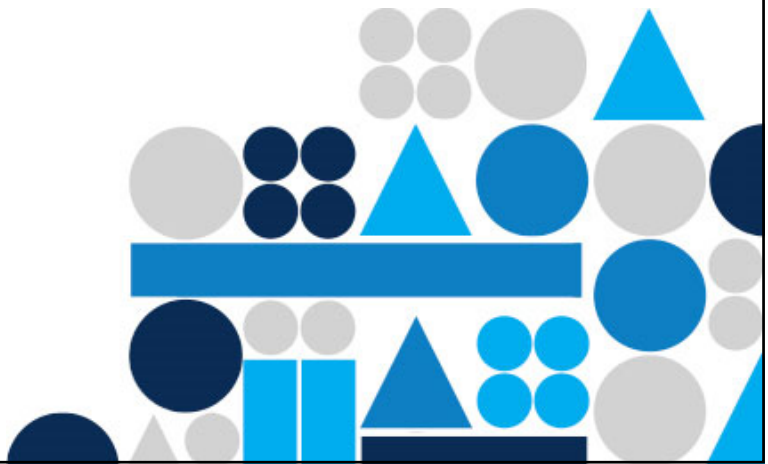


JUNE 2, 2020

In Unity Is Strength:

Research Compliance
Through Leadership



1

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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.



2



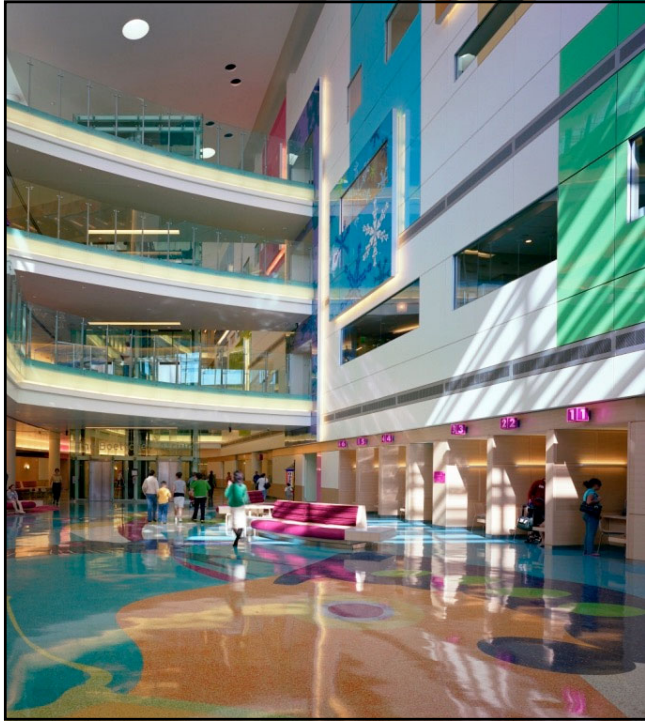
3



Moral: *In unity is strength.*

Aesop, Rackham, A., & Ashliman, D. L. (2003). *Aesops Fables*. New York: Barnes & Noble Classics.
 Aesop and Walter Crane. *The Baby's Own Aesop*. Retrieved from <http://www.gutenberg.org/files/25433/25433-h/25433-h.htm>

4



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.

5

Where Do I Find My Bundle?

Identifying your Bundle of Sticks



6

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?

7

When Do You Lead?



Preparedness

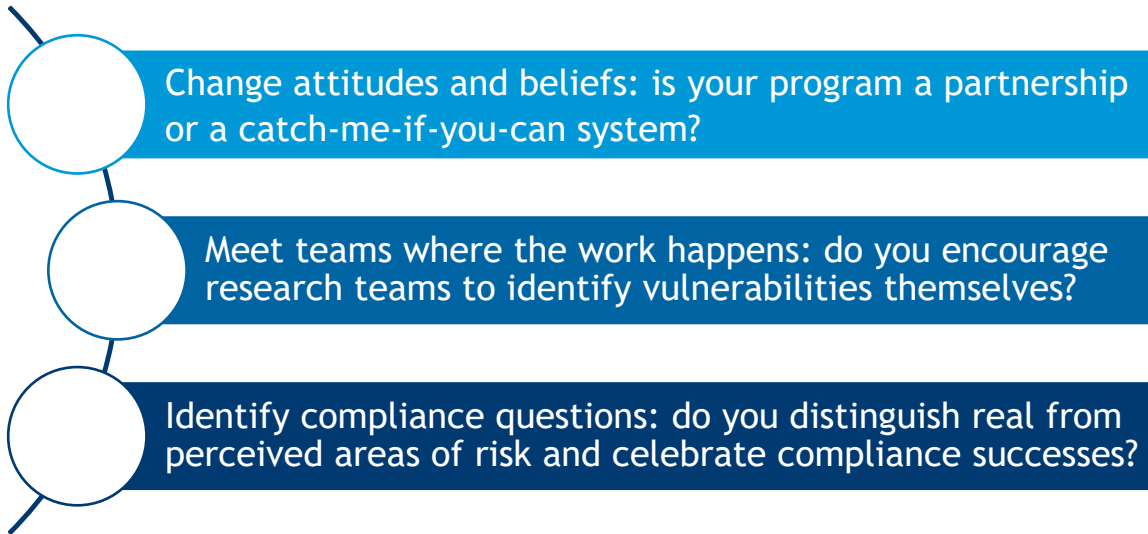
vs.



Counteraction

8

How Do You Lead?



Staley, D., Gilbert, H. (2018). Risk preparedness: The best guarantee for peaceful compliance. *Compliance Today*, November 2018, 76-80.

9

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

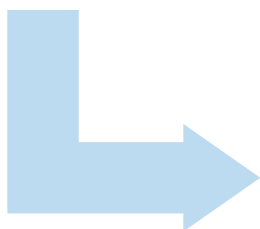
Demonstrating reliability conveys a commitment to team members; being reliable reinforces a culture of ethics and compliance.

10

Research Compliance Rounding: A Model

What Does
“Rounding”
Mean?

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



Go and
Observe

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

Excerpt From: Natalie J. Sayer & Bruce Williams. *Lean For Dummies*. Apple Books. <https://books.apple.com/us/book/lean-for-dummies/id518629304As>

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Research Compliance Rounding: A Model

Plan

- Schedule time

Inquire

- Ask insightful questions
- Ask focused questions

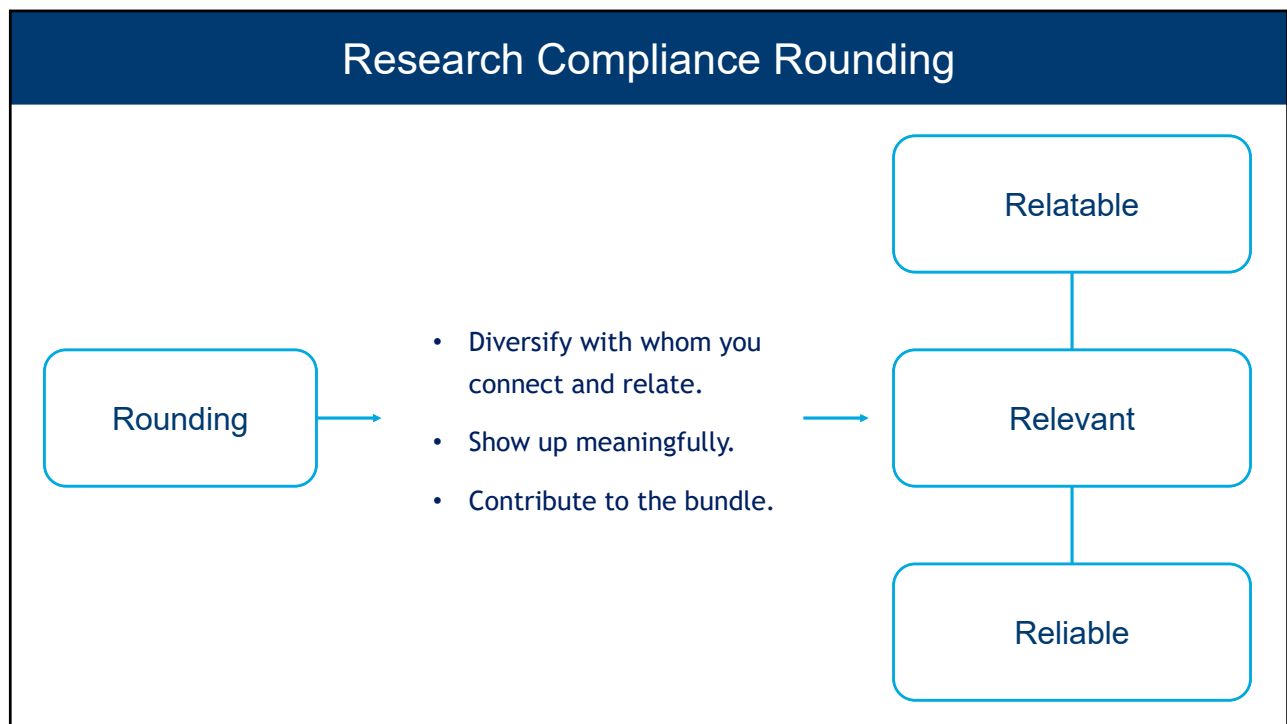
Observe

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

Commit

- Make commitments
- Follow through with action

12



13



14

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?

15

How Do I Make Sense of My Bundle?

Making Your Bundle of Sticks



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Sensemaking in Research Compliance

Sensemaking

Make sense of the research world and circumstances that surround us (organizational psychologist Karl Weick).

Interpreting

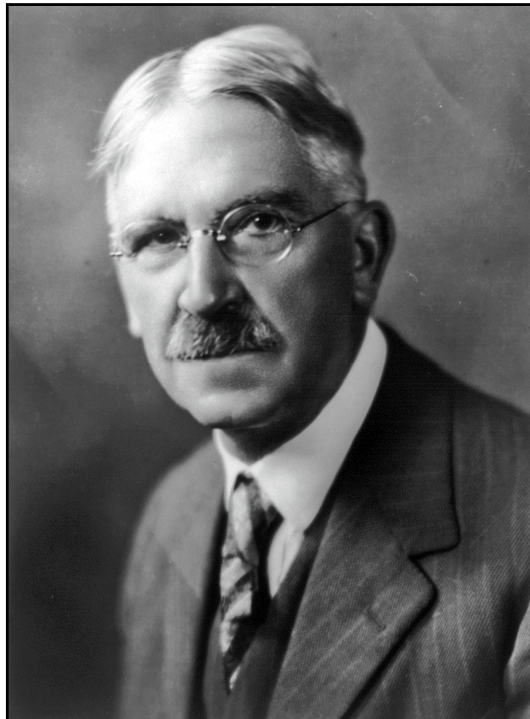
Seek understanding in the contexts in which research happens; interpret compliance in those contexts.

Cartography

Map what and where we explore in research areas, the factors we concentrate on, and the terrain we represent.

Ancona, D., Malone, T., Orlikowski, W. & Senge, P. (2011). In Praise of The Incomplete Leader In *HBRs 10 Must Reads on Leadership*. (pp. 179-195). Boston, MA: Harvard Business Review Press.

17



“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 Dewey

18

Practicing Sensemaking

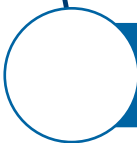
Understanding your Bundle

19

In Practice: Sensemaking Research Compliance



How will new regulatory requirements reshape research at my organization?



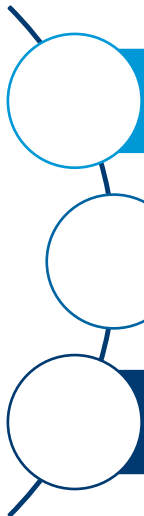
How will cultural expectations influence how research is conducted at my organization?



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

20

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?

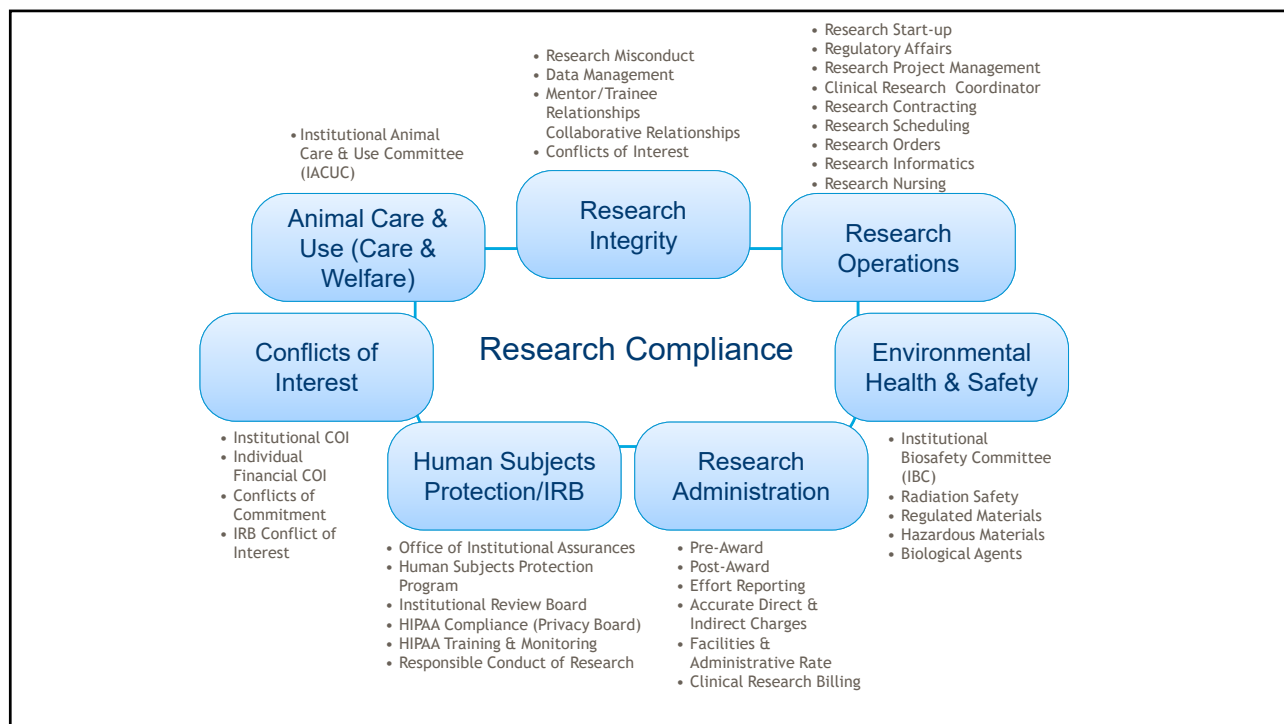
21

Bringing What Matters to The Bundle

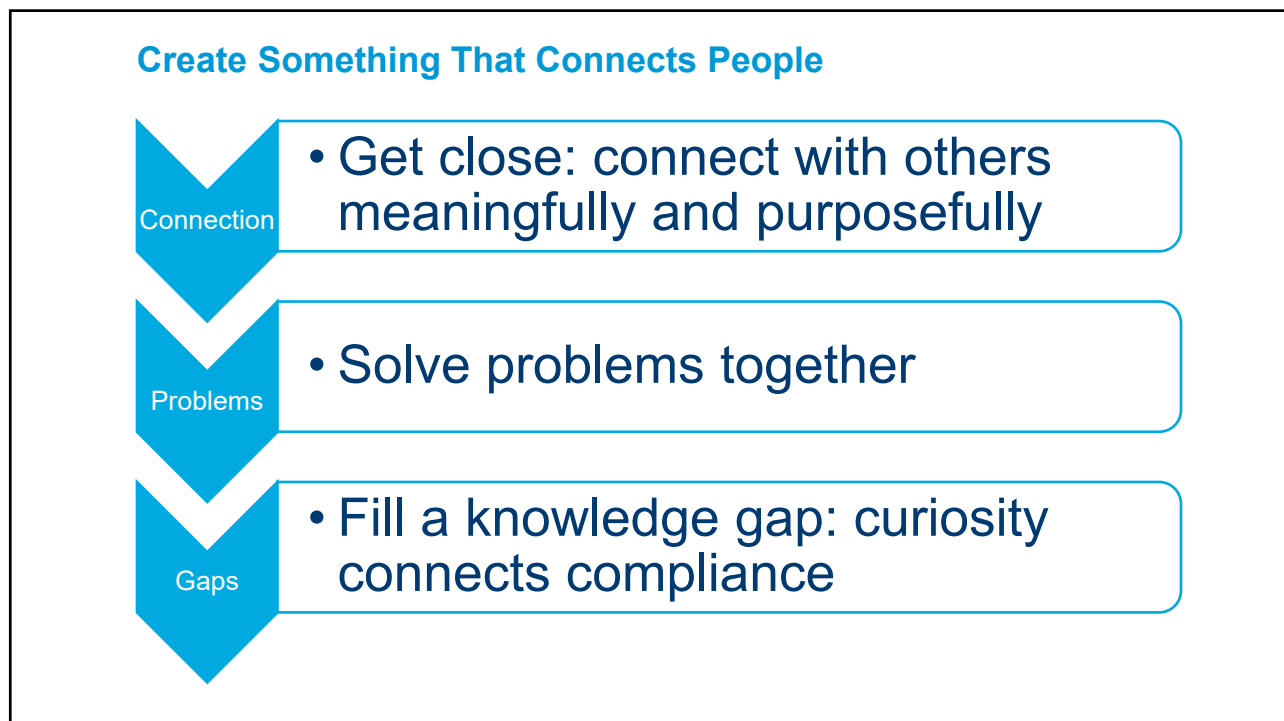
Bundles in Action



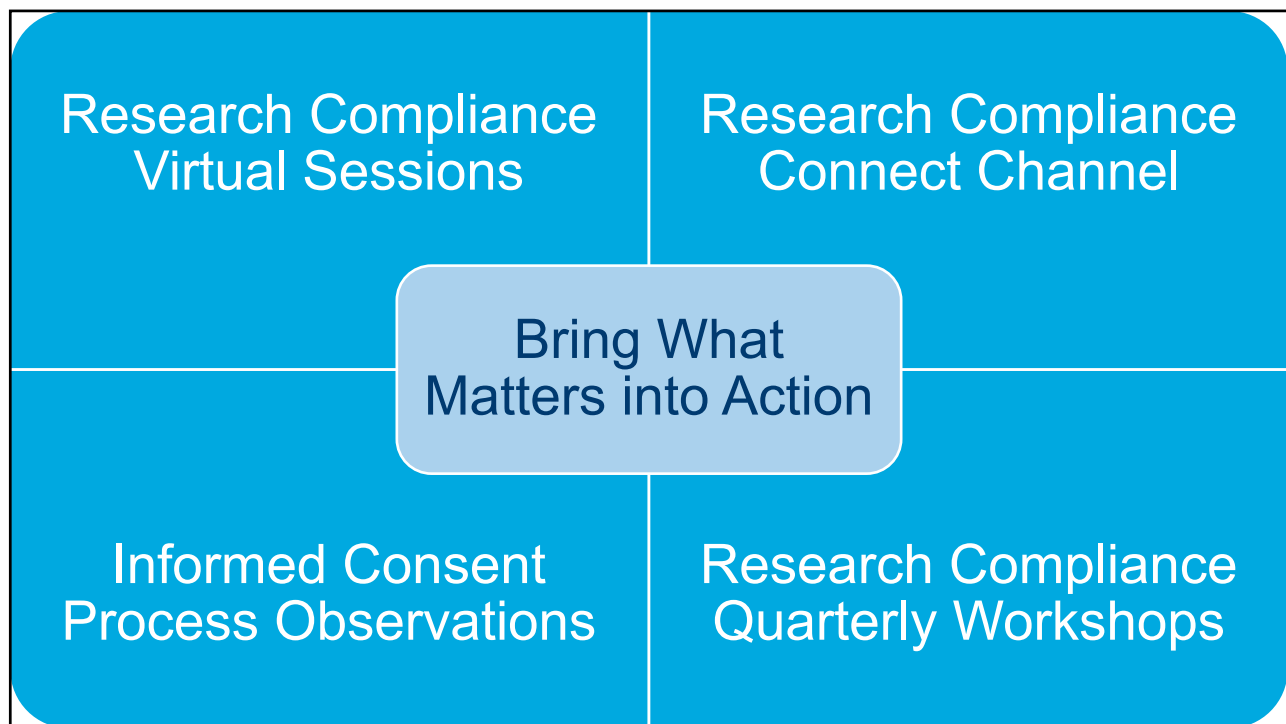
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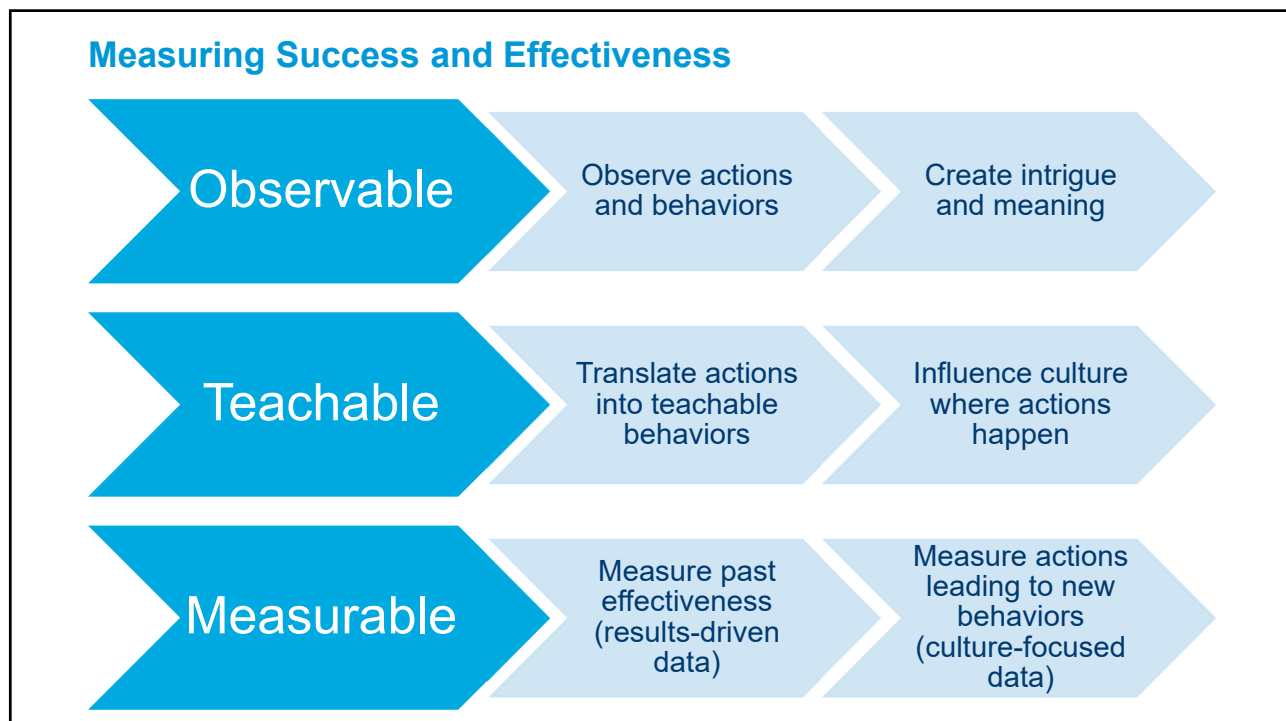
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25



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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

Topic	Date	#Attendees
Alternative Methods: Informed Consent	3 April 2020	60
Handling PHI during COVID-19	10 April 2020	47
Virtual Research Study Monitoring	17 April 2020	54
FDA Guidance Document: COVID 19	24 April 2020	69
HSR Exempt Category 4 (ii): Leftover Samples	1 May 2020	58
Investigational Products: Home Delivery	8 May 2020	53
e-Delegation of Authority Logs	15 May 2020	53

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.	4.8
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

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In Unity Is Strength: Bundle Your Sticks!

Inquire

Bring conversation
out into the open

Build relationships

Observe

Teach, praise,
reinforce

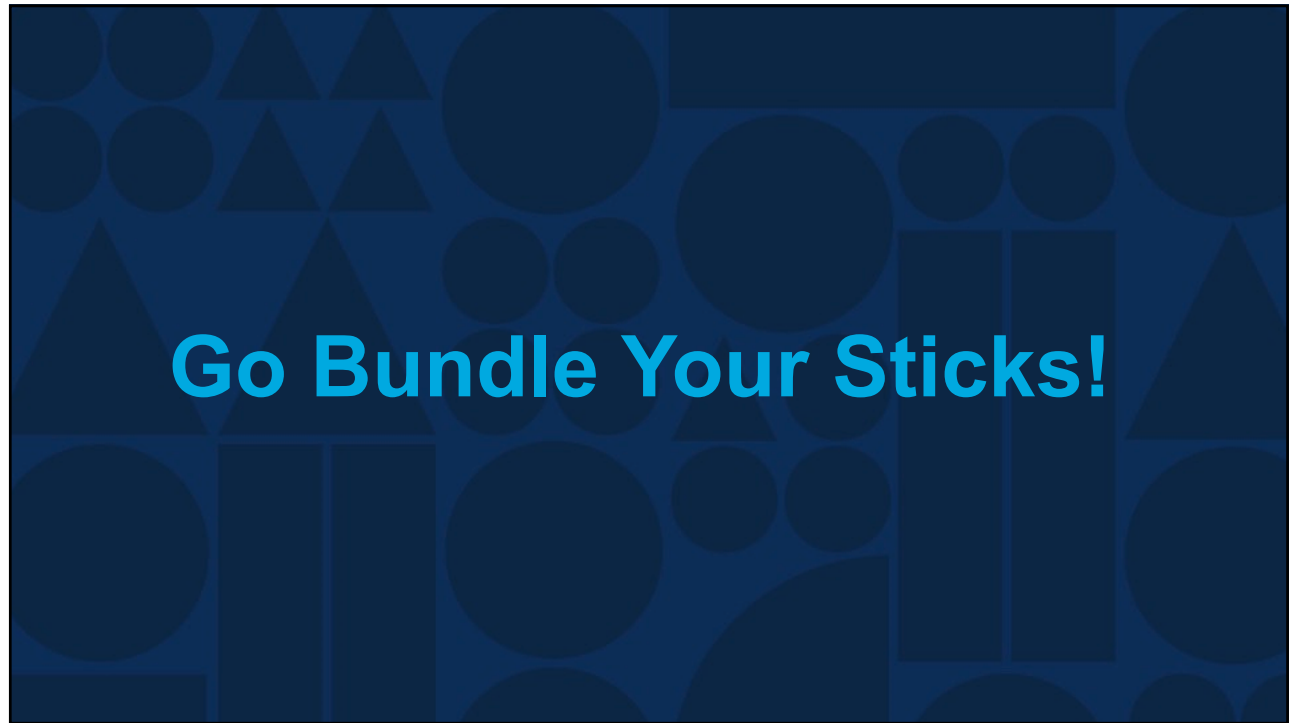
Influence culture
changes

Commit


Foster a risk-
prepared culture

Follow through
with action


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