

ITHS
Institute of Translational
Health Sciences

Think Like an Auditor

Developing a Quality Assurance Process

Mandy Morneault
ITHS Regulatory Manager
vicka@uw.edu

Who are you?

ITHS
Institute of Translational
Health Sciences

Years in research?

<1-2	2-5	6-10	10+
------	-----	------	-----

ITHS
Institute of Transformational
Health Sciences

Make a Diverse Group
(n=4-5)

Session Goals

ITHS
Institute of Transformational
Health Sciences

Learn
audit
framework

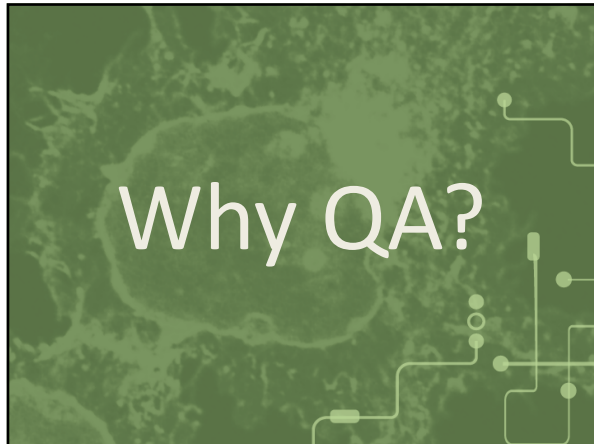
Analyze
problems

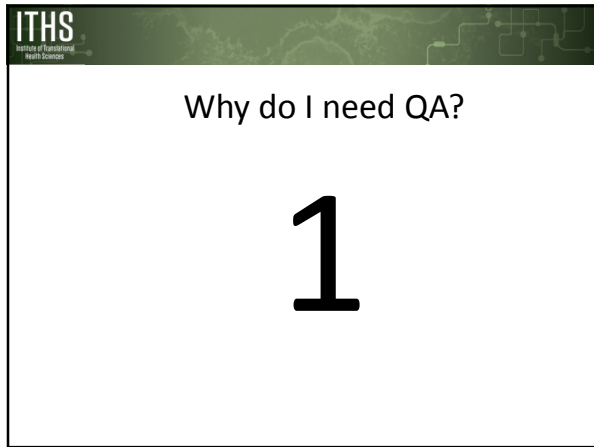
Create QA
process

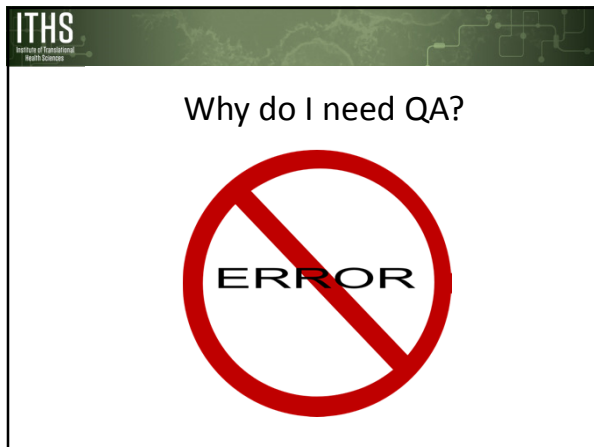












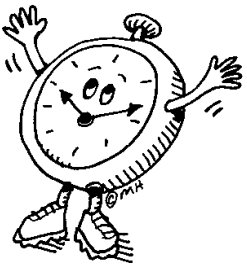
ITHS
Institute of Transformational
Health Sciences

Why do I need QA?

2

ITHS
Institute of Transformational
Health Sciences

Why do I need QA?




ITHS
Institute of Transformational
Health Sciences

Why do I need QA?

3

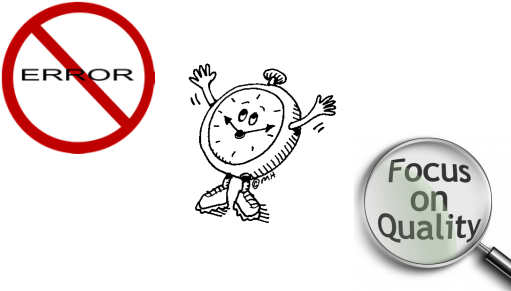
ITHS
Institute of Transformational
Health Sciences

Why do I need QA?



ITHS
Institute of Transformational
Health Sciences

Why do I need QA?



QA Triggers

ITHS
Institute of Translational
Health Sciences

QA Triggers

Policy Changes

ITHS
Institute of Translational
Health Sciences

QA Triggers

Noncompliance Events

ITHS
Institute of Translational
Health Sciences

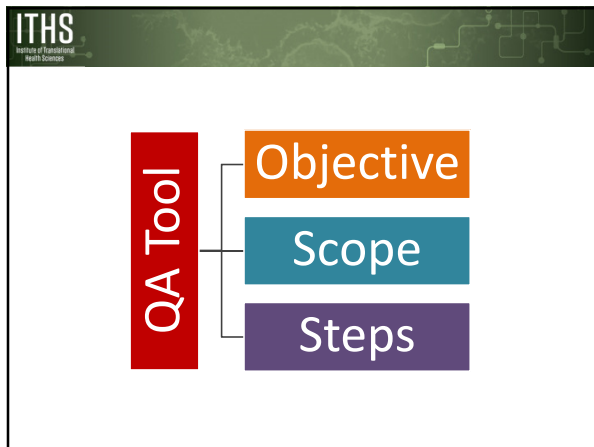
QA Triggers

Innocent Ignorance

Surprising Sloppiness

Malicious Malfeasance

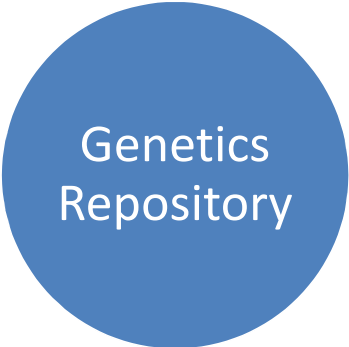






ITHS
Institute of Translational Health Sciences

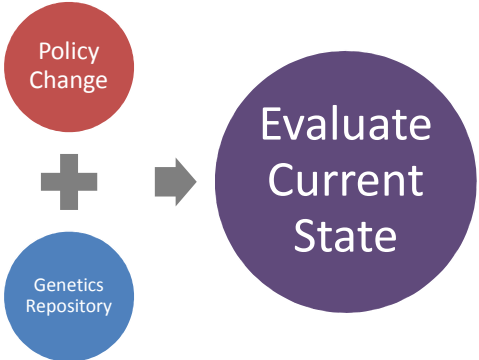
Sample Case



Genetics
Repository

ITHS
Institute of Translational Health Sciences

Sample Case



Policy
Change

+

Genetics
Repository

→

Evaluate
Current
State

YOUR TURN



ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.