

SEVEN IS A LUCKY NUMBER: SEVEN ELEMENTS OF A COMPLIANCE PROGRAM

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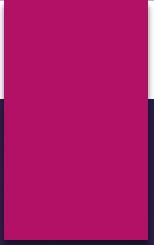
SOCIETY OF RESEARCH ADMINISTRATORS INTERNATIONAL
WESTERN/SOUTHERN SECTION MEETING
SAN DIEGO, CA
MARCH 12, 2019

HOUSEKEEPING

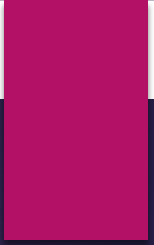
- ABBREVIATED SESSION
- BUSINESS MEETINGS
- SLIDES
 - <https://www.srainternational.org/meeting/section/2019-westernsouthern-section-meeting/presentations>
- CERTIFICATE
 - IRAM Elective (RI-I)

AGENDA AND GOALS

- HOUSEKEEPING
- GET TO KNOW EACH OTHER
- DISCUSS THE SEVEN ELEMENTS OF A COMPLIANCE PROGRAM
- IDENTIFY WAYS THAT INSTITUTIONS CAN IMPLEMENT THESE ELEMENTS
- FIND WAYS THAT WE CAN EMBED ELEMENTS TO CREATE A CULTURE OF COMPLIANCE



WHO IS IN THE ROOM?



SEVEN ELEMENTS OF A COMPLIANCE PROGRAM



1. POLICIES AND PROCEDURES AND STANDARDS OF CONDUCT

POLICIES AND PROCEDURES STANDARDS OF CONDUCT

► 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

PROCESS

- How do your institutions 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

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

PROCESS

- 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



3. EFFECTIVE TRAINING AND EDUCATION

TRAINING AND EDUCATION

- ▶ 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

PROCESS

- 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

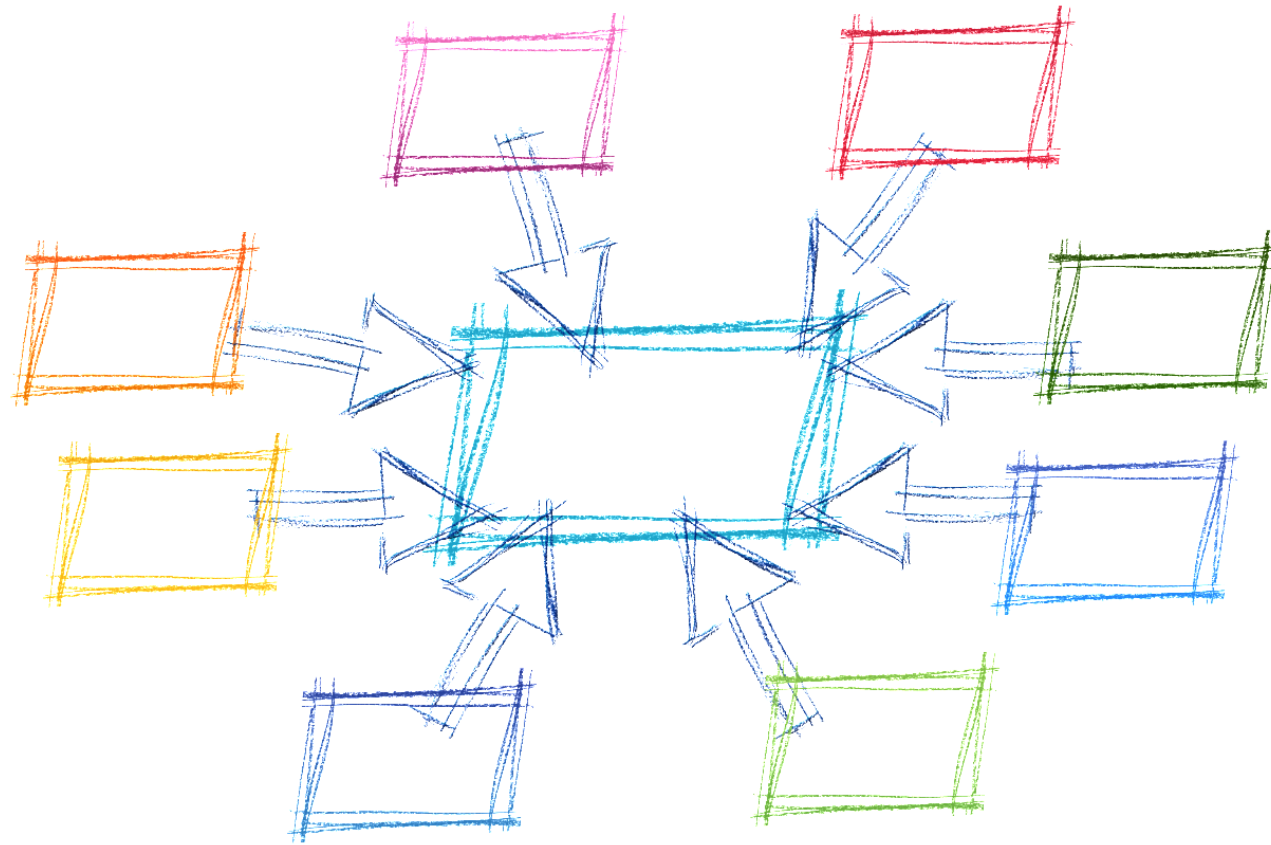


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4. EFFECTIVE LINES OF COMMUNICATION

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

PROCESS

- 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

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

PROCESS

- Does your institution have a monitoring and/or monitoring 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. ENFORCE STANDARDS THROUGH PUBLICIZED DISCIPLINARY GUIDELINES

ENFORCE STANDARDS THROUGH PUBLICIZED POLICIES

- ▶ Training
- ▶ Accessible policies and procedures
- ▶ Appropriate responses to offenses

PROCESS

- 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. RESPOND PROMPTLY AND IMPLEMENT CORRECTIVE ACTIONS

RESPOND PROMPTLY TO OFFENSES IMPLEMENT CORRECTIVE ACTIONS

- ▶ Time matters
- ▶ “Reasonable steps” to knowledge of criminal activity
- ▶ Implement modifications to program, where necessary

PROCESS

- 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?

► 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



CULTURE AND LEADERSHIP

- ▶ Leadership has to live and breathe the importance of compliance, not because they HAVE TO, but because they SHOULD
- ▶ 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

CULTURE AND COMPLIANCE OFFICER

- ▶ Compliance Officers have to live and breathe the importance of compliance, not because they HAVE TO, but because they SHOULD
- ▶ 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

CULTURE AND RESEARCH STAFF

- ▶ Research teams have to live and breathe the importance of compliance, not because they HAVE TO, but because they SHOULD
- ▶ 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



REFERENCES AND RESOURCES

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- ▶ 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>

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