

Getting to Compliant:

Personal Protective Equipment Use
in the Non-Clinical Research Setting

*I do not have any relevant
personal, professional or financial relationships
with respect to this educational activity.*

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Beth Israel Deaconess
Medical Center



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL



Holden Thorp introduction to Principal Investigator Laboratory Safety Responsibilities

<https://www.youtube.com/watch?v=d6AAsCEpTY&feature=youtu.be>

Holden Thorp, Provost at Washington University in St. Louis, discusses standards and practices to minimize laboratory related mishaps and what lab leaders need to know and do to remain safe. The university recently won an award from the Campus Safety Health and Environmental Management

Objectives for Today's Presentation

To understand the compliance concerns around personal protective equipment use in the non-clinical research lab setting



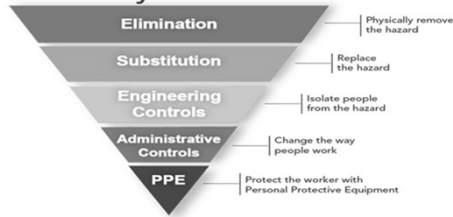
To identify compliance challenges faced by research compliance professionals in the academic medical center setting based on organizational structure and physical space



To learn strategies for PPE compliance program and policy development

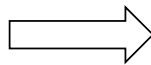
Hierarchy of Hazard Controls

Hierarchy of Controls



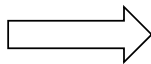
What Are the PPE Compliance Concerns?

• Access to, and correct use of :



- Lab coats
- Gloves
- Eyewear
- Footwear
- Respirators

To protect from exposure to:



- Biologics
- Chemicals
- Laser lights & radiation
- Animal bites



Biosafety Levels

Chemical Hazard Types

Get Hazard Symbols and their Definitions!

	Corrosive Causes severe skin burns and eye damage.		Flammable Highly flammable, flammable, or extremely flammable.
	Acute Toxicity Fatal, very toxic, toxic, or harmful.		Irritant Causes skin irritation or serious eye irritation.
	Environment Very toxic to aquatic life with long lasting effects.		Health Hazard May cause cancer, respiratory sensitization, or other health effects.
	Oxidizing May cause fire or explosion.		Explosive May cause explosion.

Regulatory Compliance

Federal Regulations and Guidelines in the lab:

- OSHA Standards
 - Bloodborne pathogens
 - PPE requirements
 - Respiratory Protection
 - Surveillance of exposure to certain chemicals
 - Hazardous waste operations/Emergency response
- CDC biosafety in biomedical research lab guidelines
- Dept of Homeland Security – lab security/safety
- US Drug Enforcement Agency – controlled substances
- FDA GLP (21CFR58)
- NIH rDNA
- PHS & USDA (animal research activities)
- NFPA

State & Municipal Requirements:

- Local Fire Dept
- Regional or State water authorities
- Departments of Health

What Does Non-Compliant Look Like?

- ✓ "One glove policy"
- ✓ Soiled lab coats
- ✓ No access to lab coats
- ✓ Improper lab coat use
- ✓ Wrong gloves – e.g. dry ice or liquid nitrogen necessitate cryo gloves
- ✓ Lack of or inadequate eye protection
- ✓ Seasonal issues – e.g. summer clothing
- ✓ Using unapproved equipment – e.g. personal respirator equipment without fit testing

Any examples to Share?

What are the challenges to improving compliance?

The Various Challenges to Improving Compliance....

- Breadth and depth of technical expertise required
- Physical space
- Physical plant/maintenance
- Training a transient, international workforce
- Lab activities perceived as low risk
- Lack of clear and / or enforceable compliance for behavior
- Accurately and adequately compliance determinations
- Financial limitations
- Lack of centralization of processes
- Lack of institutional continuity in policy

What are Some Strategies for Improvement?

Engaging Key Stakeholders

- Environmental Health & Safety Staff
- IACUC staff
- Animal research facility staff/vet
- Biosafety officer
- Employee health
- Research facilities
- Research faculty
- Research staff

Presence/Involvement in Operations

- Attending meetings on a regular basis
- Committee membership if possible
- Presentations to stakeholder groups
- Participation in ongoing activities –updates, website improvements, training updates
- Involvement in policy development and revision

PPE Workplan Item: A Case Example

Topic	Workplan	Specific Objectives	Tasks	Regulatory Driver
Personal Protective Equipment (PPE)/ Research Safety Audits	Audit	Audit for PPE compliance in BiDMC labs in collaboration with EH&S to improve overall compliance with RS-24 and research safety.	<ol style="list-style-type: none"> 1. Audit labs quarterly for PPE compliance and other research safety issues. 2. Document findings. 3. Keep statistical records. 4. Educate on-the-spot for policy and safety violations. 5. Notify other individuals and departments as appropriate (e.g. Lab Manager, PI, facilities, etc.) 6. Report statistical findings at least yearly. 	RS-24 Research Laboratory Personal Protective Equipment (PPE) Policy

Ohio State University Medical Center
BiDMC Manual

Title: Research Laboratory Personal Protective Equipment (PPE) Policy
Policy #: RS-24

Purpose: The purpose of the Research Laboratory Personal Protective Equipment (PPE) is to outline the basic requirements for clothing and personal protective equipment worn in the laboratory and the PPE requirements for working with specific hazards as well as outline procedures for appropriate selection, use, and maintenance of PPE.

Scope: This policy applies to all laboratory research spaces in properties and facilities owned, leased, or managed by Ohio State University Medical Center (OSUMC), including the main campus and off-site locations. In some cases, certain responsibilities under the Research Laboratory PPE Policy are shared with or delegated to local management (including parties such as faculty, research, or consultants). An exception to a particular location, this policy covers BiDMC and HMPF employee research labs, and visitors present in these facilities.

Policy Statement: In a continuing effort to provide a safe work environment, it is the policy of OSUMC that all individuals are provided proper training and proper PPE to protect against risk or stress from known workplace hazards. This policy incorporates current BiDMC practices, standard procedures, and basic requirements set forth in the United States Safety and Health Administration (OSHA) Personal Protective Equipment Standard (29 CFR 1910.133), in addition to BiDMC established PPE Program (EOPC-30).

A. Definitions:
Personal Protective Equipment (PPE): Equipment or clothing/apparel designed or intended to protect the user from a hazard or condition in the workplace capable of causing injury and/or illness.
Chemical Hazard: A toxic, irritant, or corrosive material that may cause acute or chronic health effects and/or physical harm upon exposure. Chemicals covered in this definition include, but are not limited to, carcinogens, toxic or highly toxic agents, reproductive toxins, sensitizers, mutagens, corrosives, oxidizers, sensitizers, and agents that irritate or damage the lungs, skin, eyes, or mucous membranes.

RS-24, Appendix A
PPE Expectations

A.1. Entering a research laboratory:
Requirement 1: Shirts with a closed top & tail.
Requirement 2: Long pants, slacks, or shorts that fully cover the body.

A.2. Working at laboratory benches:
Requirement 1: All gloves (responsibility for wearing lab gloves is on the user) must be worn when working at a bench, and must be changed frequently.
Requirement 2: Eye protection (safety glasses or goggles) must be worn when working at a bench.
Requirement 3: Hair must be pulled back and secured.
Requirement 4: No jewelry (including watches) is permitted in the laboratory.
Requirement 5: No eating or drinking is permitted in the laboratory.
Requirement 6: No smoking is permitted in the laboratory.
Requirement 7: No cell phone use is permitted in the laboratory.
Requirement 8: No use of mobile devices is permitted in the laboratory.
Requirement 9: No use of personal electronic devices is permitted in the laboratory.
Requirement 10: No use of personal electronic devices is permitted in the laboratory.

B. Work Area Specific PPE Expectations

B.1. Biological Hazards:
B.1.A. Respiratory Level 1 or 2:
Requirement 1: NIOSH approved respirator for protection against airborne particulates.
Requirement 2: NIOSH approved respirator for protection against airborne particulates.
Requirement 3: NIOSH approved respirator for protection against airborne particulates.
Requirement 4: NIOSH approved respirator for protection against airborne particulates.
Requirement 5: NIOSH approved respirator for protection against airborne particulates.
Requirement 6: NIOSH approved respirator for protection against airborne particulates.
Requirement 7: NIOSH approved respirator for protection against airborne particulates.
Requirement 8: NIOSH approved respirator for protection against airborne particulates.
Requirement 9: NIOSH approved respirator for protection against airborne particulates.
Requirement 10: NIOSH approved respirator for protection against airborne particulates.

PPE Research Safety Audits

- Assess baseline compliance with specific PPE categories
- Have both technical expertise and enforcement authority
- Provide on the spot education
- In-person visibility/resource
- Collect and report out data
- Identify educational gaps

Audit Tips & Tools

- Vary day and time of audits
- Practice your own safe behavior
- Stay out of the way
- Take advantage of face-to-face
- If possible have satellite space (for coats, bags, etc) – travel light

“Toolkit”

- Business cards
- Educational materials
- Cell phone
- ‘a smile’ ‘kill them with kindness’... to a point



Paper Audit Tool

Area: North		Area: South	
1	Blocked electrical panel	1	Blocked safety equipment (fire extinguisher, eye wash/shower)
2	Blocked equipment	2	Blocked impingement shield
3	Blocked walk space	3	Fire hazard
4	Blocked in work	4	Flammable in work
5	Blocked in lab	5	Emergency animal handling
6	Blocked in hallway	6	Emergency disposal of chemicals
7	Blocked use of space	7	Missed in freezer / cold room
8	Blocked open fire door	8	Shower, eyewash
9	Shower, eyewash	9	Shower, eyewash
10	Spills or leaks	10	Spilled lab coats
11	Spills or gum in trash	11	Spilled/contaminated in spill room

Online Tool – Linked to Space and PI

Bar Ilan University, Ramat Gan

Research Lab Safety Evaluation

Directions: Below is list of research lab spaces (see Codes: 250-001, 250-014, 250-181). Check building to see floors with lab(s) be assigned to one or more PI. To view assignment and with detailed background have existing evaluations.

Center for Life Sciences

Research Building

Area	Total Observed	Compliant	Non-Compliant	ESG	Dept/Dir. Evaluation
Area: North	4	4	0	None Reported	
Area: South	4	4	0	None Reported	

Compliance Actions

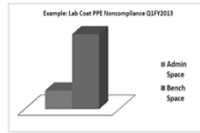
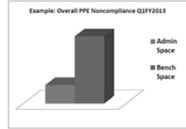
Confidential Submitter OR Confidential researcher - Public Compliance
 Provided feedback Notification required to PI/Lab manager

Back to Home, Print and Download Alerts

Return to Building Page List

Audit Findings Data Sharing

- Where to present data
 - Various key audiences
 - Other Departments may present and use data for related purposes
- How to present data
 - Breaking up information to focus on risk areas, for example:

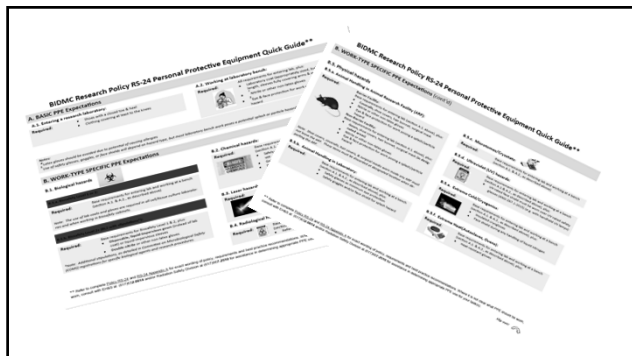


Incidental Findings

- **Be prepared: You'll have your 'compliance hat' on, be aware that there are other things you may find:**
 - *Improper disposal of hazardous substances*
 - *Children in the lab*
 - *Food and drink in the lab*
 - *Fire code violations (doors propped open, items stored improperly)*
 - *Possible IACUC violations/animal welfare concerns*
- **Use incidental findings to prompt discussion about needs for additions/revisions to policy**

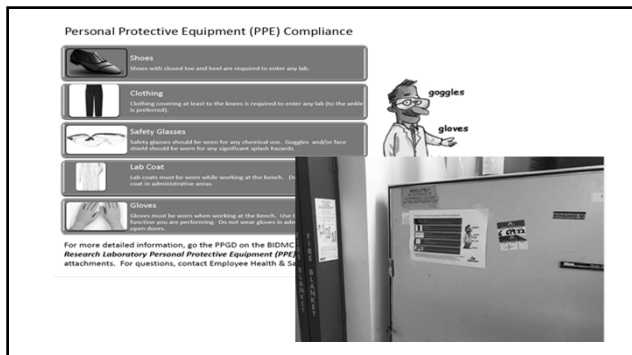
Educational Efforts

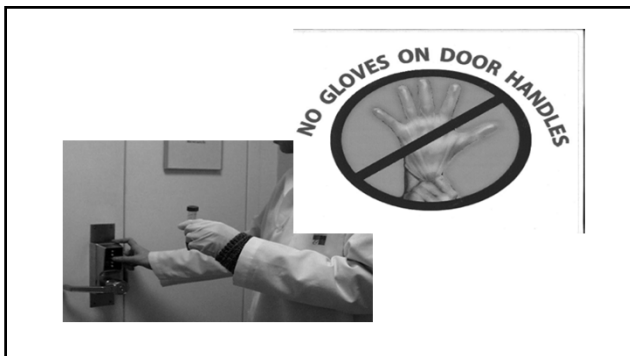
- Integrity at Work articles
- Presentations on audit findings
- Involvement in training material development



Educational Efforts

- Education materials for various audiences
 - Limited English speakers
 - Role specific materials
- Signage – e.g. stickers ‘no gloves on handles’
- Videos (produced in-house, You Tube)





Enforcement & Consequences

- Use institutional authority and follow the Escalation policy:

"...The ReSC has the authority to stop any BIDMC laboratory operations in which the health and safety of faculty and/or staff may be compromised or may result in non-compliance with applicable laws or policies."

- Targeted emails from leadership

- Notice
- Warning
- Suspension
- Appeal

**Beth Israel Deaconess Medical Center
Policy Manual**

Title: Research Safety Management Policy
Policy #: RS-22

Purpose:
This policy defines the safety management program for Research at the Beth Israel Deaconess Medical Center ("BIDMC") which is in place to protect individuals from potential hazards associated with the work that occurs in research laboratories.

Policy St:
Research Safety Environment and Evaluation Procedure

BIDMC is a
nonprofit

Research Safety Committee (RSC) Authority

As described below, the RSC has the authority to stop any BIDMC laboratory operations in which the health and safety of faculty and/or staff may be compromised or may result in non-compliance with applicable laws or policies.

1. **Lab Safety Enforcement:** To enforce the requirements set forth in regulations, audits of each laboratory are required by the RSC. The RSC may, either in a targeted manner, or in a general manner, conduct audits of each laboratory. Audits may range from a walk through audit to an on-site audit to more formal periodic observations that are more in-depth and on-site. In addition, the RSC also reports to management on a regular basis on the research lab area, and generates an after action summary. The RSC may conduct the appropriate audits for safety.

2. **General Safety Evaluation:** This section defines procedures for responding to safety concerns which are identified during the RSC operations. Complaints received from faculty, researchers, research staff, or other individuals or violations of safe practice standards/practices that may not pose an immediate threat to the safety:

- RSC or the appropriate representative will follow-up, verify, and/or follow-up with all those

Focused Monitoring

- Repeat offenders
- High risk behaviors
- Developing a monitoring/auditing plan
 - Outline scope and frequency
 - Include clear milestones to prompt step down or escalation
 - Use institutional policy to ensure authority

Have a "Wish List"

- Better engineering controls
- Increased \$\$\$ resources
- Centralization of responsibility for specific tasks – lab coats, eye protection and specific vendors
- Additional/better signage



What's on your wish list?

References, Related Regulations and Guidance

- Holden Thorp [Introduction to Principal Investigator Laboratory Safety Reps](#)
- <https://www.youtube.com/watch?v=6dA8Fy7y7I8&feature=youtu.be>
- OSHA Standards- <https://www.osha.gov/SLTP/LaboratoryStandards.html>
- OSHA Hierarchy of Hazard Controls- <https://www.osha.gov/SLTP/OSHA-Hierarchy-of-Hazard-Controls>
- "A research university's rapid response to a fatal chemistry accident: Safety changes and outcomes" <https://www.sciencedirect.com/science/article/pii/S157153314000048>
- [Safety in Academic Chemistry Laboratories BTH EDT ION](https://www.ansi.org/content/dam/ansi/education/governance/committees/chemicalsafety/publications/safety-in-academic-chemistry-laboratories-students.pdf)
- <https://www.ansi.org/content/dam/ansi/education/governance/committees/chemicalsafety/publications/safety-in-academic-chemistry-laboratories-students.pdf>
- Department of Homeland Security, Appendix A: Chemicals of Interest (COI) List <https://www.dhs.gov/appendix-a-chemicals-interest-list/DHA>
- Controlled substances
- Environmental Protection Agency Federal Clean Water Act 33 U.S.C. §1251 et seq. (1972)
- CDC biosafety in biomedical research lab guidelines <https://www.cdc.gov/biosafety/publications/nmbl/bi/>
- CDC Federal Select Agent Program Biosafety / Biocontainment Plan Guidance: <https://www.selectagents.gov/bbp-requirements.html>
- Title 21, Part 318 Good Laboratory Practice for Nonclinical Laboratory Studies <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfdv/CFRSearch.cfm?CFRpart=318>
- The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules <https://osp.od.nih.gov/biotechnology/nih-guidelines/>
- EPA Resource Conservation and Recovery Act (RCRA) Laws and Regulations <https://www.epa.gov/rcra>
- Title 49 of the Code of Federal Regulations (49 CFR), Subchapter C, "Hazardous Materials Regulations"
- NFPA 45, Standard on Fire Protection for Laboratories Using Chemicals <https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/health-care>
- CISA - [anthrax, botulism, vectors](#)
- **BIDMC Internal Policies:**
 - RS-20 "Research Safety Management Policy"
 - RS-22 Appendix A "Research Safety Enforcement and Escalation Procedure"
 - RS-24 "Research Lab PPE Policy"
 - RS-24 Appendix "PPE Expectations"

THANK YOU AND ENJOY THE REST OF THE CONFERENCE!



Beth Israel Deaconess Medical Center



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