

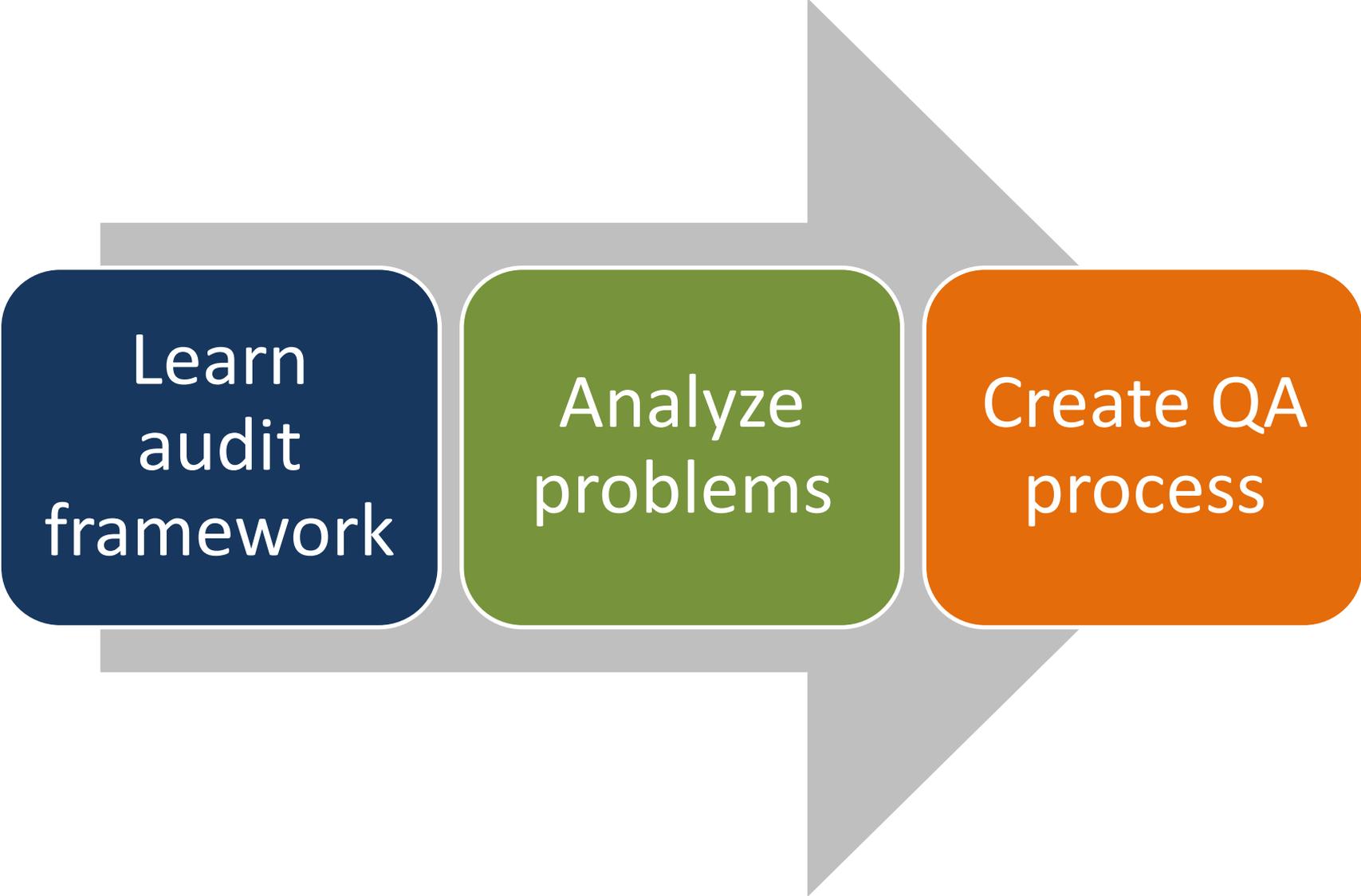
# Think Like an Auditor

## Constructive Responses to Real Study Problems

Mandy Morneault  
ITHS Manager for Regulatory Knowledge & Training  
[vicka@uw.edu](mailto:vicka@uw.edu)

# Session Goals

The background of the slide features a green-tinted microscopic image of brain tissue, showing various cellular structures and fibers. Overlaid on the right side of the image is a white circuit diagram consisting of several interconnected lines, nodes, and small circles, resembling a neural network or a technical schematic.



Learn  
audit  
framework

Analyze  
problems

Create QA  
process

# Clinical Research Goals

The background of the slide is a dark green color. It features a faint, circular microscopic image of a cell, possibly a neuron, with various internal structures visible. Overlaid on the right side of the slide is a light green circuit board pattern, consisting of lines and small circles representing components or nodes.



**SAFETY  
FIRST**



**INTEGRITY**

The background of the slide is a dark green color. It features a faint, large-scale image of a biological cell, possibly a neuron, with various internal structures and a nucleus. Overlaid on the right side of the image is a stylized, light green circuit board pattern consisting of lines, dots, and rectangular shapes, suggesting a connection between biology and technology.

# Why QA?

# Why do I need QA?

# 1

# Why do I need QA?



Why do I need QA?

2

# Why do I need QA?



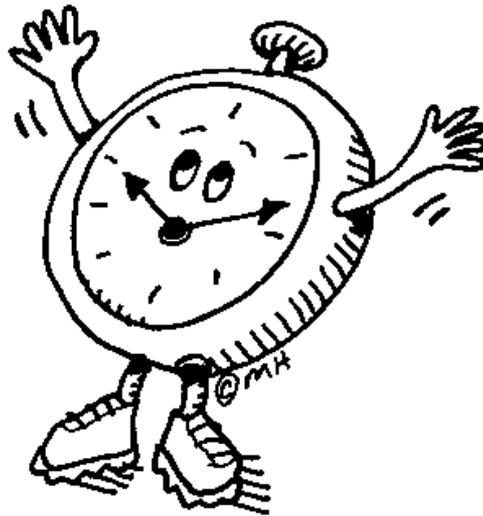
Why do I need QA?

3

# Why do I need QA?



# Why do I need QA?



# QA Triggers



# QA Triggers

Policy Changes

# QA Triggers

Noncompliance Events

# QA Triggers

Innocent Ignorance

Surprising Sloppiness

Malicious Malfeasance

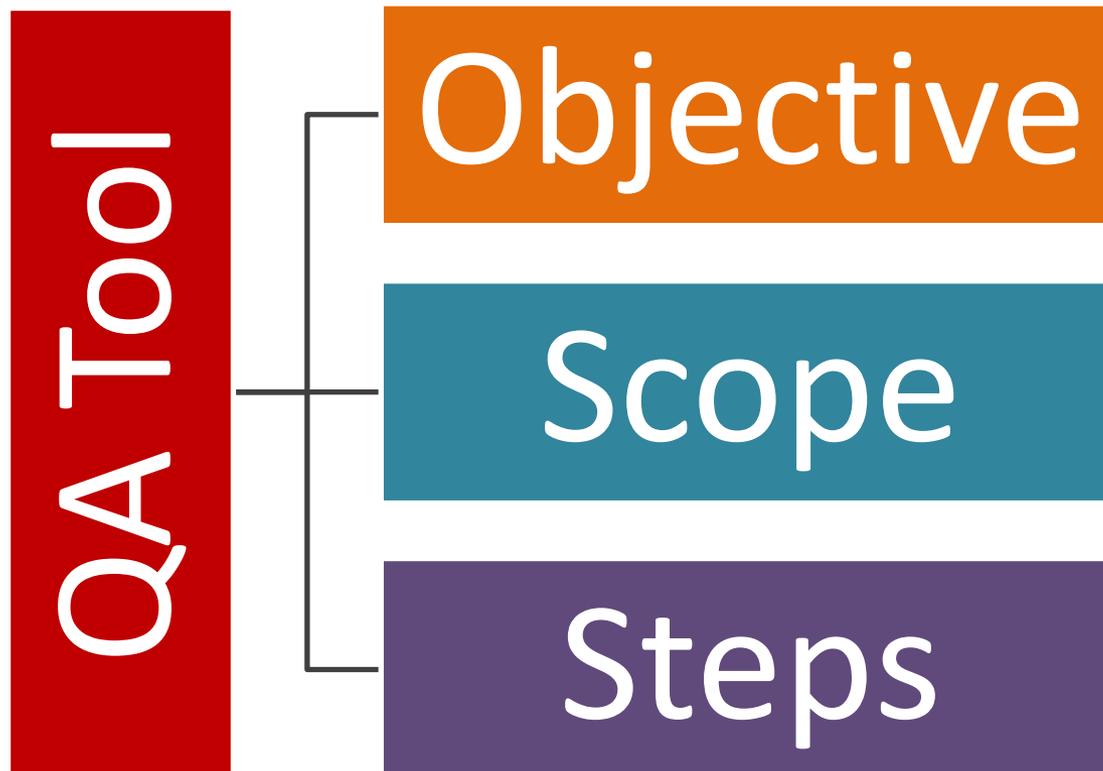
**MISTAKES**  

---

**are our best**  

---

**TEACHERS**

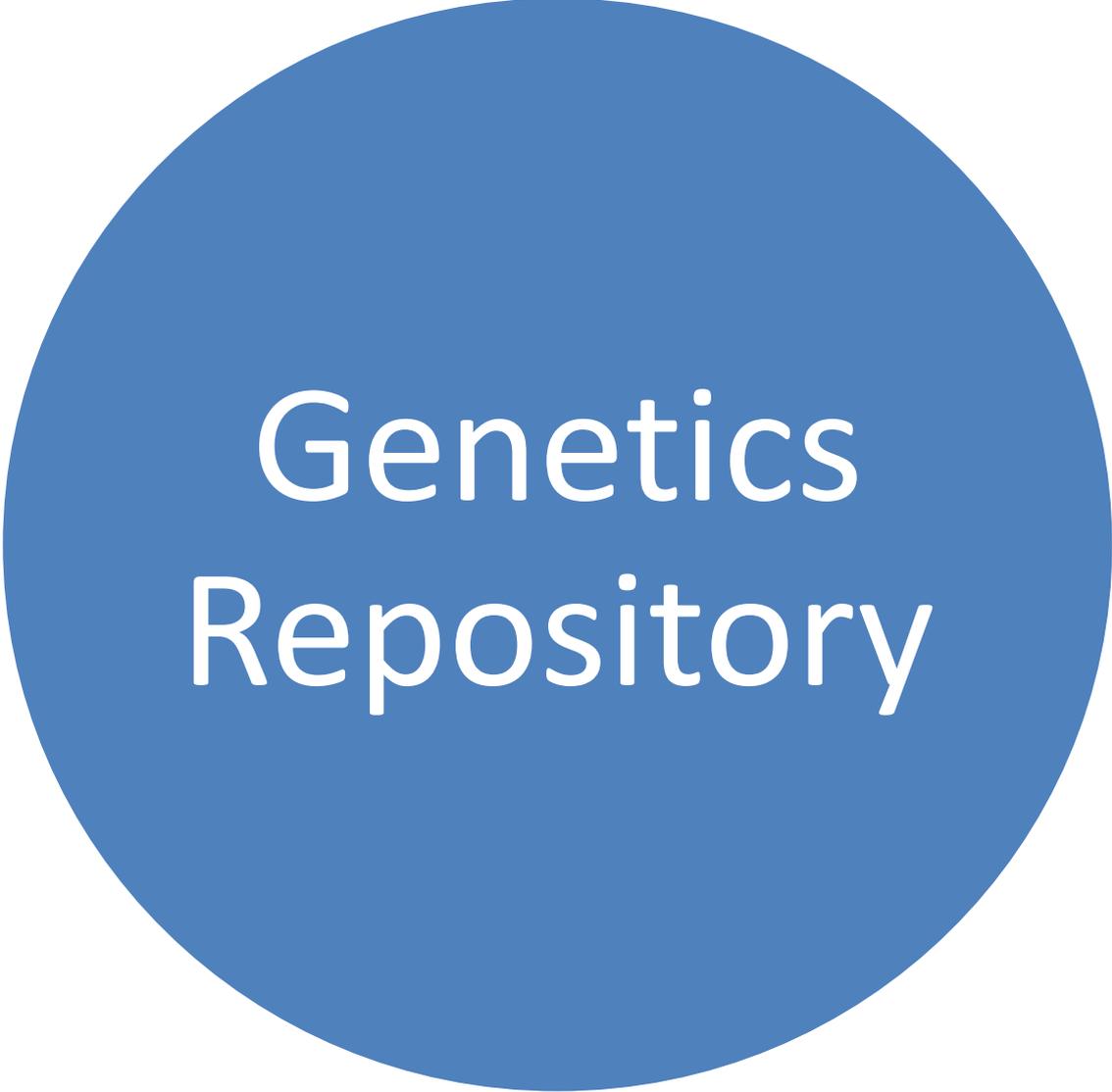


# Case Studies

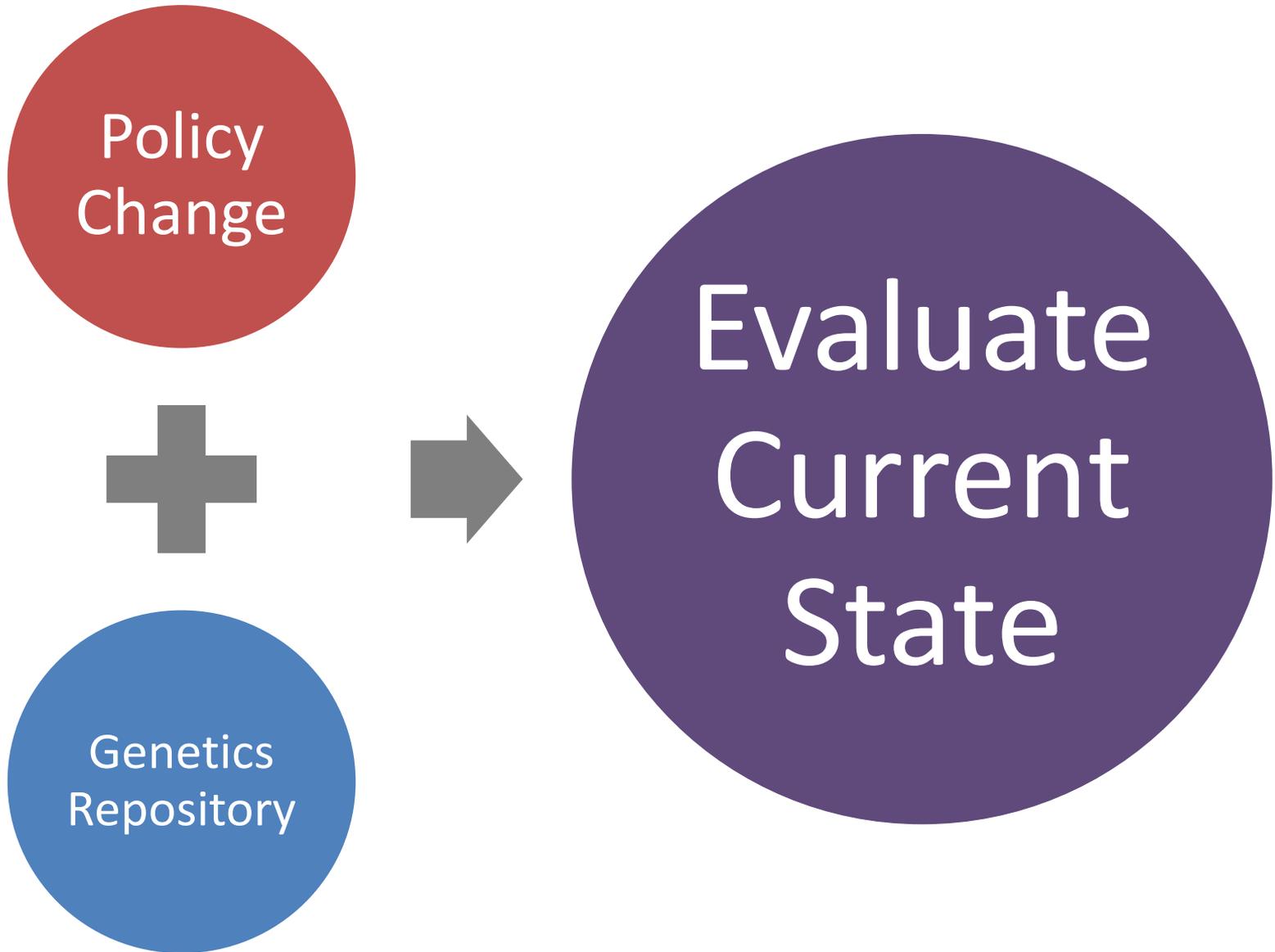
The background of the slide features a green-tinted microscopic image of brain tissue, showing various cellular structures and fibers. Overlaid on the right side of the image is a white, stylized circuit board pattern with lines, nodes, and small circles, suggesting a connection between biology and technology.

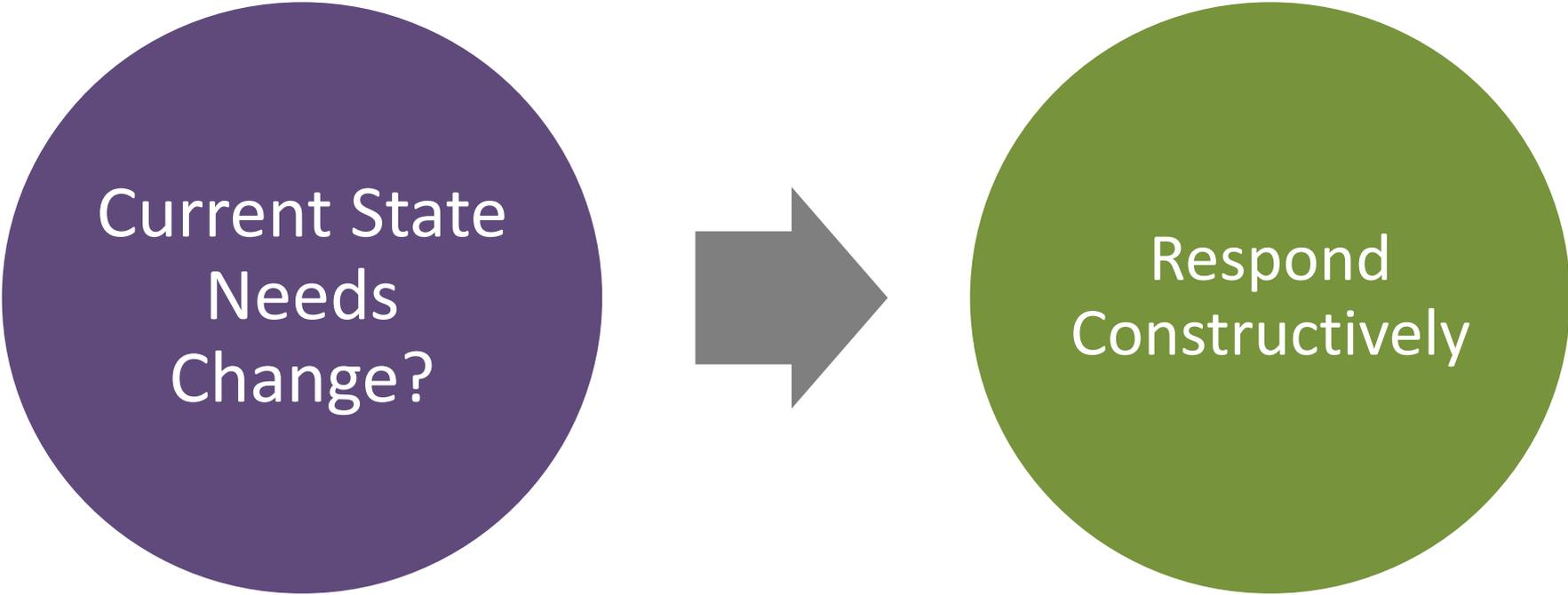


# Policy Change



## Genetics Repository



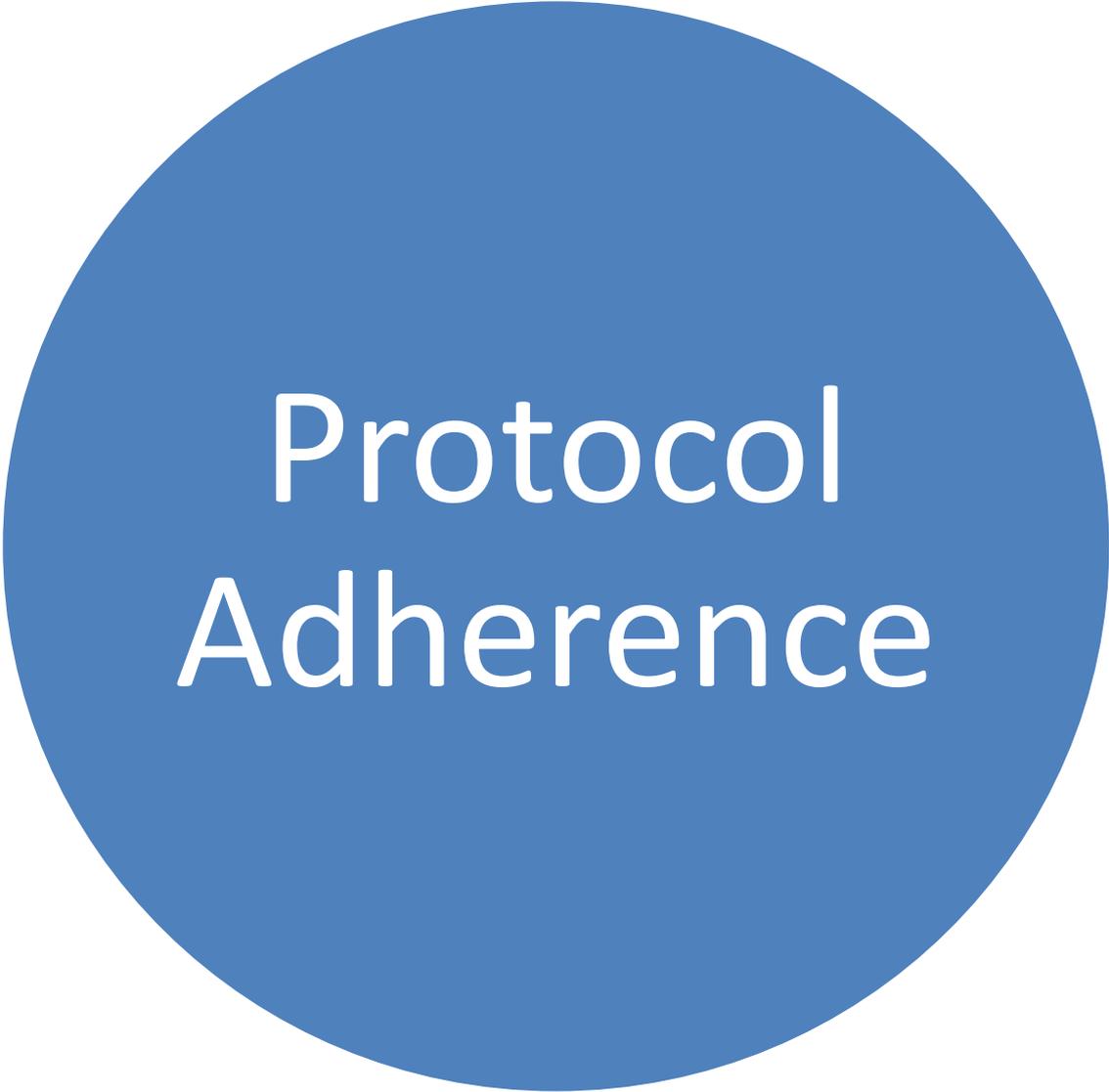


Current State  
Needs  
Change?

Respond  
Constructively

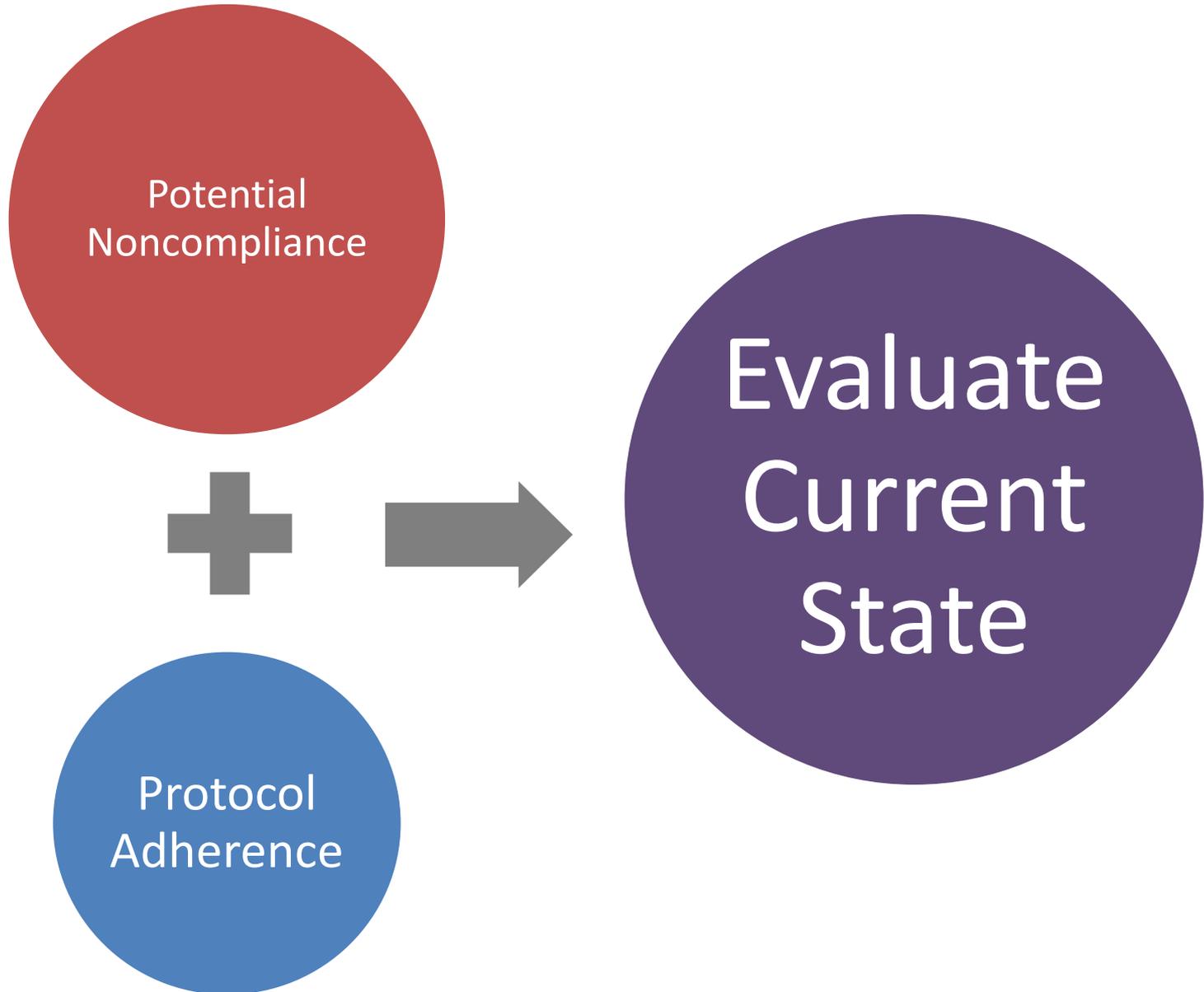


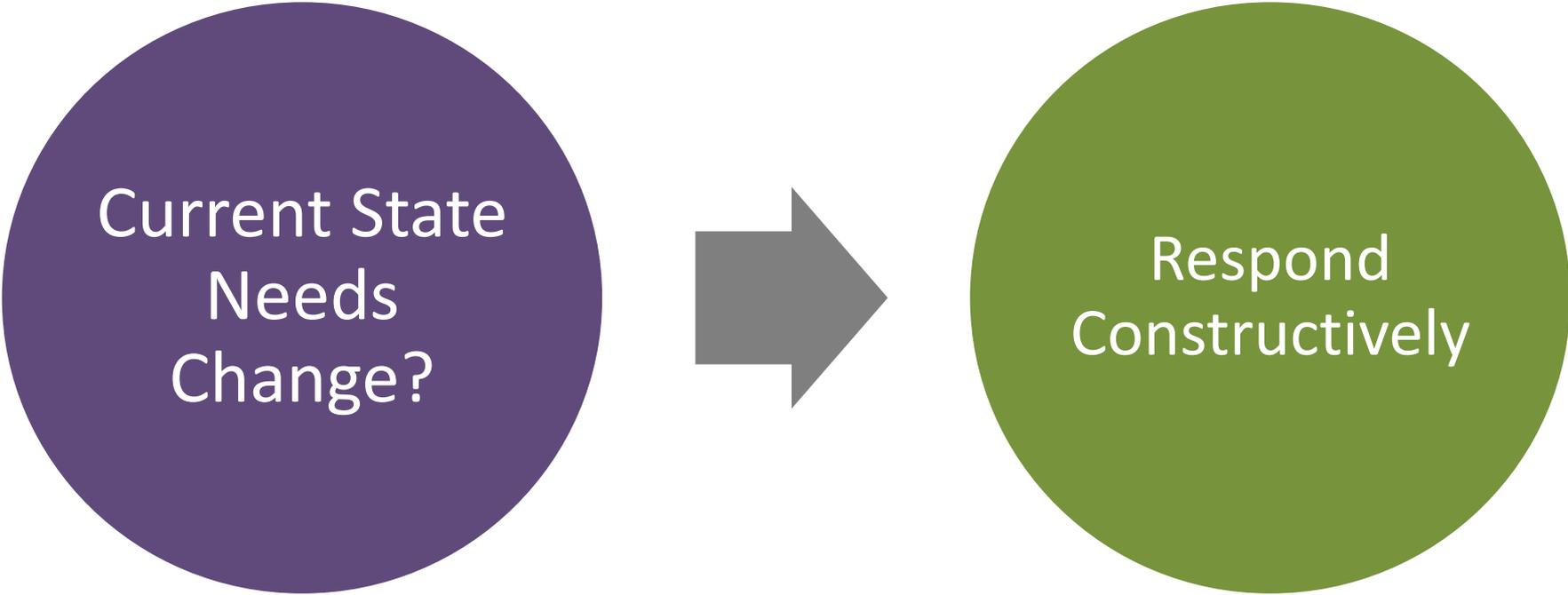
Potential  
Noncompliance:  
Surprising  
Sloppiness



## Protocol Adherence

# Sample Case 2





Current State  
Needs  
Change?

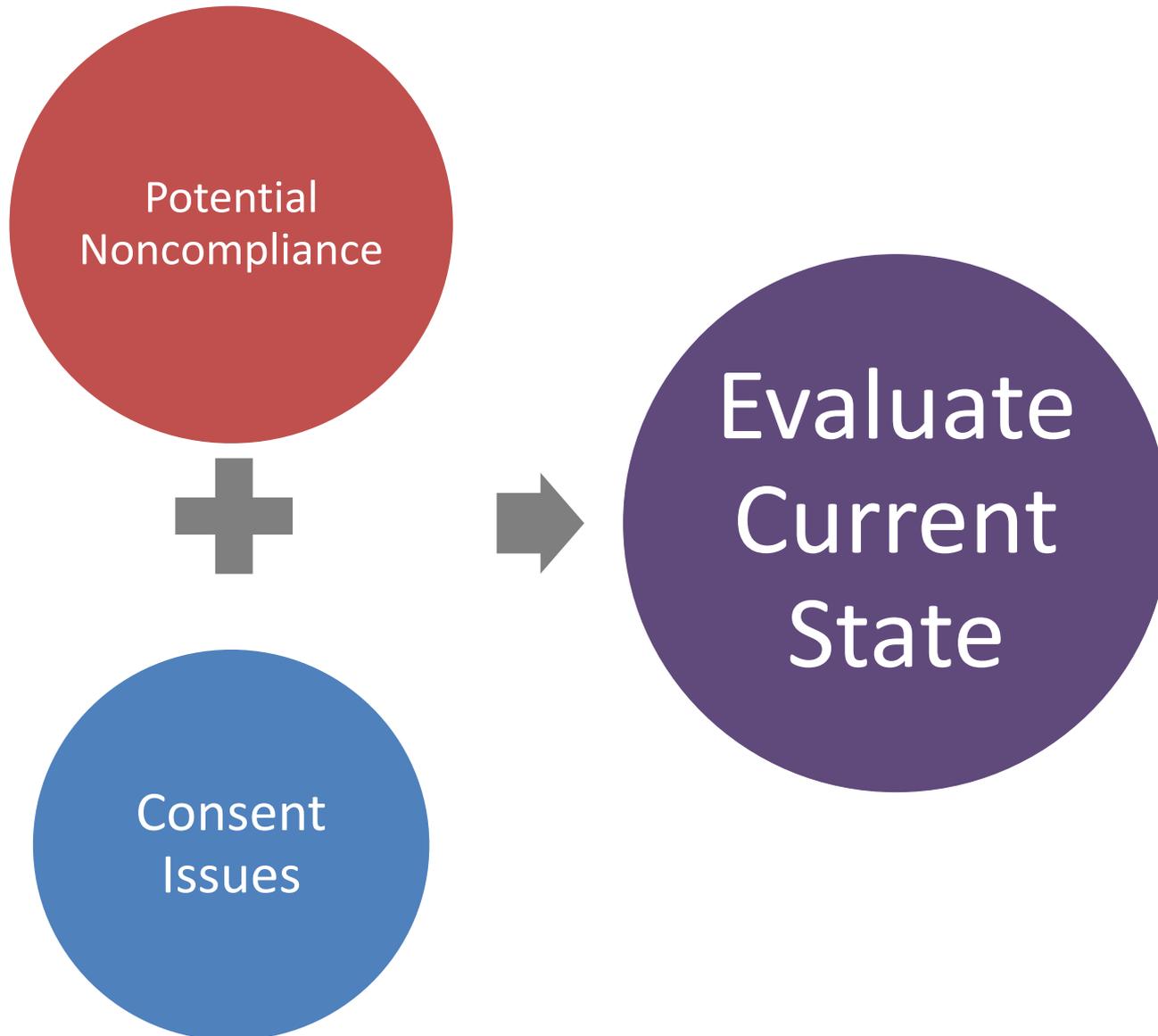
Respond  
Constructively

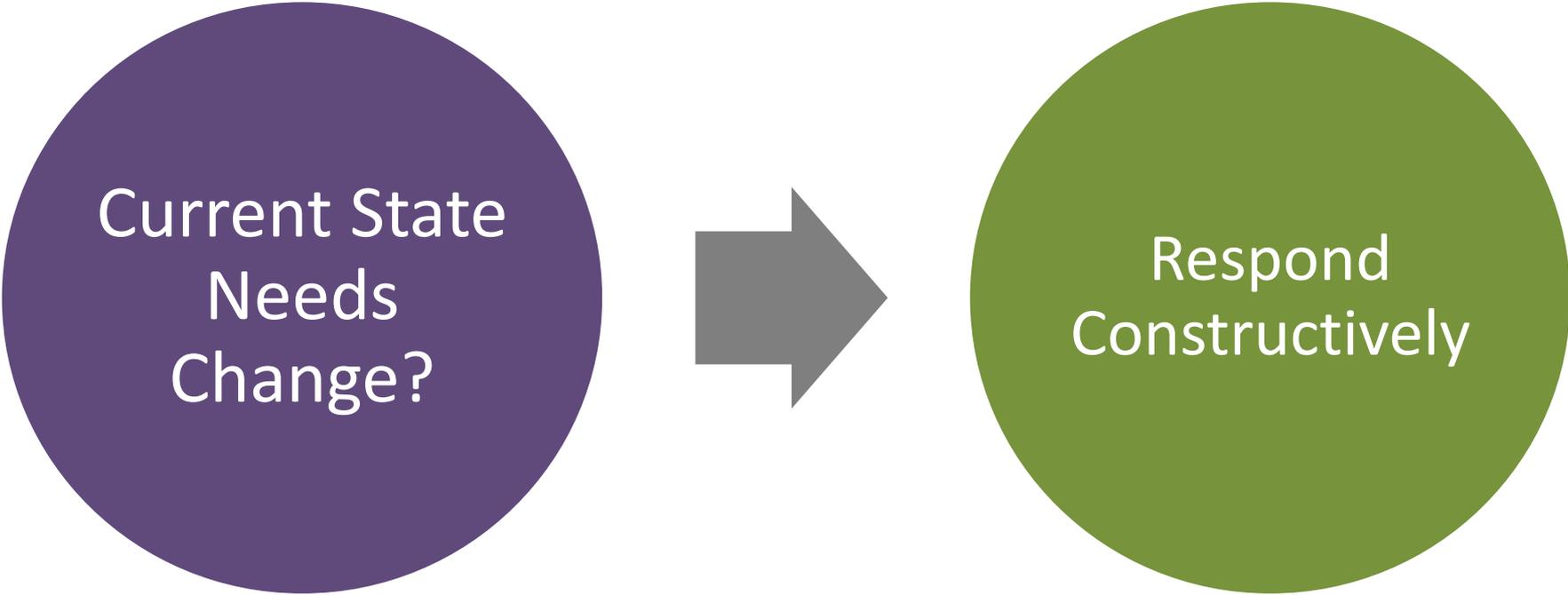
Noncompliance:  
Innocent  
Ignorance



## Consent Issues

# Sample Case 3





Current State  
Needs  
Change?

Respond  
Constructively

# YOUR TURN



**ITHS**

Institute of **Translational** Health Sciences

Accelerating Research. Improving Health.



Thank you!



## **Forecasting Regulatory Requirements**

Speaker: Karen Adams, ITHS Regulatory Specialist

Thursday, November 19, 2015, 2:30-4 pm

UW Medicine – South Lake Union