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OCTOBER 19 - 23

Seven is a Lucky Number: Seven Elements of a Successful Compliance Program (W111)

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DISCLOSURES
CERTIFICATE INFORMATION

- I have no financial disclosures to declare.

- This presentation has been presented at the following meetings:
  - SRAI Western/Southern Section Meeting, San Diego, CA March 2019
  - SRAI Webinar Series July 2019

- IRAM Certificate Elective

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OBJECTIVES

1 DISCUSS THE SEVEN ELEMENTS OF COMPLIANCE

2 IDENTIFY WAYS THAT INSTITUTIONS CAN IMPLEMENT THESE ELEMENTS

3 FIND WAYS THAT ELEMENTS CAN BE EMBEDDED TO CREATE A CULTURE OF COMPLIANCE

OFFICE OF THE INSPECTOR GENERAL (OIG)

THE SEVEN ELEMENTS OF A COMPLIANCE PROGRAM

1. WRITTEN POLICIES, PROCEDURES, STANDARDS OF CONDUCT

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► **Policies and Procedures**

- Policies
  - ✓ Rules or guidelines
  - ✓ Holds organizations and employees accountable
  - ✓ Framework of organization's structure and operations

- Procedures
  - ✓ Specific process
  - ✓ Operationalize policy for staff and managers

► **Standards of Conduct**

- Ethical principles
- Professional standards
- Acceptable behaviors
- Typically stem from or form mission and vision statements of an organization

1. WRITTEN POLICIES, PROCEDURES, STANDARDS OF CONDUCT

QUESTIONS TO ASK YOURSELF

- How does your institution handle SOPs?
- How are they approved?
- How often are they reviewed and updated?
- Does your institution have a separate Standards of Conduct statement?

▶ **Policies and Procedures**

- Templates available
- Other institutions have information posted
- Network with colleagues
- Make sure they work for your institution!

▶ **Standards of Conduct**

- Embed this as part of the mission and vision statement
- Design activities around these principles
- Back up the principles by living the culture as leaders or future leaders
- Design training, projects, initiatives around these principles

2. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE

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2. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE

COMPLIANCE OFFICER AND COMMITTEE

► **Compliance Officer**
- Specific individual(s) assigned to compliance and ethics program
- Direct access to Board/Leadership

► **Board/Leadership**
- Governing authority with knowledge and oversight of the compliance and ethics program
- Provide resources and appropriate authority to Compliance Officer and Personnel

► **Compliance Personnel**
- Day-to-day implementation of program
- Report to Board/Leadership
- Should have direct access to Board/Leadership and Compliance Officer

2. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE

QUESTIONS TO ASK YOURSELF

- Do you know who your compliance officer is at your institution?
- Is your institution operated by a Board of Directors or otherwise?
- How do employees and compliance personnel access the leadership?
- Who qualifies to be a Compliance Officer?

▶ **Compliance Officer**
  - Legal background
  - Compliance background
  - Property authority

▶ **Board of Directors/Leadership**
  - Ensure the reporting structure is clear
  - Compliance personnel must have direct access

▶ **Compliance Personnel**
  - Qualifications
  - Access to training and tools
  - Proper authority

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3. EFFECTIVE TRAINING AND COMMUNICATION

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3. EFFECTIVE TRAINING AND COMMUNICATION

- ▶ Initial Training
  - Policies and Procedures
  - Standards of Conduct
  - Consequences

- ▶ Ongoing Training
  - Annual training
  - Changes to policies, procedures, ethical principles
  - Consequences

- ▶ Incentives and Disciplinary Actions
  - Incentives and engagement of employees
  - Follow-through of disciplinary actions

3. EFFECTIVE TRAINING AND COMMUNICATION

QUESTIONS TO ASK YOURSELF

- How are staff members, investigators, leadership, and Board of Directors trained?
- What type of training is mandatory?
- What are the consequences for not completing training requirements?
- Are there various ways to train with ongoing exposure to the concepts?

▶ **Initial and Ongoing Training**
  - Important to determine mandatory, required, recommended, etc.
  - Format of training program
  - Annual training
  - Updates

▶ **Disciplinary Responses**
  - Suspension, Termination
  - Records
  - Timeliness
  - Consistency

▶ **Incentives for Participation and Education**
  - Rewards
  - Games with prizes

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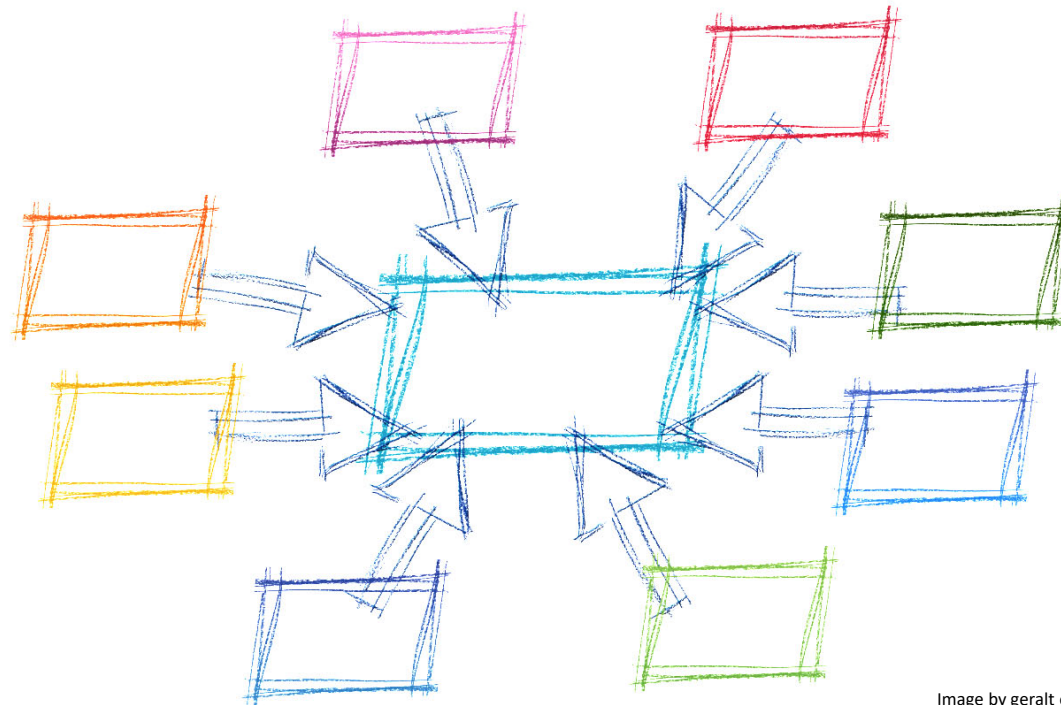OCTOBER 19 - 23

4. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

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4. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

▶ **Initial and Ongoing Training**

- Policies and Procedures, Standards of Conduct
- Frequency of training
- Updates of policies, procedures, ethical principles

▶ **Incentives and Disciplinary Actions**

- Incentives and engagement of employees
- Follow-through of disciplinary actions

▶ **Reporting**

- Confidentiality
- Process of reporting
- Non-retaliation policy

4. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

QUESTIONS TO ASK YOURSELF

- How is information provided to institutional stakeholders?
- Do people at your institution feel safe to report issues of non-compliance?
- How do people report non-compliance issues?
- Does the leadership follow the policies, procedures, standards of conduct?

▶ **Accessible Information**

- Orientation
- Websites
- Engagement activities
- Meetings

▶ **Non-Compliance Reporting**

- Hotline
- Website, Email
- Compliance Officer
- Confidentiality process
- Non-retaliation policy

5. CONDUCTING INTERNAL MONITORING AND AUDITING

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5. CONDUCTING INTERNAL MONITORING AND AUDITING

Programs designed to detect issues, violations of policy or law, and evaluate effectiveness of organization's program.

▶ **Monitoring**

- Informal process
- Internal staff
- Detect issues that can be corrected
- Educational opportunity

▶ **Auditing**

- Formal process
- External staff
- Detect issues that have occurred
- Report to Leadership/Board

5. CONDUCTING INTERNAL MONITORING AND AUDITING

QUESTIONS TO ASK YOURSELF

- Does your institution have a monitoring and/or auditing program?
- Does this process feel adversarial?
- Where do reports go when the process is complete?
- Are these educational?
- Is it structured and consistent?

▶ **Monitoring**

- Develop self-monitoring programs for department
- Provide standard checklists and resources
- Use this as an educational opportunity
- Can lead to more serious oversight

▶ **Auditing**

- Can be more adversarial by nature
- Conduct these with individuals outside of the department
- Transparent process, consistent
- Review facts and report appropriately
- Confidentiality

6. ENFORCEMENT STANDARDS WITH PUBLICIZED DISCIPLINARY GUIDELINES

6. ENFORCEMENT STANDARDS WITH PUBLICIZED DISCIPLINARY GUIDELINES

▶ Training

▶ Accessible policies and procedures

▶ Appropriate responses to offenses

6. ENFORCEMENT STANDARDS WITH PUBLICIZED DISCIPLINARY GUIDELINES

QUESTIONS TO ASK YOURSELF

- How are policies and procedures publicized and made available?
- Do these policies and procedures clearly identify consequences?
- Are the policies written in a straightforward way?
- When incidents occur, how are responses addressed?

▶ **Training**
- Primary way to publicize
- Banners in hospital
- Weekly reminders of key points
- Case histories in newsletters

▶ **Accessible Policies and Procedures**
- Websites
- Employee portals
- Handbooks

▶ **Responses to Offenses**
- Follow policy
- Investigate facts
- Confidentiality
- Appropriate reporting

7. PROMPT RESPONSE TO DETECTED OFFENSES AND CORRECTIVE ACTIONS

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▶ Time matters

▶ "Reasonable steps" to knowledge of criminal activity

▶ Implement modifications to program, where necessary

7. PROMPT RESPONSE TO DETECTED OFFENSES AND CORRECTIVE ACTIONS

QUESTIONS TO ASK YOURSELF

- Does the compliance policy outline a timeline for responding, investigating, and reporting?
- What would your institution define as "reasonable steps?"
- How amenable are institutions to change?
- How will changes be implemented?

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► **Timeliness**
- Follow policy on investigations and reporting
- Shows oversight authorities that an institution takes matters seriously
- Creates more trust with employees

► **"Reasonable steps" to criminal activity**
- Consider types of disciplinary actions when there is an allegation versus a finding
- Reporting is important, know where you need to report incidents

► **Implement Changes to Program**
- Opportunities for addressing an element in the system that isn't working
- Improve process
- Involve key stakeholders
- Remember – only write policies you can follow!

CREATING A CULTURE OF COMPLIANCE

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CREATING A CULTURE OF COMPLIANCE

CULTURE AND LEADERSHIP

▶ Leadership has to live and breathe the importance of compliance, not because they <u>HAVE TO</u>, but because they <u>SHOULD</u>

▶ Developing policies and procedures around a culture of compliance will build a strong institution that can follow the regulations

▶ Living the Standards of Conduct and designing programs that follow these principles can direct the institution's value system

▶ Providing a safe culture of asking questions and addressing issues will allow an institution to identify problems earlier, address them, and avoid strict sanctions

CREATING A CULTURE OF COMPLIANCE

CULTURE AND COMPLIANCE OFFICER

▶ Developing a program that is efficient and works within day-to-day workflow is more likely to be followed

▶ Being approachable and willing to listen is important for building a safe environment

▶ Compliance Personnel act on the leadership of the Compliance Officer so creating an environment of trust, knowledge, and integrity will direct the personnel's interaction with the research community

CREATING A CULTURE OF COMPLIANCE

CULTURE AND RESEARCH STAFF

▶ Policies and Procedures as well as Standards of Conduct are created to improve the institution and care for patients and stakeholders and lead to a compliance

▶ Questions are important and not asking if there is a concern can lead to non-compliance and could place a staff member at risk

▶ Research staff members are important in the process of keeping institutions compliance, not just the leadership

DON'T GIVE UP!

REFERENCES AND RESOURCES

► Office of Inspector General (OIG) Sentencing Guidelines

https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2014/CHAPTER_8.pdf

► Health Care Compliance Program Tips (OIG)

https://oig.hhs.gov/compliance/provider-compliance-training/files/compliance101tips508.pdf

QUESTIONS

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