Think Like an Auditor
Constructive Responses to Real Study Problems

Mandy Morneault
ITHS Manager for Regulatory Knowledge & Training
vicka@uw.edu
Session Goals
Learn audit framework

Analyze problems

Create QA process
Clinical Research Goals
Why QA?
Why do I need QA?
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QA Triggers
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Policy Changes
QA Triggers

Noncompliance Events
QA Triggers

- Innocent Ignorance
- Surprising Sloppinessness
- Malicious Malfeasance
MISTAKES are our best TEACHERS
QA Tool

Objective

Scope

Steps
Case Studies
Sample Case 1

Policy Change
Sample Case 1

Genetics Repository
Sample Case 1

Policy Change

Genetics Repository

Evaluate Current State
Sample Case 1

Current State Needs Change?

Respond Constructively
Sample Case 2

Potential Noncompliance: Surprising Sloppiness
Sample Case 2

Protocol Adherence
Sample Case 2

Current State Needs Change?

Respond Constructively
Sample Case 3

Noncompliance: Innocent Ignorance
Sample Case 3

Consent
Issues
Sample Case 3

- Potential Noncompliance
- Consent Issues

Evaluate Current State
Sample Case 3

Current State Needs Change?

Respond Constructively
YOUR TURN
Thank you!
Forecasting Regulatory Requirements

Speaker: Karen Adams, ITHS Regulatory Specialist

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

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