In Unity Is Strength:
Research Compliance Through Leadership

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I do not have any conflicts of interest to report. The views and opinions expressed in this presentation do not reflect the opinions of Children's Hospital Colorado; they are my own.
Moral: In unity is strength.
Objectives

• Identify your bundle of sticks as a leader in research compliance.

• Frame a culture of research compliance by engaging with others, making commitments, and being present.

• Construct tools that empower compliance leaders in bringing what matters to a collaborative space.

Where Do I Find My Bundle?

Identifying your Bundle of Sticks
Who are your “go-to” people?

Write down three (3) names of team members with whom you connect and relate most frequently.

What are their professional roles and responsibilities?

What three (3) observations do you notice about your “go-to” people?

When Do You Lead?

Preparedness vs. Counteraction
How Do You Lead?

Change attitudes and beliefs: is your program a partnership or a catch-me-if-you-can system?

Meet teams where the work happens: do you encourage research teams to identify vulnerabilities themselves?

Identify compliance questions: do you distinguish real from perceived areas of risk and celebrate compliance successes?


Relating in Research Compliance

- Be Relatable
  Relating means being present; being present means going to where the research happens and understanding it.

- Be Relevant
  Being relevant entails asking meaningful questions; being relevant removes barriers to connect with team members.

- Be Reliable
  Demonstrating reliability conveys a commitment to team members; being reliable reinforces a culture of ethics and compliance.
What Does “Rounding” Mean?

• Reality: Go to the actual place; gather actual facts—the action!

• Gemba: “Gemba is where you go when you “go and observe.””


Research Compliance Rounding: A Model

Plan

• Schedule time

Inquire

• Ask insightful questions
• Ask focused questions

Observe

• Learn about research practices
• Listen: teach, praise, reinforce

Commit

• Make commitments
• Follow through with action
Research Compliance Rounding

- Diversify with whom you connect and relate.
- Show up meaningfully.
- Contribute to the bundle.

Relatable

Relevant

Reliable

Making a Rounding Plan

Assembling your Bundle
Commitments: Research Compliance Rounding Plan

- With whom will I round and relate on a weekly basis for at least 10 minutes?
- How will I ensure to round and relate in the area where the team members do their work?
- What commitments will I make with team members from viewpoints, findings, and observations gained from my rounding and relating?

How Do I Make Sense of My Bundle?

Making Your Bundle of Sticks
Sensemaking in Research Compliance

- **Sensemaking**: Make sense of the research world and circumstances that surround us (organizational psychologist Karl Weick).
- **Interpreting**: Seek understanding in the contexts in which research happens; interpret compliance in those contexts.
- **Cartography**: Map what and where we explore in research areas, the factors we concentrate on, and the terrain we represent.


“What’s in a question, you ask? Everything. It is evoking stimulating response or stultifying inquiry. It is, in essence, the very core of teaching.”

—John Dewy
Practicing Sensemaking

Understanding your Bundle

In Practice: Sensemaking Research Compliance

How will new regulatory requirements reshape research at my organization?

How will cultural expectations influence how research is conducted at my organization?

In what ways has a multi-generational workforce influenced attitudes about research ethics and compliance at my organization?
In Practice: Sensemaking Research Compliance

Reflect upon team effectiveness: Do you understand roles and responsibilities?

Observe the environment: Do teams feel safe to raise issues and to talk openly about systemic issues?

Define “normal” compliance: How can teams spot “abnormal” compliance without defining “normal” compliance?

Bringing What Matters to The Bundle

Bundles in Action
Create Something That Connects People

**Connection**
- Get close: connect with others meaningfully and purposefully

**Problems**
- Solve problems together

**Gaps**
- Fill a knowledge gap: curiosity connects compliance
Bring What Matters into Action

Research Compliance Virtual Sessions
Informed Consent Process Observations
Research Compliance Connect Channel
Research Compliance Quarterly Workshops

Measuring Success and Effectiveness

**Observable**
- Observe actions and behaviors
- Create intrigue and meaning

**Teachable**
- Translate actions into teachable behaviors
- Influence culture where actions happen

**Measurable**
- Measure past effectiveness (results-driven data)
- Measure actions leading to new behaviors (culture-focused data)
COVID-19: Research Compliance Virtual Sessions

**Observable**
- Show up: Be present
- Engage and connect
- Address relevant topics

**Teachable**
- Ground ourselves
- Support each other
- Foster learning with context

**Measurable**
- Measure valuable feedback:
  - The session’s content
  - The session’s approach
  - The attendees’ experience

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1-Strongly Disagree | 2-Disagree | 3-No Opinion | 4-Agree | 5-Strongly Agree | Average Score

- My learning style matched the pace of the session. 4.6
- I learned something new and valuable from the session. 4.6
- I felt connected with the Research Community at Children’s Hospital Colorado 4.6
- My questions were answered during the session. 4.6
- My expectations for the session were met. 4.6
- I feel that our team is more likely to contact Research Compliance in the future. 4.6

In Unity Is Strength: Bundle Your Sticks!

**Inquire**
- Bring conversation out into the open

**Observe**
- Teach, praise, reinforce
- Influence culture changes

**Commit**
- Foster a risk-prepared culture
- Follow through with action
Go Bundle Your Sticks!

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