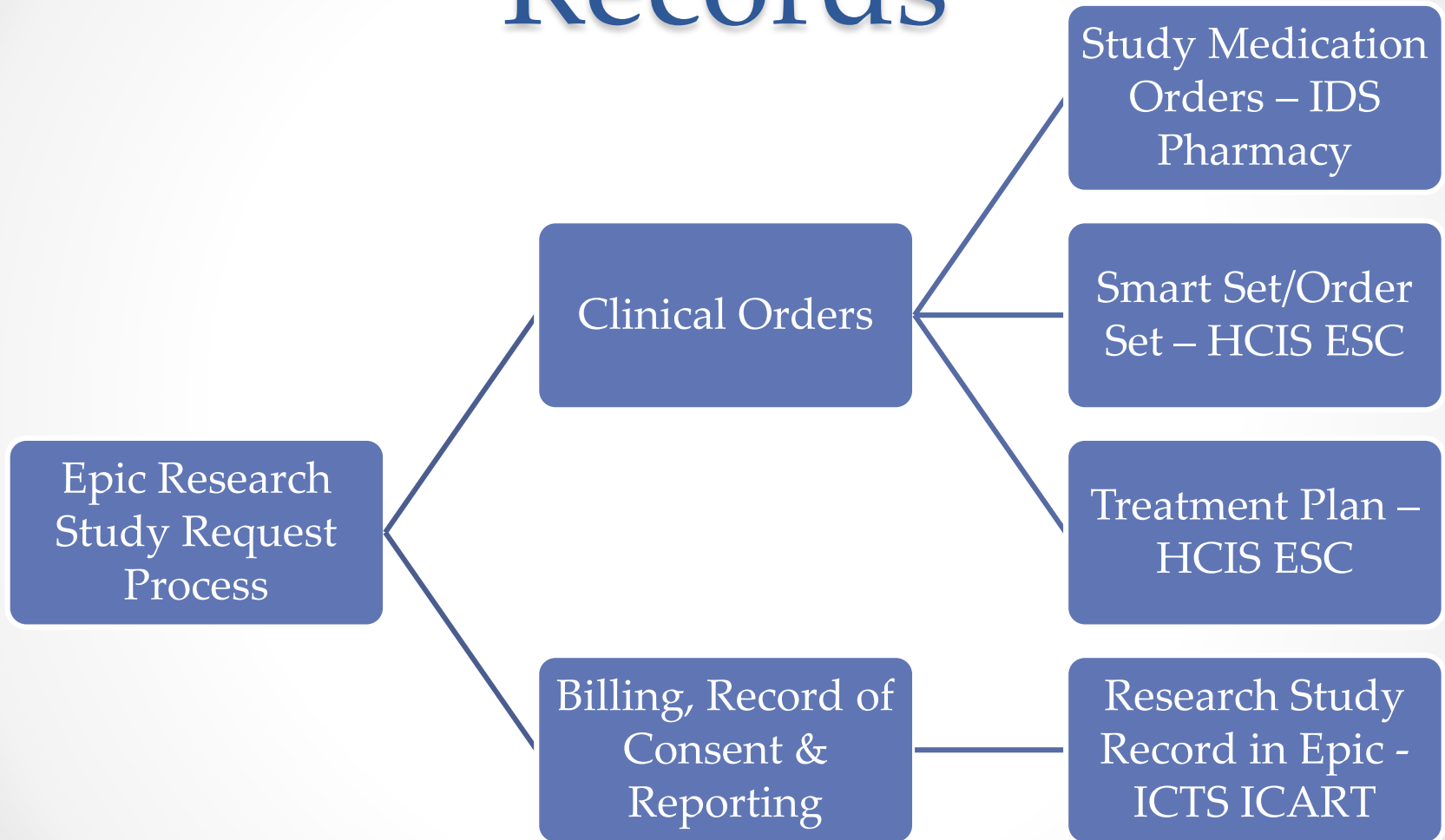
EPIC Tools for Clinical Research

Shara Power, RN, BSN, OCN

Application Developer, EPIC – Beacon Oncology

UIHC Healthcare Information Systems

Epic Research Study Records



Epic Research Study Records



Billing & Record of Consent

Request Build of Research Study Record

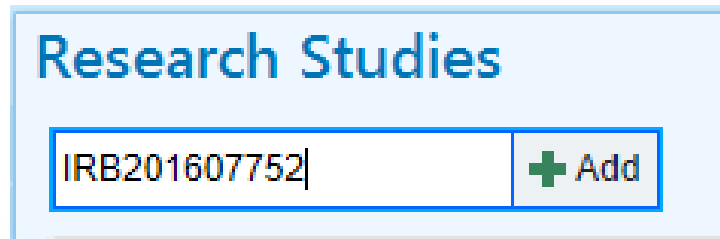
- To be able to associate patients to a research study in EPIC, you must first have a Research Study record created.
- Please submit your request via the I-CART system managed by ICTS

<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**.
 - Search for your study by IRB Number



The screenshot shows a light blue rectangular box with a thin border. At the top left of the box, the text "Research Studies" is written in a bold, blue font. Below this text is a white input field with a blue border. Inside the input field, the text "IRB201607752" is entered. To the right of the input field is a small, light blue button with a green plus sign and the text "Add" in black.

Billing & Record of Consent

Associate Patients to Your Study

- Complete Appropriate Fields
 1. Coordinator
 2. Status **(required)**
 3. Active Start Date **(required)**
 4. Comments

Research Studies ? ↗ ✕

Add a new study to list + Add Show: Inactive Pre-consent Deleted

PED: Sarepta 4045-301 IRB201607752

Study: PED: Sarepta 4045-301 IRB201607752 [RSCH-PED-NEU-201607752]

Coordinators: **1**

1	Carrie M. Stephan, RN	Participant ID:	
2		Active start date:	3 9/11/2018

Status: **2** Enrolled Active end date:

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Comments:

Consent signed at 1400 on 9/11/2018. **4**

Accept Cancel

Billing & Record of Consent

View Research Study Details

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

Research Studies ? ↶ ✕

Show: Inactive Pre-consent Deleted

Enrolled

PED: Sarepta 4045-301 IRB201607752

Study Code: RSCH-PED-NEU-201607752
Coordinators: Carrie M Stephan, RN
IRB #: 201607752
Study Type: Interventional

Start Date: 09/11/2018
Principal Investigator: Mathews, Katherine D, MD
NCT #: 02500381

1 [Study Description](#)

Ⓜ Patient may be enrolled in this study. For questions please contact:

Coordinator: Carrie Stephan
email: carrie-stephan@uiowa.edu
phone: 319-356-2673
Investigator: Katherine Mathews, MD
email: Katherine-Mathews@uiowa.edu
phone 319-356-1851

Patients in this study will receive study drug or placebo via IV infusions weekly x 2 yrs then will move into Open Label extension x 2 yrs. See G12 for info on study drug.
see G12 for info on study drug.

[Enrollment Comments](#)

Consent signed at 1400 on 9/11/2018.

2 [Past Updates](#)

Updated	Status	Branch	Coordinators	Start Date	End Date	Modifying User	Source
09/11/2018 09:15 AM	Enrolled		Carrie M Stephan, RN	09/11/2018		Shara L (Test) Power	Research Studies Activity

Consent signed at 1400 on 9/11/2018.

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 Studies ⓘ ↻ ✕

Show: Inactive Pre-consent Deleted

Enrolled Past Updates

PED: Sarepta 4045-301 IRB201607752

Study Code:	RSCH-PED-NEU-201607752	Start Date:	09/11/2018
Coordinators:	Carrie M Stephan, RN	Principal Investigator:	Mathews, Katherine D, MD
IRB #:	201607752	NCT #:	02500381
Study Type:	Interventional		

Study Description ⓘ

Patient may be enrolled in this study. For questions please contact:

Coordinator: Carrie Stephan
email: carrie-stephan@uiowa.edu
phone: 319-356-2673
Investigator: Katherine Mathews, MD
email: Katherine-Mathews@uiowa.edu
phone 319-356-1951

Patients in this study will received study drug or placebo via IV infusions weekly x 2 yrs then will move into Open Label extension x 2 yrs. See G12 for info on study drug.
see G12 for info on study drug.

Enrollment Comments ⓘ

Consent signed at 1400 on 9/11/2018.

Interested Additional Info Past Updates

Incisional negative pressure wound therapy;irradiated pelvic&lower extremity soft tissue sarcoma

Study Code:	201512762	Principal Investigator:	Miller, Benjamin J, MD
IRB #:	201512762	NCT #:	02638298
Study Type:	Interventional		

Study Description ⓘ

Incisional negative pressure wound therapy for preoperatively irradiated pelvic and lower extremity soft tissue sarcoma wounds. A prospective, randomized clinical trial.

WITHDRAWN Past Updates

Efficacy of Axicabtagene Ciloleucei in Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)

Study Code:	201801733	Branch:	Axicabtagene Ciloleucei Treatment
Start Date:	09/06/2018	Coordinators:	Karen E Parrott, RN
Principal Investigator:	Farooq, Umar, MD	IRB #:	201801733
NCT #:	03391466	Study Type:	Interventional

Study Description ⓘ

A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy of Axicabtagene Ciloleucei versus Standard of Care Therapy in Subjects with Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)

Enrollment Comments ⓘ

Test comments for reporting.

Billing & Record of Consent

EPIC Education Resources for Research

<https://hcis.healthcare.uiowa.edu/EpicSupport/resources/modules/research/research.html>

Research

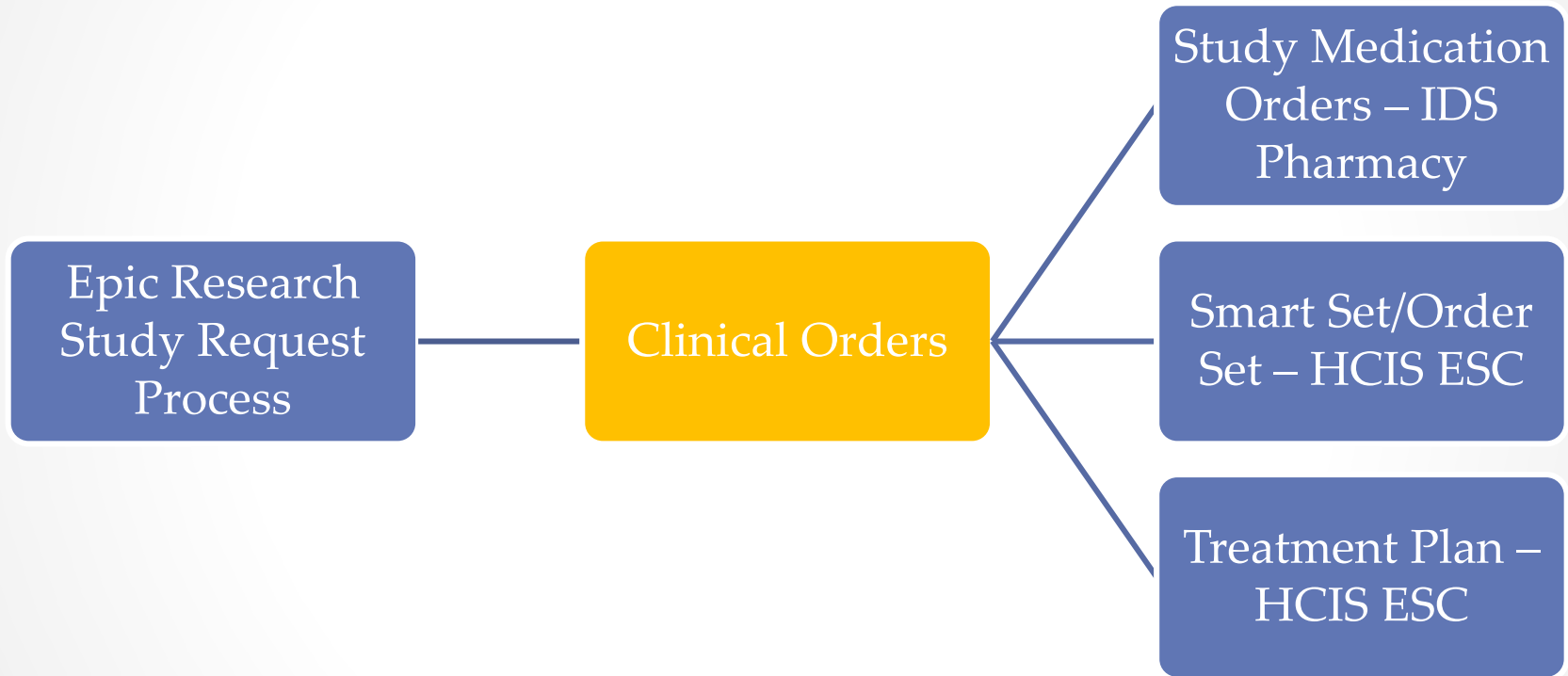
EPIC's research support features assist in setting up and maintaining research studies at the UIHC including research study patient tracking, research billing, and other features related to BestPractice Advisories and reports. The Research Study Maintenance activity allows research coordinators to create 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.

Epic Research Study Records



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

After visit Medications ^					
	Name	Type	Patient Formular Type	Pref List	ERX #
	diphenhydrAMINE (BENADRYL) capsule 25 mg	Medication	Generic...	UIHC RX FA...	2509

During visit Medications ^			
	Name	Type	Dose
	diphenhydrAMINE (BENADRYL) capsule	Medication	25 mg

- 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

ECG - EKG 12 LEAD



Remove

ONCE First occurrence Today at 1245

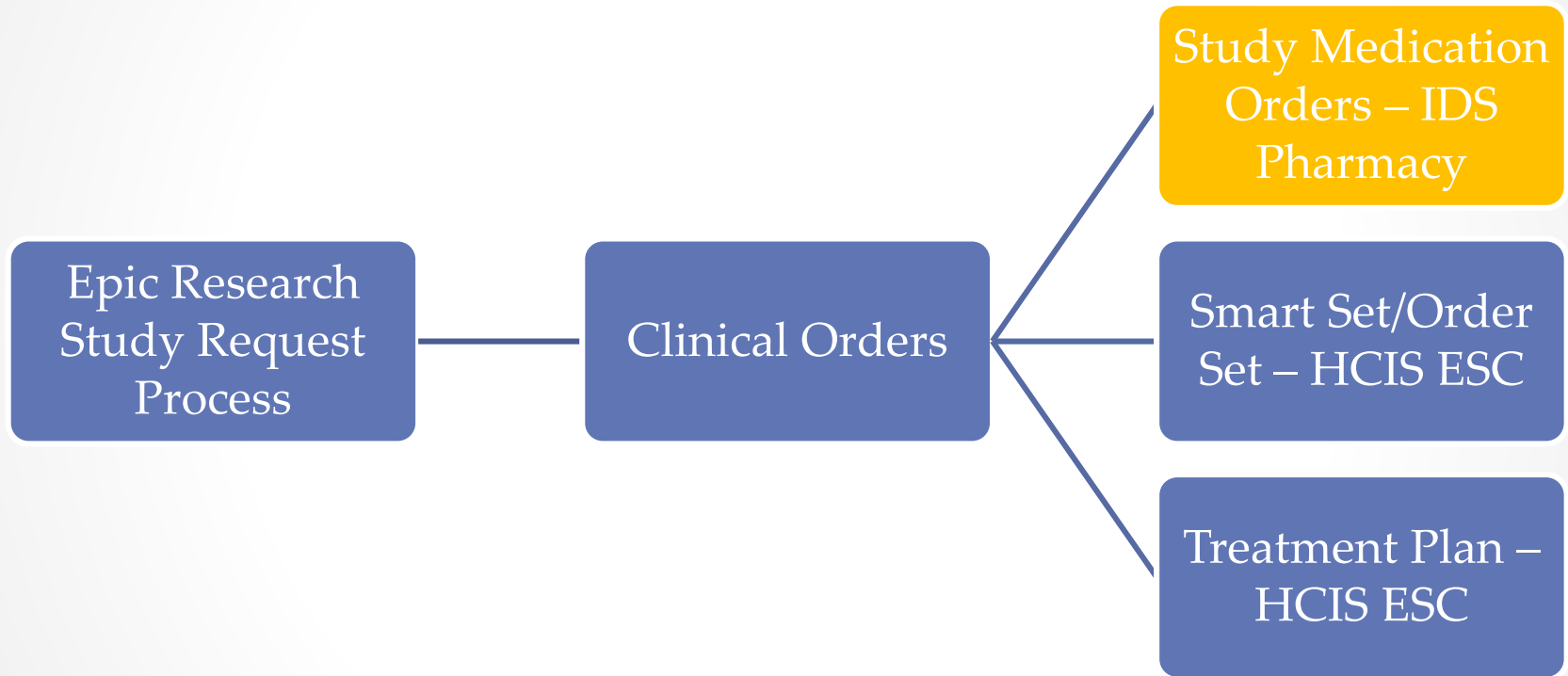
RESEARCH EKG ■



Remove

Order details


Epic Research Study Records




Clinical Orders

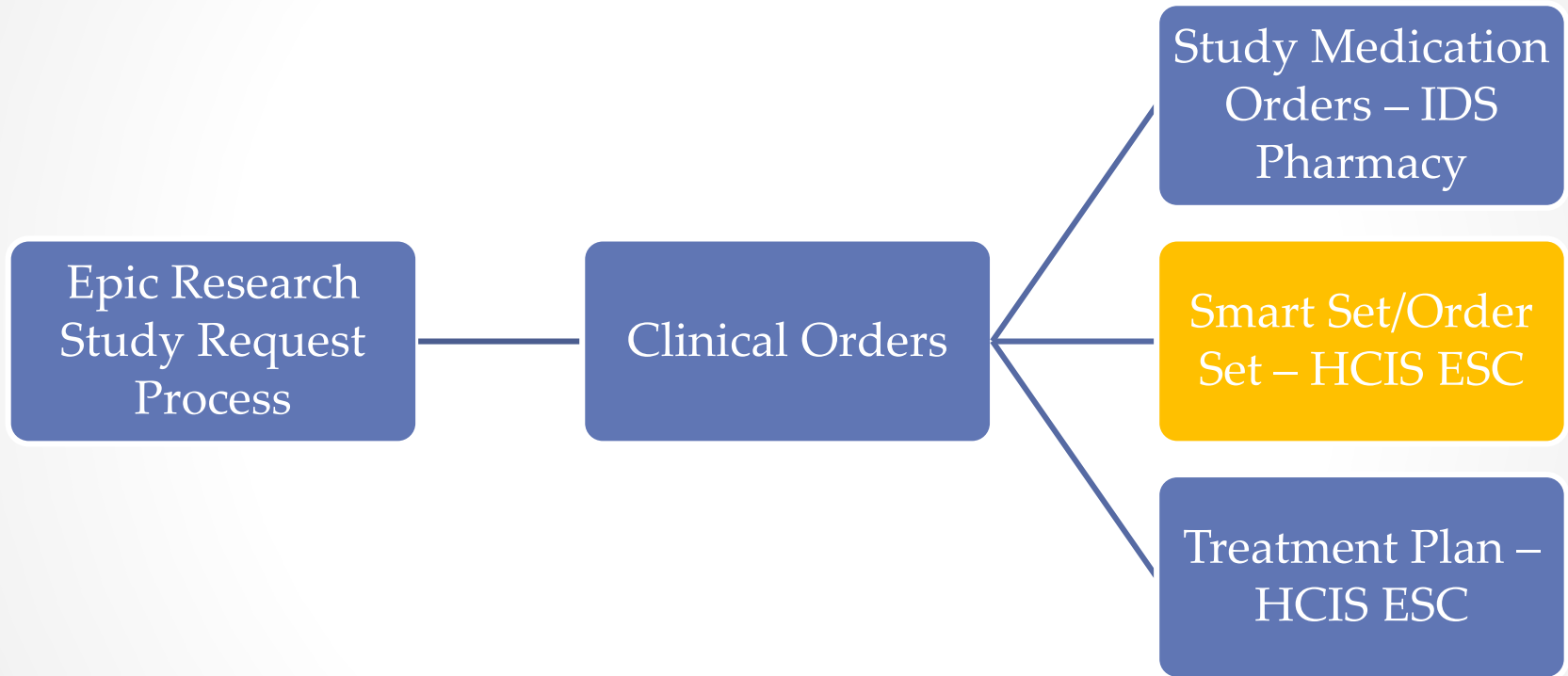
Study Medication Orders

- 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.

After visit Medications ^			
	Name	Type	
	*INV SRP-4053 or placebo (4045-301 ESSENCE STUDY...	Medication	

During visit Medications ^			
	Name	Type	Dose
	*INV SRP-4053 or placebo (4045-301 ESSENCE STUDY) IV bag	Medication	30 mg/kg

Epic Research Study Records



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

The screenshot displays the 'SmartSets' interface in Epic. At the top, there is a search bar labeled 'Search for new SmartSet' with a '+ Add' button. Below this, the main heading is 'RSH:RESEARCH STANDARD ORDERS'. The interface is organized into three main categories, each with a dropdown arrow and a sub-heading: 'Research Study', 'Nursing', and 'Labs'. Under 'Research Study', there is one item: 'INITIATE RESEARCH STUDY'. Under 'Nursing', there are seven items: 'RESEARCH VITAL SIGNS', 'RESEARCH WEIGHT', 'RESEARCH HEIGHT', 'RESEARCH BODY MEASUREMENT', 'RESEARCH BIO-NUTRITION-DIETARY', 'RESEARCH IV PLACEMENT', and 'RESEARCH COMMUNICATION ORDER'. Under 'Labs', there are five items: 'RESEARCH POC PREGNANCY', 'RESEARCH URINE DIPSTICK 10, POINT OF CARE', 'RESEARCH BLOOD DRAW', 'RESEARCH NON-BLOOD COLLECTION', and 'RESEARCH SAMPLE PROCESSING ONLY'. Each item has a checkbox and a small purple square icon to its right.

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

Clinical Orders

Custom Smart Set/Order Set

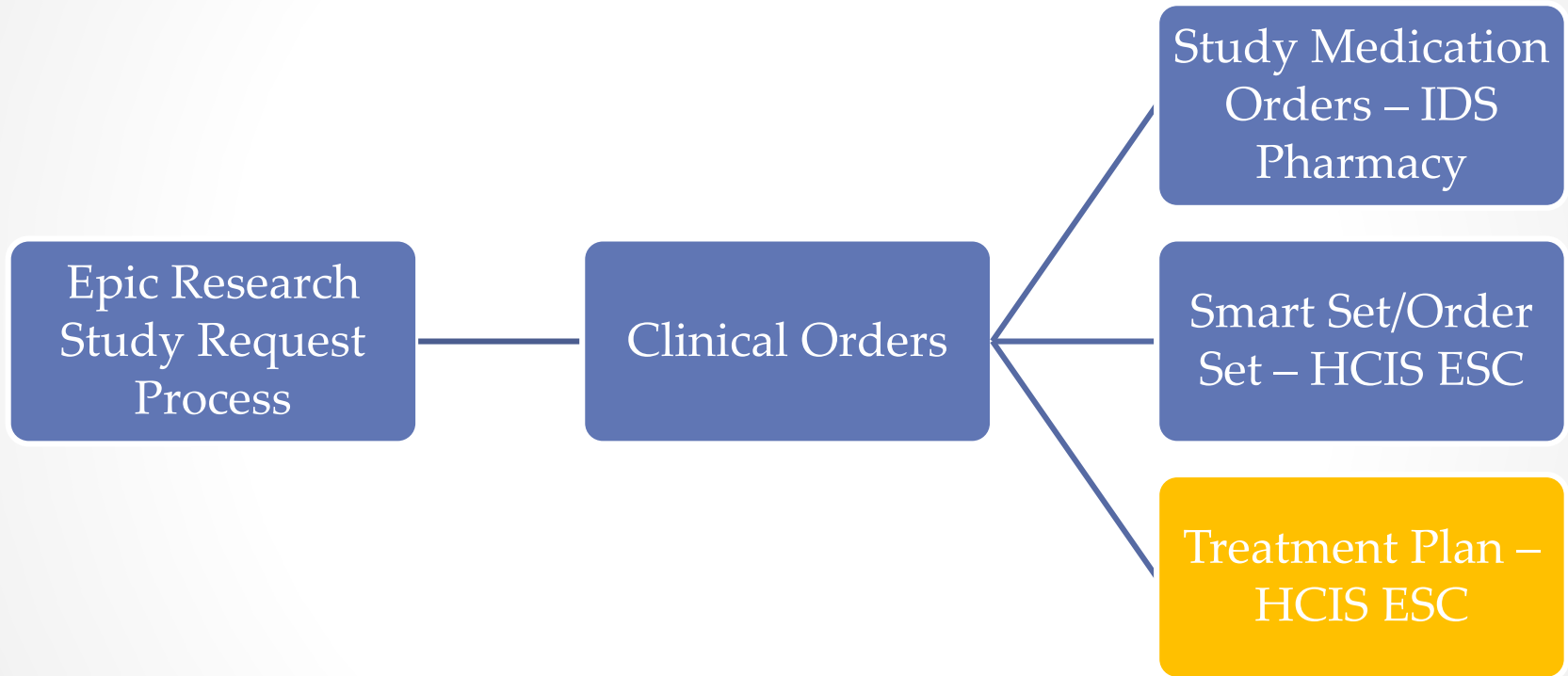
- Best for studies with multiple visits or large accrual volume.
- Can be used for any visit at UIHC.
- Easily place multiple orders at once.
- Orders released when the patient checks into their appointment.
- Orders need to be placed prior to each appointment.
- Custom Smart Sets can be created for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

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



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

INF: RSH: 4658-301-AL: INV ETEPLIRSEN Edit Plan

TP Height: None **TP Weight: 75 kg Δ +0.0 % just now** **TP BSA: 1.5 m2 Δ +0.0 %** Walgreens Drug Store 10985 - CORALVILLE, IA - 2...

Day 1, Cycle 1 – Planned for 9/11/2018 Complete Day Actions

Check Signed Check Unsigned Release Selected Sign Selected

Nursing Orders

TREATMENT PLAN DEFAULT SETTINGS #1
Patients should receive eteplirsen 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 eteplirsen within the same 60-hour period.
Nursing staff may changed "planned date" to match actual scheduled date up to 3 days before or after the original planned date.

Dose Modifications

DOSE MODIFICATIONS #1
There is no provision for dose alteration in this study. See protocol section 9.4.1 for details.

Medications

TREATMENT PLAN INSTRUCTIONS #1
Patient is to be observed for 1 hour post end of infusion.
Nursing staff to record VS (oral temp) at the following intervals:
Within 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 eteplirsen dose is to be based off weights obtained every 4 weeks. (Weeks 1, 4, 8, 12, etc).

INV eteplirsen/AVI-4658 (PROMOVI 4658-301 STUDY) 2,250 mg in sodium chloride 0.9% 100 mL IV bag
2,250 mg (30 mg/kg \times 75 kg Treatment plan weight), Intravenous, Once, Starting when released, For 1 dose

Supportive Care

HEParin (pf) 10 unit/mL flush syringe 30 Units
30 Units, Intravenous, As Needed, Flush per policy, Starting when released

HEParin (pf) 100 unit/mL 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.

DSW continuous infusion
at 30 mL/hr, Intravenous, Continuous, Starting when released
As needed TKO for line maintenance.

HEParin (pf) 10 unit/mL flush syringe 50 Units
50 Units, Intravenous, As Needed, Flush per policy, Starting when released

Check Signed Check Unsigned Release Selected Sign Selected

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 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 enter 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

Colorectal C35001 Appts [8342] as of Wed 3/8/2017 1:41 PM

Filters Options Expand Appts Research Studies Encounter Link to Research Study

Research Study Nm	Patient	MRN	Date	Appt Time	Department	Prov/Res	Appt Stat	Type	Canc Date	Canc Reason	Rescheduled	Cancel User
ONC: RSH: COLORECTAL: C35001: IRB201312504	Test, Beacon Two	00000426	03/09/2017	8:00 AM	MED HEMATOLOGY/ONCOLOGY	BERG, DANIEL J	Sch	RETURN				
ONC: RSH: COLORECTAL: C35001: IRB201312504	Test, Beacon Two	00000426	03/08/2017	2:00 PM	CLINICAL RESEARCH CLINIC, CL...	CR INFUSION BED C CR INFUSION CHAIR A	Sch	CR INFUSION				

Beacon Treatment Plan Research Study Enrollment

Treatment Plan Information

ONC: BREAST: HER 2+: ADJ: PERTUZUMAB + TRASTUZUMAB

Current Cycle 1 of 17 cycles	Treatment Dates 3/8/2017 to 2/7/2018	Line of Treatment	Treatment Goal Curative	Treatment Plan Provider Milhem, Mohammed M, MD	Treatment Department Comprehensive Cancer Center	Status Active
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Protocol
ONC: BREAST: HER 2+: ADJ: PERTUZUMAB + TRASTUZUMAB - As of 3/8/2017 8:22 AM

Reference Links
1. NCCN Guidelines

Treatment Plan Management
Go to Treatment Plan Manager

Created by: Power, Shara L (Test) on 3/8/2017 8:22 AM
Updated by: Power, Shara L (Test) on 3/8/2017 8:22 AM

Protocol Notes

** No Notes for this Protocol **

- 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>

The screenshot displays the Enterprise Service Center (ESC) self-service portal. At the top left is the ESC logo. The main header reads "Enterprise Service Center". To the right, contact information for the Help Desk is provided: (319) 356-0001 or helpdesk-hcis@uiowa.edu. Below the header are navigation links for Home and Submit Feedback. A dashboard section shows three metrics: "My Open Requests" with a count of 67, "My Open Incidents" with a count of 0, and "My Open Projects" with a count of 0. Below these are three yellow action buttons: "Need Something? Submit a Request" (with a dome icon), "Having A Problem? Submit an Incident" (with a speech bubble icon), and "Reset Password" (with a padlock icon). At the bottom, a row of four service tiles is shown: "Epic Assistance" (with a first aid kit icon and a red border), "Under Construction" (with a network icon), "Help Guides" (with a monitor icon), and "Service Catalog" (with a book icon).