Working with the Research Pharmacy (RP) Investigational Drug Services (IDS)

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Goal and Objectives

- **Goal**
  - To familiarize participants with the procedures of the RP
- **Objectives**
  - To understand the procedures of receiving, storing, dispensing, and ordering investigational drugs
  - To understand the different requirements of the RP

RP Background

- **Hours of Operation**
  - Monday – Friday 7:30am – 5pm
  - Phone: 202-444-3771 Fax: 202-444-4883
  - On-Call Services (OFF-Hours)
    - 202-405-3538
    - Covered by Research Pharmacists and Oncology Pharmacists
  - Back-Up Research Pharmacy Manager – 202-405-0177
- **Main Hospital Pharmacy**
  - 24/7/365

RP Background

- **Two research pharmacists and two technicians**
  - Pharmacists
    - Safae Chouraichi, Pharm.D.
      - Safae.chouraichi@gunet.georgetown.edu
    - Alim Gebrou, RPh
      - AAG2@gunet.georgetown.edu
  - Pharmacy Technicians
    - Shireta Hatcher, CPTh
      - Shireta.briscoe@gunet.georgetown.edu
    - Ako Tabetah, CPTh
      - Ako.tabetah@gunet.georgetown.edu
  - Simona Armanca, Pharm.D. – Clinical Pharmacist

RP Background

- **Dedicated to clinical trials**
- **Over 200 active protocols**
- Lombardi Cancer Center, Neurology, Memory Disorders, Movement Disorders, Infectious Diseases, Transplants, Surgery / Wound Care, Neonatal, Pediatrics, and PI Initiated Studies
- Phase I to IV, Feasibility, and Pilot Studies
- Inpatients and Outpatients
General Regulations and Policies

• Why do I have to use a Research Pharmacy?
  – FDA
  – Department of Health/Board of Pharmacy
  – MedStar/MGUH/GUMC
    • Intervventional
    • Exceptions

RP Services

• Core Services
  – All aspects of handling of study medications
  – No - Radiation Materials and certain devices
• Protocol Review and RP Budgeting
• Basic Randomization
• Admixing/Compounding
• Blinding
• Protocol/Grant Submission – Pharmacy Procedures
• IRB Participations
  – IRB Committees, AE Subcommittees, DSMC, CRC

RP Investigational Product (IP) Procedures

• Receipt
• Storage
• Dispensing
• Accountability
• Procurement
• Return
• Destruction
• Sponsor Visits
• Records Storage

IP Procedures - Receipts

• Insulated Storage Containers
  – TempTale, FreezeTag, TempDatalogger, Libero, TempTracer
• Invoices / Shipping Forms

IP Procedures - Storage

• Security / Restricted Access
• Equipments
  – Subzero (-20°C) and UltraLow Freezers (-70°C)
  – Liquid Nitrogen Freezer (-180°C)
  – Refrigerators (2-8°C)
  – Controlled Room Temperature (15-30°C)
IP Procedures - Storage

• Temperature Monitoring Devices
  • Min. and Max.
  • Temp. Datalogger - Elpro
  • Alarm System - Sensaphone

IP Procedures - Dispensations

• Registration – Non-Lombardi
  – SMS Invision
  – PharmNet
  – Centricity ≠ Cerner PharmNet
  – Reregistered Monthly
• Lombardi – Own Registration

IP Procedures - Dispensations

• Pre-Printed MD Order Form
• Chemo Order Form

IP Procedures - Dispensing

• IV - Compounding

IP Procedures - Dispensing

• Oral IPs
  – IVRS Assigned Kit Numbers

• Labeling
  – MGUH’s Labels

IP Procedures – Dispensing Forms

• Drug Accountability Record Form (DARFs)
  – NCI / PMB
  – DAIDS/ACTG
  – Sponsor Provided Forms
  – MGUH RP Printed Forms
IP Procedures – Dispensing Forms

- Standard of Care Meds
  - Lot # and Expiration
- Monthly Reconciliation ACTG / NCI Protocols
- Expiry Tracking
  - Re-test Dates

IP Procedures – Procurement

- NCI / CTEP-IAM Website
- ACTG / DAIDS
  - Faxes
- Industry / Sponsor Specific Procedures
  - IVRS / IWRS / IXRS
  - RAMOS
  - Forms
  - Email / Fax
- Contact RP – dormant protocols

IP Procedures – Patient Drug Returns

- WebForm
- Excel Database

IP Procedures – Return Storage & Destructions

- Space
  - Limited
- Destruction SOP
- Off Site SOP
  - Incineration

RP Procedures – Sponsor Visits / Audits

- Pre-Qualification / Site Selection Visits
- Site Initiation Visits
  - SIV Questionnaires
  - Site Standard Procedures Packet – Pending
- Routine Monitoring Visits
- Close Out Visits
- Audits
  - Internal
  - Sponsor
  - FDA

RP Procedures – Records Storage

- Recall, Inc (Iron Mountain) - 5 Years
  - Shipping Documents / Invoices
  - Accountability Logs
  - Temperature Logs
  - All Correspondence
  - Emails, Faxes, Letters, Memos To File (MTF)
  - Destruction or Drug Return Forms
  - Training and Delegation Logs
- Can sponsor take their originals at close out?
- Why does the RP store records separate of the regulatory documents?
RP - WebPages
- Internal
  - Webpage
- External
  - CRU
  - CTO

RP - WorkFlow

Future Directions
- Electronic Inventory and Accountability
- Patient Counseling
- Drug Interactions Review

Questions?
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