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

Health Care Compliance Association
Research Compliance Conference

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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
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
Research and Training

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

Research and Training

- 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 2013.
## Overview of Pressures on Investigators

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

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

Attitudes Toward Training

- Low priority
- Time consuming
- Uninspiring
- Punitive
- “Check the Box”
- Irrelevant
- Stale
- Not useful at all
Attitudes Toward Training

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 to which they are subject.

The Necessity of Training

- **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.
  - Reduces risk - Research is a business fraught with regulatory pressures, complexity, patient care issues, and patient safety challenges.
  - Builds an ethical culture
  - Provides forum to communicate values, principles, and expectations.
  - Accurate and practical information is essential for research practitioners to comply with regulations.
  - Saves you money!
  - Reduces the probability of legal claims, costs of investigations, litigation, and claims resolution.
Implications on Non-Action

Insufficient Training

- 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.
Insufficient Training

- 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

The majority of research education is focused on these topics.

Insufficient Training

- 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.”
Outcomes of Insufficient Training

• **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.

Outcomes of Insufficient Training

• **Regulatory Consequences**

  • Corporate Integrity Agreements and Certification of Compliance Agreements
  
  • Federal-wide Assurance
  
  • Loss of letter of credit funding authorization
  
  • Suspension, debarment, and exclusion of individuals (or even entire programs or institutions) engaged in research
  
  • Additional monitoring
Case Study: How Did UK HealthCare Initiate Plans to Design its Training Program?

Designing A Research Compliance Training Program

UK HealthCare

• Academic Medical Center
  • Six health care colleges (Medicine, Dentistry, Nursing, Pharmacy, Public Health, Health Sciences)

• Multi-Hospital system – about 1,000 beds currently
• Freestanding clinics
• Management plans of community-based hospitals and clinics
• Markey Cancer Center
• Center for Clinical and Translational Sciences
  • Clinical Research Development and Operations Center (not mandatory)
• Decentralized clinical research environment
Curriculum Development

Gap Analysis

Step One: Identify risk areas

Step Two: Assign risk priority (rank highest to lowest)

Step Three: Address highest risk areas first

Step Four: Identify existing training

Step Five: 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.
Curriculum Development

Gap Analysis

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

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"
Curriculum Development

Key Questions for Your Work Group

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

Curriculum Development

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)
Curriculum Development

- 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

Curriculum Development

- 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
Curriculum Development

- **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

Consider the Target Audience

- **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
Example Personnel Training Grid

<table>
<thead>
<tr>
<th></th>
<th>Investigator</th>
<th>Coordinator</th>
<th>Billing Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Coverage Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinical Trial Agreement</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget Preparation</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Budget Management</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIPAA in Research</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Process Summary

- **Step 1**
  - Identify risk areas
  - Identify unmet training needs (Gap)

- **Step 2**
  - Develop training materials
  - Identify audience (role-based training)

- **Step 3**
  - Deliver training
  - Assess effectiveness
Continuous Quality Improvement

Case Study Outcomes

**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
Training Effectiveness Assessment

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?

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

Optimizing the Experience

- 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.
One Approach: Research Credentialing

• Based on the complexity of one’s research roles and responsibility, graduated levels of training are required. For example:

<table>
<thead>
<tr>
<th>LEVEL ONE RESEARCH PRIVILEGES:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Who? Clinicians and staff who do retrospective chart reviews, anonymous survey research and minimal risk research not conducted on human research participants.</td>
<td></td>
</tr>
<tr>
<td>Requirements: CITI training</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL TWO RESEARCH PRIVILEGES:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Who? PIs and research personnel who act in a sub-investigator capacity and who have contact with patients.</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

Research Credentialing

<table>
<thead>
<tr>
<th>LEVEL THREE RESEARCH PRIVILEGES:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.).</td>
<td></td>
</tr>
<tr>
<td>Requirements: Same as Level Two plus COI training, and basic GCP training.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL FOUR RESEARCH PRIVILEGES:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Requirements: Same as Level Three plus Good Manufacturing Practices (“GMP”), and other FDA related training.</td>
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</tr>
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Another Approach: CEU’s

- 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 (role-based CEU earnings)
  - Provide options to earn additional CEUs by creating and delivering a training course
    - People support what they help create

Continuing Education Units

- 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
  - May require careful coordination with Human Resources
Earned Certification

- 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.

- UK example: Research Administration Training and Education program (RATE)

That’s all great, but...

- How do I make trainings valuable to faculty?
  - Involve faculty members in curriculum development.
  - Get Dean/VP level buy-in
  - Incorporate participation into annual faculty evaluations
    - Did they teach research compliance?
    - Did they do research into research compliance (review regs, explore history, etc)?
    - Did they provide service to a research compliance committee (internally or externally)?
Questions & Additions and Discussion

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