

# 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

- |  |   |
|--|---|
| • 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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