



# **2019 ANNUAL MEETING**

OCTOBER 19 - 23

## **2019 SRAI Annual Meeting October 19-23**

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# Behind the Curtain of Research Compliance

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## A Backstage Look at the Oversight and Management of Regulatory Requirements and Safety Expectations

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# Overview

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In this session, we will review regulatory and compliance expectations for both laboratory and clinical research and examine how these requirements are fulfilled at a multi-campus university and academic teaching hospital setting.



# Overview



If we are successful, you should leave this talk with a greater knowledge of:

- Compliance expectations for federally funded clinical and laboratory research grants
- Institutional programs that implement and oversee research compliance
- Communication and oversight mechanisms that comprise a comprehensive safety compliance oversight program

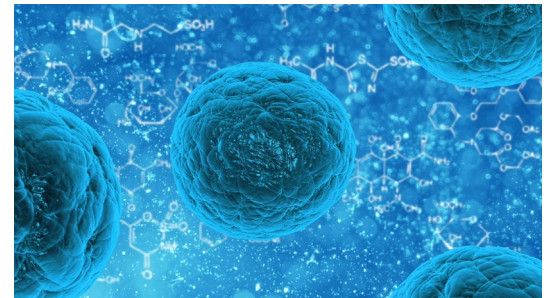
# Compliance Expectations

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As you know, federal grant application forms such as SF424/PHS 398 specifically ask about:

- Human subjects
- Animal welfare
- Select agents
- Human embryonic stem cells

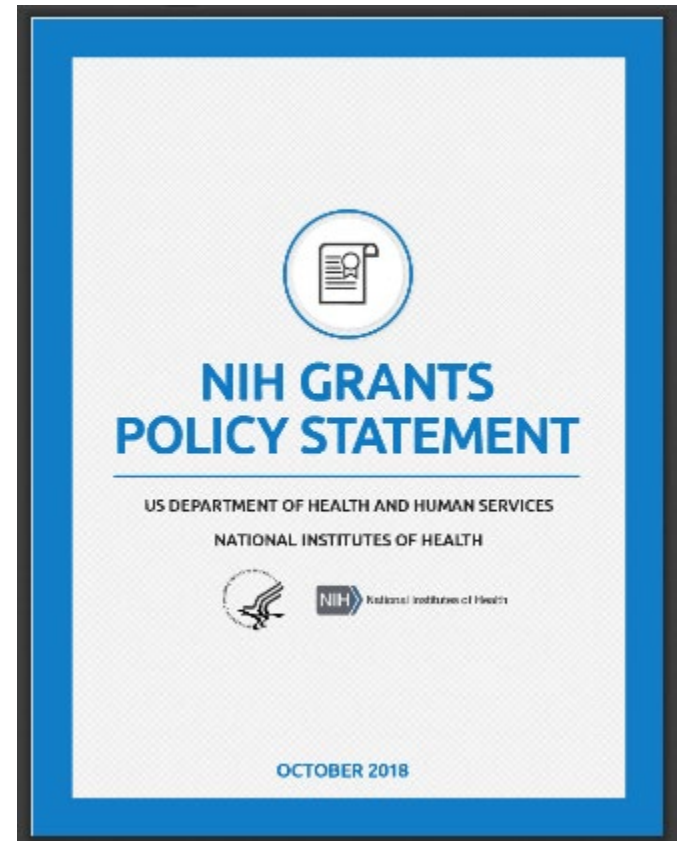
But....



# Compliance Expectations

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Did you know federal funding comes with the expectation of compliance with all applicable federal, state, and local health and safety requirements as stated in section 4.1.12 of the NIH Grants Policy Statement?



# NIH Grants Policy Statement

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## 4.1.12 Health and Safety Regulations and Guidelines

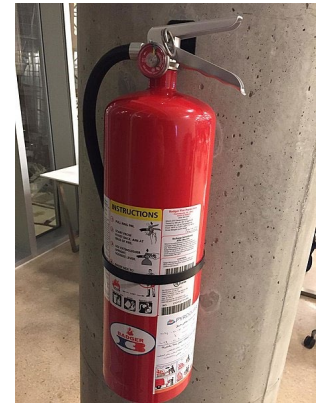
Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR 1910.1030, Bloodborne pathogens
- 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.).
- **Other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR 1910.**

# OSHA's 29 CFR 1910 Covers A Lot:

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- Recordkeeping
  - Exit Routes, Emergency Action Plans
  - Forklifts
  - Hazardous Materials
  - Personal Protective Equipment
  - Medical and First Aid
  - Fire Protection
  - Compressed Gases
  - Eyewashes
  - Hand and Portable Powered Tools
  - Electrical
  - Asbestos
  - Much, much, much more!
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- And don't forget the General Duty Clause!!!





# Additional Federal Compliance Items

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Other than OSHA there are plenty of other agencies one needs to adhere to in research lab environments including:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Import/Export Permit issues with CDC and USDA/APHIS
- Commerce Department Restrictions on transfers of materials/technology
- IATA and DOT Shipping Regulations and Requirements
- EPA Highly Hazardous Chemicals
- DEA Controlled Substances



# Additional Federal Compliance Items

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But Then Add In Your State, Local, and Institutional Compliance!

## **State and Local Regulations Regarding Research Labs May Include:**

- Hazardous Material Handling and/or Disposal Regulations
- State-specific OSHA Requirements
- Local Fire Codes



## **Institutional-specific policies regarding Research Labs May Include:**

- Hazardous Material Registration Requirements
- Hazardous Material Training Requirements
- Hazardous Material Handling and/or Disposal Requirements

# How Does an Institution Ensure They are in Compliance?

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1. Institutional Policies
  - Promulgation
  - Enforcement and Reinforcement
2. Gatekeepers and Control Mechanisms
  - Entities such as IRB, IACUC, IBC that are “hard stop” compliance checks
  - Forms or permits that are required to perform work or purchase materials
3. Compliance oversight groups to inspect and monitor:
  - Biosafety
  - Chemical Safety
  - Environmental Safety
  - Occupational Safety
  - Radiation Safety
  - Occupational Health



# Policies



- Writing policies is easy. Enforcing policies is hard.
- Policies are borderline useless if no one is aware of the policy or how to comply with the policy.
- Dissemination of policy expectations has to be more than posting on a website.
- Training is a great time to reinforce policies
- Be sure to include all the following folks:
  - Faculty
  - Students and fellows
  - Department administrators
  - Housekeeping, Security, and Facilities!
  - Don't forget your Administration Colleagues! Research Admin, IRB, IACUC, MTA, etc.

# A Few Friendly Reminders About Training

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Bloodborne Pathogens—annual requirement for anyone working WITH or AROUND blood/body fluids including human cell lines.

Respirator – annual requirement including fit testing for anyone required to wear a respirator (N95, PAPR, ½ face piece, etc).

Hazardous goods shipping – required every two years

High Containment Lab Safety training—annual requirement

Hazard Communication—required upon hire and any time a new chemical is introduced into the work environment.

General lab safety—based upon institutional policy



# Gatekeepers

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Gatekeepers are great because they have the power to prevent things from happening outside of policy requirements.

Examples include:

- IRB
- IACUC
- IBC
- IRE
- Radiation Safety Committee
- MTA and Import/Export Offices



At Johns Hopkins, Radiation Safety is a gatekeeper because they are the only authorized entity for ordering radioactive materials on campus.

Requiring a work permit for “hot work” or such is also a gatekeeper

But...Gatekeepers are not foolproof....

# Compliance Oversight Groups

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Compliance oversight groups serve as monitoring and enforcement entities as well as information resources for the campus and, in so doing, help disseminate and reinforce policy and safety information through their efforts.

Routine inspections or responses to requests for help or emergency response can be used to reinforce safety policy requirements and identify compliance variances.

Common oversight groups include:

- Biosafety
- Chemical Safety
- Environmental Safety
- Occupational Safety
- Radiation Safety



# Information Gathering At Your Desk

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Information gathering is key to successful oversight and can be accumulated through many mechanisms.

- Research registration databases can be mined for info: Bio, Chem, Rad, AESP
- Your colleagues are a great resource. Ask around!!
- Training databases can be used to check who is up to date on their training requirements.
- And don't forget about looking at employee incident reports. When hazards exist and employee are injured these should be turfed to the appropriate safety team for follow up whether it be exposures in the lab, ergonomic issues, slips and falls, etc.





# Information Gathering in the Field

## Laboratory, Facility, or Fire Inspections

- Visual observations
- Surveys or questionnaires that are required

Training Sessions: Good time to ask your faculty, students, staff what they are up to

## Federal or State Oversight Inspections

CDC

USDA/APHIS

AAALAC or other oversight

OSHA or state OSHA group

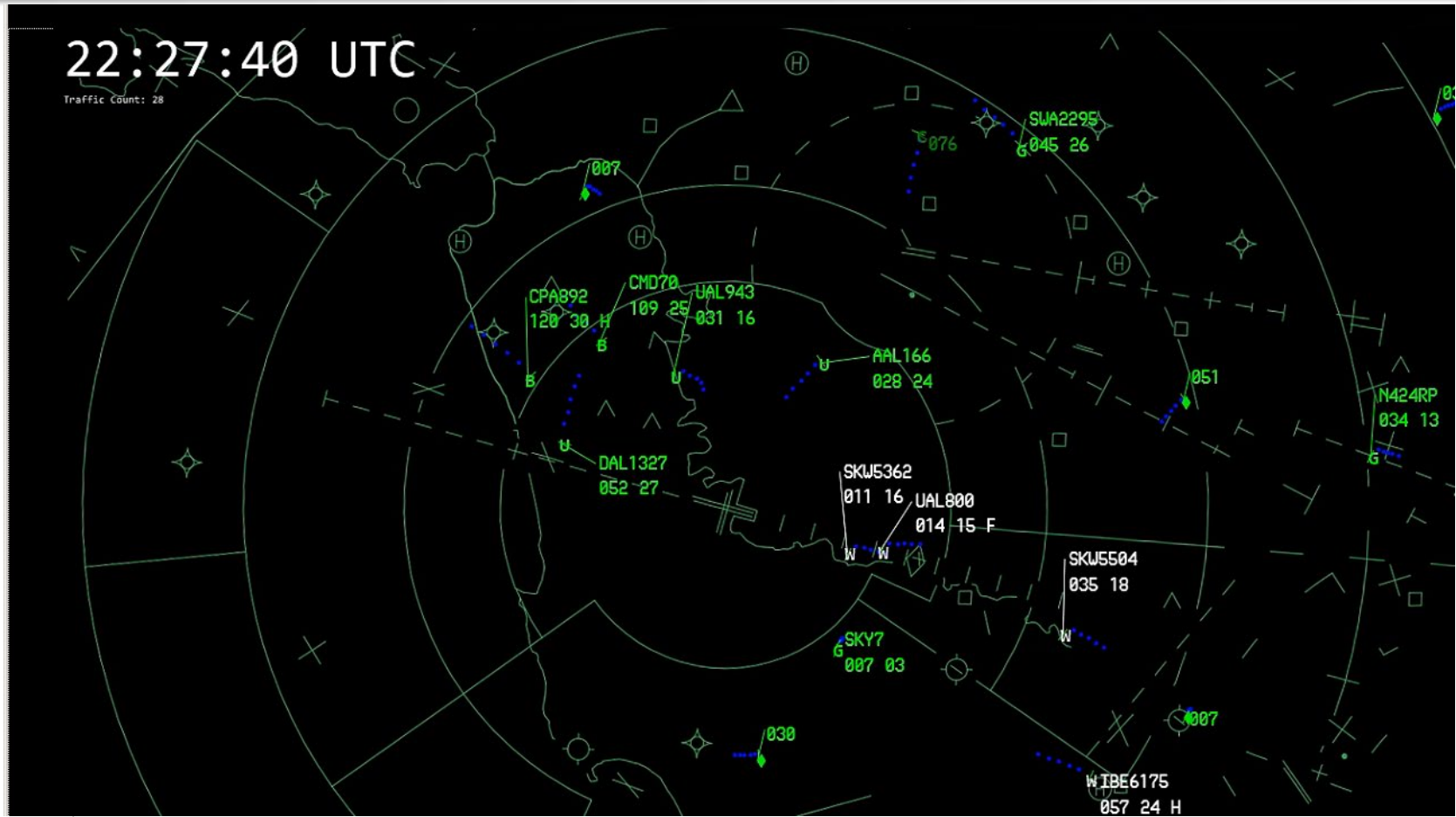
Joint Commission for Hospitals



Routine conversations with colleagues in Facilities or Housekeeping or Admin can yield surprising tidbits of interest as can your institution's publications!

# Bringing It All Together

Building a comprehensive program of safety and compliance  
(Image courtesy of VasAviation)



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# Typical Research Compliance at Any Institution

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- Institutional Biosafety Committee (IBC)
- Animal Care and Use Committee (ACUC)
- Institutional Review Board (IRB)
- Materials Transfer and Licensing
- Import and Export
- Institutional Review Entity (IRE)
- Radiation Safety Committee
- Chemical Safety

# Each has a Similar Approach to Oversight

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- Some sort of form
- Database of items of interest
- Some sort of review
- Some sort of approval mechanism or acknowledgement
- Some sort of follow up mechanism

# Each has Similar Interests and Concerns

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- What is currently on campus?
- What is being done with that?
- What is coming onto campus?
- What is leaving campus?
- Are we capturing everything we are supposed to?

# Each has Strengths and Weaknesses

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The IRB is powerful. It's highly unlikely a study gets past them. But they need research materials compliance assistance.

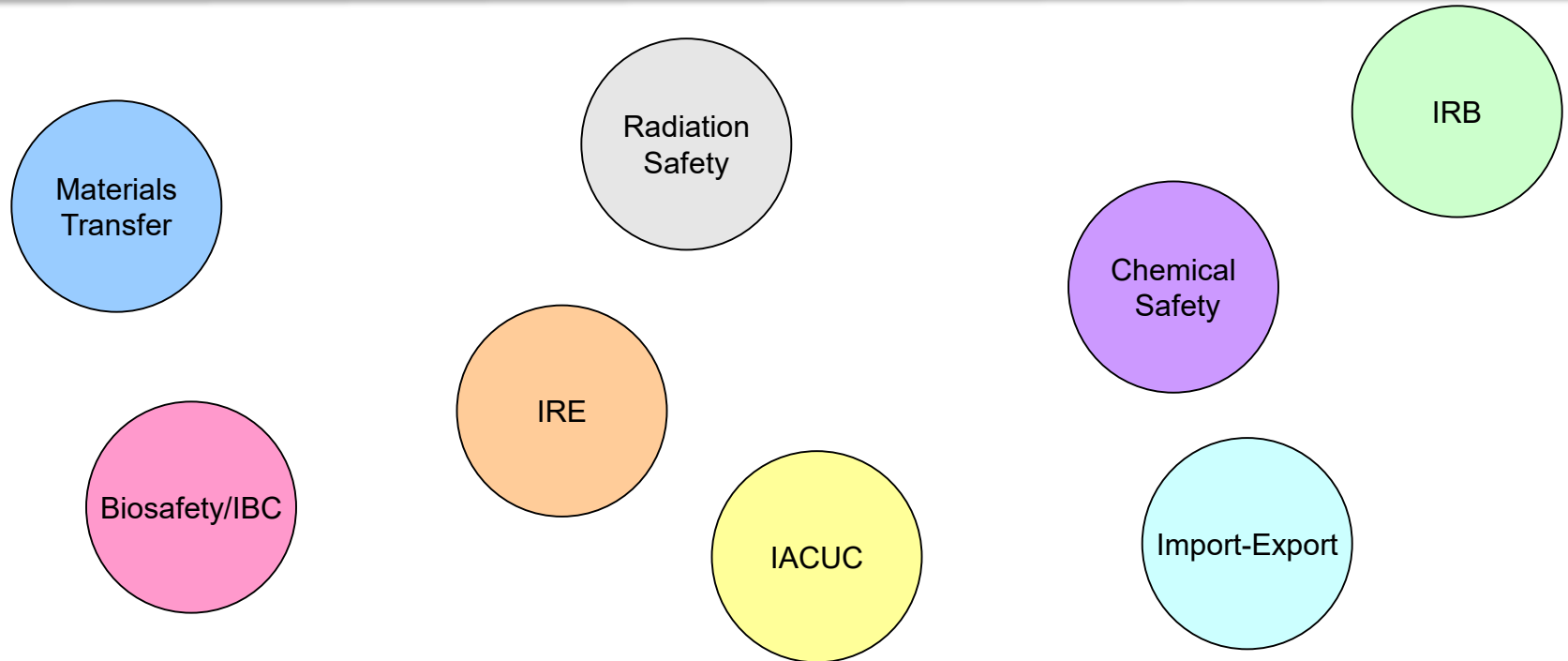
The IACUC is powerful. Animal acquisition is often linked to IACUC approval. But they also need research materials compliance assistance.

MTA Office is semi-powerful. Incoming materials that require a signed MTA are captured. But outgoing materials are highly dependent on investigator compliance.

Research material oversight groups like biosafety, chem safety, rad safety (to a degree), and import/export have expertise, but are highly dependent on investigator compliance due to the rather fluid movement of materials in collaborative science which complicates compliance efforts.

# Efforts Are Often Not Coordinated

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**Which is unfortunate...but understandable**

# Barriers to a Coordinated Effort Include

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- Inertia -  
People tend to be apprehensive about changing how they do things...which is understandable
- Resources – concerns about time, money, or staffing
- Location -  
Groups are often scattered around campus in various buildings and don't interact much, if at all
- Institutional barriers -  
Turf wars, prior bad experience with a group, politics
- Databases not compatible – doesn't have to be an issue



# Benefits to a Coordinated Effort Include

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- Increased Reach -  
You now have multiple registration systems feeding your oversight duties and increasing compliance
- Increased Awareness –  
The more people you touch, the more people that know who you are and what is required
- Greater Collegiality -  
Establishing ties and working together increases productivity, reduces barriers (real or imagined) and enhances communications and interactions between groups

# Little Tweaks Can Make a Difference

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**For example, the Biosafety Office is required by Federal rules and/or JHU policy to provide oversight of:**

Recombinant or Synthetic Nucleic Acid Molecules

(Federal requirement)

Potentially Infectious Agents and Pathogens

(Institutional policy unless CDC or APHIS permit or select agents, then federal)

Biological Toxins

(Institutional policy unless select agents, then federal)

Human-derived tissues, body fluids and cell lines

(Institutional policy that assists with OSHA Bloodborne Pathogens Requirements)

And since these materials could be used in a clinical trial, or animal study, and are often shared or shipped to colleagues, our database is useful for other groups too.

# Biosafety Registration Form

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Our primary data capture effort is the research registration. It is required of the investigators by JHU policy and includes:

- Investigator data, contact information, and lab location(s)
- Narrative describing materials and procedures to be used
- Description of potential risks and how mitigated
- Description of spill and exposure response
- Annual renewal and update to remain in force

We also query our investigators about their research programs and associated materials during our scheduled laboratory inspections and cross-check findings with our database.

# Is This Sufficient? Can We Improve?

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The problem in compliance is that you never know if you are achieving 100%. No one knows what the denominator is.

And, unfortunately, just because something is required doesn't mean it gets done.

So you need to maximize capture methods to improve your system.

Just a few tweaks can make a big difference.

For us, simple changes to our forms and procedures resulted in big results.

# The Changes Were Rather Simple

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Specific research material compliance questions were added to the IRB, IACUC, MTA and Export/Import forms.

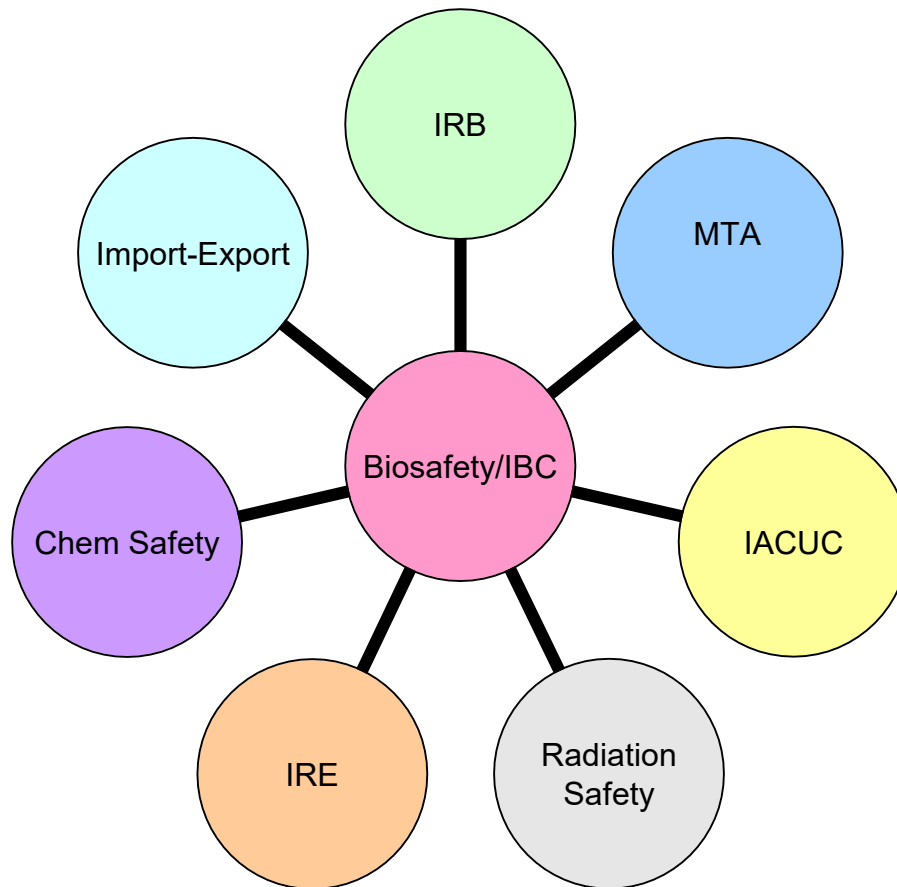
Hard stops were inserted in approval processes to help ensure safety compliance was in place prior to moving forward.

Increased surveillance of forms was initiated. The Biosafety Office reviews every IACUC protocol for biosafety, chem safety, rad safety or other compliance issues that may need to be addressed and report these data to both the IACUC and the relevant oversight group(s).

A compliance check system was initiated for MTA and Import/Export requests that involve biologicals. Items coming in or going out are cross-checked with our database.

# Getting There?

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# What Have We Learned?

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There is no question that leveraging areas of overlap between compliance groups created new avenues for capture of potential compliance items. We have picked up investigators in all overlap sectors that need to register the materials they intend to use. Would they have found their way to us eventually? We hope so.

Check boxes are surprisingly fallible in the hands of some investigators. Many times an item checked “no” is found to be “yes” in the narrative.

Narratives, though staff and time intensive to read, are a better tool for identifying potential compliance issues in a research program because they tell the story of the work to be done.

No one balked at doing a little extra work to help each other out. We have great colleagues...which is always a recipe for success.

# Questions?

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