

# Research Pharmacy Services

## Introduction and Overview

**Jennifer Petrolati, PharmD, BCPS Pharmacist**  
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OREGON CLINICAL + TRANSLATIONAL RESEARCH INSTITUTE



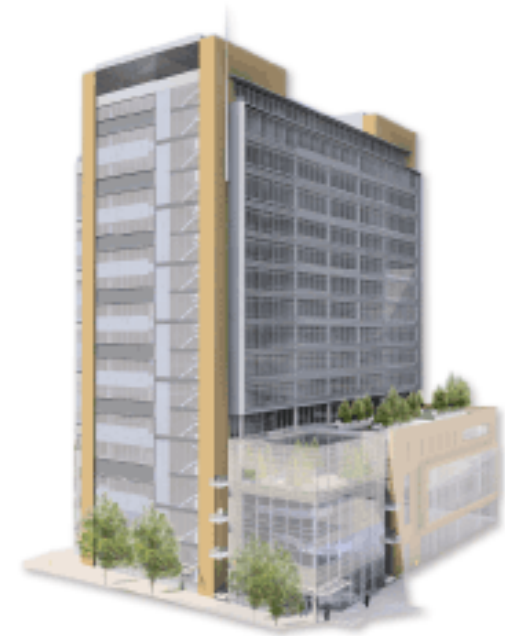
# Research Pharmacy Staff

- Jennifer Petrolati, PharmD, BCPS, Lead Pharmacist , PIC
- Jeanne Liming, PharmD, BCOP, Pharmacist
- Frank Mistretta, PharmD, Pharmacist
- Brad Fujisaki, PharmD, BCPS, Pharmacist
- Sara Blefgen, RPh, CCRP, Pharmacist
- Joshua Wong, CPhT, Technician
- Morgan Marjama, CPhT, Technician
- Pamela Elbon, CPhT, Technician
- Erin Corella, PharmD, BCOP, Manager, Ambulatory Pharmacy Services
- Majid Tanas, PharmD, MS, Assistant Director



# Location

- Off the hill
  - Center for Health and Healing, 3303 SW Bond Ave., Portland, OR 97239
  - 12<sup>th</sup> floor, Room 12106
- On the hill
  - Central pharmacy (4C - hospital)
  - Outpatient pharmacy (Physician's Pavilion)



# Hours & Contact Information

- Hours of operation
  - M-F 8:00-16:30
  - After hours – Central Pharmacy, Research Pharmacist on-call (pager 11932)
- Contact info
  - Phone – (503) 494-6865
  - Fax – (503) 494-1096
  - Email – [invdrugs@ohsu.edu](mailto:invdrugs@ohsu.edu)
  - [www.ohsu.edu/pharmacy/rps](http://www.ohsu.edu/pharmacy/rps)



# Research Pharmacy Services

- **Purpose**
  - Ensure research involving investigational medicine is conducted appropriately, maximizing patient safety
- **The Joint Commission**
  - MM 7.40 – Investigational medications are safely controlled and administered
  - Pharmacy responsible for the storage, dispensing, labeling, and distribution)
- **Oregon Board of Pharmacy**
  - OAR 855-041-0130 - All investigational drugs shall be stored in the pharmacy and distributed only from the pharmacy



# Research Pharmacy Services

- Drug ordering
- Drug storage
- Drug delivery & transport
- Monitor visits
- Budget estimates
- Compounding
- Dispensing
- Drug information
- Protocol review
- Special labeling
- Billing services
- Patient monitoring
- Dose adjustments
- Drug interaction checking
- Temperature monitoring



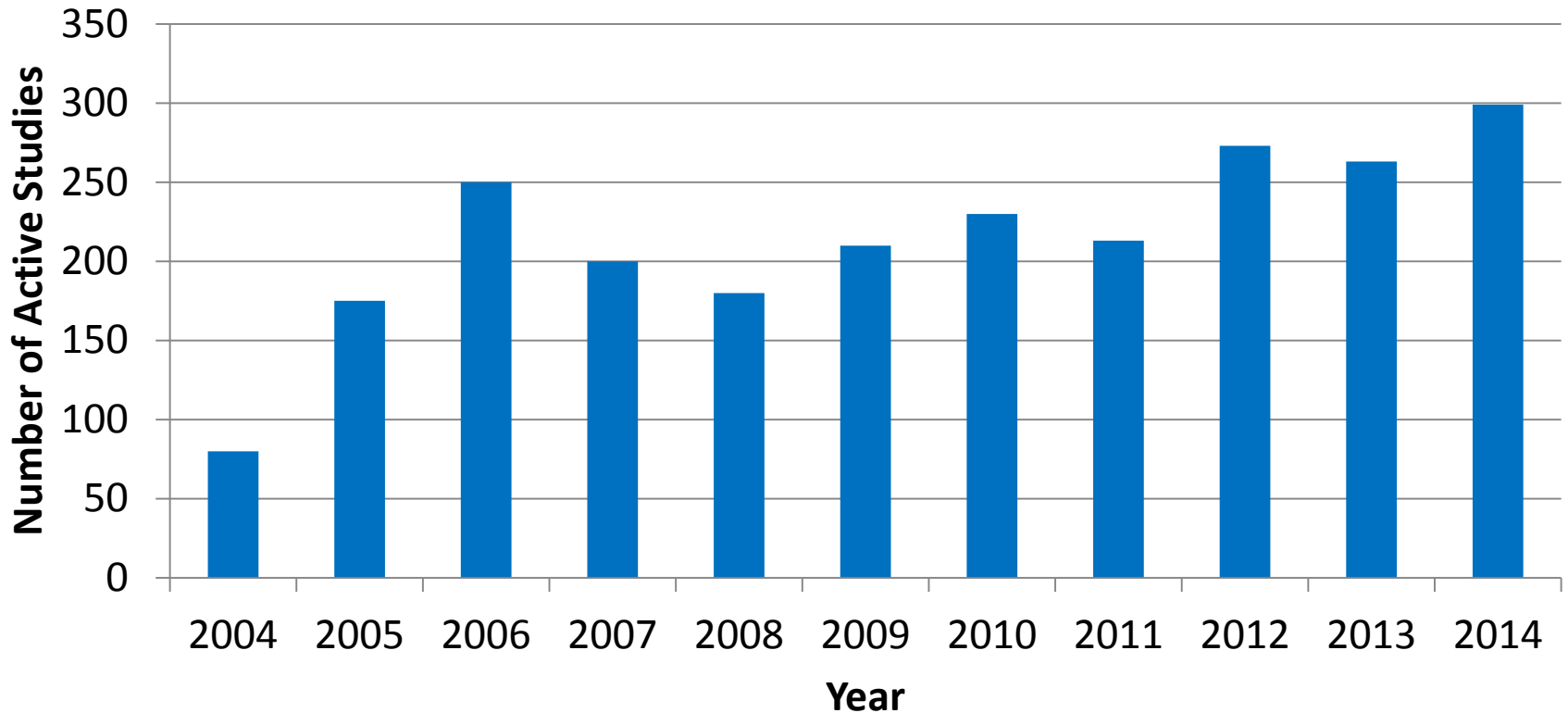
# When Is RPS Required to Be Involved?

- RPS must dispense
  - Any investigational medication
  - Any medication requiring preparation
  - Any medication requiring repackaging or labeling
  - Any medications being charged to sponsored project accounts
- Exceptions:
  - Prepackaged oral medications in non-OHSU Health System buildings
  - Medications filled by prescription and billed to 3<sup>rd</sup> party/patient
  - Over-the-counter medications in original packaging and not requiring patient specific label
- If study involves veterans, the PVAMC Research Pharmacy will need to dispense medications to veterans



# Studies Involving RPS

## RPS Study Volume





# Initiating RPS – Required Information

- Draft protocol or grant
- Investigational Drug Brochure (IDB), if applicable
- RPS Cost Estimate
  - Usual turnaround, 2-5 days
  - Assess legal requirements and any special needs
  - Evaluates ability to conduct study
  - Remember to include pharmacy fees in research contract or grant



# Requirements Prior to First Dispensing

- Drug
- Final Protocol & Investigator's brochure (e-file ok)
- Notice of IRB Approval (eIRB #) – study must be approved by IRB
- Final order form (templates available on website)
- Grant/Study Specific Account Numbers (at least 24 hours in advance)
  - OGA Alias (SPA – Sponsored Projects Administration)
  - Research rate request form
  - Industrial account number (PBS billing)
  - FAID (fiscal authority)



# Required Medication Order Contents

- Drug Study Name
- Industrial Account #
- Patient demographics
- Patient MRN and Study ID#
- Allergies
- Drug Name, Dose, Route & Frequency of Administration
- Quantity or Duration
- Directions
- LIP signature
- Rx/order states that this drug is for an investigational study
- Date and time medication is needed



# Additional Ordering Requirements

- Customized order form template – must be reviewed by Research Pharmacy Services prior to first use
- Scheduled (II-V) medications
  - Contact us for requirements
- Order completion
  - All required elements
  - Approved abbreviations only ([www.ohsu.edu/pharmacy](http://www.ohsu.edu/pharmacy))
  - Signatures
    - Who: MD, PA (special requirements may apply), NP (only if FDA approved medication)
    - No signature stamps
  - Verbal orders
  - Advance orders



# Ongoing Requirements

- Monitoring visits – at least 24-48 hours advanced notice required, however 3-4 weeks notice recommended (limit 3 visits/day)
- Copy RPS on all:
  - Protocol modifications
    - Change drug dose or handling of drug
    - Change protocol
  - IRB renewals
  - IDB Updates
- Pharmacy termination  $\neq$  IRB termination



# Ten Things to Remember When Using RPS

- 1) Contact RPS early and often
- 2) Remember to budget for RPS
- 3) Have RPS sign research rate request form
- 4) Notify RPS in writing about status of study (termination, extension, changes in protocols, etc)
- 5) Provide plenty of notice for upcoming monitor visits
- 6) Provide accurate and up-to-date account numbers

<http://www.ohsu.edu/xd/research/about/integrity/crbo/definitions.cfm>



## Top Ten Things to Remember when Using RPS

- 7) Fax **COMPLETE & SIGNED** orders in a timely fashion
- 8) Outsourcing of pharmacy services must be done with the knowledge & approval of RPS
- 9) No samples – all drugs dispensed in the outpatient setting at OHSU must be labeled per ORC and dispensed from a licensed pharmacy
- 10) Notify RPS regarding patient schedules and visits

