

Pursuing Research Compliance Program Effectiveness

Why It Is Essential and How to Get There

June 11, 2023



1

YOUR SPEAKERS



SARAH COUTURE

Senior Managing Director

Ankura Consulting

Sarah.Couture@ankura.com

+1.859-421-7356

- Registered Nurse
- Certifications: CHC, CHRC, CHPC
- Compliance program expertise in academic medical center, hospital, physician practice, pharmacy, long-term care, and research settings, including program development and assessment, risk assessment, interim staffing, and training.
- Over 22 years clinical and/or compliance experience in hospital, AMC, physician practice, pediatric, skilled nursing facility, Federally Qualified Health Center, and free clinic settings.
- Charter faculty for HCCA Compliance Essentials Workshops; HCCA Research Compliance Academy faculty.



KATHERINE COHEN

Chief Compliance Officer

Southern Illinois University Medicine

kcohen65@siumed.edu

+1.217.545.8532

- JD
- Certifications: CHC, CHRC
- Compliance program expertise including program development, policy and procedure drafting, education and training, investigations, auditing and monitoring, research compliance and IRB.
- Compliance experience in hospital, physician practice, AMC, FQHC and research settings.



2

1

RESEARCH COMPLIANCE PROGRAM

Presentation Highlights

WHY EFFECTIVENESS MATTERS

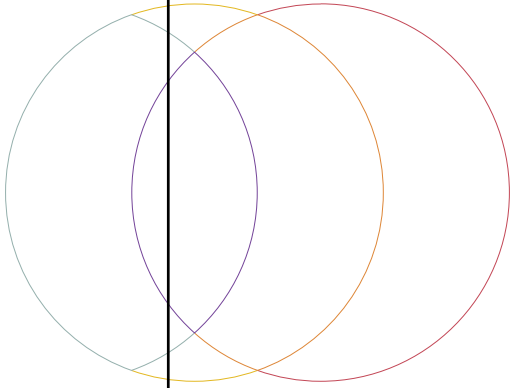
What does effectiveness mean for research compliance programs and why it matters

PROGRAM EVALUATION FRAMEWORK

Develop a sustainable framework for evaluating and achieving program effectiveness

IMPLEMENTING THE RESULTS

Implement the evaluation findings and results to evolve your program

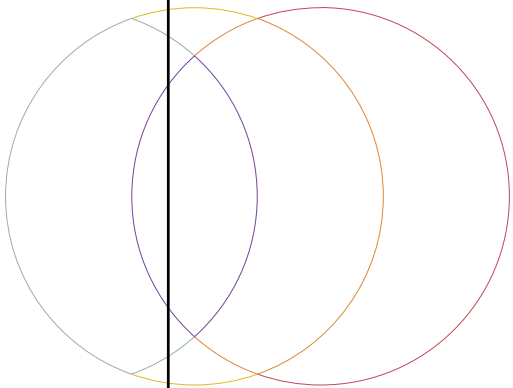


3

RESEARCH COMPLIANCE PROGRAM EFFECTIVENESS

WHY EFFECTIVENESS MATTERS

What does effectiveness mean for research compliance programs and why it matters



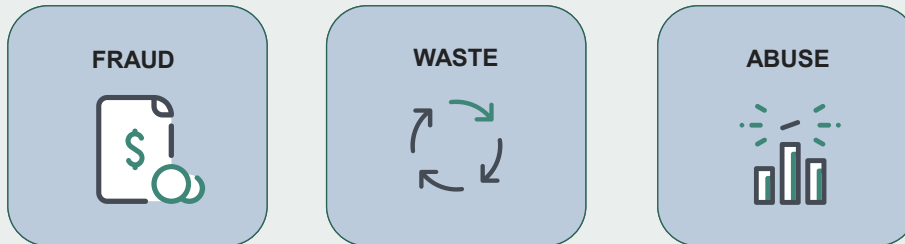
4

WHY EFFECTIVENESS MATTERS

Objective: Identify what effectiveness means for a research compliance program and why it matters

- Effectiveness is the expectation
- Can help “mitigate the ultimate punishment of an organization”
- It is not enough to simply have a research compliance program—it must be effective and lead to the desired outcome

DESIRED OUTCOME IS PREVENTING AND DETECTING:



5

WHY EFFECTIVENESS MATTERS



6

WHY EFFECTIVENESS MATTERS

Effective research compliance programs **MUST** be based on
PRIORITIZED RISK!



Risk Assessments: Why, What, When, How

Sarah Couture and Christopher Tonellato (ankura.com)

<https://angle.ankura.com/post/102hwtpr/risk-assessments-why-what-when-how>



7

WHY EFFECTIVENESS MATTERS



8

WHY EFFECTIVENESS MATTERS

Quality and Safety of Research

- Human subject protections
- Good clinical practices
- Research misconduct
- Biosecurity, biosafety and biorisk

9

WHY EFFECTIVENESS MATTERS

Data & Privacy

- Patient Privacy
- Data Security
- Data Retention and Records

10

WHY EFFECTIVENESS MATTERS

Enforcement

- FDA regulated research
 - Drugs
 - Devices
- False Claims Act
- Grants compliance
 - Time and effort reporting
- Export controls

11

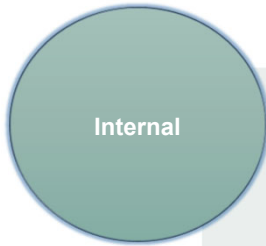
WHY EFFECTIVENESS MATTERS

Financial

- Clinical research billing
- Overpayments
- Grants financial compliance
- Conflicts of interest

12

WHY EFFECTIVENESS MATTERS



Internal

- Sufficiency of internal controls
 - Risk awareness & assessment
 - Oversight and responsibility
 - Policies and procedures
 - Communication & engagement
 - Education and training
 - Auditing and monitoring
- Internal culture
 - Turnover
 - Structure of operations
 - History of issues

13

ASO

WHY EFFECTIVENESS MATTERS



<https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf>

14

Slide 14

- ASO** Standards, policies & procedures
Program Administration
Screening & evaluation
Communication, education & training
Monitoring, auditing & reporting systems
Communication, education & training

Ana Simon, 2023-05-10T15:03:47.186

WHY EFFECTIVENESS MATTERS

How Do you Help Mitigate Research Risks and Engage Operations?



- Research administration and staff
- PI Community
- IRB and IACUC
- Research policies and procedures
- Research education and training
- Research compliance committee

15

WHY EFFECTIVENESS MATTERS

Research compliance program effectiveness: overlay effectiveness concepts and  assessment approaches to research compliance.

Keys to Pursuing Effectiveness

- **Collaboration**
- **Documentation**
- **Planning and intentionality**
- **Re-evaluation and evolution**

Prioritizing research compliance program effectiveness should ensure program improvement and evolution, and help you stay on front end of changing regulatory landscape.

16

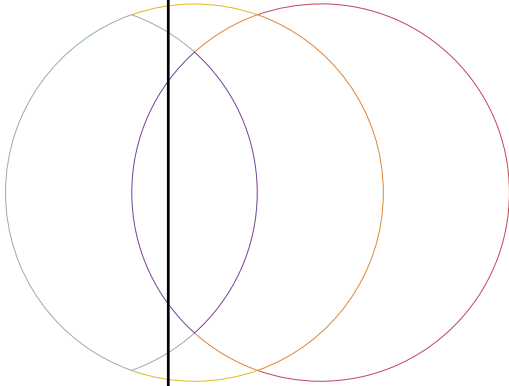
Slide 16

CTO Maybe this slide could be removed?
Christopher Tonellato, 2023-05-17T15:07:38.416

RESEARCH COMPLIANCE PROGRAM EFFECTIVENESS

PROGRAM EVALUATION FRAMEWORK

Develop a sustainable framework for evaluating and achieving program effectiveness



PROGRAM EVALUATION FRAMEWORK

Objective: Develop a sustainable framework for achieving program effectiveness

- Must have an intentional plan and approach
- Should include regular (i.e., annual), internal self-assessments, as well as intermittent outside, independent/objective assessments (i.e., every 2-3 years)
- Ensure the plan, approach, results of assessment, and any follow-up needed is well-documented—evidence of the great work you have done!
- There's no silver bullet or single “right way”
- Tailor the framework to the specifics of your organization (i.e., services/types of research, risk profile, size, complexity, culture)
 - What do we want to find out in the assessment?
 - What are our goals?
 - How are we doing?
 - What is keeping us from being more effective?

PROGRAM EVALUATION FRAMEWORK

- **Develop a plan and approach for self-assessment**
- **Our approach – building blocks**
 - Tools, concepts, methods
- Use what building blocks makes sense for your organization, and use them to develop your own tailored, pragmatic plan...



...that will evolve as you go!

Chasing the Goal: How do You Know if Your Compliance Program is Truly Effective?
Sarah Couture (Ankura.com)

<https://angle.ankura.com/post/102hm1x/chasing-the-goal-how-do-you-know-if-your-compliance-program-is-truly-effective>



PROGRAM EVALUATION FRAMEWORK

Tools available to assist with evaluating your program

Guidance Documents

- OIG/HCCA - <https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf>
- DOJ - <https://www.justice.gov/criminal-fraud/page/file/937501/download>
- Draft CPG for PHS recipients - [https://oig.hhs.gov/documents/compliance-guidance/795/PHS Research Awards Draft CPG.pdf](https://oig.hhs.gov/documents/compliance-guidance/795/PHS_Research_Awards_Draft_CPG.pdf)

Surveys & Interviews

- Knowledge of research compliance program
- Perception of culture of compliance
- Rounding, interviews, engagement survey

Benchmarks

- External
- Internal

Audit results

- Internal
- External

Data analytics

- Program data
- Risk-related data



PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Standards, Policies, and Procedures
- Compliance Program Administration
- Screening and Evaluation of Employees, Physicians, Vendors and other Agents
- Communication, Education, and Training on Compliance Issues
- Monitoring, Auditing, and Internal Reporting Systems
- Discipline for Non-Compliance
- Investigations and Remedial Measures

21

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Standards, Policies, and Procedures
 - Code of Conduct
 - Policies and procedures addressing the compliance program
 - Policies and procedures addressing the primary risks of the organization
 - Applicability to research operations and known risk areas
 - Accessibility of policy documents

22

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Compliance Program Administration
 - Research compliance officer authority and independence
 - Research compliance committee
 - Research compliance staff expertise, investment, engagement
 - Engagement and buy in by research operations staff and research leadership

23

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Screening and Evaluation of Employees, Physicians, Vendors and other Agents
 - Appropriate screening of staff related exclusion
 - Vendor compliance management approach including exclusion
 - Conflict of interest process

24

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Communication, Education, and Training on Compliance Issues
 - Intentional and meaningful communication from research compliance program
 - Promotes understanding of compliance program
 - Promotes understanding of relevant regulatory standards applicable to the organization
 - Research compliance education and training plan tied to risk assessment
 - Completion rate and accountability
 - Effectiveness of training
 - Tailored to audience- high risk positions/areas receiving training designed to reduce noncompliance
 - Dynamic, evolving education and training
 - Education that demonstrates commitment to compliance
 - Employees, agents, vendors, anyone else who might impact organization's compliance

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Monitoring, Auditing, and Internal Reporting Systems
 - Presence and promotion of anonymous hotline
 - Not just HOW to report, but WHAT to report
 - Auditing plan based on risk assessment
 - Monitoring by research operations of high risk functions with regular communication to compliance program
 - Routine, for cause and requested auditing
 - Communication of audit results and findings
 - Leadership
 - Government

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Discipline for Non-Compliance
 - Collaboration with HR
 - Fair and consistent
 - Auditing of documentation
 - Incorporation into performance evaluations
 - Plan for incentives

27

PROGRAM EVALUATION FRAMEWORK

Focus Area #1

Design, implementation, and maturity of the seven elements



- Investigations and Remedial Measures
 - Trained and qualified staff
 - Established process
 - Defined scope and documentation for audits
 - Consistency
 - Timely follow up

28

PROGRAM EVALUATION FRAMEWORK

Focus Area #2

Risk assessment, prioritization, and orientation

- Documented and regular risk assessment
- Collaboration with research operations
- Work plan based on risk assessment
- Approach for updating risk assessment as risks change, new risks emerge



PROGRAM EVALUATION FRAMEWORK

Focus Area #3

Data and documentation management

- Approach to documentation and tracking
- Data analysis and trending
- Design data collection with future effectiveness evaluation in mind



PROGRAM EVALUATION FRAMEWORK

Focus Area #4

Collaboration and engagement with operations and partners

- Collaboration and engagement with risk areas
 - Research Compliance Committee
 - Standing meetings and committees
 - Relationships

- Collaboration with other risk-related and/or administrative functions:
 - Corporate compliance
 - Legal
 - IA
 - Risk management
 - HR
 - IT
 - Export Controls
 - Tech Transfer
 - Others as needed



SIU SCHOOL
of MEDICINE



31

31

PROGRAM EVALUATION FRAMEWORK

Focus Area #5

Smart use of resources

- Appropriately scoping the effectiveness assessment

- Industry resources
 - Benchmarks
 - Training
 - Support and networking

- Outside professionals and experts
 - On specific issues – audits, investigations, etc.
 - Objective outside program effectiveness assessment every 2-4 years

- Quantity and use of resources
 - Staffing
 - Budget
 - Tools



SIU SCHOOL
of MEDICINE



32

32

PROGRAM EVALUATION FRAMEWORK

Focus Area #6

Culture and perception

- Culture of compliance at organization – survey and interviews
- Level of engagement of research operations – owning their own compliance
- Perception and reputation of research compliance program and team
- Research compliance staff satisfaction and performance

33

PROGRAM EVALUATION FRAMEWORK

Q: How do you communicate to leadership the purpose of the effectiveness assessment?

A: Communicate to organizational and research administrative leadership early, before engaging in the exercise. Explain the reasoning and value it will provide. This should assist with gaining buy-in and make explaining the results and next steps easier.

Q: What is the best way to utilize a compliance committee in the process?

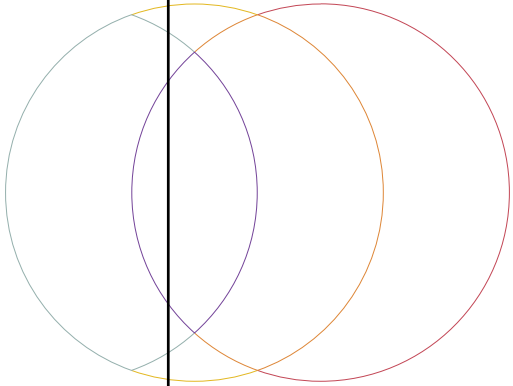
A: Engage not only your research compliance staff but your research compliance committee in the assessment. Present your framework and approach and get input. Solicit their input on implementation. Then work with them on the follow up planning.

34

RESEARCH COMPLIANCE PROGRAM EFFECTIVENESS

IMPLEMENTING THE RESULTS

Implement the evaluation findings and results to evolve your program



35

IMPLEMENTING THE RESULTS

Objective: Know what to do with the evaluation results once you've assessed your program.



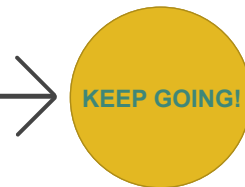
Develop Plan to
Address Findings



Report Results to
Leadership



Implement Plan



36

IMPLEMENTING THE RESULTS



Develop Plan to Address Findings

- Prioritize findings in accordance with risk
 - Address what is on fire before the things that would just be nice to have
 - Urgent, important, best practice
- Identify team members needed to collaborate with:
 - Compliance staff
 - Research compliance committee members
 - Risk area managers
 - Operations staff
 - Others as needed
- Develop action/work plan to address opportunities
 - Prioritized
 - Consider timing for specific items
- Incorporate the plan into the annual risk assessment and work plan/audit plan, as appropriate

37

IMPLEMENTING THE RESULTS



Report Results to Leadership

- Communicate overall findings, including best practices identified and opportunities for improvement
- Communicate the plan, including priorities and timing, to address opportunities
- Consider how/when to provide the information to your governing board
- Present any clearly defined research compliance program needs (i.e., resources, access, etc.)

38

IMPLEMENTING THE RESULTS

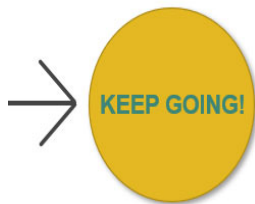


Implement Plan

- Implement the plan in accordance with priorities and timing.
- Stay connected to operational partners, such as research compliance committee members.
- Report on efforts in regular research compliance reporting forums.
- Be flexible to adjust as needed to be more effective.

IMPLEMENTING THE RESULTS

...and last, but certainly not least...



- Don't rest on laurels—compliance programs should be **dynamic**, always on the front edge of the industry
- Keeping risk assessments current, then flexing program accordingly
- Be intentional – focus on effectiveness as you go, incorporating lessons learned and a continuous improvement mindset into the fabric of your program.

Questions?

Thank you!

Sarah.couture@ankura.com

kcohen65@siumed.edu