

The Ten Steps to an Effective Research Compliance Program: A Practicum for Research Compliance Professionals

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Presentation Objectives

- **Identify key steps necessary to foster an effective research compliance program**
- **Understand importance of prioritizing steps for different research compliance areas**
- **Recognize and leverage opportunities to build an effective compliance program**

Colleague Participation!!

- You *know* these
- We do not know everything
- Let's learn from each other
 - Share at least one step you feel is critical for a research compliance professional to take in order to facilitate an effective compliance program

Our Top 10 Steps

1. **Develop a Strategic Plan, incl. Work Plan**
2. **Develop a Communication Plan**
3. **Build Relationships Within Organization**
4. **Emphasize Training**
5. **Develop Self-Monitoring Tools**
6. **Build Relationships Outside Organization**
7. **Maintain a Mix of Reactive and Proactive Compliance Projects**
8. **Prioritize Work According to Risk**
9. **Focus on clear, concise and consistent policy framework**
10. **Work Closely with Subject Matter Experts**

1. Develop a Strategic and Work Plan

- Determine plan methodology: risk assessment (OIG workplan, etc.), strengthening research infrastructure?
- Include programmatic/functional metrics
- “Work” the work plan throughout the year (ensure appropriate “priority” vis a vis other responsibilities)
- Revise/adjust the work plan as needed
- Report on workplan/metrics

It does not matter what type of organization or unit you are managing, or how young/old your unit is, a compliance workplan is a good idea to get you on track and keep you on track! Accomplishments in your workplan may serve as a basis for your annual report.

2. Develop a Communication Plan

Understand your several audiences/stakeholders/leaders

- Consistent, clear and frequent communications
 - Consistent messaging
 - Consistent look/style
 - Mix of FYIs/requests
 - Closing loop on requests with add-value demonstration
- Share compliance “wins” via email notices, newsletters, website, etc.

An effective communication plan will build trust with stakeholders

3. Build Relationships Within Organization

- Gain understanding of culture of organization, leadership engagement, employee motivational drivers, stakeholder perspectives; identify potential compliance “ambassadors”
- Collaborate and build trust – offer to help
- Insert yourself in meetings where you will learn about compliance risks and position your unit to help prevent non-compliance

If stakeholders trust you and understand your mission/functions, they are more likely to involve you when potential compliance issue *arise*.

4. Emphasize Training

- Even if your unit does not develop/conduct training, work closely with training unit to develop/offer appropriate compliance training as needed
- Use training as a tool to “sell” to stakeholders as a means of preventing untoward outcomes (i.e., mandatory HIPAA training)
- Ensure training is offered in high risk compliance areas; work toward mandatory training in highest risk areas
 - Benchmark practices of other institutions
 - Communicate benchmark data and federal/state settlements/enforcement actions against similar organizations (suggestions re sources)

Training is a key area in which metrics may be measured (% of workforce trained) to evaluate compliance with applicable regs/policies covered by training

5. Develop Self-Monitoring Tools

- Add value by providing useful self-monitoring tools to units/locations for process improvements/compliance enhancement
- Use reg/policy language and subject matter expert when possible in developing tool (note, leaders of operational areas should be subject matter experts)
- Challenge to get individuals/units to use tool when not mandatory
 - Coordinate with Internal Audit and agree on scope of self-monitoring tool--add to audit plan in subsequent year.
 - If units believe they have an opportunity to self-assess their areas prior to an audit, they are more likely to 'participate'.
 - Could make the self-monitoring tool mandatory.

If you track the self-monitoring tool to required checklist items, rather than 'nice to have', and ask your subject matter expert to provide training on the tool, stakeholders may perceive the tool as more valuable.

6. Build Relationships Outside of Organization

- Consult with compliance professionals at other organizations on tough issues; utilize expertise available at associations such as HCCA, COGR, AAMC, NACUA
- Use conferences to "get to know" regulators
- Gather list of subject matter experts

If there is an institution that parallels your own is willing to share information, you may want to set up recurring conference calls with key individuals for this purpose.

7. Maintain a Mix of Responsive and Proactive Compliance Projects

- We all operate in reactive mode depending on what issues arise
- Carve out time to focus on longer-term projects that will mature the program and meet your strategic and workplan/metrics goals
- Several elements of an effective compliance program require long-range planning
 - Training programs
 - Policy drafting/revisions
 - Auditing/monitoring

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8. Prioritize Work According to Risk (but maintain awareness of “sleeper” issues)

- Depending on compliance risk, focus on the highest priority issues/tasks first
- While it is hard to let other things go, it is often more important to spend resources mitigating the highest risk compliance issues for the organization
- Using workplan should help prioritize, although landscape changes in real-time, so workplan priorities could change

9. Clear, Concise and Consistent Policy Framework is Your Foundation

- Clear policies are critical for compliance program success—used as prime tool for communicating expectations to stakeholders and important for use by internal/external auditors.
- If your stakeholders are confused because they find different policy messages across disparate policies of the organization, promoting compliance to the policy is impossible.
- Fix policies that need to be fixed, and use the opportunity to communicate the new policy and the importance of compliance
- Add enforcement language to policies as needed

10. Work Closely with Subject Matter Experts

- You can't know everything—Identify reliable subject matter experts (General Counsel, Risk Management, HC Compliance, Privacy Officers, etc.)
- Use subject matter experts outside your organization to strategically analyze issues/conduct and audit/assessment
 - Some areas are better reviewed by those outside the organization who can bring a fresh perspective
 - Recommendations may be viewed as more 'important' than if they had come from IA or Compliance units (better acceptance of findings)

Questions & Discussion