

CLINICAL RESEARCH FISCAL COMPLIANCE: DEVELOPING IN-HOUSE TRAINING

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HCCA Research Compliance Conference, October 2009

OBJECTIVES

- ◎ Strategies for curriculum development
- ◎ Reaching your target audience
- ◎ Training program assessment



UK HEALTHCARE SYSTEM

- ⊙ Academic Medical Center
- ⊙ Multi-Hospital system
- ⊙ Freestanding clinics
- ⊙ Markey Cancer Center
- ⊙ Center for Clinical and Translational Sciences
 - ⊙ Clinical Research Development and Operations Center (not mandatory)
- ⊙ Decentralized clinical research environment



MEDSTAR HEALTH SYSTEM

- ⊙ Multiple Hospitals in different cities
- ⊙ 1 Academic Affiliate
- ⊙ Both human and animal research
- ⊙ MedStar Research Institute
- ⊙ Decentralized clinical research environment



DISCUSSION POINT

- ⊙ What types of institutions do you represent?



CURRICULUM DEVELOPMENT

- ⊙ Gap Analysis
 - ⊙ Identify risk areas
 - ⊙ Assign risk priority (rank highest to lowest)
 - ⊙ Address highest risk areas first
 - ⊙ Identify existing training
 - ⊙ Identify opportunity for training development



CURRICULUM DEVELOPMENT

- ⊙ Training personnel
 - ⊙ Identify subject matter experts
 - May be managers, directors, etc...who “clean up” errors
 - May be designated training staff
 - External consultants
 - ⊙ Leverage existing relationships
 - Auditors, monitors



CURRICULUM DEVELOPMENT

- ⊙ Some items 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?
 - ⊙ Remedial training



DISCUSSION POINT

- ⊙ What other types of curricular matters have you considered regarding implementing your own in-house training programs?



YOUR TARGET AUDIENCE

- ⊙ Who needs the training? Which training?
 - ⊙ Important to have support from the top!
- ⊙ Utilize grass-roots resources, informal networks
- ⊙ Identify “key” contacts for each unit
 - ⊙ “Go To” person
- ⊙ Devise registration tracking tool
- ⊙ Advertise!



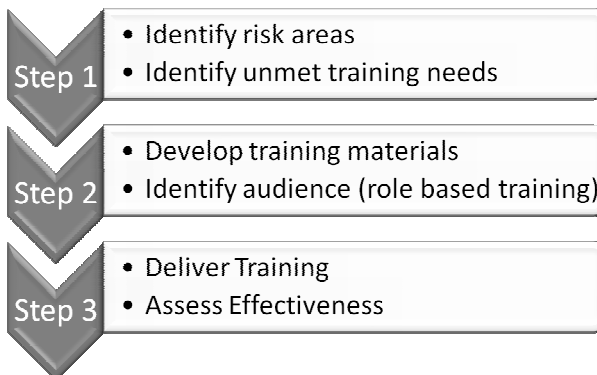
YOUR TARGET AUDIENCE

Example
Training
Requirements
Grid

	Investigator	Coordinator	Billing Staff
Medicare Coverage Analysis	X	X	X
Clinical Trial Agreements	X		
Trial Budget Preparation	X	X	X
Budget Management		X	X
HIPAA in Research	X	X	X



FISCAL COMPLIANCE EDUCATION DEVELOPMENT





FISCAL COMPLIANCE TRAINING AT UK HEALTHCARE

- ⊙ Five-part live training series
- ⊙ Investigators, coordinators, nurses, billing staff, registrars (hospital and clinical)
 - ⊙ Training is role-specific
- ⊙ Required every three years
- ⊙ Personnel identified through IRB
- ⊙ 90 days to complete training



FISCAL COMPLIANCE TRAINING AT UK HEALTHCARE

Example Fiscal
Compliance
Assessment
Questions for
Annual Reporting

- Describe how Medicare Coverage Analyses are completed for Clinical Research Trials (CRT's) that involve patient billing.
- List department personnel (name and position) responsible for monitoring CRT billing and registration.
- How many CRT personnel have completed Fiscal Compliance training? How many CRT personnel are in your department?
- How are CRT budgets developed and itemized, and how are delineations made between research and standard of care items and services.
- List the department personnel responsible for monitoring Local and National Coverage Determinations. How often do they monitor LCD's and NCD's?
- Do you use the CR-DOC for regulatory issues or manage those issues in-house?
- Describe how your department reviews and corrects CRT-related billing issues.



FISCAL COMPLIANCE TRAINING AT UK HEALTHCARE

Example Fiscal
Compliance
Training and
Indicator
Development
Approval Process



FISCAL COMPLIANCE TRAINING AT MEDSTAR HEALTH

- ⊙ Two separate trainings determined by role
- ⊙ Occurs annually
- ⊙ Personnel identified through HR



FISCAL COMPLIANCE TRAINING AT MEDSTAR HEALTH

Corporate Finance Training

- ⊙ Target: Directors and other financial managers
- ⊙ Institutional Code of Ethics for financial managers
- ⊙ Includes small group exercises
- ⊙ Outside auditors help with the training
- ⊙ Personnel identified through Corporate HR



FISCAL COMPLIANCE TRAINING AT MEDSTAR HEALTH

Research Institute Training

- ⊙ Target: Research financial oversight personnel
- ⊙ Focused on integration of technology with compliance responsibilities
- ⊙ Completely in-house
- ⊙ Personnel work for the Research Institute



TRAINING EFFECTIVENESS ASSESSMENT

- ⊙ Two-pronged approach:
 1. Is the training well-received?
 - Questionnaires, evaluations, surveys
 2. Are the participants internalizing and utilizing training materials?
 - Monitoring, auditing, testing



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