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

OUR ANNUAL ISO 9000 AUDIT IS NEXT WEEK.

WE CAN PASS THE AUDIT IF WE PUT ALL OF OUR NON-CONFORMING DOCUMENTS IN THE TRUNKS OF OUR CARS.

DOESN'T THAT DEFEAT THE PURPOSE OF A VOLUNTARY AUDIT? AND THEN TORCH THE CARS.

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
The 7 Elements of an effective compliance program:

- 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


(MORE) COMPLIANCE STRUCTURES

- STRUCTURE OF COMPLIANCE LEADERSHIP
- INVOLVEMENT OF SENIOR LEADERSHIP
- MISSION & VISION
- CUSTOMER SERVICE
- RESPONSIBILITIES & ACCOUNTABILITIES
- POLICIES & PROCEDURES/WRITTEN STANDARDS
- RISK EVALUATION & MITIGATION
- TRAINING & EDUCATION
- QUALITY SYSTEMS
- CORRECTION & PREVENTION
- EVALUATION AND FEEDBACK
- ENFORCEMENT AND DISCIPLINARY ACTIONS
- COMMUNICATION
- HOTLINE: ANONYMOUS 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 (PI, sponsor)
- Lack of accountability
- Inflexibility
OPTIMAL COMPLIANCE APPROACH

- Standardized Systems
- Flexibility and Influence
- Proactive Approach
- Emphasis on Prevention
- Improved Communication
- Clear Roles/Responsibilities
- Increased Accountability
- Collegial Collaboration

HOW DO WE IMPLEMENT THOSE STRUCTURES?

- Identification, analysis & mitigation of research related risks
- Determination and prioritization of highest risk areas
- Holistic approach and continuous improvement = long-term success
- Customer focus and involvement of key stakeholders

Holistic approach and continuous improvement = long-term success
**HOW DO WE APPROACH IT?**

- Communication
- Negotiation
- Credibility
- Relationships
- 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?

Good Intentions

All organizations have a “compliance culture”

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 without fear of sanctions – how do we treat whistleblowers?

Able to trust that management cares

Aware that unethical behavior is punished at all levels → consequences

PI’s and Research Team Members Must Be


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
- Training and education
- Policies and Standard Operating Procedures
- HIPAA
SO, WHO CAN DO THIS ALL?
THE COMPLIANCE PROFESSIONAL

- change agent
- credible collaborator
- knows and adapts to their audience
- demonstrates values, brings simple solutions to complex situations
- empowers others
- can be silent
- calm cool and collected
- keep calm and carry on
- knows how to compromise
- relationship builder
- never gives up

HUMILITY

- builds trust
- relevant
- knows that it's not about being right

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
- Policies & Procedures
- Researcher & Teams
- IRB Compliance
- Quality Systems
- Support of Management
At the U, we transform lives through teaching, research, and service.

CONTACT INFORMATION

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