
Faculty Training for Research Compliance Professionals

Angelique Dorsey, JD, CHRC
Research Compliance Director
MedStar Health

Overview

- Why train?
- Establishing effective training programs
- Curriculum development
- Increasing participation through evaluation

Why train?

Why train? Training vs. Teaching

<u>TRAINING</u>	OR	<u>TEACHING?</u>
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- | | | |
|-------------------------|--|----------------------|
| ▪ Facilitator | | Expert |
| ▪ Real-Life | | Theoretical |
| ▪ Active | | Passive |
| ▪ You do it | | Watch me |
| ▪ What would
you do? | | Here's how you do it |

Why train?

Common Reasons

- Communicate organizational goals
- Enhance performance
- Meet government expectations
 1. US Sentencing Guidelines
 2. Element of effective compliance programs

Why train?

Primary reason for training should be to effect a change in AKB . . .

- Abilities
- Knowledge
- Behavior

Why train?

A = Abilities

- Focus is on procedures
 - Concrete skills
 - how to a perform task
 - steps to take to do something

Example Title: "How to Submit a Protocol Using InfoEd"

Why train?

K = Knowledge

- Knowledge
 - critical thinking
 - decision making

Example Title: "When Quality Improvement Activities Become Research"

Why train?

B = Behavior

- Behavior
 - ethics/values
 - attitudes

Example Title: "Influence of Sponsor Consulting Arrangements on Research"

Establishing effective training programs

Establishing Training

Group exercise #1

List barriers to establishing faculty training programs

Establishing Training

Barriers

- Diffused nature of research and research compliance education
- No single office responsible for all training
- Lack of strategic analysis and planning
- No link to job performance objectives
- Time constraints of faculty
- Lack of strategic communication plan/approach

“Commentary: Compliance Education and Training: A Need for New Responses in Clinical Research” (Steinberg and Rubin, Academic Medicine, Vol. 85, No. 3, March 2010)

Establishing Training

Strategies

- Engage stakeholders and organizational leadership
- Explore consolidation of training
- Incorporate communications plan into strategic planning
- Work with HR to set training objectives
- Develop comprehensive training evaluation plan

“Commentary: Compliance Education and Training: A Need for New Responses in Clinical Research” (Steinberg and Rubin, Academic Medicine, Vol. 85, No. 3, March 2010)

Curriculum Development

Curriculum Development

Group exercise #2

Develop a list of topics/subject areas for research compliance training

Curriculum Development

Some Common Research Compliance Training Topics

- Conflicts of Interest
- Informed Consent Process
- Time and Effort Reporting
- IRB, IACUC, IBC Training
- Fiscal Compliance Training
- Responsible Conduct of Research
- HIPAA for Researchers

Curriculum Development

ADDIE Model (Hodell, C., ISD from the Ground Up, 2000)

- **Analysis**
 - formal/informal needs assessment
 - determine goals & objectives
- **Design**
 - determine the content
 - determine delivery method
- **Development**
 - create the materials
- **Implement**
 - deliver the content
- **Evaluation**
 - results based on objectives

Curriculum Development: Analysis

- Find the gaps
 - AKB = Abilities, Knowledge & Behaviors
 - Gaps = what is known (AKB) minus what is needed to be known
- Determine how training can help
- Determine training objectives
 - How will this improve performance, research quality, or regulatory compliance?

Curriculum Development: Objectives

Developing Objectives

- **Detailed**
 - state desired results in specific detail
- **Measurable (or observable) Outcomes**
 - use verbs to describe what faculty will learn
- **Activity**
 - describe an action that faculty will perform during the session
- **Realistic**
 - Outcomes are achievable within the allotted time-frame

Curriculum Development: Design

- **Some points to consider:**
 - How often should training be provided?
 - How many courses/topics?
 - Electronic vs. live delivery
 - Tele-connect to remote locations?
 - Mandatory or voluntary?
 - For whom?

Curriculum Development: Design

- **Brainstorm the topic**
- **Eliminate what isn't necessary to match your needs assessment results and objectives**
- **Consider limitations due to:**
 - facilities
 - length of training
 - delivery method
 - how quickly the training needs to happen

Curriculum Development: Design

Methods of delivering training

- | | |
|---------------------------|----------------------|
| ■ Live Instruction | ■ Web-based |
| ■ Interactive | ■ Single person |
| ■ Group | ■ Distance Education |
| ■ Lecture | ■ On-Demand |
| ■ Hands-on | |
| ■ Set times | |

Curriculum Development: Considerations for Training Faculty

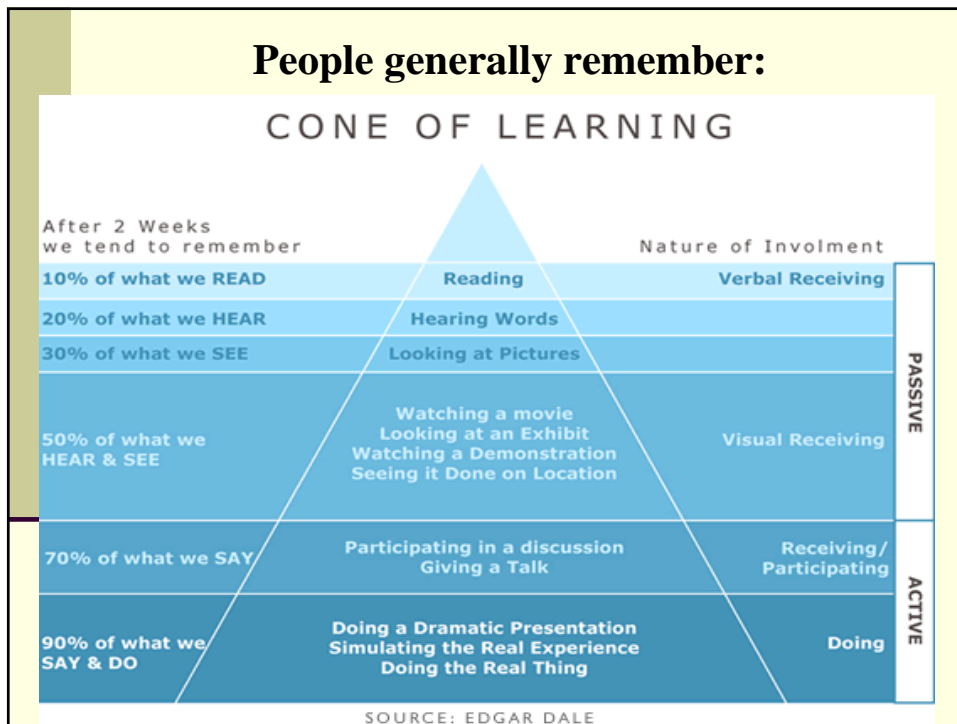
- **Know your audience**
 - Faculty are highly educated and competitive
 - Increased rules are considered barriers to patient care/saving lives/research
- **How will it effect their daily responsibilities**
 - Faculty/Physicians are in the business of improving the quality and safety of their patients/research
- **Relate training to something they know**
 - Use examples that relate to their area of interest/specialty

Curriculum Development

Group exercise #3

How would you approach training on a topic depending on which learning area (Ability, Knowledge, or Behavior) you are trying to effect?

People generally remember:



Training Resources

- ADDIE Process
<http://www.intulogy.com/addie/index.html>
- NIH Research training resources
<http://bioethics.od.nih.gov/casestudies.html#research>
- Free Management Library's articles on various training topics
http://managementhelp.org/trng_dev/trng_dev.htm

Questions?

Angelique Dorsey, JD, CHRC

angelique.p.dorsey@medstar.net

410-772-6625