Session 2
Training: Lost in the Shuffle
Presenters

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The opinions expressed are those of the presenters and may not necessarily reflect Montana State University.
Our Session Goals

• Acknowledge Regulatory Training Requirements
• Offer Strategies to Manage Training Compliance: Delivery & Tracking Options
• Discuss Philosophy & FAQs
• Share Challenges
• Demo CITI
Piled Higher and Deeper by Jorge Cham

TRAINING TELEPHONE

1. This is how you do it.
2. This is how I do it.
3. This is how some people do it.
4. What are you doing?!!

Title: "Training Telephone" - originally published 1/26/2018
Interactive Survey

I WAS TOLD

I WOULD NOT HAVE TO DO THE TRAINING
Protocol Lifecycle

- Activities Requiring a Protocol
- Training
- Develop, Route, and Submit Protocol
- Manage Project
- Renew / Close Out Protocol
- Find Funding

You Are Here
Checking the Box
AND
Changing the Culture
Adding training requirements

- Is it necessary?
- Is it beneficial?
- In response to problems
- Subject to evolve
Define for your constituents:

- WHO must take training
- WHY based on proposed scope of work or research activities
- WHEN (how long does it take, due by, renewal cycle)
### Faculty or Staff Base Requirement - must choose one

<table>
<thead>
<tr>
<th>Personnel Type</th>
<th>Working with...</th>
<th>CITI Training Name</th>
<th>Protocol Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty or Staff</td>
<td>Social and behavioral research with human subjects</td>
<td>IRB Social and Behavioral Research</td>
<td>Base Requirement</td>
</tr>
<tr>
<td>Faculty or Staff</td>
<td>Biomedical research with human subjects</td>
<td>IRB Biomedical Research</td>
<td>Base Requirement</td>
</tr>
<tr>
<td>Faculty or Staff</td>
<td>Data or biospecimens acquired from human subjects. This course is appropriate for researchers who will not have direct contact with human subjects but will be working with secondary samples that are identifiable and private.</td>
<td>IRB Data or Specimens Acquired from Human Subjects</td>
<td>Base Requirement</td>
</tr>
</tbody>
</table>
https://www.montana.edu/orc/training
Clinical Trial

Is this study considered a clinical trial?

See [Clinical Trials](#) for guidance.

- **Yes**
  - Personnel must take a relevant Good Clinical Practices training course in CITI and may also need to register the trial federally or convene a DSMB depending on funding requirements.

- **No**

### ADD-ON Requirements for Faculty, Staff, or Students

<table>
<thead>
<tr>
<th>Personnel Type</th>
<th>Working with...</th>
<th>CITI Training Name</th>
<th>Protocol Requirement?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty, Staff or Student</td>
<td>Confidential information, Protected Health Information (PHI), or HIPAA associated data obtained from a covered entity</td>
<td>IRB Information Privacy Security for PHI or HIPAA</td>
<td>Required add-on if protocol involves Protected Health Information (PHI)</td>
</tr>
<tr>
<td>Faculty, Staff or Student</td>
<td>Clinical Trials</td>
<td>IRB Clinical Trials and Good Clinical Practice...</td>
<td>Required add-on if protocol meets the definition of a clinical trial</td>
</tr>
</tbody>
</table>
Committee Member Training
Institutional Training Approaches

• DIY - Using your Learning Management System (LMS)

• In-Person

• Third Party Online
DIY - Using your Institution’s LMS for Training

Creating your own trainings and host on your LMS (ex: D2L, Moodle, etc.)

**Pros**
- You create specifically for your institution
- May have central office maintaining LMS

**Cons**
- Content must be created/updated with changes
  - Who creates the content?
  - Who tracks the training?
- Enrollment of personnel to course(s)
- Central office maintaining LMS
In-person Trainings

Pros
- Build relationship with researchers
- Lab specific
- Hands-on
- Q&A session at training

Cons
- Limited availability
- Time consuming
- Schedule conflicts
Third Party Online Trainings

(ex: CITI, other federal options)

• Pros
  • Content is created
  • May be able to customize, as needed, as time permits
  • Personnel may be able to associate more than one institution

• Cons
  • Cost – is it worth the money?
  • Which trainings to choose?
Non-Affiliate Personnel Training Approaches

- For researchers outside of your institution

- But your institution is still obligated to confirm they have training

- MSU requires Single Sign On (SSO) to log in to most of our resources
Tracking the Training

• How do you track your trainings?
• Who has access?
• How do you keep files updated?
• Who adds training records to protocols?
• How are your training records connected to your protocols?
Group Guidelines

• Stories stay, lessons leave
• Make sure everyone is heard in your small group discussions
  • Limit your comments to a couple of sentences so that you don’t dominate the discussion.
  • Three and me principle where you allow three people to speak before you speak again.
• Speak with the expectation you will be heard and listen with the opportunity to be changed.
• Use “I” statements so that you are speaking from your personal experience.
• Take risks and expect discomfort: We ask that you contribute to discussions and exercises by sharing your thoughts, feelings, and experiences. Sometimes this may involve personal discomfort and risk taking. It is up to you the degree of risk or disclosure you make.
Discussion

Instructions:

- Discuss the questions with your group.
- Designate someone to report out.
1. What is your opinion of training in general?

2. How do you counter the perception that training is a waste of time?

3. What are some FAQs you receive about training? How do you handle these?
Training Challenges - Examples
Challenge 1: Taking the wrong training
Challenge 2: Emails, G-mails, and initial integration, oh my!
Challenge 3: Software

COMPLIANCE TRAINING BE LIKE
Challenge 4:

Separating Records – Students and Class projects
Challenge 5:

Provide further customization
Recap of Our Session

• Acknowledge Regulatory Training Requirements
• Offer Strategies to Manage Training Compliance: Delivery Options & Tracking Options
• Discuss Philosophy & FAQs
• Share Challenges
• Demo CITI
Wrap-Up & Questions
• **CITI** – our online training software
  • Demo mode
  • **Explore Our Courses**
  • Assigning courses/removing course from accounts
  • Course completion history
  • Customized course and/or select curriculum page
  • Support tab
  • Reports/data pulls

• **TOPAZ** – our protocol system
  • Where to find training records