Research Pharmacy – An Ancillary Review
Objectives

1. Review the goal of the Research Pharmacy (RP) and its origins
2. Discuss the role of the Research Pharmacy across the lifecycle of a clinical trial
3. Review role of the RP pharmacists in IRBMED process
4. External IRB Oversight and Drug Accountability
• **Research Pharmacy (RP):** Health-system service within the Department of Pharmacy Services that ensures human subject research involving investigational drugs is conducted safely, efficiently and correctly.
  
  - Also known as **Investigational Drug Service (IDS)**

• RP operations are structured to comply with the guidelines/policies and key stakeholders

  - Good Clinical Practice (GCP) Guidelines
  - Institutional Standards
  - Local, State, and Federal Law
  - The Joint Commission
  - FDA/Code of Federal Regulations
  - Study Sponsors
Established **July 1984** at the *University of Michigan Hospital*

Created in response to several factors:
- NCI medication handling and compliance guidelines published in 1983
- Issues with medication storage, inventory management, documentation
- Medication errors and protocol deviations
- Noncompliance with state laws regarding dispensing (licensure, labeling, etc.)

Mandated by the hospital and medical school

Work under Delegated Authority of Principal Investigator (PI)
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Research Pharmacy Role
Study Feasibility Assessment

Site qualification visit

- Tour of major areas involved in the protocol, including pharmacy
- Discussion of standard institutional processes and sponsor requirements

Protocol review and pharmacy budget estimate
Fees are charged for the following services:

- Study Initiation
- Dispensing Costs
- Study Maintenance
- Clinical Services
- Study Closure
- Miscellaneous Costs
Research Pharmacy Role
Study Initiation

- Study team submits eResearch application
- RP will review sponsor-provided materials
  - Materials include: protocol, IB/package insert, pharmacy manual, drug preparation forms
  - Assess study safety and feasibility with respect to pharmacy practice/procedures
  - Identify potential issues/questions
- RP will Ancillary Committee Approve the study
Once IRB approval is obtained for the study:

Lead pharmacist meets with study team and sponsor to discuss study logistics/procedures

Prepare key study-specific documents
  i. Order Set (Paper or Electronic)
  ii. Dispensing Guideline (DG)
Key components include:

1. Indication of investigational drug involvement
2. Protocol-specific identifiers
3. Patient study number
4. Names of investigational/commercial drugs involved
5. Potential dosing levels
MiChart (onsite administration of doses) vs. paper (bulk home administration of doses)

RP starts build process; study team to review

Need to build time into initiation of study for MiChart build

All investigational drug names begin with IRB number “HUMXXXXXXXX”

e.g. HUM00078186 Dalbavancin (DUR001) ___mg in D5W

Order Sets: All names begin with “RSCH” and include the HUM protocol number
Pharmacy staff instructions on how to perform the delegated pharmacy roles:

- Drugs involved
- Patient registration procedures
- Assignment of treatment/dosing
- Preparation and dispensing
- Study design and general drug information
- Drug acquisition and storage details
- Contact information for study team/sponsor
• Document all drug-related activity; maintain accurate drug-related study records
• Order, receive drugs and properly store drugs
• Randomize subjects to protocol treatment (IVRS/IWRS)
• Prepare, label, and dispense drugs upon receipt of prescription
• Upon receipt of order, assume subject qualifies for study, is enrolled in study, IC is obtained and prescriber is authorized to prescribe
• Processing patient drug returns
• Disposition of study drug
Research Pharmacy Role
Study Maintenance – Additional Activities

• Billing for RP services
• Reviewing protocol amendments
• Updating dispensing guidelines, order sets, and study procedures as needed per amendments
• Facilitation of monitor visits and audits from regulatory bodies

Auditing Bodies

- FDA
- Michigan Institute for Clinical & Health Research
- Lilly
- Final closeout visit with sponsor
- Centralization of all study materials
- Disposition of remaining study supplies
- Retention of drug-related study documents
- Finalization of RP charges
- Long-term storage of study files
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Initial applications and amendments: RP reviews and approves
SCR: RP receives notice of approval
AEs/ORIOs (ADVs): not reviewed or approved by RP
• eResearch sections for RP
  – Section 7-1.7: Special Considerations, Drug as test article
Indicating “yes” to question 7-1.7, prompts you to complete Section 15: Drugs, Biologics, Etc.

- What unit will be responsible for storing and dispensing the agent(s)?
  RP or waiver for RP or other
- List all agents that are administered as the object of the study
  – Agents not approved by the FDA
  – FDA-approved agents used "off-label"
  – FDA-approved agents used “on-label”
Research Pharmacy Role
Ancillary Committee of IRBMED

Indicating RP will store dispense (Section 15), prompts you to complete Section 15-1: RP Detail

- Authorized prescribers
- Patient status: outpatient or inpatient
- When will drugs be dispensed? 24/7 or M-F, 8-4:30pm
- Drug source? RP to purchase or supplied by sponsor
- List drugs provided by sponsor and drugs RP needs to purchase
- List drugs RP needs to compound
- Duration of patient recruitment
- Duration of patient drug treatment
Ways you can help: Communicate!

Early in the process
- Appropriate budget
- Necessary documents and information

At study opening
- Inclusion at SIV
- Coordination of initial drug supply
- Enrollment of first subjects
Ways you can help: Communicate!

During the study
- Potential patients and enrollment issues
- Monitor visits
- Drug expiration and other sponsor correspondence

At study closing
- Notification of study status
- Coordination for close out visits
- Final drug disposition
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External IRB Oversight

IRBMED Oversight vs. External IRB Oversight

No difference in RP review!

The role of the RP is to handle the drugs and manage drug accountability when the RP serves as the Pharmacy for the UM-site. This is independent of who serves as the IRB. RP cannot dispense drug for patients at other centers; RP dispenses for Michigan Medicine subjects.
Compounding

- Compounding involves preparing personalized medications.
- Typically used in research for blinding purposes.
- RP cannot compound for other institutions.
- RP can only compound drugs for UM subjects.
  - Can help develop blinding plan and compounding instructions for uniformity across sites
Your Research Pharmacy Team

RP Pharmacists

• Anna Christich, PharmD
• Cathy Dasse, PharmD
• Cathy Francis, PharmD
• Kirk Haddas, PharmD
• Jeff Hurren, PharmD
• Kim Redic, PharmD, BCPS (manager)
• Kate Reeves, PharmD
• Amy Skyles, PharmD
• Helen Tamer, PharmD
RP Contact Information

Research Pharmacy Service (M-F, 8-4:30)
  – Phone: 734-936-7469
  – Fax: 734-647-9302
On-Call Support (24/7): Pager 2944
Thank You!

Questions?