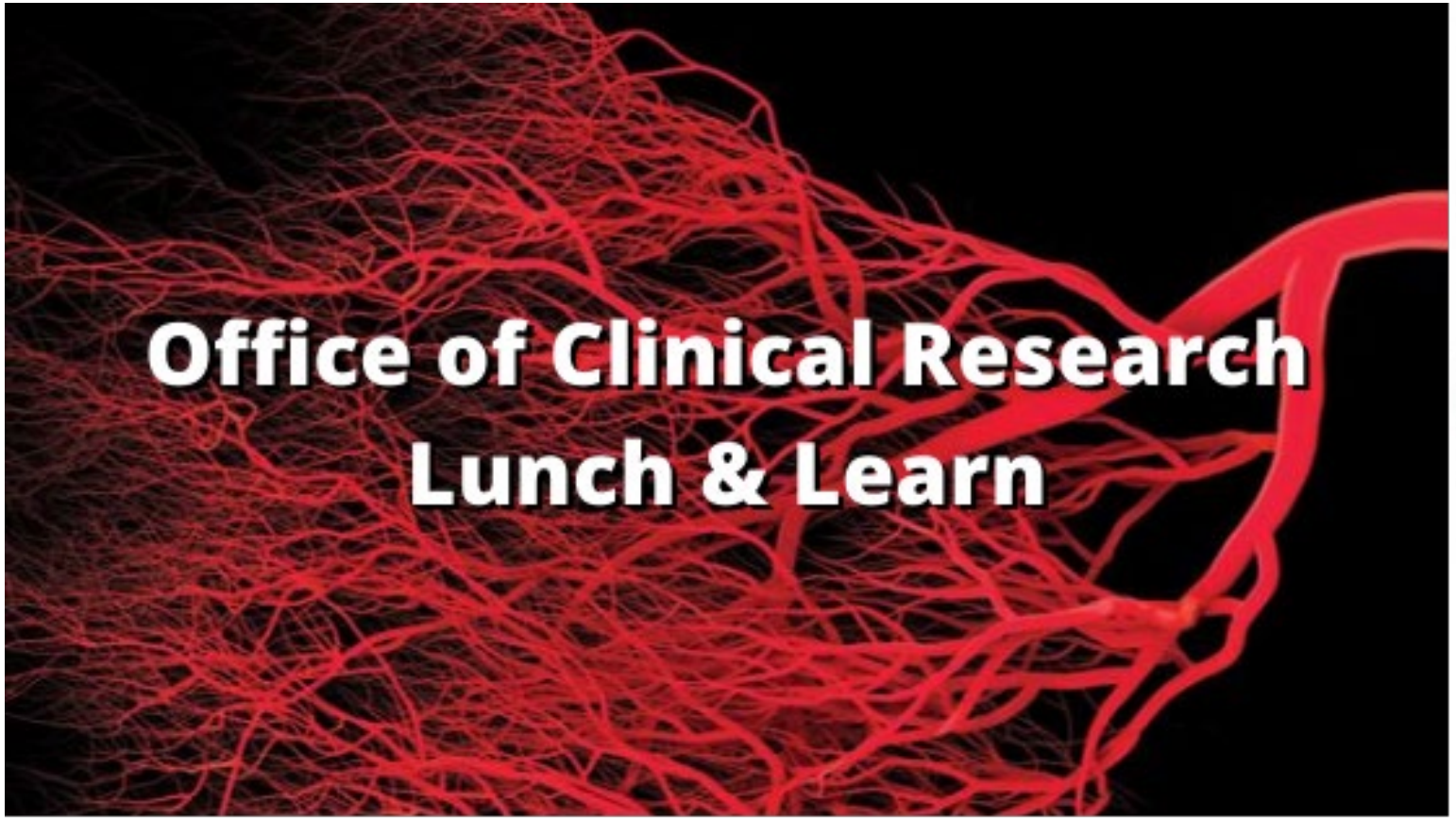


UC Health Investigational Pharmacy (IDS): Overview, Updates, Best Practices and FAQs

Thursday, June 17th, 2021

UC Health

June 2021 Study of the Month

Adolescents with Depression and/or Anxiety

and a parent or sibling with Bipolar Disorder

What

The purpose of this research study is to investigate brain changes in adolescents who are currently experiencing depressive and/or anxiety symptoms and have a family history of bipolar disorder. Participants will be randomized to escitalopram and psychotherapy or placebo and psychotherapy for 16-week treatment.

Who

Adolescents 12 to 17 years of age who are experiencing depressive and/or anxiety symptoms or have been diagnosed with depression and/or anxiety may be eligible to participate.

Pay

Participants will receive compensation for their transportation and/or time for the study visits. All visits, tests, procedures and medication will be provided at no cost to participants.

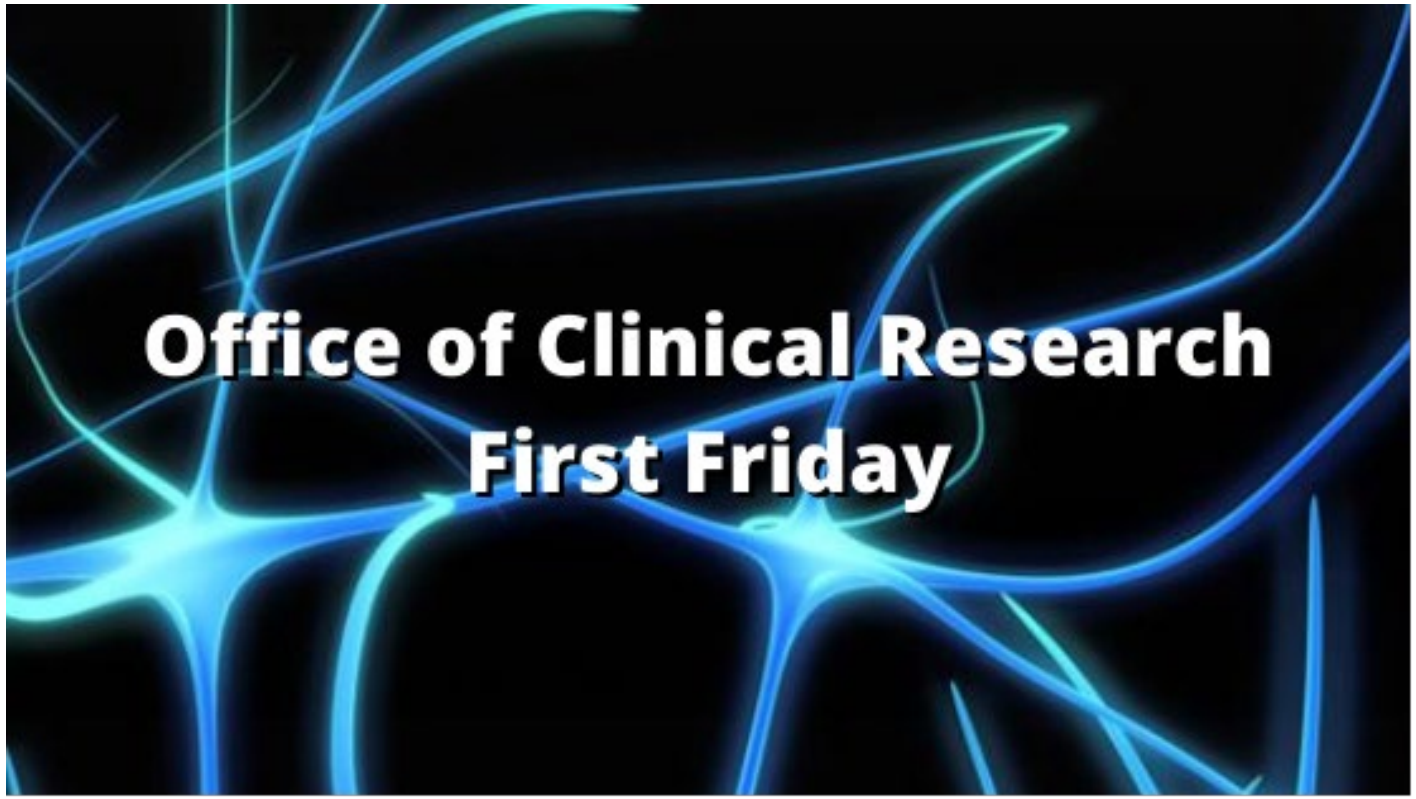
Details

Participants will have MRI scans. For more information, contact Kaitlyn Bruns at kaitlyn.bruns@uc.edu or call 513-558-5303.

UC Health | Cincinnati Children's

60-15 CCHMC IRB # 2015-5735

UC Health



THERE WILL BE NO FIRST FRIDAY FOR JULY 2021

Due to the Holiday weekend

Enjoy your 4th of July!!!

UC Health

Today's Presentation:

UC Health Investigational Pharmacy (IDS): Overview, Updates, Best Practices and FAQs

An overview of best practices and frequently asked questions when it comes to engaging Investigational Pharmacy (IDS) for your studies. Also updates to IDS procedures, as well as a refresher/overview of Beacon Builds.

Lisa Altenau, PharmD, RPh

Mary Burns, PharmD, RPh

Caron Sue, PharmD, PhD

University of Cincinnati Medical Center
UC Health Office of Clinical Research
Investigational Pharmacy

UC Health

UC Health Office of Clinical Research

Investigational Pharmacy

Lisa Altenau, BS, PharmD, RPh

Mary Burns, PharmD

Judy Houston, BS, RPh

Dorice Smith, BA, CSPT, CPhT

Justin Ragle, CSPT, CPhT

Caron Sue, PharmD, PhD

New IDS staff will be starting in July

EPIC Infusion Plans and Treatment Plans

Infusion Plans

- Used for outpatient infusion visit
- Incorporates protocol treatment into one seamless physician order
- More than one infusion plan can be applied to patient at a time
- Used by Oncology and Non-Oncology practices

Treatment Plans (Physician orders/BEACON)

- Inpatient or outpatient physician order
- Used in Oncology practice
- Only one treatment plan and one supportive care plan can be assigned to a participant at a time

Inpatient medication order

Orders are needed for all medications administered to participants that are assigned an inpatient status.

- **IDS can help determine if an order, order panel, or order set is needed.**
- **Order sets are recommended for complex investigational medication treatments.**
- **Kinds of inpatient orders:**
  - EPIC (order, order panel, or order set)must be signed by eligible provider
  - Written must be signed by eligible provider
  - Telephone must be communicated by an eligible provider to a pharmacist.

EPIC Outpatient Infusion Plans and Treatment Plans

- **Enter an IS&T self service ticket**
  - This requires a manager to approve the ticket.
  - Complete the Infusion Plan or Treatment Plan form.
  - Attach form, protocol and pharmacy manual as attachments to ticket.
- **The EPIC team will build the order**
  - The EPIC team will notify study coordinator, IDS Pharmacy, and possibly a clinical pharmacy specialist once build is complete. An extract of the build will be sent to the study staff for review.
  - Once the study coordinator and pharmacy have approved, the EPIC team will ask the study coordinator to obtain PI approval of plan.
  - After all approvals are obtained, EPIC team migrates the plan into production.
- **The EPIC team will migrate the plan into production**
  - Any changes to the protocol or pharmacy manual that affect the plan will need to have a new ticket submitted. The process is the same as the original ticket.

UC Health IDS

Personnel

- Lisa Altenau, B.S., Pharm. D. , R.Ph. - IDS Pharmacist (lisa.Altenau@uchealth.com)
- Judy Houston, B.S., R.Ph. – IDS Pharmacist (Judy.Houston@uchealth.com)
- Dorice Smith, B.A., C.Ph.T – Technician (Dorice.Smith@uchealth.com)
- Justin Ragle, C. Ph.T – Technician (Justin.Ragle@uchealth.com)
- Mary Burns, Pharm.D., R.Ph. – IDS Pharmacist (Mary.Burns@uchealth.com)
- Eric Mueller, Pharm.D., FCCM, FCCP – Assistant Director (Eric.Mueller@uchealth.com)

Service Email: IDS-Pharmacy@uchealth.com

Location: Medical Science Building G253

Contact IDS for shipping address

Contact Numbers

During IDS Office Hours (M-F 0700-1630 or by appointment)

1. IDS Research Pharmacist Office 513-584-1766
2. Central Pharmacy 513-584-1768
3. Central Pharmacy IV Room 513-584-7263

After IDS Office Hours*

1. Central Pharmacy 513-584-1768
2. Central Pharmacy IV Room 513-584-7263

*Central pharmacy will contact IDS and manager on-call for urgent matters.

What is UC Health Investigational Pharmacy?

- **Pharmacy licensed to dispense investigational agents**
- **Approximately ~300 studies**
- **Study Sites:**
  - UCMC
  - UCGNI
  - Barrett
- **Satellite Sites:**
  - WCH

Services Provided by IDS and UCHealth Pharmacy Services

- Study design and set up
- Budgetary consultation
- Randomization
- Pharmacy regulatory guidance and support
- Multiple site coordination of UC Health Pharmacy Services
- EPIC order guidance
- Drug procurement, storage, inventory management, accountability, preparation, compounding, dispensing, monitoring
  - Oral dosage forms to hazardous drugs
  - Sterile product preparation and compounding
  - Capsule/masked product compounding

IDS Fee Schedule Structure

- Study Types
  - Industry
  - Investigator-Initiated
  - Cooperative Groups
  - Federal
  - Stem Cell study
- Fee Categories
  - Start-up
  - Annual/Maintenance
  - Dispensing
  - Close-out
- Considerations
  - Monitoring and documentation intensity
  - Drug handling complexity (e.g., controlled substance, hazardous; special storage; waste/destruction)

Drug Purchase Quotes

- Historically based on patient care charge structure
- Updated process
  - Drug Costs
    - CMS (Medicare and Medicaid) Drug Pricing File: (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/).
    - UCMC wholesaler or manufacturer acquisition price
  - Study type
  - Inpatient or outpatient
  - Patient or research billing
  - Wholesaler availability
  - Purchased by item or bulk package
  - Independent of administration and dispensing fees

What does IDS need to start a trial?

- Latest copy of protocol, investigator brochure, pharmacy manual (if available), and general informed consent
- Complion access or provide IDS information
- IRB approval letter (including UC's if using an outside IRB)
- UC Health approval letter
- A physician order template: hard copy prescription, infusion plan, treatment plan, or EPIC order set
- List of authorized prescribers (on 1572 or DOA)

What does Pharmacy need to randomize a patient?

- **First and signed page of the informed consent**
- Documentation of patient name, medical record number, study ID number, and date of birth
- Signed order for medication by approved provider
- IVRS vial assignments (if applicable)
- If the patient is in an infusion area, the patient will need an ok to treat order placed (green light)
- If the patient will be treated at an outside institution

Vestigo™ (http://www.mccreadiegroup.com/vestigo/)

- Electronic accountability system
- Automated platform to improve accuracy, efficiency, and safety
- Web-based supports ‘remote’ users and system-wide access
- Monitors granted access upon request
- Temperature logs, shipment receipts, etc.

UC Health

Vestigo

Main | Help & Support | Log Out

User: Mary Burns
Facility: UCMC Investigational Pharmacy

Protocol Search | Address Book | Billing Management | Inventory Management | Protocol Management | Reports | Process Returns | Search Subject and Rx's | Calendar | Forum

My Facilities | Prescriptions (12) | Pending Shipments (0) | Monitor Visits (58) | Inventory Status (143) | Drug Returns (1206) | Protocol Operations (5)

Refresh Alerts

	Last Updated
There are 12 Patient Visits pending	06/16/2021 14:27

Protocol Search | **Add New**

[ ] Open Search

Protocol	Status	Number	IRB Expiration	Facilities
EXPEDITE: A 16-Week, Multicenter, Open-label Study of Remodulin Induction Followed by Orenitram Optimization in Subjects With Pulmonary Arterial Hypertension	Recruiting	TDE-PH-402 EXPEDITE | Remodulin; 2018-4805 | IDS # 2646-18 Site 069 | P410	5/8/2022	UCMC Investigational Pharmacy
B-Cell Targeted Desensitization with Carfilzomib for Preformed Anti-HLA Antibodies in Patients Awaiting Kidney Transplantation. Protocol Carfilzomib Desensitization	Recruiting	2344-14 | 2014-0577 | Carfilzomib Desensitization | P204	9/1/2021	UCMC Investigational Pharmacy, Barrett Pharmacy, UCMC Inpatient Pharmacy
ABTL0812 in Combination With FOLFIRINOX for First-line Treatment of Metastatic Pancreatic Study	Recruiting	ABT-C11-2020 | 2020-0078 | IDS# 2900-21 | P716	3/6/2022	UCMC Investigational Pharmacy
A Phase III Multicenter, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Teriflunomide in Adult Patients with Relapsing Multiple Sclerosis; Roche Protocol GN42272.	Not yet recruiting	GN42272 | 2883-21 | P710	Not Tracked	UCMC Investigational Pharmacy
A 12-month, Open-label, Multicenter, Randomized, Safety, Efficacy, Pharmacokinetic (PK) and Pharmacodynamic (PD) Study of an Anti-CD40 Monoclonal Antibody, CFZ533 vs. Standard of Care Control, in Adult de Novo Liver Transplant Recipients With a 12-month Additional Follow-up (CONTRAIL I)	Recruiting	CCFZ533A2202 | IDS# 2684-19 SITE # 1005 | P520	12/1/2021	UCMC Investigational Pharmacy

Pitfalls and Limitations

- **Lack of appropriate paperwork prior to patient treatment**
- **SIV Scheduling**
  - Make sure to include IDS
- **No available IP to treat first patient/Ordering confusion**
- **Shipments sent to the incorrect address**
- **Incomplete Orders/Prescriptions**
  - Weight different in IWRS vs. Epic, Hard copy RX not appropriately filled out, etc
- **Limited Refrigerator Space/Freezer Availability**
- **Late emails**

Communication Tips

1. If a potential study or grant will involve investigational drugs or related supplies, please contact IDS as early as possible in the process. This includes during grant writing and budget construction as well as initial review of protocols for industry-sponsored or cooperative group studies. IDS also welcomes the opportunity to participate in site initiation visits (SIV)

2. The preferred contact for IDS is via email (IDS-Pharmacy@uchealth.com). Using this address will promote better communication among IDS pharmacists and technicians, allowing IDS to better serve the needs of the research team. If there is a delay in IDS response, please call IDS directly or contact eric.Mueller@uchealth.com

3. Include the following information in all email correspondences:

   - Subject line: IDS# (if available) and purpose of the request (e.g. refill, quote, monitoring visit)
   - Body of email:
     - Be as descriptive as possible including brief study title, running header or name (e.g. CORTICUS)
     - Study Drug prescriptions: Subject # and MRN (if available) and date and time study drug is needed
     - The primary contact if different from the person sending the email.

Recommended Timeframes For Specific IDS Requests

• Scheduling Initiation or Monitoring Visits	2 weeks
• Prescription Requests	48 hours
• Scheduling Infusion Visits	1 week
• Transfer of Investigational Product to Another Site	1 week
• Sending Approval Documents to IDS	As Soon As Received