

Applying Concepts Presented at the HCCA Research Academy

A Case Study of the Implementation Process

Discussion Objectives

- Review how we are assessing the infrastructure and activities recommended at the HCCA Research Academy for applicability in our entity's environment.
- Describe how we are prioritizing our efforts to enhance research compliance program activities.
- Describe obstacles we have, or anticipate we might, encounter and solutions we can deploy to overcome challenges to our efforts.

How We Became a Research Entity . . .

- 1882 - Maurice Porter Memorial Hospital in a four bed cottage in 1882.
- 1904 - became Children's Memorial Hospital, a Chicago institution.
- Over decades – evolved into the Children's Hospital of Chicago Medical Center, which includes the Ann & Robert H. Lurie Children's Hospital of Chicago and the Stanley Manne Children's Research Institute.
- Now partners with Northwestern University Feinberg School of Medicine as primary pediatric teaching hospital.
- The Stanley Manne Children's Research Institute focuses on improving child health, transforming pediatric medicine, and ensuring healthier futures.

How is That History Pertinent?

- Organizational Culture
- "Organic" process development
- Community Support
- Professional Commitment
- Research focus/Priority
- Comfort/Resistance to Change

Deciding to Apply Research Academy Concepts

Compliance Program evaluation raises questions:

- Should Research Compliance be included in the general Compliance Program?
- Should Research Compliance be separate from the general Compliance Program?
- Or can we leverage the value and avoid potential detriment of each by designing hybrid, or bridged, or collaborative Compliance Program activities?
- Centralized or Decentralized?

Research Academy Topics \Rightarrow Road Map for Assessment

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| • Research Compliance as specialized compliance area | • Auditing and Monitoring |
| • Scientific Misconduct | • Privacy and Security Issues in Research |
| • Research Billing | • Conflicts of Interest |
| • Human Subjects Protection | • Research Risk Assessment |
| • FDA-Regulated Research | • Data and Safety Monitoring Issues |
| • Research Records Management | • Animal Research |

Essential Underpinnings for Success

Willing partners in Corporate Compliance and Research Compliance

- Proactive approach
- Set the tone
- Invest resources in the effort
- Plan and prepare for change as need is identified
- Educate, train, and lead

First Steps in Assessment and Planning

- Respond to the urgent needs
 - Research billing support
 - Consistent response to auditor access requests
- Maintain/improve well-established activities, e.g., Conflict of Interest disclosure and management activity
 - Compare General Compliance and Research Compliance processes
 - Combine or enhance processes, as possible

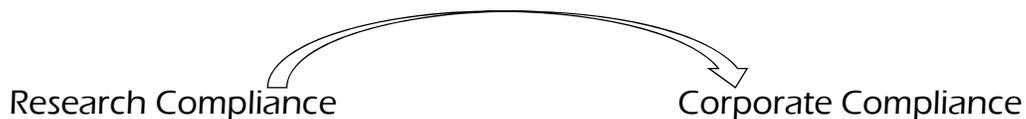
We Are Building Bridges!



Corporate Compliance activity identifies issue with research activity implications \Rightarrow escort it across the bridge to the proper Research Compliance resource.

Example: erroneous billing for research service invites review of coverage analysis, billing grid by Research, but repayment direction by Corporate Compliance.

We Are Building Bridges!



Research Compliance activity identifies issue with non-research activity implications \Rightarrow escort it across the bridge to the proper Corporate Compliance resource.

Example: Research Compliance staff identify a potential conflict of interest through research disclosure, but the activity of concern is corporate focused \Rightarrow escort it across the bridge to the proper Corporate Compliance resource.

Prioritizing First Stage Efforts

- We are prioritizing our efforts to enhance partnership in corporate and research compliance program activities:
 - Responding collaboratively to workforce requests
 - Focusing on respective infrastructure that will support future work
 - Finding quick wins

Navigating the Change

- Describe obstacles we might encounter and solutions we can deploy to overcome challenges to our efforts.
 - “This is how we’ve always done it.”
 - Disconnect between hospital-focused care and research-focused activity
 - Resources, resources, resources
- Communication, data, and results as obstacle removers.

Questions? Please, feel free to ask now!
Or later – contact info below:

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