

# Building a Biosafety Program from Scratch

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# Penn State Campuses



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## Penn State Milton S. Hershey Medical Center CAMPUS MAP





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# PSU/College of Medicine facts

- 1700 ongoing IRB approved protocols
- 300 Biosafety approved protocols
- 300 IACUC approved protocols
- 200 Basic Science Research faculty
- 350 Research labs
- Cancer Institute
- Hershey Center for Applied Research (HCAR)
- Central Animal Quarters(CAQ)and Animal Research Farm (ARF)
- Zebra Fish and Transgenic Mouse core
- 12 additional technical Research Core Facilities
- \$100 M in research funding
- 11000 employees



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# Biosafety Structure



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# Redefined role of Biosafety

- Biosafety responsibilities were removed from the Department of Safety in 2010 and assigned to the newly formed Research Quality Assurance Office. (RQA)
- The intent was to create a model Biosafety program to ensure compliance with IBC Committee-approved protocols and SOPs, while increasing research lab oversight, training and approvals.



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# RQA Staff

- Biosafety Officer
- Human Research Trials Compliance Manager
- Assistant Biosafety Officer
- Clinical Trial Compliance Specialists
- Research Compliance Specialists
  - Administration of IACUC and IBC Committees



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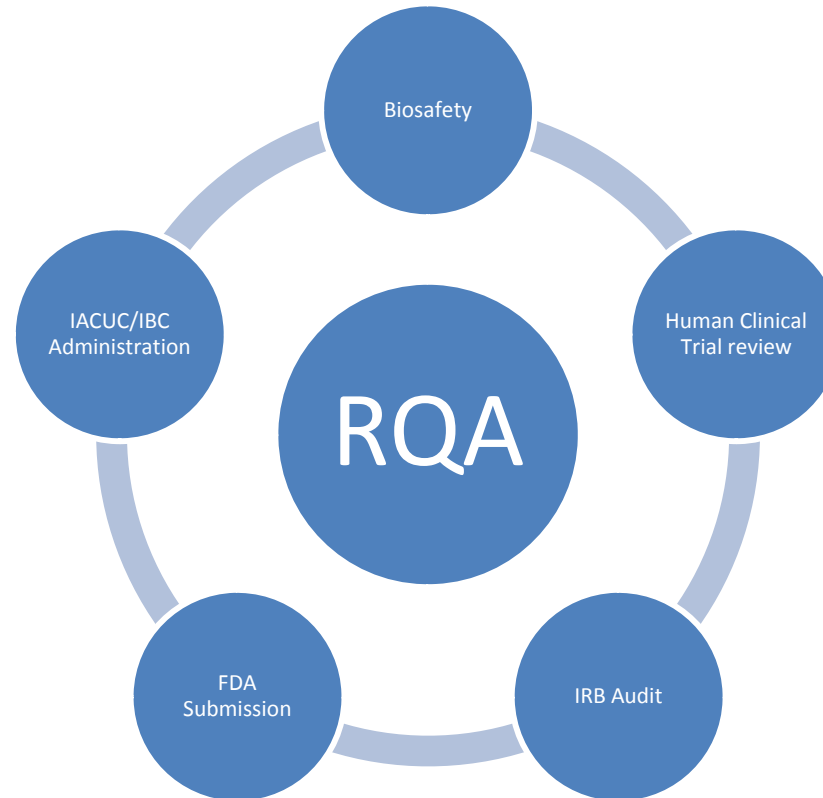


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# Research Quality Assurance Office



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# Reporting structure

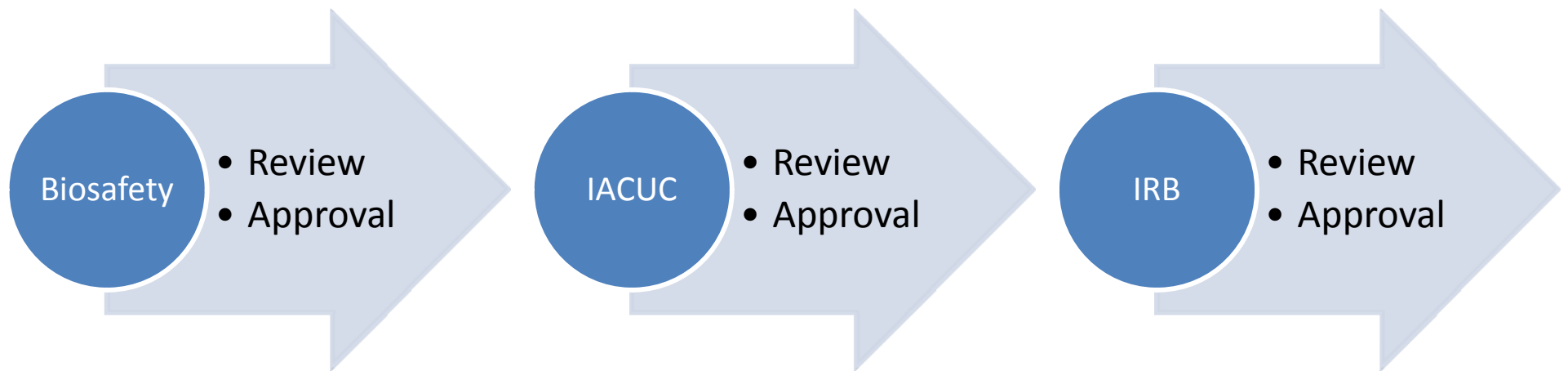


# COM/HMC Process for review

- All work with biologicals in a research setting, or work with clinical biological products used for research, must be approved in the following order prior to the initiation of the project.
  - IBC/BSRD Committee (*Biosafety and Recombinant DNA*)
  - IRB
- Ancillary reviews via the electronic compliance protocol system, CATS (Central Automated Tracking System), to ensure all work is reviewed and approved by appropriate personnel in the RQA and IRB offices.



# Ancillary Committee Review



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# Biosafety Program Components

- Developed a unified complete lab survey and follow up visit based on the Biosafety Level of the approved agent
- Increased biosafety training and collaboration activities
- Provide timely ancillary reviews for all IRB, IACUC and IBC for grant approval and renewal



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# Biosafety Program Components

- Established a Lab equipment asset management program to insure quality of equipment in all funded and unfunded research labs as required by the CDC/NIH
- Creation of a home grown cyber-secure LabManager database system to centralize all research lab information for complete and easy access
- Liaison with the Chemical Safety Officer from the Department of Safety through the use of a unique ticket



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# IBC Requirements at COM

- The COM reviews and approves all biological materials as well as Recombinant DNA used on campus.
- Specific SOPs must also be included with each submission for review and approval
- The lab survey is scheduled to ensure all aspects of the approval are in place prior to start of project
- BSO voting member of IBC
- Reviews biological components of IACUC submissions
  - Monthly guest of IACUC for discussion and Biosafety update



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# Biosafety Approval required

- ✓ Unfixed human or non-human primate materials?
- ✓ Biological toxins or carcinogens?
- ✓ Infectious agents?
- ✓ Recombinant infectious agents?
- ✓ Recombinant retroviruses?
- ✓ Recombinant DNA?
- ✓ Recombinant DNA **in animals**?
- ✓ Biohazards **in animals**?
- ✓ Genetic manipulation **in animals**?
- ✓ Human embryonic or pluripotent stem cells





# SOP requirements for all IBC approved protocols

- As always, specific procedures must be posted where work is being performed, as well as documented in the approved lab biosafety notebook
  - *Procedure to follow in the event of an accidental spill*
  - *Procedure to follow in the event of an accidental exposure*
  - *Documentation of PI training for use of agent*





# Formal Lab survey process

- **Survey and follow up**
  - Initial shared information with PI and all lab staff
  - Lab walk through and procedure review
  - Components of Biosafety level specific survey
    - Survey overview
  - Follow up of items found during survey
    - Sign off procedure
    - Informational Lab visits

**T4318 – Survey: 2017-09-07 (Initial)**

**EHR Numbers:**

EHSR: [blank] | IACUC: [blank]

**SOP (BRC, IACUC) on File:**

Type of Agent	Lab Agent	1	2	3	YOC	NO	N/A
<b>Conditions</b>							
2A. Lab access limited/controlled when experiments or work with cultures/specimens are in progress.							
2B. Lab personnel wear knee high kneeling lab coats, shoe covers, gloves, or lab gowns.							
2C. No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab.							
2D. Operator wears eye safety glasses, goggles or face shields.							
2E. Hand stored outside Lab in designated substrate/configuration.							
2F. Mechanical pipetting devices are used (i.e., no mouth pipetting).							

# Initial Lab Survey Components

- Snapshot of all PI Biosafety, IACUC and IRB approvals
- MTA forms and procedures
- NIH Guidelines for Recombinant and Synthetic DNA
- BMBL 5<sup>th</sup> edition
- NIH responsibility guideline from the NIH
- Lab specific/equipment specific emergency plan template
- IBC process flowchart
- Biosafety manual table of contents
- Approved agent SOP for cleanup and exposure
- Disinfection method overview



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# Lab Survey make up

- Listing of all Current IBC, IACUC AND IRB Approvals
- Approved SOPs
- All Agents filed under Biosafety approval
- Survey Questions based on Approved BSL #
  - Standard Microbiological Practices
  - Special Practices
  - Safety Equipment (Primary Barriers)
  - Laboratory Facilities (Secondary barriers)



# Lab Survey Summary

- Survey Findings
- Training verification
- Signed summary after completion of survey findings

**Laboratory Survey Summary Report**

Lab members in attendance: XXXXXXXX,XXXX -XXXXXXXX,XXXX -XXXXXXXX,XXXX	Room #: XXXXX Survey Date: 01/01/00	BSL Level: BSL-A	IRLA members in attendance: Schertz, Jay -Arthur, Kevin
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The lab survey was conducted at XXXX covering the specific topics of:

Lab specific Emergency plan Laboratory Biosafety Notebook Specific spill and exposure SOP	Laboratory Decontamination Biosurvey completion CITI Training recommendation
---	--

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A review of all above-labeled topics and other regulatory policies was completed and found to be in compliance, with the following exceptions/observations:

**Action Required:**

- Lab was instructed to send the Quantified Biological Inventory (Bio Stewardship) to RQA – **OVERDUE**
- Lab was instructed to send Biosafety all training dates/types immediately
- Lab was instructed to post the [Lab Specific Emergency Plan](#) where research product is being stored
- Food and/or drink containers were observed in laboratory space - **Absolutely NO food or drink is allowed in the lab at ANYTIME!** This includes food waste and food stored in desks/bags
- Lab was instructed to place an in-line filter before wall filterboxes in use, routinely changed every 6 months or as needed based on saturation
  - Product example: [SLEPDS10 / Millipore Filter Unit 0.20µm hydrophobic PTFE](#)
- Lab was observed not wearing lab coats(s) - Lab was reminded about requirement for all lab users in a BSL2 (or higher) facility to **wear lab coats when ANY work is being completed by 1 or more persons**
- Unwashed sharps observed in lab - **Sharps must be in secondary containment when not directly in use**
- Lab was observed reusing gloves/PIPs - **Gloves/PIPs are to be disposed at immediately after removal**
- Lab was instructed to immediately empty "Red Bag" biohazardous and/or sharps waste **when 75% full**
- Lab was instructed to place a **"No food or drink"** sign on lab microwave

**Non-Action:**

- Lab was given template for eyewash stations - check/fill out accordingly (1x2min flush/agg)
- Lab was advised about benefits of decontaminating using iodophores and disinfectant solutions
  - o Product example: [Wescodyne 2.400 @/1000](#)
- Lab was given cleanup/spill/regulation SOP flyers to be posted in work areas immediately

**FOLLOW-UP:**

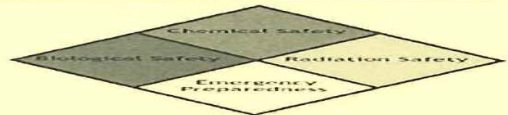
**\*\*UNANNOUNCED INSPECTION WILL RETURN WITHIN THREE WEEKS TO ENSURE COMPLIANCE\*\***

I was aware of the name and have been notified when and there is no need to insure and/or send or research, model or culture collection.	<b>SURVEY CLOSEOUT – LAB COMPLIANT</b>
_____ Principal Investigator	_____ Biosafety Officer

# Informational Lab Visit

<b>Date</b>	
<b>Room #</b>	
<b>PI</b>	
<b>Inspection Items</b>	<b>Check</b>
Biosafety Approval #	
IACUC Approval #	
IRB Approval #	
Radiation use Approval	
Placard Information accurate	
Biological inventory available?	
Chemical inventory available?	
"Extremely Hazardous" Inventory available (if applicable)?	
SAA log book available?	
SAA properly maintained?	
PPE worn?	
Controlled substances secure?	
DEA License active	
Lab Cleanliness	
Door locking	
Lab Specific Emergency Plan	
Comments	

**INFORMATIONAL LAB VISIT**



# Biosafety Manual

- Lab Survey overview provided at the survey by the RQA office
- Specific lab Emergency Plan developed by individual lab
  - Include all emergency contact numbers
- Approved protocols
  - Biosafety
  - IACUC
  - IRB
- Approved SOPs
- Specific procedures for disinfection in case of a spill
- Lab staff training dates and updates
  - General Training
  - Blood Borne pathogen if required
  - Shipping Training
  - Lab specific training



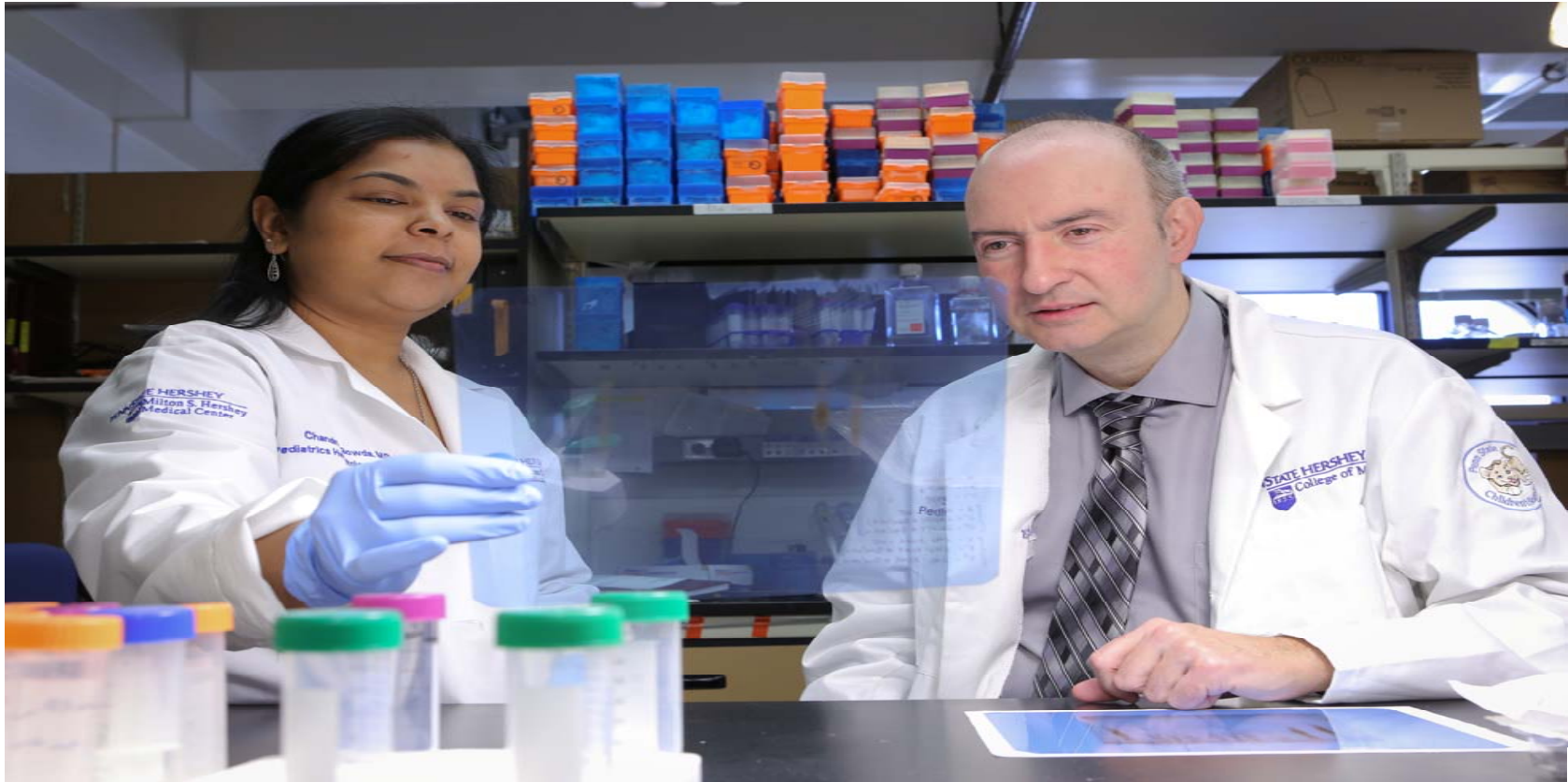
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# Training



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# Training Initiatives

- **RQA Monthly Lunchtime Lecture**
  - Increased campus research collaboration
  - Update all staff on biosafety issues
  - Forum for questions on any RQA issue
- **RQA Quarterly Regulatory Workshop**
  - Federal, state or local issue regarding agent use and general biosafety in research lab.



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# Training Initiatives

- **Annual Spring Training**
  - Compliance overview (IBC, IACUC, IRB, MTA, Import)
  - Biosafety and CITI Biosafety
  - Centrifuge use and care
  - BSC and CFH operations
  - Autoclave use
  - Safety Lab Inspections/Chemical inventory
  - Security/Emergency Management
  - Freezer and Incubator care
  - Informational system training module
  - Pipette, vaporizer and balance overview



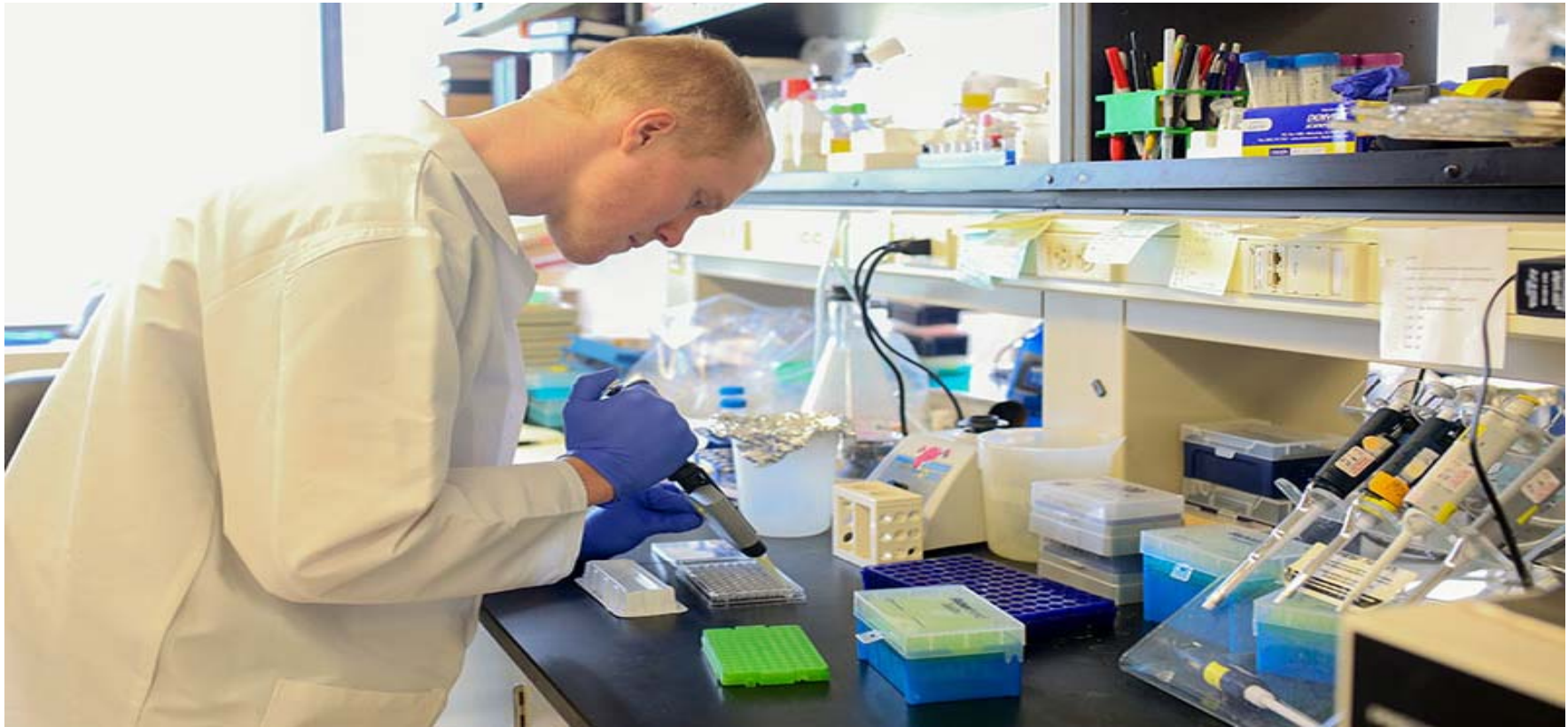
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# Asset Management



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# COM Laboratory Equipment Maintenance Program Description

- Duration > five years.
- Includes traditional equipment used in most basic science research laboratories.
- Cost for preventative maintenance (PM) services funded centrally.
- Each year, essential lab equipment receives PM and calibration or certification at no charge to the principal investigator (PI) or department.
- Program also includes an equipment inventory that has been used to form an asset management system (Lab Manager) for COM lab equipment.



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## Routine PM/Calibration/Certification Equipment Volume

• Anesthesia Machines/Vaporizers	47	• DI Carbon Exchanges	31
• Autoclave, Large	16	• Incubators	487
• Autoclave, Small	21	• Micropipettes	2584
• Balances	407	• RO Operational Check	20
• Bedding Dispensers	2	• Ventilated Cage racks	174
• Biosafety Cabinets	294	• Washers, Cage	2
• Centrifuges, Benchtop	219	• Washers, Large Glassware	4
• Centrifuge, High Speed	29	• Washers, Tunnel	6
• Centrifuge, Microfuge	318	• Ultra Low freezers	265
• Chemical fume Hoods	221		



# Covered Equipment

<b><u>Essential Equipment</u></b>	<b><u>Type of Annual Service</u></b>	<b><u>Paid By</u></b>
• Biosafety Cabinet	PM with Certification	COM Admin
• Fume Hood	PM with Certification	COM
• Incubator	PM with Calibration	COM
• Ultra-Low Temp Freezer	PM with Calibration	COM
• Centrifuge	PM w/Calibration or Total Service	COM / PI
• Small Autoclave	PM with Calibration	COM
• Large Autoclave	PM with Total Service and Parts	COM
• Pipettes	PM with Calibration	COM
• Balances	PM with Calibration	COM
• Glass Washers	PM	COM
• Vaporizers	PM	COM
• Deionized Water System	2 Carbon      Tank Exchanges	COM
• Reverse Osmosis System	Operational Check	COM
• Ventilated Rack	PM	COM



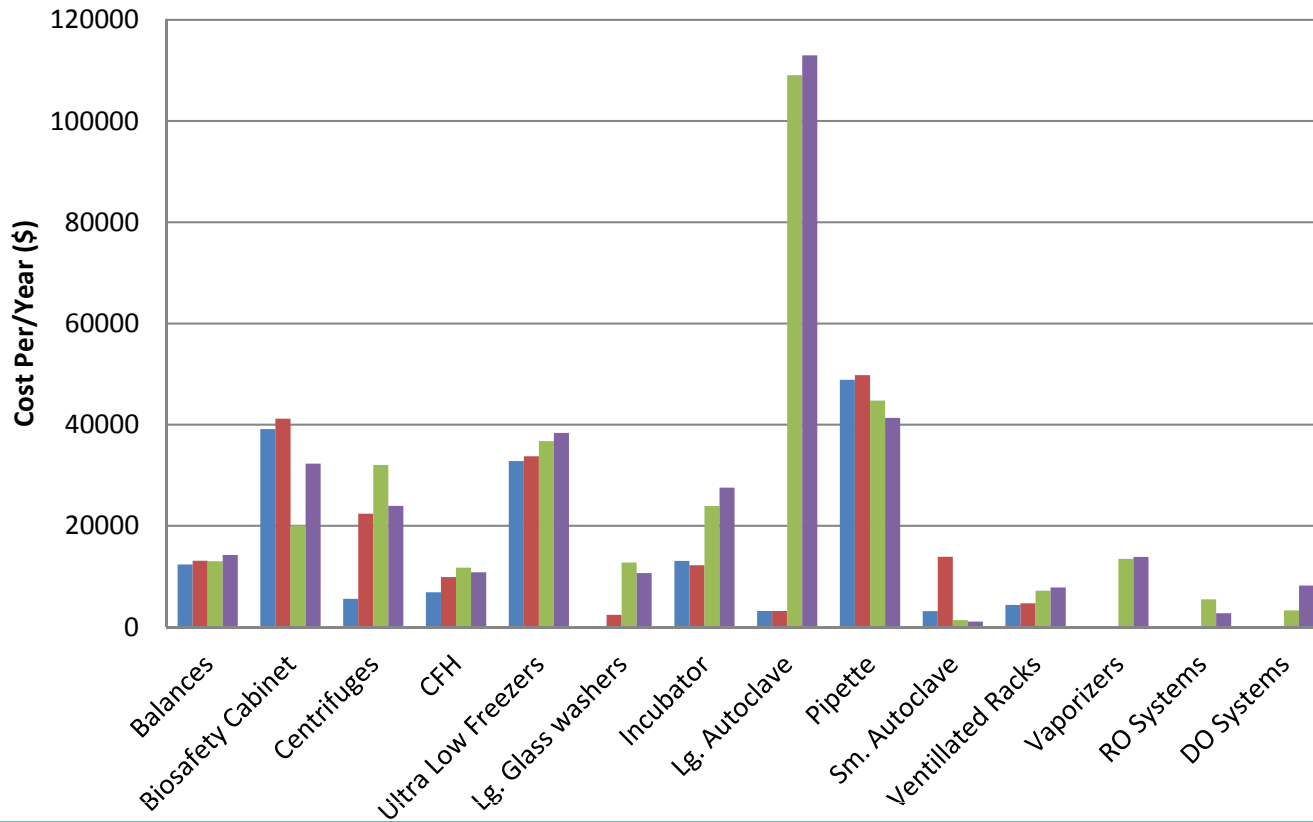
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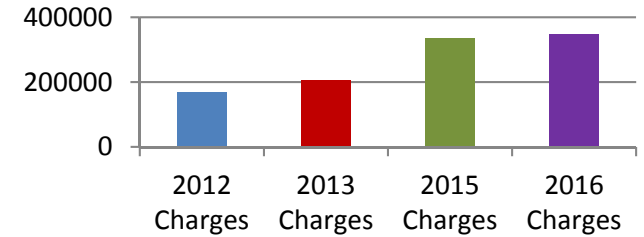
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# Program Costs - Routine PMs Paid by COM Administration



## Total Costs



- 2012 Charges
- 2013 Charges
- 2015 Charges
- 2016 Charges



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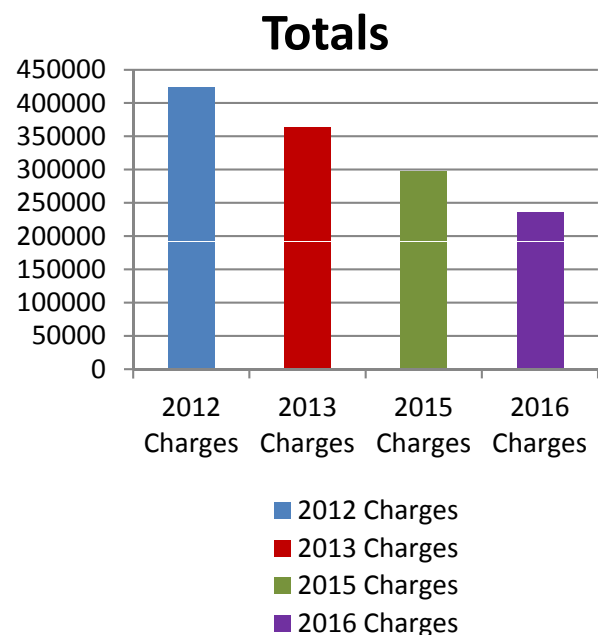
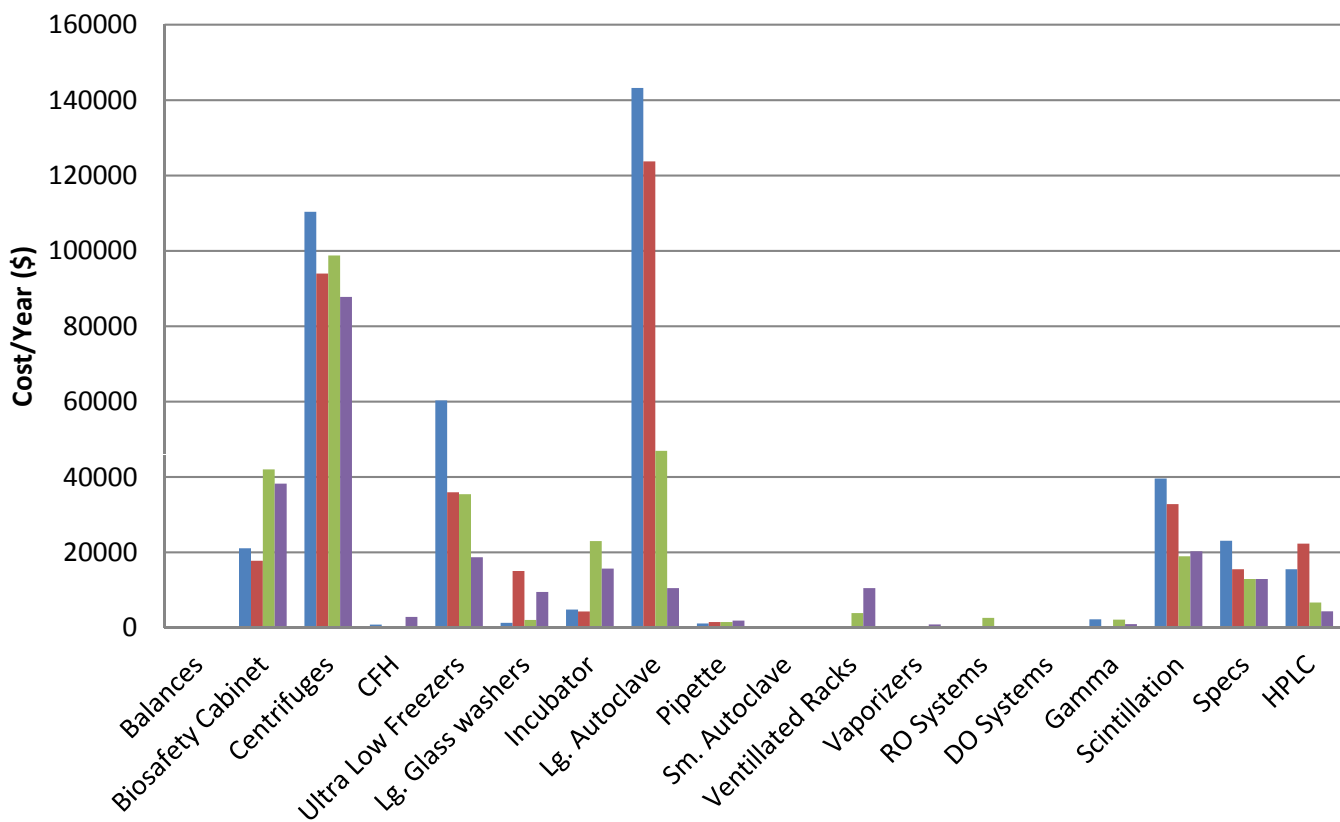


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## Program Costs – Non Routine PMs Paid by PI



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# Non Routine Service - PI cost overview

- The overall cost paid by PIs/Departments has decreased by 35% since program inception
- The decreased costs may be attributable to better-maintained equipment due to regular service, and increased training for lab personnel. While much of COM lab equipment is aging, RQA remains in contact with investigators to provide guidance on the potential for replacement of outdated equipment
- Replacement of older equipment by central administrative funding will be put in place over the next several years to further reduce PI operating costs



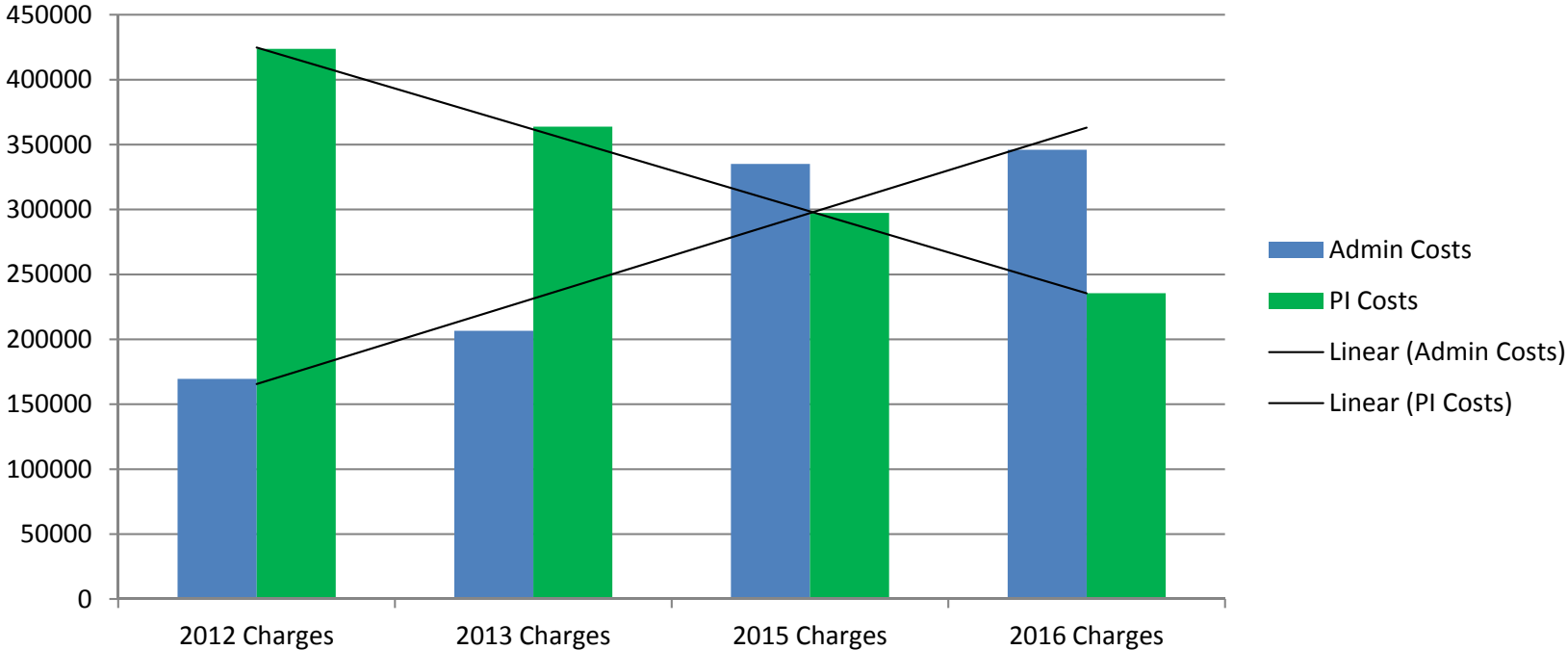
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# Summary of Costs per category



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# Lab Management

# LabManager database



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# LabManager

- The establishment of a concise data informational system for use in laboratory settings has become essential in all aspects of the research laboratory
  - *LabManager is a database repository designed to maintain and consolidate all aspects of sound laboratory management in one useful tool.*
- The system was developed mutually by the College of Medicine Research Quality Assurance (RQA) and Research IT teams



# LabManager development

- The system was developed in several phases;
  - Placement of the standardized Biosafety Level Lab Survey in the specific lab associated with the survey
  - Loading of the established lab equipment inventory and service records directly to the specific laboratory for proper tracking
  - Updating and placement of a lab placard template to the specific lab area emphasizing the proper emergency lab contacts
  - The ultimate goal is the ability to link all appropriate lab compliance areas on a simple lab specific platform



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# LabManager capabilities

- **LabManager has proven to be a practical resource and an effective Laboratory Management tool at all levels of the campus including:**
- **College Administration** (develop reports and reference information on)
  - *Capital equipment replacement schedules*
  - *Specific research being performed in college labs*
  - *Chemical and radiation use by specific labs and training compliance by all laboratory personnel*
- **Principal investigators**
  - *Seek out potential collaborators for research grant submissions*
  - *Assist in identifying items such as cell lines and research products that may be available internally rather than having to wait to obtain product from outside labs or companies*



# LabManager capabilities

- Provides proper documentation of:
  - Laboratory approvals
  - General lab safety, blood borne pathogen, CITI, lab specific, and biosafety training dates
  - Preventative maintenance, certification and calibration records ensuring lab equipment is maintained according to established standards and specifications
  - CDC, NIH, OSHA required lab specific emergency plans
  - Specific agent and Biosafety level search capabilities
  - IBC, IACUC, IRB DURC and Bio- Stewardship inventory



# LabManager capabilities

- The ability to manage all laboratory information in an accurate and concise method
- Enhances university funding possibilities in a time where funding has been decreased at all levels.
- Allows the RQA staff to leverage resources to ensure safety and reduce institutional risk by providing a means efficiently track compliance and identify specific areas of improvement within all our campus research labs.



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# Lab Manager Summary

- **System provides investigators and technical staff the ability to access their respective lab information including**
  - Individual lab placards and emergency contacts
  - Inventory, location and service records of all basic laboratory equipment
  - Annual required lab surveys
  - Lab specific training dates
  - Lab specific SOPs
  - Approved IBC, IRB, and IACUC protocol numbers
  - Campus-wide equipment search mechanism to save the lab time and money when planning individual laboratory experiments.



# LabManager Specific Lab View

## College of Medicine – C4605A

Laboratory information is listed below. Clicking on a category heading will expand it to present more detail. Clicking on any of the icons will allow you to add an item of that category to the Lab. Clicking on any of the icons will allow you to remove that item from the Lab. Clicking on any of the icons will take you to more information on that particular item. Clicking on any of the icons will allow you to edit that particular item.

### General Information

Phone Number	Unknown
Principal Investigator	Raymond Scheetz
Supervisor	Raymond Scheetz
Emergency Contact	Raymond Scheetz
Biosafety Level	Unknown
Fire Extinguisher	✗

### Placard Information

Flammable Liquids	✗
Corrosive Materials	✗
Toxic Chemicals	✗
Flammable Gas	✗
Carcinogens	✗
Compressed Gas	✗
Laser Light	✗
X-Ray Generator	✗
Electric Hazard	✗
Toxic Gas	✗
Ultraviolet Light	✗
Download Placard	

### Surveys

### Equipment

Type	Brand	Model	Serial Number	Owner	
Bench Top Centrifuge	FISHER MARATHON	3200	64540467	Raymond Scheetz	<input type="checkbox"/>
Incubator	NIHAIRE	NIH-2700	15278001000	Raymond Scheetz	<input type="checkbox"/>



# LabManager Equipment Search View

## Equipment Listing

Please select a brand, model, and/or type of equipment. To deselect a brand and/or model, please click the X next to the brand and/or model. For more information on a particular piece of equipment, please click the e-mail link on the left.

Autoclave	Balance	Bench Top Centrifuge	Biological Safety Cabinet	Centrifuge	Centrivap	CFH	Cryostat	Electroporator	Film Processor	Floor Centrifuge	Fraction Collector	Freezer	Choose a Brand			
Gel Dryer	Harvester	High Speed Centrifuge	HPLC	Imager	Incubator	Incubator Bottom	Incubator Oven	Incubator Shaker	Incubator Top	Incubator Top/Bottom	LFCB	Lyophilizer	Choose a Model			
Microfuge	Microscope	Neg Flo	Oven	PCR	PCR Workstation	pH Meter	Pipette	Plate Reader	Real-Time PCR	Refractometer	RO Water	Rocker	Rotator	Scintillation Counter	Search	Clear
Semi-Dry Blotter	Shaker	Sonicator	Spectrophotometer	Tissue Chopper	Ultra Centrifuge	Unknown	Vacufuge	Vacuum Oven	Vacuum Pump	Water Bath	Water Purification System					

No Search Conditions Selected

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Associate Dean for Research  
Associate Professor of Pharmacology  
Penn State College of Medicine
- **Ralph Keil, PhD**  
Chair, Biomedical Sciences Graduate program  
Chair, Biosafety and recombinant DNA Committee
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Research Compliance Specialist  
Research Quality Assurance



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  - Research Compliance Specialist
    - FDA Clinical Trials
- **Rachel Panas, M.S**
  - Research Compliance Specialist (IACUC, IBC, Radiation Safety)
- **Courtney Williamson**
  - Research Compliance Specialist (IACUC, IBC, Radiation Safety)



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# Words to live by in the Compliance World

Two of the greatest qualities of Life are:

Patience...



...and Wisdom



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