Research Compliance Structures and Quality Systems

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OBJECTIVES

- Define key elements of (research) compliance structures
- Analyze existing quality systems
- Recognize the role of the Compliance Professional

ONE POSSIBLE APPROACH
WHAT IS COMPLIANCE?

Merriam-Webster
The ability of an object to yield elastically when a force is applied – flexibility
http://www.merriam-webster.com/dictionary/compliance

COMPLIANCE STRUCTURES

Internal monitoring and auditing
Implementing compliance and practice standards
Designating a Compliance Officer to contact
Conducting appropriate training and education
Responding appropriately to detected offenses and developing corrective actions
Developing open lines of communication
Enforcing disciplinary standards through well-publicized guidelines

The 7 Elements of an effective compliance program

(MORE) COMPLIANCE STRUCTURES

STRUCTURE OF COMPLIANCE LEADERSHIP
ENGAGEMENT OF SENIOR LEADERSHIP
MISSION & VISION
CUSTOMER SERVICE
POLICIES & PROCEDURES/WRITTEN STANDARDS
RISK EVALUATION & MITIGATION
TRAINING & EDUCATION
QUALITY SYSTEM
CORRECTION & PREVENTION
EVALUATION AND FEEDBACK
ENVIRONMENT AND DEVELOPMENT ACTIONS
COMMUNICATION
WHISTLEBLOWER REPORTING
Seriously - LET'S TALK ABOUT COMPLIANCE

“You realize, we're going to have enforcement issues.”

COMPLIANCE ROADBLOCKS

- Problem detection after the fact
- Silo approach
- Unclear roles and responsibilities
- Lack of oversight (P, sponsor)
- Lack of accountability
- Inflexibility

OPTIMAL COMPLIANCE APPROACH

- Flexibility and influence
- Clear roles/responsibilities
- Increased accountability
- Collegial collaboration
- Improved communication
- Emphasis on prevention
- Standardized systems
- Proactive approach
HOW DO WE IMPLEMENT THOSE STRUCTURES?
- Identification, analysis & mitigation of research related risks
- Holistic approach and continuous improvement = long-term success
- Determination and prioritization of highest risk areas
- Customer focus and involvement of key stakeholders

HOW DO WE APPROACH IT?
- Communication
- Negotiation
- Credibility
- Humility
- Collaboration
- Triple C

COMPLIANCE CULTURE
Character is doing the right thing when nobody's looking. There are too many people who think that the only thing that's right is to get by, and the only thing that's wrong is to get caught.

J. C. Watts
Where do we stand?

All organizations have a “compliance culture”

Good Intentions

Not getting caught is not a sign of a compliant organization

Objective & Measurable

Formal, systematic and nonthreatening approach

Remediation and learning from problems

COMPLIANCE CULTURE CHALLENGES

Able to receive regulatory advice from within the organization – Quality Systems

Willing to inform management of problems and report violations to management – how do we treat whistleblowers?

Able to trust that management cares

Aware that unethical behavior is punished at all levels – consequences

WHAT ARE QUALITY SYSTEMS?

Processes and structures implemented to achieve and maintain compliance and to continuously improve the research enterprise
EXAMPLES OF QUALITY SYSTEMS

- Institutional Review Boards
- Research Compliance
- Quality Assurance
- Conflict of Interest
- Monitoring
- Teaching and Evaluation
- Policies and Standards
- Operating Procedures
- HIPAA

SO, WHO CAN DO THIS ALL?
The Compliance Professional

- Change agent
- Credible collaborator
- Active listener
- Humility builds trust
- Relationship builder
- Calm, cool, and collected
- Knows how to compromise
- Keeps calm and carries on
- Knows and adapts to their audience
- Can be silent
- Empowers others
- Helps to bring simple solutions to complex situations

WHAT ARE THE GOALS?
- Ensure continuous funding
- Reduce liability
- Ensure public trust
- Ensure quality of research output
- Demonstrate that the University takes compliance seriously
NON-COMPLIANCE IS RISKY

- Increased risk to subjects, institution, CIs, sponsors, etc.
- Fines and penalties
- Negative publicity and reputation
- Suspension of and decrease in federal awards and funding

FINAL WORDS

Education & Training
Organizational Structure
Researcher & Teams
IRB Compliance
Support of Management
Policies & Procedures
Quality Systems

At the U, we transform lives through teaching, research, and service.
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