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UK HealthCare

Clinical Research Compliance:
Developing an Effective In-House Training Program

Health Care Compliance Association
Compliance Institute

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Presentation Objectives

- **Summarize the importance and need for having an accessible education and training program for members of your clinical research community**
- **Detail some of the risks of having an underdeveloped program.**
- **Describe the approach taken by UK HealthCare to design and develop a robust research compliance educational series.**
- **Present curriculum alternatives.**
- **Comment on various strategies for how to encourage participation in the program.**

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Why is Research Compliance Education Necessary?

Research and Training
Introduction

- **Priorities for researchers:**
  - Interact with Sponsors
  - Identify new funding opportunities
  - Keep clinical research coordinators supported
  - Publish
  - Make money
  - Enroll more subjects
  - Navigate hospital administrative requirements
  - Complete data reports and other paperwork
  - Attend conferences
  - Maintain clinical responsibilities
  - Teach, grade papers, advise students

Participating in training or engaging in compliance-focused education is not often a high priority for investigators or their study teams.

- **Researchers are dealing with considerable uncertainty.**
- **Many organizations have failed to make a *proportionate* investment in the compliance infrastructure necessary to keep risks in check and ease some of the pressures facing researchers in 2012.**

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Research and Training
Overview of Pressures on Investigators

Conflict of Interest scrutiny	⇧
International collaboration	⇧
Competing institutions sinking more into strategic growth of clinical research increases challenge of landing funding	⇧
Sub-recipient monitoring	⇧
Stem cells and other scientific controversy	⇧
Effort reporting, unique employment terms / appointments, consulting arrangements and other comp-related complexities	⇧
Clinical Trials billing	⇧
HIPAA issues	⇧
Compliance requirements with clinicaltrials.gov	⇧
Patent protections / Intellectual property / tech transfer	⇧
Funding levels	⇨

Training can help demystify the regulatory environment and provide valuable knowledge to simplify the mounting challenges that researcher face.

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Research and Training
Introduction

- **Priorities for compliance professionals:**
  - Preserve organizational integrity
  - Survey regulatory environment
  - Keep track of recent cases, legislation or other new laws that could impact the institution
  - Conduct investigations
  - Carry out monitoring activities
  - Develop and follow compliance work plan
  - Perform audits
  - **Design and deliver training programs**
- **Because training is sometimes low priority and often seen as a time consuming, uninspiring, punitive, "check the box" type of activity, the need to develop a program that is FRESH and USEFUL or RELEVANT to the DAY-TO-DAY ISSUES is imperative.**

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Research and Training
Introduction

The challenge for Compliance Officers is creating an educational program for the research community that is able to overcome these criticisms while staying current on regulatory issues. Moreover, they must ensure that the expectations spelled out in organizational policies are understood and that there are tools available for personnel to 'live' the policies they are subject to.

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Research and Training
Necessity is the Mother of Invention

- **Difficult situations inspire ingenious solutions**
- **Effective training programs are a must for any institution that aims to grow research and nurture organizational integrity and compliance:**
  - Required by law. Component part of those items which the US Sentencing Guidelines say will help mitigate penalties.
  - Reduce risk. Research is a business fraught with regulatory pressures, complexity, patient care issues, and patient safety challenges.
  - Builds an ethical culture.
  - Forum to communicate values, principles, and expectations.
  - Accurate and practical information is essential for research practitioners to comply with regulations.
  - Saves you money!
  - Reduce the probability of legal claims, costs of investigations, litigation, and claims resolution.

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Implications of Non-Action

Implications of Non-Action
What Happens When Training is Insufficient?

- **Most organizations that nurture research – big or small – insist that their researchers participate in the so-called "CITI training."**
  - The Collaborative Institutional Training Initiative (CITI) is often the primary educational requirement for research institutions.
    - Online
    - Simple
    - Seen as the standard
    - Non-intrusive
- **Other educational options may include:**
  - Brown bag lunches
  - Articles
  - Links on a research office web-site
  - Grand rounds speakers
  - Participation in conferences

But, without a structured, topical approach, these scattershot training alternatives may not achieve the type of regulatory, operational, and policy awareness that organizations seek.

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Implications of Non-Action
What Happens When Training is Insufficient?

- **The rules and regulations are clear only in certain areas of clinical research management / compliance.**
  - Human subjects protections
  - Conflict of interest
  - HIPAA
  - Researcher misconduct
  - FDA

Majority of research education is focused here.

- **Operational aspects of clinical research are more open to interpretation and are more of an art than a science. The standards are not established at the state or federal level. Most of know-how is in institutional policies.**
  - Study initiation
  - Budgeting
  - Contracting
  - Research patient billing
  - When, how, why, and where to interact with the Research Office
  - Use of forms, checklists, who should sign, where to send

Knowledge of how to manage these policies and procedures is more "word of mouth."

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Implications of Non-Action
What Happens When Training is Insufficient?

- **Reputational Impact**
  - No organization wants to become the "poster child" for wrongdoing.
    - Northwestern ($5.5MM), Hopkins ($2.6MM) & Harvard ($2.4MM) – effort
    - Penn – informed consent & COI
    - Mayo Clinic ($6.5 MM) & Yale ($7.6MM) – cost transfers, effort, cost sharing
    - Rush ($1MM) – clinical trial billing
    - Vermont – research misconduct
    - U. of Oklahoma – informed consent
  - These cases, and many others, have brought considerable unwanted attention to research institutions.
- **Regulatory Consequences**
  - Corporate Integrity Agreements and Certification of Compliance Agreements
  - Loss of letter of credit funding authorization
  - Suspension, debarment, and exclusion of individuals (or even entire programs or institutions) engaged in research
  - Additional monitoring

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Case Study: How Did UK HealthCare Initiate Plans to Design its Training Program?

Designing A Research Compliance Training Program
Case Study

UK HealthCare

- **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**

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Designing A Research Compliance Training Program
Curriculum Development Process

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**

A "Gap Analysis" implies you know your current state and your desired future state. Therefore, take time to define where you want to go. Understanding the "distance" between your current program and your desired program is the gap.

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Designing A Research Compliance Training Program
Curriculum Development Process

Gap Analysis

Training Need	Offered By	Delivery Method	Frequency	Required/ Optional	Who?
Human Subjects Protection	ORI CITI Dunn & Chadwick	On-line	Every 3 years	Required	All study personnel
Fiscal Compliance Training	Office of Corporate Compliance	In person	As needed	Required	All study personnel
Biosafety Training	Office of Bio Safety	On-line In person	▪ Gene Transfer: every year ▪ Other: ??	▪ Required in IBC programs ▪ ???	All IBC faculty, staff & students ▪NEED
Indemnity	???	???	???	???	NEED

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Designing A Research Compliance Training Program
Curriculum Development Process

Training Personnel

- **Identify subject matter experts**
  - Managers
  - Directors
  - Those who "clean up" errors
  - Designated training personnel
  - External consultants, lawyers, or other vendors
- **Leverage existing relationship**
  - Auditors
  - Monitors and/or quality assurance personnel
  - Legal staff from your Office of General Counsel
- **Physicians / Researchers**
  - Some investigators are more likely to hear it more clearly from a peer
  - "People support what they help create"

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Designing A Research Compliance Training Program
Curriculum Development Process

Key Questions for Your Work Group

- **How often should training be provided?**
- **How many courses or topics?** *alternatives on the subsequent two slides*
- **Electronic vs. Live delivery?**
- **Tele-connect to remote locations?**
- **Mandatory or voluntary?** *more on this later*
- **For whom?**
  - Required
  - Recommended
  - Optional
- **Remedial?**
  - Part of a corrective action
  - Resulting from a compliance investigation, a 483, or other patterns of poor behavior

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Designing A Research Compliance Training Program
Curriculum Development Process

Determine Content Needs Based on Info Gathered Through the Process

- **Conflict of Interest**
  - For Designated Officials
  - For Researchers
- **A-Z's of Research**
  - Adverse Events
  - Admission & registration
  - Applying for NIH funding at your institution
  - Budget preparation & negotiation
  - Pricing, discounts, etc.
  - CTAs
  - Clinical research patient billing
  - Clinical research financial management
  - Commercially sponsored clinical trials
  - Coordinator responsibilities
  - Working with the FDA (INDs / IDEs)
- **Environment, Health & Safety**
  - Bloodborne Pathogens (BBP)
  - Iodine Safety
  - Injury & Illness Prevention (IIP)
  - IIP lab (i.e., those who work in a lab)
  - Laser Safety Training
  - Radiation
  - Area Safety Coordinator Orientation
  - Assessing Chemical Hazards
  - Bio-safety Principles
  - Controlled Substances
  - Hazardous Waste
  - Recombinant DNA
- **Post Award**
  - Effort

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Designing A Research Compliance Training Program
Curriculum Development Process

Determine Content Needs Based on Info Gathered Through the Process

- **Human Research**
  - Basic Principles of Human Research Subjects Protection
  - Good Clinical Practices
  - Research Aspects of HIPAA
  - Working with and submitting to the IRB
  - Working with and submitting to the DSMB
- **Working with Your CTO**
  - About the CTO (services, forms, checklists, tools)
  - Grant proposal overview
  - Grant proposal budget prep
  - Grant writing 101
  - Introduction to grants.gov & clinicaltrials.gov
- **Stem Cells**
  - Intro to Stem Cell Ethics
- **Ethics**
  - Ethics in Scientific Research
  - Scientific Ethics
  - Scientific Integrity
- **Tech Transfer**
  - Patents & Patent Searching
  - Intellectual Property in research agreements
  - Legal issues in Research and Licensing agreements
  - Non-exclusive, Royalty-Free Invention Rights
- **International**
  - Export Controls
  - Working with Int'l companies

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Designing A Research Compliance Training Program
Careful Consideration of the Target Audience is a Must

- **Who needs the training? Which training?**
  - Support from the top
  - Set forth who, what, and when in policy. Formalize the expectations.
- **Utilize grass-roots resources, informal networks**
- **Identify "key" contacts for each unit**
  - Identify a "go to" person
  - Ensure that contacts are part of the curriculum development process
- **Devise a registration tracking tool**
  - Maintain records of who attends
  - Require attestation before / after training
- **Advertise!**
  - Eliminate excuses that people did not know about training
  - Provide repeats of certain key trainings at variable times of day

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Designing A Research Compliance Training Program
Example Training Grid

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

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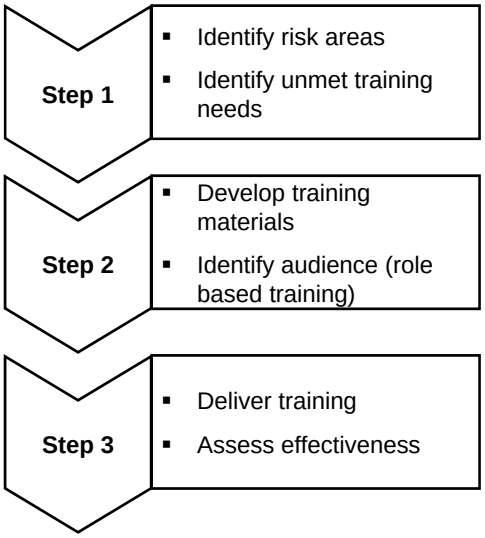
Designing A Research Compliance Training Program
Summary of Process



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Designing A Research Compliance Training Program
What was the Outcome?

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.**
  - Acknowledge that other institutions require refresher training annually
- **Other institutions require it more**
- **Personnel identified through the IRB**
- **90 days to complete training**

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Designing A Research Compliance Training Program
Once Implemented, Self Evaluate

Training Effectiveness Assessment

- **Is the training well-received?**
- **Questionnaires, evaluations, surveys**
- **Are the participants internalizing and utilizing training materials?**
- **Monitoring, auditing, testing**
- **What is a "passing score" at your institution?**

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Alternative Approaches

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Alternative Approaches
Participation is Key

- **Optimally, the research community will buy in**
  - Value is clear
  - Easy to attend
  - Multiple media and other communication channels accessible
  - Diverse curriculum
  - Timing of training events are flexible
  - Well resourced
- **Reality is that most institutions must "force" research community to attend training and educational events.**
- **Many institutions will, at a minimum, require CITI training at least every two years and annually for IRB members.**
- **But, others structure policies that insist upon more consistent attendance at training events based on one's responsibility, purview, or title.**

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Alternative Approaches
Research Credentialing

- **Based on the complexity of one's research roles and responsibility, graduated levels of training are required. For example:**
  - ***LEVEL ONE RESEARCH PRIVILEGES*:**
    - **Who?** Clinicians and staff who do retrospective chart reviews, anonymous survey research and minimal risk research not conducted on human research participants.
    - **Requirements:** CITI training
  - ***LEVEL TWO RESEARCH PRIVILEGES*:**
    - **Who?** PIs and research personnel who act in a sub-investigator capacity and who have contact with patients.
    - **Requirements:** CITI and HIPAA privacy. For those individuals who participate in FDA regulated research, these individuals will also be required to obtain training in 21 CFR 312

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Alternative Approaches
Research Credentialing (continued)

- ***LEVEL THREE RESEARCH PRIVILEGES*:**
  - **Who?** Principal Investigators on sponsored, funded or unfunded research, clinical research coordinators, research nurses, and other staff who are employed *primarily* to support research activities (i.e., research lab technicians, research pharmacists, etc.).
  - **Requirements:** Same as *Level Two* plus COI training, and basic GCP training.
- ***LEVEL FOUR RESEARCH PRIVILEGES*:**
  - **Who?** Principal Investigators who hold their own INDs and/or who act as a "sponsor" in connection with research studies. Also, all members of the IRB.
  - **Requirements:** Same as *Level Three* plus Good Manufacturing Practices ("GMP"), and other FDA related training.

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Alternative Approaches
Embedding Education into the Research Community's Responsibilities

- **Establish a CEU model.**
  - Set standards for how many CEUs (which can be earned by attending any number of training events held throughout the year) are needed depending upon who it is and their responsibilities.
  - Provide options to earn additional CEUs by creating and delivering a training course.

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Alternative Approaches
Embedding Education into the Research Community's Responsibilities

- **Some institutions have set CEU levels and expectations that are pre-requisites for Clinical Research Coordinators to move from being a CRC I to a CRC II to a CRC III.**
  - Establishes the career path
  - Formalizes a sort of curriculum necessary to 'graduate" to the next level which usually has associated benefits, comp, and other aspirational qualities.

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Alternative Approaches
Embedding Education into the Research Community's Responsibilities

- **Establish rewards, incentives and value for employees who earn research compliance-based certifications.**
  - Certified in Healthcare Research Compliance (CHRC)
  - Certified Clinical Research Professional (CCRP)
  - Clinical Research Associate
  - Other programs available through HCCA, ACRP, SoCRA, SRA, NCURA, and others.

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Questions & Additional Discussion

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