INVESTIGATIONAL DRUG SERVICE

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08 September 2023

ACCREDITATION

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- The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

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DISCLOSURES

- The speaker, Amy Adams has no personal or professional financial relationships with a commercial entity producing healthcare goods or services.
- The planning committee members, Katie Rea, MSCR, BSN, RN, CCRC; Lori Elder, RN, BSN, CCRA; Kimberly Underwood, BS, CCRC; and Maria Davenport, MPH, CCRP; have no personal or professional financial relationships with a commercial entity producing healthcare goods or services.
- **Activity Code: 146406**

OBJECTIVES-

- Understand who your IDS team is and how to contact them
- Learn procedures for protocol set up in IDS
- Understand how IDS complies with regulations for your studies
- Know your options for utilization of IDS Services

OVERVIEW

OUR TEAMS-

- Main Hospital IDS-
    - Serving all disciplines, both inpatient studies and outpatient studies – includes pediatric Hem/Onc studies
- Cancer Center IDS:
    - Manages all Adult Oncology Trials – Inpatient and Outpatient

OVERVIEW

OUR STAFF-

- 3 Full-TimePharmacists
  - Amy P. Adams, PharmD, CCRP
  - Brittani Collins, PharmD, MS
  - Becky Armstrong, PharmD, BCPS
- 2 Full-Time Certified Pharmacy Technicians
  - Cedric Copeland, CPhT
  - Robyn Amon, CPhT
- Main IDS Pharmacy Office, M-F, 730-530, 982-1048
- Location: Main Pharmacy, University Hospital, Zero Level
- 24/7/365 dosing for inpatient studies – coverage provided by inpatient staff
- Follow Clinic Holiday Schedule

MAIN HOSPTIAL IDS TEAM

OVERVIEW

CANCER CENTER IDS STAFF

Full-Time Staff:

- 5 Pharmacists:
  - Kyle Luedtke, PharmD, BCPS → Lead Pharmacist
  - Lauren Benusa, PharmD, CCRP
  - Michele Campolieto, PharmD, BCPS
  - Cameron Lee, PharmD, BCPS
  - Chloe LeBeague, PharmD, BCPS
- 2 Certified Pharmacy Technician Specialists
  - Shanel Tibbs, CPhT
  - Trashida Long, CPhT
  - Vidisha Sharma, CPhT
- Cancer Center IDS Pharmacy Office, M-F, 8-430, 982-5385
- Located in the Infusion Center, 4th Floor EC4
- Manages inpatient, outpatient and infusion center dosing
- Serving all disciplines related to Adult Oncology

UNIVERSITY of VIRGINIA HEALTH SYSTEM

CANCER CENTER IDS TEAM

UVA HEALTH SYSTEM UVA PHARMACY

IDS WORK SPACE

EQUIPMENT / STORAGE / CAPABILITIES

- Three 2-8°C Refrigerators – *adding another soon*
- -20 Freezer
- -80 Freezer – making a return
- Ambient Temperature
- USP 797 Compliant Clean Room – Sterile
    - Lateral and Horizontal Laminar Flow Hoods
- USP 795 Compliant space – Nonsterile
    - Capsule compounding machines
    - Liquid preparations
- Blinding
- Randomizations
- Continuous Temperature Monitoring – data readily available

UNIVERSITY of VIRGINIA HEALTH SYSTEM

UVA PHARMACY

ROLE OF IDS

REGULATORY COMPLIANCE

- GCP, NCI, NIH, TJC, IRB, VA board of Pharmacy , FDA, USPs , ASHP
- Drug control management guidelines followed
- Blinding management – via IRT, compounded product
- Secure access
- Source document archiving
- Proper licensing to prepare and dispense study drugs

TYPES OF STUDIES MANAGED BY IDS

STUDIES MANAGED BY IDS & DOCUMENT AVAILABILITY

- Sponsor
  - Typically supplies most documents
  - Frequently missing Pharmacy Manual
- Investigator-Initiated
  - Important to include the Pharmacy Section of the IRB Applicaiton
- Federal
  - Multiple places to find documents, assistance may be needed
- Cooperative
  - Documents are usually complete and easy to find (COG)
- Platform
  - Multiple places to find documents, assistance may be needed

PROTOCOL START UP PROCESS

FIRST STEPS

- SQV – include IDS SOPs
- CR Connect
- Feasibility for IDS
    - Utilize any documents uploaded
    - Missing documents – incomplete review
- IDS reviews & completes approval and uploads to CR Connect – closes step
- Protocol is added to queue in IDS

PROTOCOL START UP PROCESS

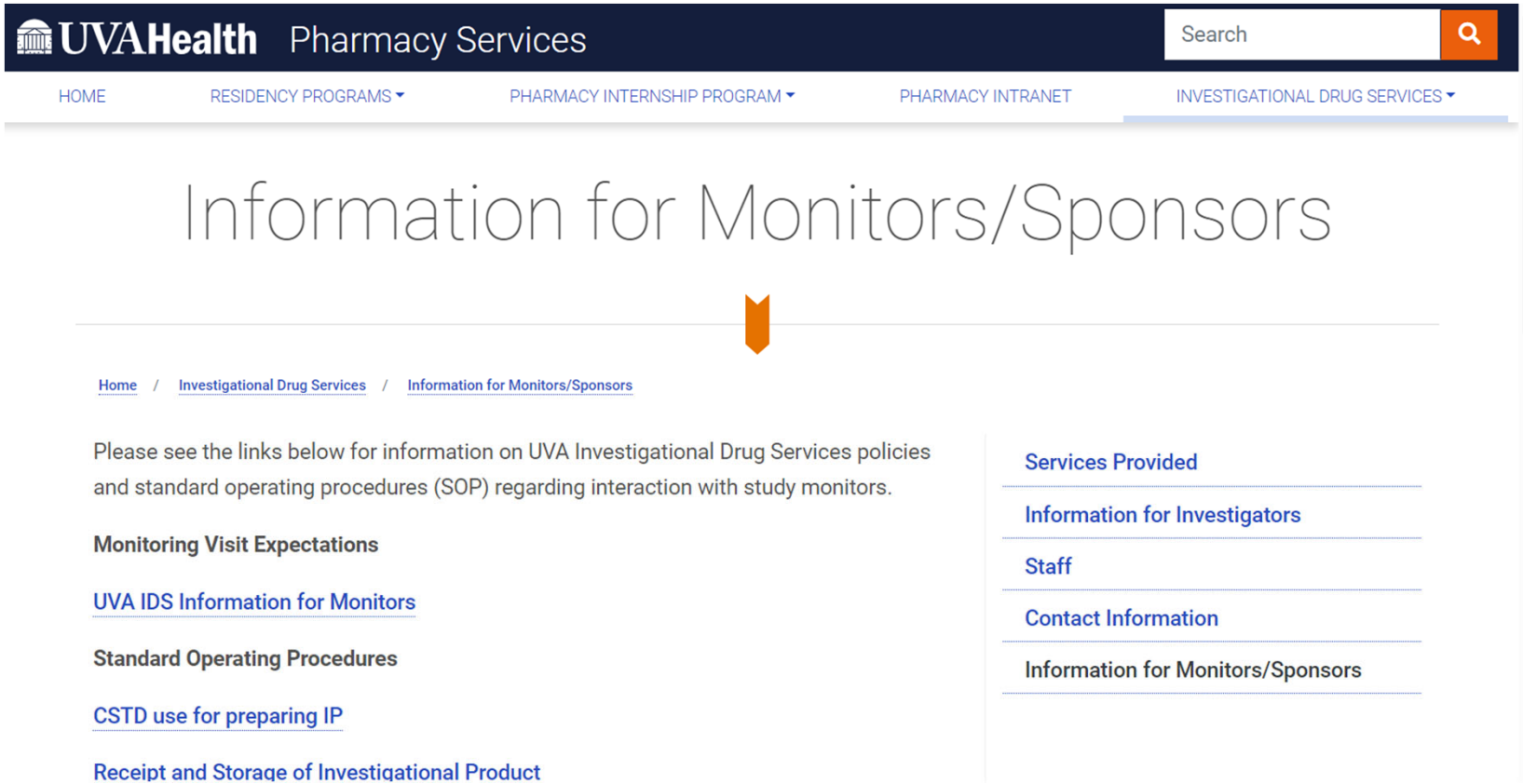
SITE QUALIFICATION VISIT

- Important to include IDS in this visit.
- Set up a time to come by at least a few days in advance
- IDS SOP document to be given to sponsor at SQV to set expectations
- Frequently asked for SOPs and other pertinent sponsor information can be found here:

  https://www.medicalcenter.virginia.edu/pharmacy/investigational-drug-services/information-for-monitors-sponsors/

IDS WEBSITE FOR SPONSORS

HTTPS://MEDICALCENTER.VIRGINIA.EDU/PHARMACY/INVESTIAGATIONAL-DRUGS-SERVICE/INFORMATION-FOR-MONITORS-SPONSORS/



Investigational Drug Services

Main Hospital IDS
UVA Main IDS Pharmacy
1 Lane Road | Loading Dock | Rm G-541
Charlottesville, VA 22908
Phone: 434.982.1048
Fax: 434.982.2900
Email: CLPharmacyInpatientIDSpersonnel@hscmail.mcc.virginia.edu
Contacts:
Amy Adams, Pharm.D., CCRP
APA4N@uvahealth.org
Brittani Collins, Pharm.D.
CSZ2UC@uvahealth.org
Rebecca Armstrong, PharmD, BCPS
RLV4P@uvahealth.org
Cedric Copeland, CPhT
CJC3M@uvahealth.org
Robyn Amon, CPhT
RA2EF@uvahealth.org

Cancer Center IDS
UVA Cancer Center IDS Pharmacy
1240 Lee Street | Room 4326
Charlottesville, VA 22903
Phone: 434.982.5385
Fax: 434.243.7394
Email: clpharmacyec4idsservices@hscmail.mcc.virginia.edu
Contacts:
Lauren Benusa, Pharm.D., CCRP
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DZK5XY@uvahealth.org
Vidisha Sharma, CPhT
VS6X@uvahealth.org

Monitor Information

Drug Accountability

- Vestigo is our exclusive drug accountability source in IDS
- IDS will grant monitors access to Vestigo the day prior to their visit. You will receive an email with login information.
- "Check off" transactions that were reviewed in the monitor review section of Vestigo.
- Document which items are authorized for destruction or return to sponsor
- After the visit, the Vestigo session will be closed and your account will be deactivated until your next visit.
- See Vestigo Protocol Reviewer Guide for further information
- See 'Establishment of Vestigo as exclusive IDS DARF source' SOP for accountability documentation details

Drug Destruction

- IDS will provide certificates of destruction upon request
- UVA approved third party vendor will be used for incineration of IP.
- See SOP for Destruction of Disposition of Investigational Drug Products in Investigational Drug Pharmacy

Site Initiation Disclosure:

- IDS will provide specific documentation of procedures at SIV

Temperature Records

- Temperatures are recorded every 15 minutes using the Hampshire device
- Staff receive alerts through email, pager, and telephone
- Temperature records will be emailed to the monitor for the requested date range
- Temperature documentation includes daily max/min and daily average
- Further detail will be provided in the event of an excursion

Equipment

- Calibrated temperature devices include Room Temperature, Refrigeration (2-8°C), Freezers including –20°C and –80°C
- USP 800 Compliant Clean Rooms
- Biosafety Level 1 & 2 designated compounding area
- Capsule Compounding

Record Retention and Storage

- UVA IDS maintains all physical closed records on site for up to 1 year.
- After 1 year, all physical files are transferred to a UVA contracted off-site facility,
- Electronic and physical records are maintained until authorization to destroy has been obtained from the protocol owner/sponsor.

Scheduling Visits

- Appointments should be made at least 2 weeks in advance if possible and will not be allowed with less than 3 business days advance notice
- See Pharmacy Appointments SOP

We're on the Web!

https://www.medicalcenter.virginia.edu/pharmacy/investigational-drug-services

UVA Health PHARMACY

Version: 28 Aug 2023

PROTOCOL START UP PROCESS

FEES

- Flat Fee structure
- Accessible for easy estimation of study set up
- Information not on website:
    - Cost of drug or supplies purchased by IDS for study
    - Total cost of compounding bulk product
- Structure can be found here:

- https://www.medicalcenter.virginia.edu/intranet/pharmacy/investigational-drug-services/information-for-investigators

- Do not send this link to anyone outside of UVA
- Share only the applicable fees with the sponsor

PROTOCOL START UP PROCESS

FEE STRUCTURE

Study Type	Initiation/Operations	Maintenance	Bulk Compounding	Closeout
Industry-Sponsored	$4500	$100/month	$100/hr	$200
Investigator-Initiated	$440	$35/month	$50/hr	$80
Federal Group	$440	$35/month	$50/hr	$80
Cooperative Group	$220	$18/month	$25/hr	$40
Biosafety Level 1 or 2	$5000	$150/month	$100/hr	$300

PROTOCOL START UP PROCESS

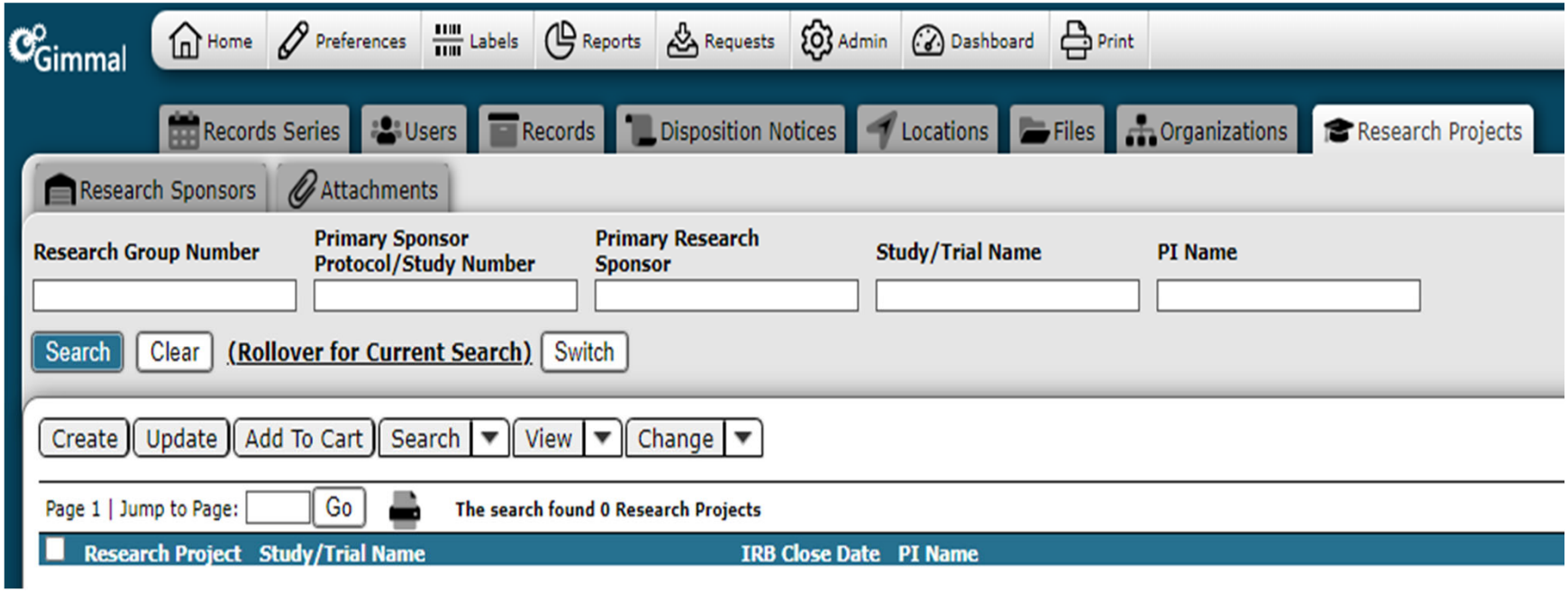
NEXT STEPS

- IDS begins review of study documents to develop procedure documents
    - Documents needed by IDS **from** study team:
        - Protocol, IB, Pharmacy Manual. IRT Manual, MOP, others
        - Study Team may facilitate access to IRT platforms for all staff
        - Florence
    - Documents created for use within IDS:
        - Pharmacist Information form, Drug Fact Sheet, Prep Checklists, EPIC orders, Infusion pump orders, randomization form and others as needed
        - URMA
        - All authorized Investigators (prescribers) listed on Pharmacist Information form

PROTOCOL START UP PROCESS

UNIVERSITY RECORDS MANAGEMENT APPLICATION

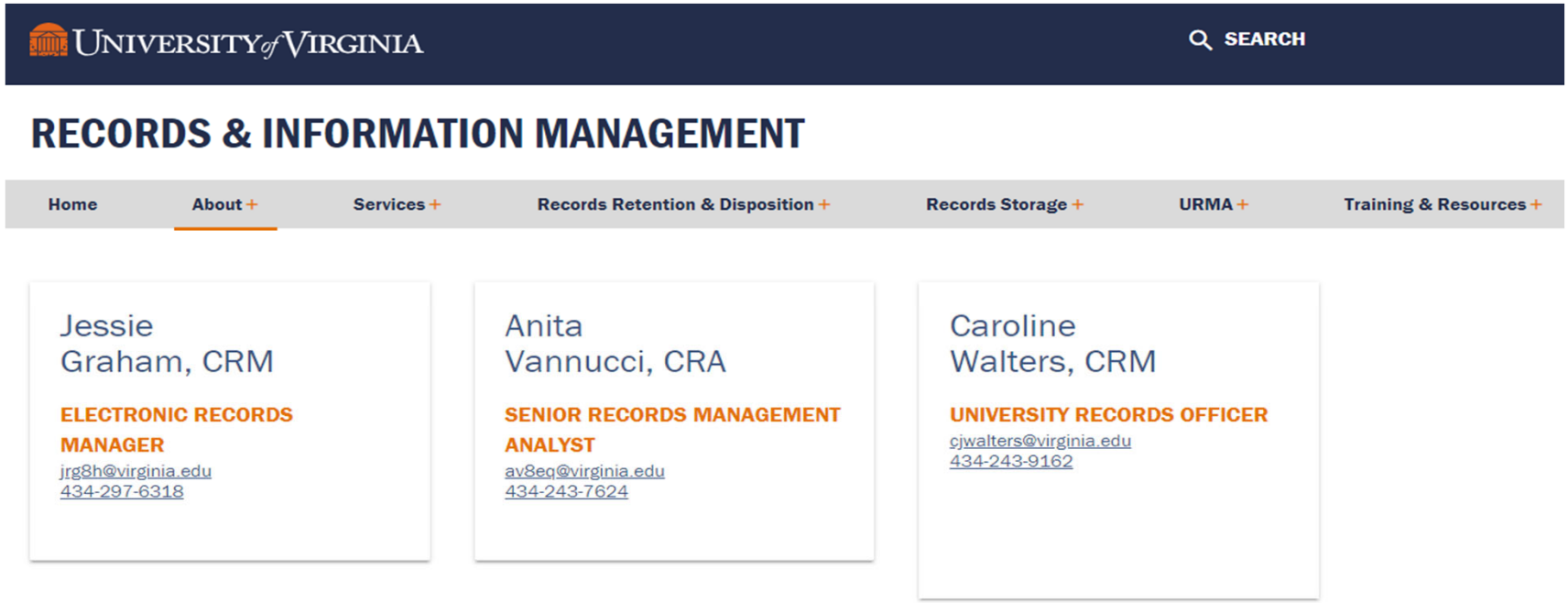
IDS loads every study into URMA at start up by creating a Research Project.
You can connect your study to the project we set up at the start of the study



PROTOCOL START UP PROCESS

UNIVERSITY RECORDS MANAGEMENT APPLICATION

- Website: http://recordsmanagement.uva1acsf.acsitefactory.com/people
- Contact Information:

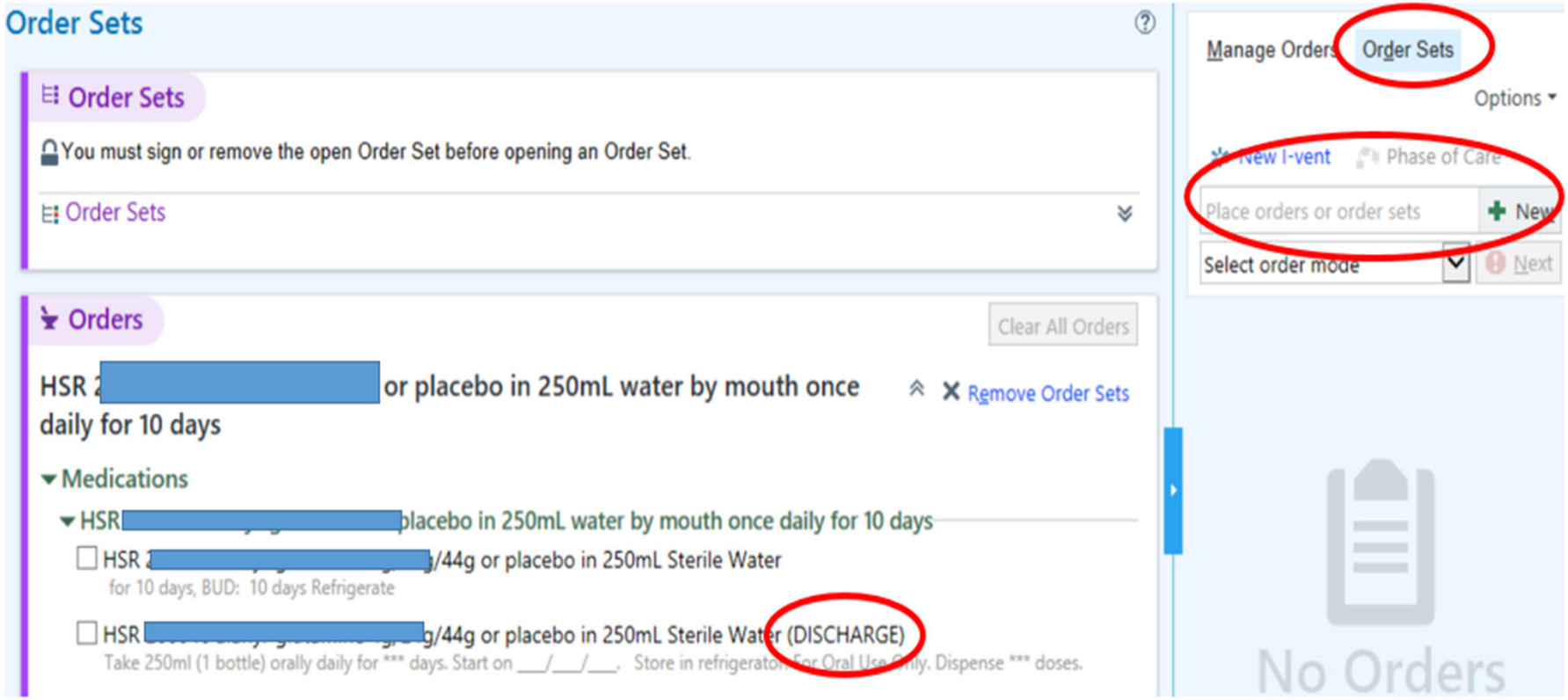


PROTOCOL START UP PROCESS

EPIC – INPATIENT – ORDER SETS

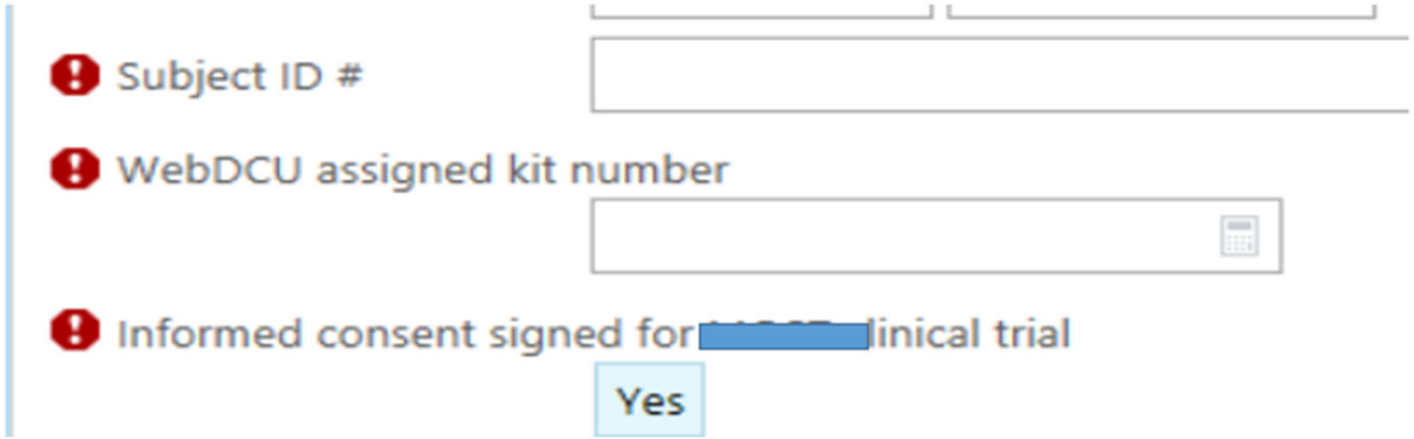
- Created for each study
- Build can take several weeks
- Once draft order set is in Test, IDS sends screenshots for review by PI and Study Team
- Order set moved to Production after approval
- PI or SubIs are the only authorized prescribers
- If authorized prescriber list is updated – Please let IDS know
- When an order is entered, let IDS know – we are not in the queue

EPIC ORDERS


Order Sets
Order Sets
You must sign or remove the open Order Set before opening an Order Set.
Order Sets
Orders
Clear All Orders
or placebo in 250mL water by mouth once daily for 10 days
Remove Order Sets
Medications
placebo in 250mL water by mouth once daily for 10 days
/44g or placebo in 250mL Sterile Water
for 10 days, BUD: 10 days Refrigerate
/44g or placebo in 250mL Sterile Water (DISCHARGE)
Take 250ml (1 bottle) orally daily for *** days. Start on ___/___/___. Store in refrigerator. For Oral Use Only. Dispense *** doses.
Manage Orders
Order Sets
Options
New I-vent
Phase of Care
Place orders or order sets
New
Select order mode
Next
No Orders

EPIC ORDERS

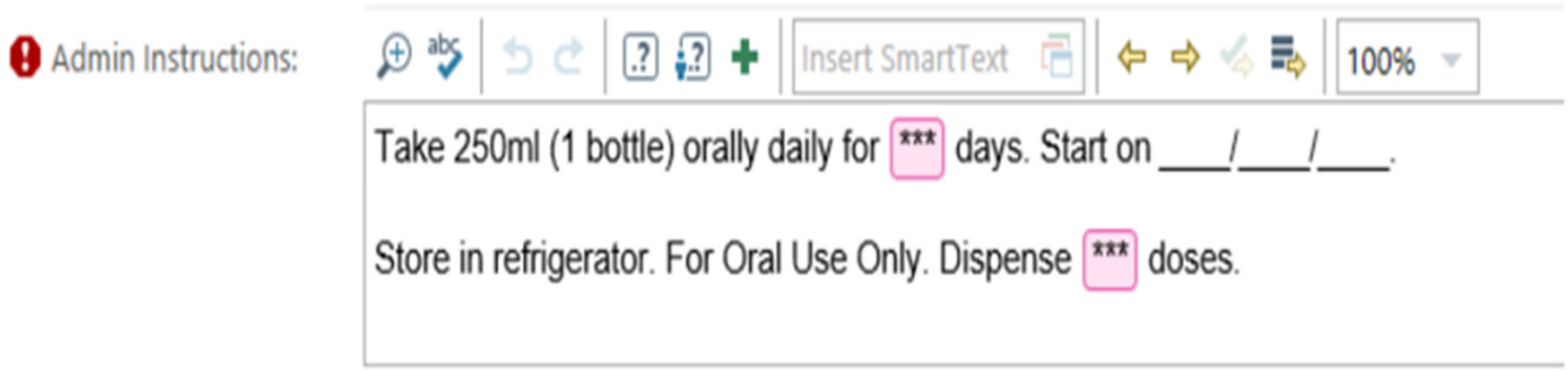
REQUIRED QUESTIONS



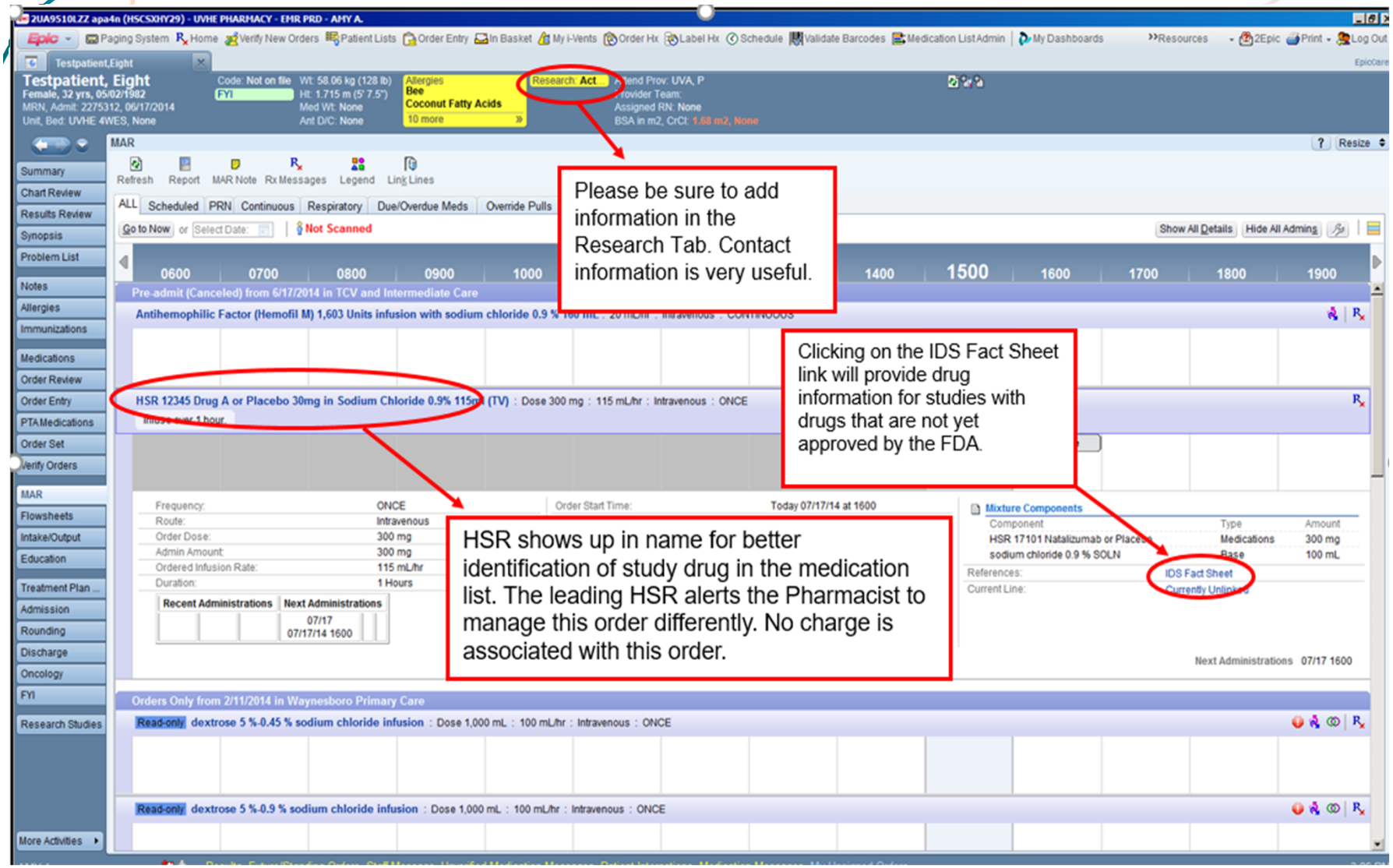
PROTOCOL START UP PROCESS

EPIC – INPATIENT – DISCHARGING DURING OFF-HOURS

- Order for discharge prepared and included in order set

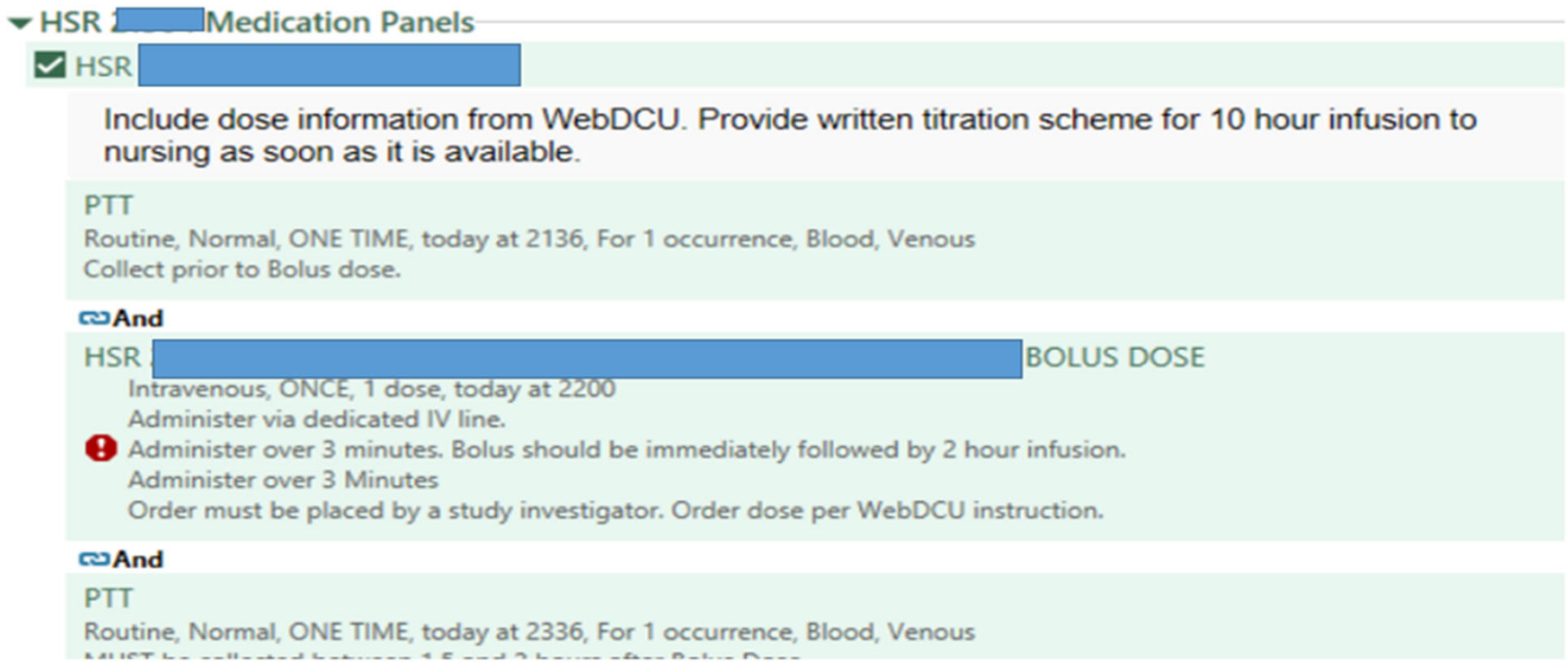


UNIVERSITY of VIRGINIA HEALTH SYSTEM



EPIC ORDERS

ORDER PANELS ARE AN OPTION



PROTOCOL START UP PROCESS

EPIC – BATTLE BUILDING – OUTPATIENT CLINIC DOSES

- COG studies - A growing area
- ERx record ‘dropped’ into treatment plan drug build by study team
- Treatment plans are being built for all studies in Battle Building that will need in-clinic dosing
- IDS supports Treatment Plan process by providing the ERx record for each investigational agent
- New process so it’s a bit fluid at the moment

PROTOCOL START UP PROCESS

EPIC – DRUG FACT SHEET

- Required for drugs that are not yet approved by the FDA
- IDS follows ASHP best practices which includes
- Available for non-study and study staff in MAR – as shown earlier.

DRUG NAME AND SYNONYMS:

DRUG FORM(S) AND STRENGTH(S):

USUAL DOSE RANGE, SCHEDULE AND ROUTES OF ADMINISTRATION:

OBJECTIVE:

PRINCIPAL INVESTIGATOR:

STUDY COORDINATOR:

PROTOCOL DESIGN:

PROTOCOL DOSAGE RANGE:

PHARMACOLOGY:

PROJECTED PLACE IN THERAPY:

ADVERSE EFFECTS:

CONTRAINDICATIONS:

ADMINISTRATION AS PER STUDY:

STORAGE AND STABILITY:

DRUG INTERACTIONS, IF KNOWN:

PROTOCOL START UP PROCESS

ALARIS PUMP ORDERS

- IDS does this alongside EPIC order set build
- Required for Interoperability
- Goes through MUP in pharmacy
- Infusion update done once per month – toward the end of the month

Intermittent Drugs - ADULT

Drug Name *Therapy*	Available As		Total Dose Limits				Concentrations	Module		Duration Limits (hh:mm)				Concentration Limits				Clinical Ads. Name
	Pri.	Sec.	Dosing Units	Soft Min	Soft Max	Hard Max		P	S	Hard Min	Soft Min	Soft Max	Initial Value	Conc. Units	Hard Min	Soft Min	Soft Max	
HSR20 MB CB	X	X	mg	799	801		--- mg / --- mL	X			00:30	02:00	00:30	mg/mL		7	9	Filter
HSR20 or CB	X	X	mg	1.9	2.1		--- mg / --- mL	X			00:15	00:25	00:20	mg/mL		0.033	0.037	
HSR20 cb	X		mg	1,800	1,801		1,800 mg / 293 mL (6.1433 mg / mL)	X	X		01:30	02:00	01:30	n/a				Filter

PROTOCOL START UP PROCESS

PRESCRIPTIONS – OUTPATIENT / CLINICAL RESEARCH UNIT

- Send schedule of appointments ahead of time
- IDS makes protocol-specific prescriptions for each drug
- Enter date and time needed for pick up
- Fax prescriptions – ***Legal Requirements***
    - Keep original with wet ink signature in your file
    - Each script must be signed individually
- No e-prescribing yet – *working on it!*

PROTOCOL START UP PROCESS

CLINICAL RESEARCH UNIT –

- IDS provides services for studies done in the CRU
- All orders are paper – prescription
- No EPIC, No Pump available
- Emergency meds are not provided by IDS

PROTOCOL START UP PROCESS

FINAL SET UP STEPS

- SIV
- Pharmacy document review / approval received
    - Sponsor
    - Study Team
- Worktag
- Contact at sponsor
- Drug order procedures established
- EPIC orders activated
- All accesses received by Pharmacy Team
- Drug received or understood to be shipped at screening, as appropriate
- Study activated in Vestigo
- Binder made in Pharmacy
- GREEN LIGHT

ACTIVE STUDY MANAGEMENT

DAILY TASKS

- Receive shipments
- Temptale management
- Inventory count
- Termperature monitoring - Continuous
- Excursion management
- Documentation of Training
- Process prescriptions / Orders
- Manage patient returns / used vials
- Manage reorders
- Amendments – Florence….
- Updated IP information – expiry dates, etc.
- ‘Continuation’ review in IDS – update prescribers, CIRBs, etc.
- Moving toward paper-light office

ACTIVE STUDY MANAGEMENT

VESTIGO

- Accountability
- Monitor access
- SC access
- Scanned in docs – scripts, temps, shipping documents, training Logs??
- Daily counts
- Pt Returns
- Destruction
- Return to sponsor
- Monthly billing

ACTIVE STUDY MANAGEMENT

WHAT IDS NEEDS FROM YOU-

- Updated Study Documents
    - Protocols
    - Amendments
    - Pharmacy Manuals
- Authorized prescriber updates
- Schedule of patients / notice
- Schedule monitor visits with about a week notice

ACTIVE STUDY MANAGEMENT

MONITOR VISITS

- IMV, COV
- Scheduling
    - CRC
    - Direct to IDS
    - 1 week ahead of time
- Remote
- Onsite / In Person
- Vestigo Access
- Follow up
- 1 monitor at a time due to space issues

CLOSED STUDY MANAGEMENT

PROCEDURE TO CLOSE A STUDY

- Sponsor close out visit or notice of closure in writing
- Reconcile inventory
- Disperse as instructed – destruction or ship back to sponsor
- Close out study in Vestigo after all product is at zero.
- 20 step process to close out studies and prepare records for proper storage
- Enter info in to URMA – including file location for pharmacy documents
- Record retrieval of physical records, electronic records, mix
- If acceptable, it's beneficial to close out pharmacy – even if site is not closed.

OFF HOURS

INPATIENT – COVERAGE

- Inpatient Pharmacists provide coverage
    - Evenings, weekends, holidays
    - All are provided training on procedures for processing orders for studies
    - Will sign off on Pharmacy training logs as 'just in time' training
- New starts and continuing doses can be accommodated
- Randomization considerations for off-hours – documents sent to staff
- Off Hours Discharges – processed through EPIC as described earlier
    - *Note: discharges during IDS working hours are prescriptions*
- Strong communication is essential

STAT ORDERS

INPATIENT - ALL HOURS

- STAT orders are about 30 min in standard hospital orders.
    - These don't require randomization, checklist prep, etc.

- IDS strives to meet that same timeline despite the additional requirements
- To help us achieve this, we ask that you/your team:
    - Contact IDS or Inpatient Pharmacy as soon as you ID a potential patient & when orders are in
    - IDS/ Inpatient Pharmacist will pull binder and begin to familiarize themselves with the study.

Remember that if an inpatient pharmacist is working on this order, it's likely the 1st time they've seen it so they will use this advance time to get prepared*

- When you speak with the pharmacist handling the order, get their name, number and email so you can forward any randomization information to them and keep up with prep time or questions they may have.

HOUSEKEEPING

COMMUNICATION

No call too small!

- We strongly encourage high levels of communication.
  - Inpatient enrollments
  - Outpatient prescriptions ask for date and time of pick up
  - Send a schedule of patient visits/appointments
    - – we'll put them on our calendar
  - Scheduling monitor visits
  - Prepping for SQV, SIV, IMV, COV, or audits of any kind
- We are available to chat!
  - If there are complications or things don't go as planned. Let's get together and reassess things to improve the process as well as your satisfaction and participant satisfaction

HOUSEKEEPING

USEFUL INFORMATION:

Shipping Address:

UVA Health
Dept. of Pharmacy, Invesigational Drugs
1 Lane Rd., Loading Dock, Rm. G-541
Charlottesville, VA 22908
Attn: <Name of Pharmacist Handling Study>

Group Email: CLPharmacyInpatientIDSpersonnel@hscmail.mcc.virginia.edu

Group Vocera: Pharmacist Inpatient Investigational


THANK YOU FOR LISTENING
ANY QUESTIONS?
imgflip.com