

Kelé Piper

Director Research Compliance
Massachusetts General Hospital



Eleanor Kuszmar

Associate Director for Research Compliance
Harvard Medical School



OFFICE FOR
Academic and Research Integrity

Compliance

The Benefit of Collaboration between Compliance and Business Units: Enhancing Compliance at Your Institution

1

Objectives



Define the role Research Compliance can play in a collaborative initiative, including recognizing scope creep into operations



Discuss when Research Operations - Research Compliance collaborations can be effective for your institution



Practice mapping possible collaborative initiative scenarios from a compliance perspective

Disclosures

We have no conflicts to disclose. We are not being paid for our presentation nor are we endorsing any products or companies.

2

Poll Question #1

What type of institution do you represent?

1. AMC
2. Hospital/Clinical
3. Private medical practice
4. University
5. Pharma
6. Other

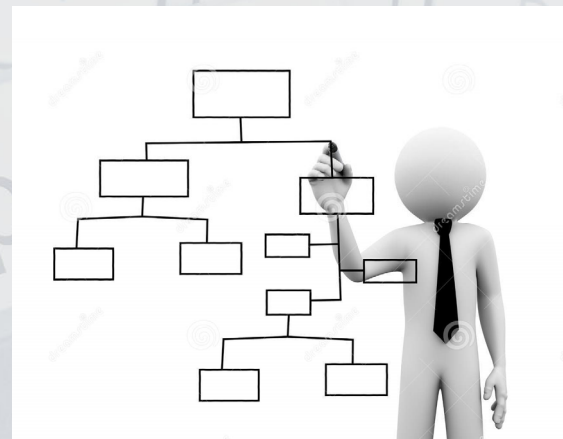


3

Poll Question #2

What best describes your compliance structure?

1. Independent/stand alone department
2. Part of corporate compliance
3. Combination of compliance and operations
4. Other



4

Poll Question #3

What best describes your role in compliance?

1. Leadership
2. Staff
3. Support role
4. Not in compliance
5. Other



5

Why have collaboration between Compliance and Operations?

Collaborative decisions lead to a better outcomes



Better change management

- Better buy-in
- Consistent and consolidated communications
- Expertise at the table
- Efficiency of resources



Integration of compliance into business processes

- “Build in” compliance to everyday activities
- Compliance built into tools, processes and procedures
- Compliance not as an added layer
- Aligns requirements and products from the very beginning

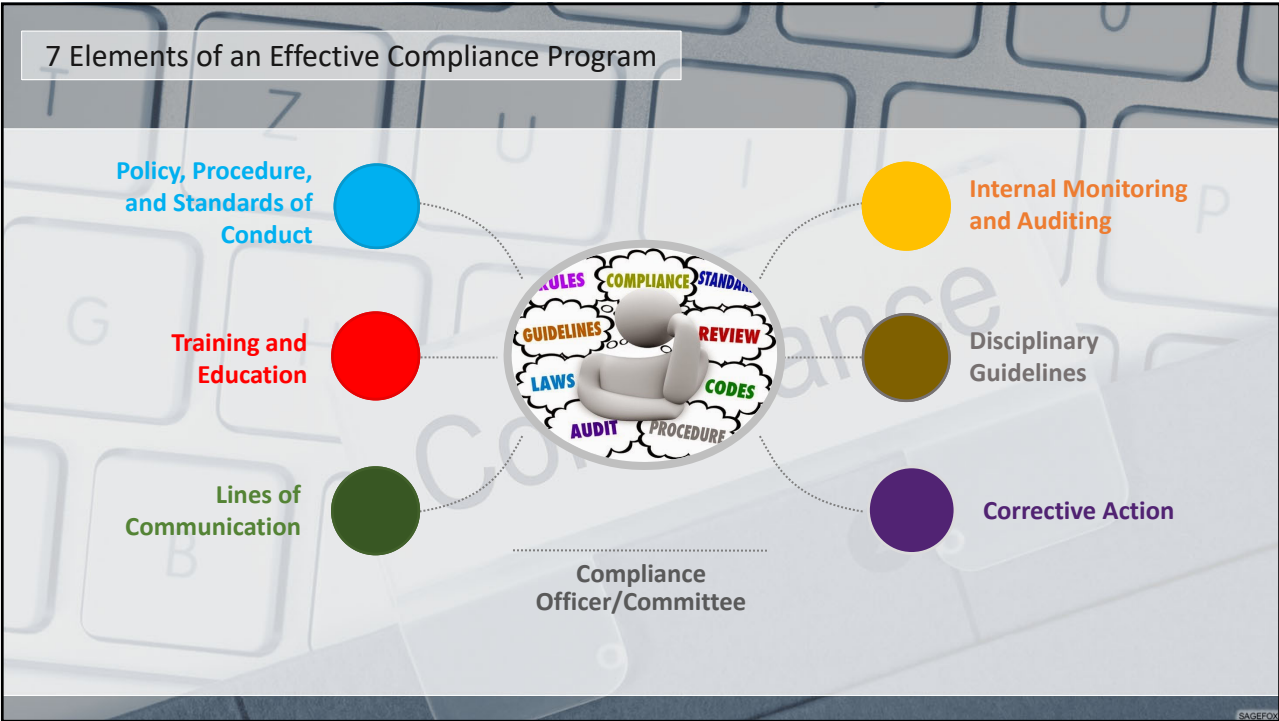


Builds trust and confidence

- Close knowledge gaps
- Very easy to get siloed
- Very few people have larger or whole picture
- Learn from each other

Collaborations support successful implementation of the 7 Elements of an Effective Compliance Program

6



7



8

Case Study #1



Controlled Substances

A controlled substance, Ketaved, is found in a hallway by a facilities maintenance employee. Not knowing what to do with the bottle, the employee takes it to Police and Security. Police and Security then takes it to the Pharmacy because it is a drug. The Pharmacy notices right away that it is a non-human drug and is used in animals and contacts Environmental Health and Safety who then contact the third-party vendor to come and destroy the drug.

9

Case Study #1, Poll Question #1

Is this a research compliance issue?

1. Yes
2. No
3. Maybe
4. Not sure

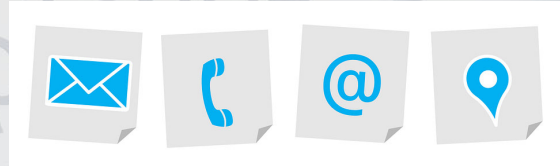


10

Case Study #1, Poll Question #2

Would your compliance department be contacted in this scenario?

1. Yes
2. No
3. Maybe
4. Not sure



11

Case Study #2, Poll Question #3

Who would be responsible for reporting to federal and state agencies?

1. Person who found it
2. Police & Security
3. Pharmacy
4. EH&S
5. Third-party vendor
6. Research Compliance
7. Not sure
8. None of the above



12

Case Study #1



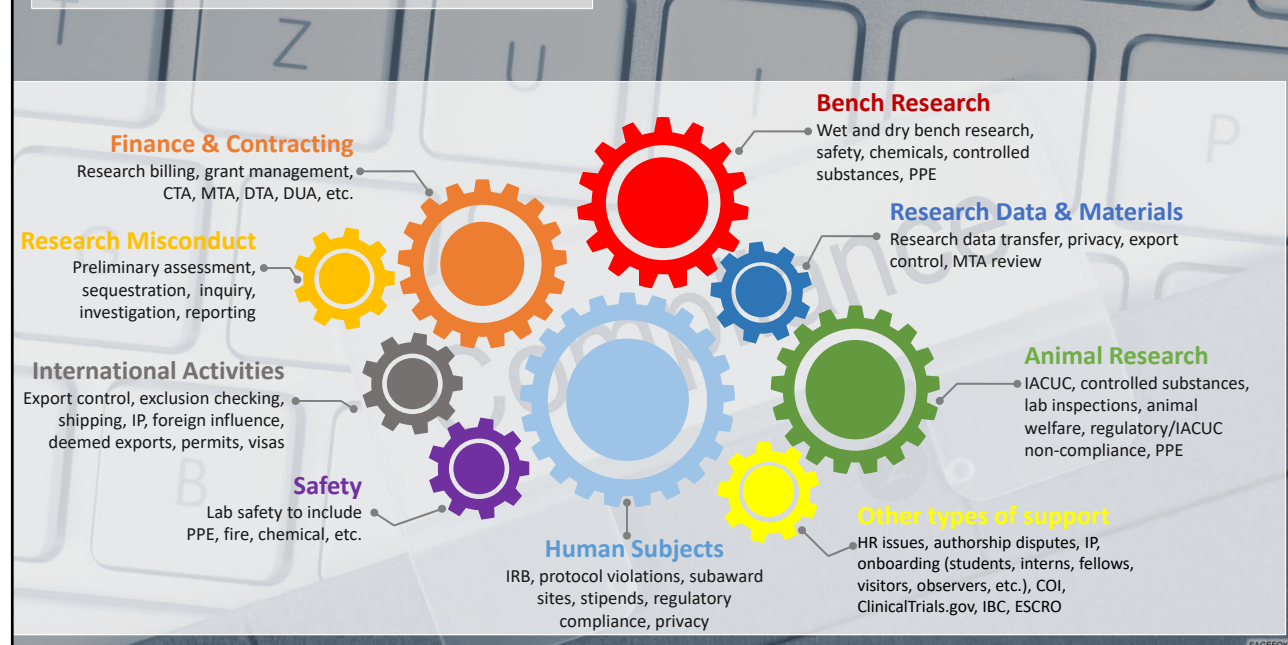
Controlled Substances

A controlled substance, Ketaved, is found in a hallway by a facilities maintenance employee. Not knowing what to do with the bottle, the employee takes it to Police and Security. Police and Security then takes it to the Pharmacy because it is a drug. The Pharmacy notices right away that it is a non-human drug and is used in animals and contacts Environmental Health and Safety who then contact the third-party vendor to come and destroy the drug.

- How would this get to compliance?
- How was the analysis done?
- What departments were involved?
- Does this require long-term solution?

13

What can research compliance look like?



14

Poll Question #4

What areas of research does your research compliance department support?

1. Bench research
2. Animal research
3. Human Subject Research
4. Research Misconduct
5. Research Billing
6. Export Control
7. Conflict of Interest
8. All of the above
9. Some combination of the above



15

Policy, Procedure, and Code of Conduct



What is the role of compliance?

- Create strong policy
- Review for regulatory compliance
- Provide interpretation and guidance for laws, regulations, and institutional policy
- Bring together content experts to write policy and procedure
- Ensure successful implementation and operability



Collaborating with business partners.

- Serve on policy review committees
- Provide regulatory support
- Monitor/audit for compliance
- Assist with big picture understanding of how all the pieces fit together



16

Training and Education



What is the role of compliance?

- Provide training and education for new regulations to key stakeholders
- Determine training needs
- Create clear training based on laws, regulations, and policy
- Evaluate training efforts for effectiveness



Collaborating with business partners.

- Co-facilitate on training initiatives
- Review training materials
- Look for opportunities to build training into daily process, institutional initiatives, and other training programs

17

Lines of Communication

What is the role of compliance?

- Identify when communication fails
- Disseminate information about regulations, policies, and code of conduct
- Connect the dots between people and resources

Collaborating with business partners.

- Bring the right people to the table
- Socialize issues to leadership and stakeholders
- Facilitate open and safe discussions



Clear, concise, effective, frequent, supportive, accurate, understandable

18

Internal Monitoring and Auditing



What is the role of compliance?

- Unbiased review of institutional business
- Develops deep understanding of issues and requirements
- Gathers data to inform decisions



Collaborating with business partners.

- Helps manage downstream effect of decision making
- Mediates viewpoints and helps with negotiation of risk approaches
- Brings understanding and direction of regulatory requirements

19

Disciplinary Guidelines



What is the role of Compliance?

- Clear enforcement within policy
- Make recommendation(s)
- Ensure consistency
- Monitor completion
- Ensure proper reporting

Collaboration with business partners.

20

Corrective Action



What is the role of compliance?

- Advise based on interpretation, benchmarking, risk tolerance, and experience
- Monitors reporting obligations and corrective actions for completion
- Provide interpretation
- Helps to align decisions with laws, regulations, and institutional policy



Collaborating with business partners.

- Provide guidance and recommendations
- Empower departments/individuals to make decisions/improvements
- Helping to maintain topic focus

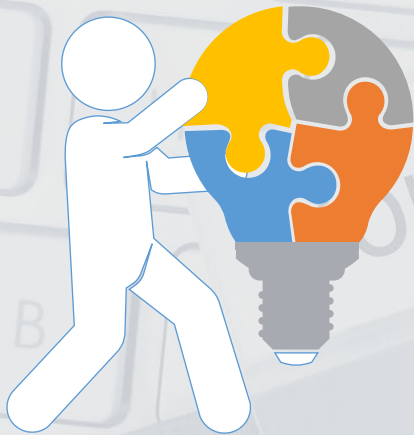


21

Case Study #2

Process Improvement

Your team has been tasked with making improvements to shipping compliance at your institution.



22

Case Study #2, Poll Question #1

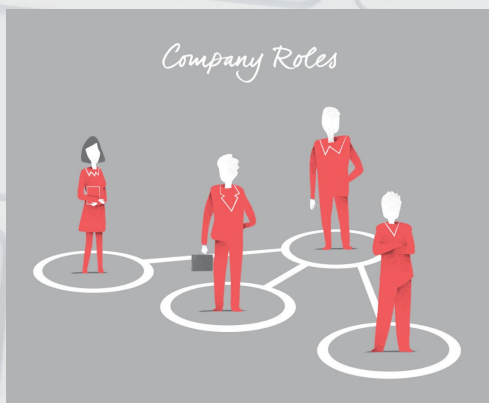
Is this a research compliance issue?

1. Yes
2. No
3. Maybe
4. Not sure



23

Case Study #2, Poll Question #1



What role at your institution would research compliance fulfill in addressing this issue?

1. Audit
2. Policy
3. Communication
4. Education/Training
5. All of the above
6. None of the above
7. Not sure

24

Case Study #2



Process Improvement

Your team has been tasked with making improvements to shipping compliance at your institution.

- How did this get to compliance?
- How is the analysis done?
- What departments will be involved?
- Does this require long-term solution?

25

Pitfalls for Compliance with Collaborative Initiatives



Program Model

Losing sight of the 7 Elements of an Effective Compliance Program or any other compliance model



Guiding Principles

Losing sight of focus on laws, regulations, and institutional policy



Scope Creep

- Not accepting operational decisions
- Taking ownership of operational activities



Communication

Not clearly communicating risks, regulatory obligations, policy changes, institutional expectations



Institutional Support

Not getting buy-in from your research community, key stakeholders, and institutional leadership


26

Tips of Successful Collaborations

- 1**
Create safe space for people to speak openly and without fear of retaliation or retribution
- 2**
Allow people opportunity to think creatively
- 3**
Be respectful of each collaborator's contribution
- 4**
Communication
 - Give credit freely
 - Communicate early
 - Communicate often
- 5**
Set clear expectations for collaboration. Assign work equitably and in accordance with each collaborator's expertise and role.

27

Additional Case Studies



Benchmarking Risk

You notice in the news that a number of OIG audits have targeted time and effort reporting for jointly appointed faculty.

Preliminary Analysis

You run a small sample/probe audit on a subsection of faculty who are jointly appointed at your institution and at least one other. You notice that faculty time and effort reporting may not be aligned with the documented time allocated to your institution. You also notice that documentation for joint appointments are inconsistent and there is confusion with calculating institutional base salary and coordinating Other Support pages.

- How did this get to compliance?
- How is the analysis done?
- What departments will be involved?
- Does this require long-term solution?

28

Additional Case Studies

Ancillary Findings

While investigating a separate issue, you come across a sponsor policy requiring that animal charges associated with unapproved protocol activities be removed from all sponsor's grants and that the sponsor be notified regarding findings of non-compliance and removal of charges. You know that your institution has not been following this practice.

- How did this get to compliance?
- How is the analysis done?
- What departments will be involved?
- Does this require long-term solution?



29

Compliance

Questions?

30