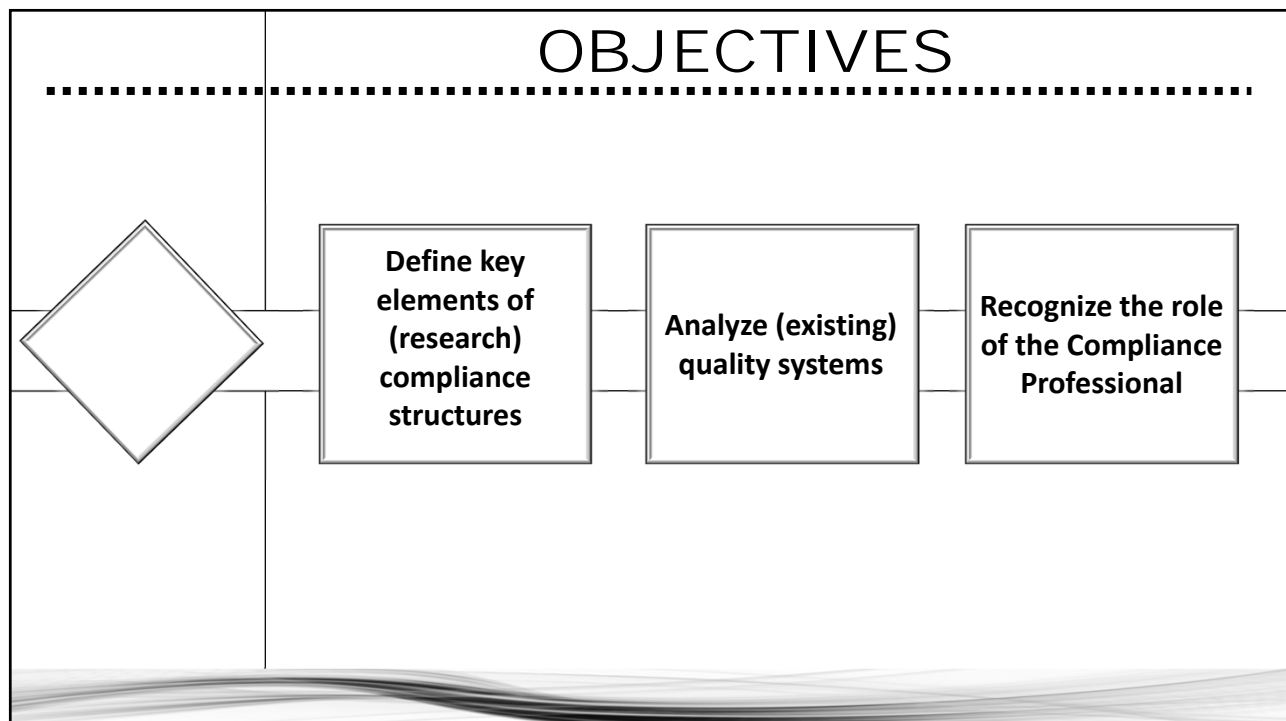
 <p>UNIVERSITY OF MIAMI</p>	<h1>Research Compliance Structures and Quality Systems</h1> <p>Johanna Stamates, Executive Director, Research Compliance and Quality Assurance</p> <p>Author: Johanna Stamates</p>
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ONE POSSIBLE APPROACH

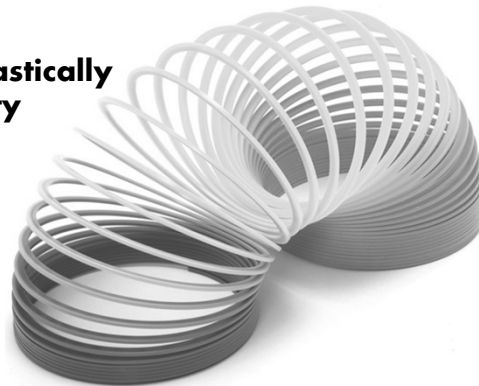


WHAT IS COMPLIANCE?

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

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

<https://www.oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf>

(MORE) COMPLIANCE STRUCTURES

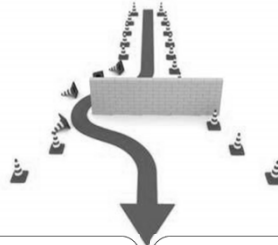
- | | |
|--|--------------------------------------|
| STRUCTURE OF COMPLIANCE LEADERSHIP | TRAINING & EDUCATION |
| INVOLVEMENT OF SENIOR LEADERSHIP | QUALITY SYSTEMS |
| MISSION & VISION | CORRECTION & PREVENTION |
| CUSTOMER SERVICE | EVALUATION AND FEEDBACK |
| RESPONSIBILITIES & ACCOUNTABILITIES | ENFORCEMENT AND DISCIPLINARY ACTIONS |
| POLICIES & PROCEDURES/ WRITTEN STANDARDS | COMMUNICATION |
| RISK EVALUATION & MITIGATION | 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

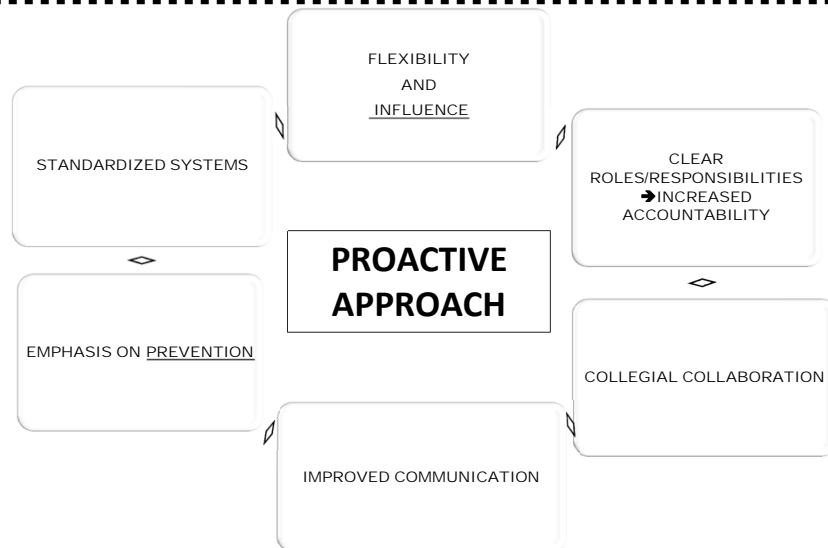
**Unclear roles and
responsibilities**

**Lack of oversight
(PI, sponsor)**

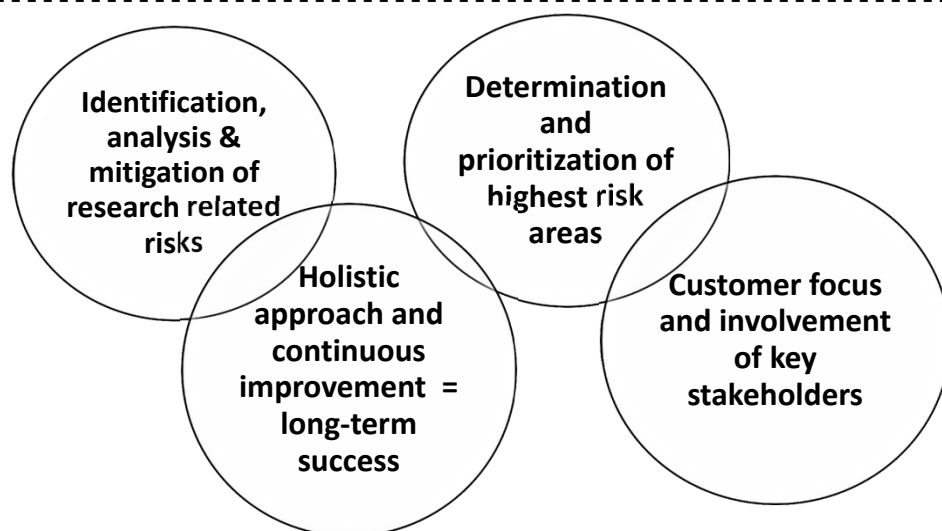
**Lack of
accountability**

Inflexibility

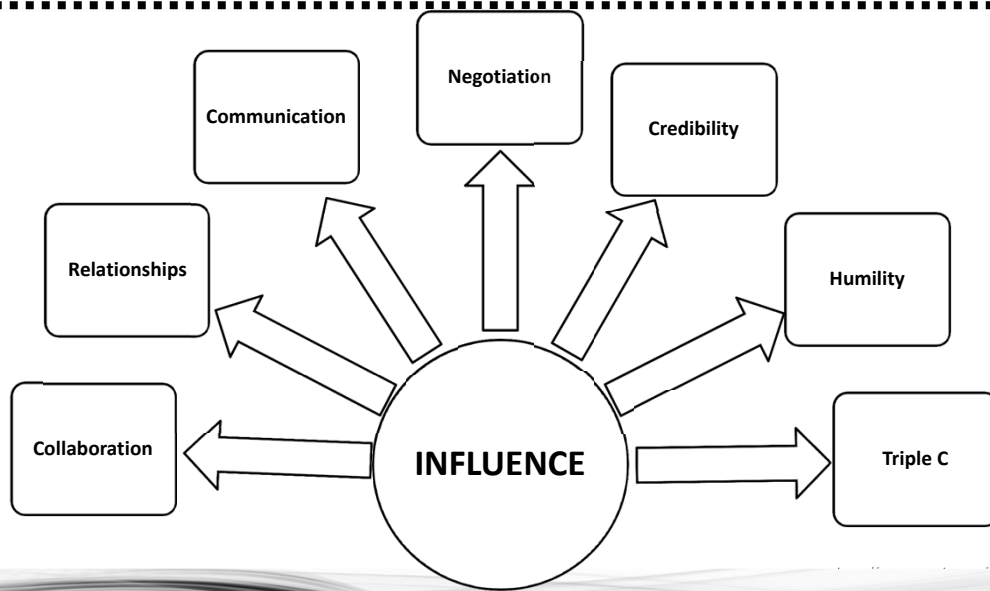
OPTIMAL COMPLIANCE APPROACH



HOW DO WE IMPLEMENT THOSE STRUCTURES?



HOW DO WE APPROACH IT?



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

COMPLIANCE CULTURE

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

PI's and Research Team Members Must Be

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

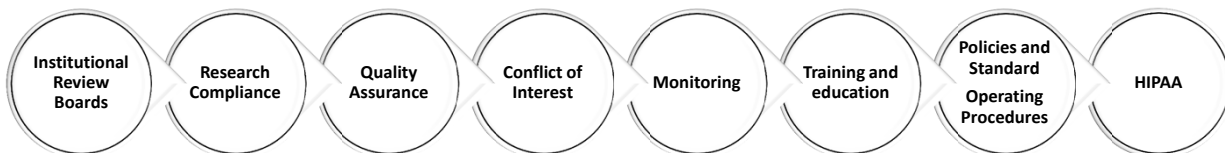
Managing Ethics and Legal Compliance: What works and what hurts, Trevino et al., 41 California Management Review, No. 2 1999. AND
The Culture of Compliance By Lori A. Richards, Director, Office of Compliance Inspections and Examinations, U.S. Securities and Exchange Commission
<http://www.sec.gov/compliance/coc/04092009.htm>

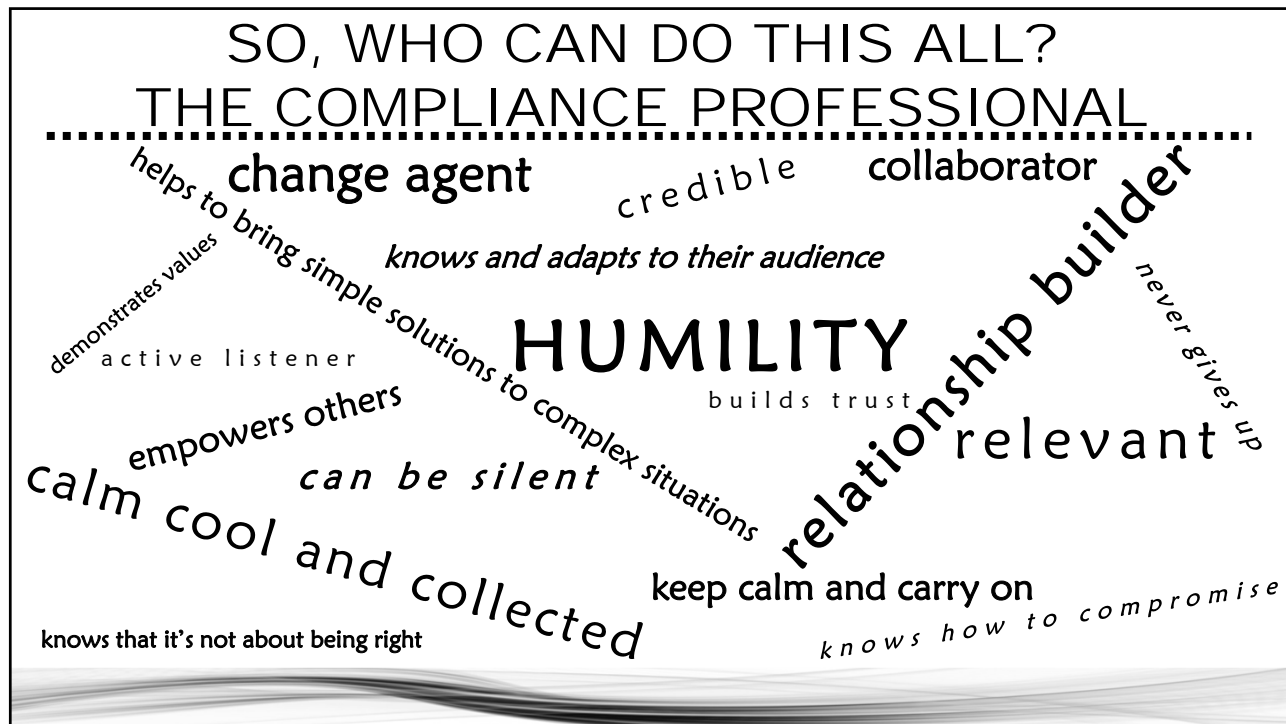
WHAT ARE QUALITY SYSTEMS?



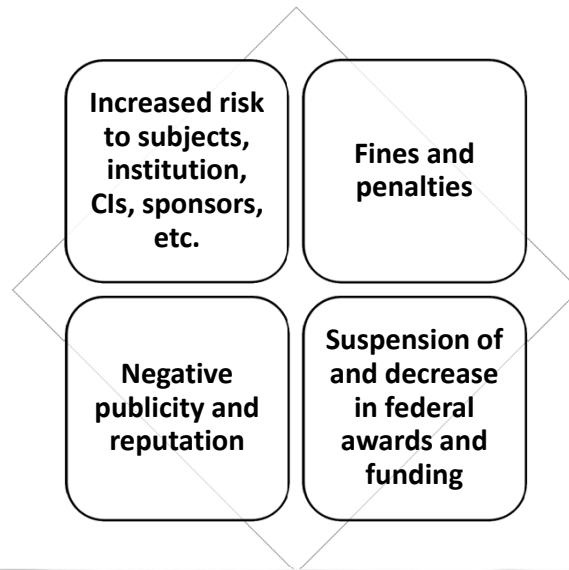
**Processes and structures implemented to
achieve and maintain compliance and to
continuously improve the research enterprise**

EXAMPLES OF QUALITY SYSTEMS

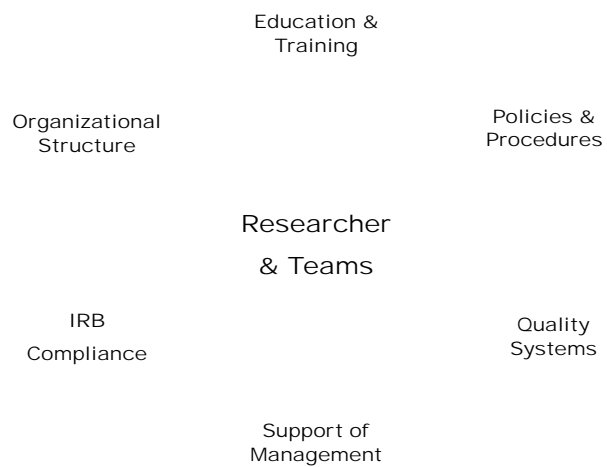


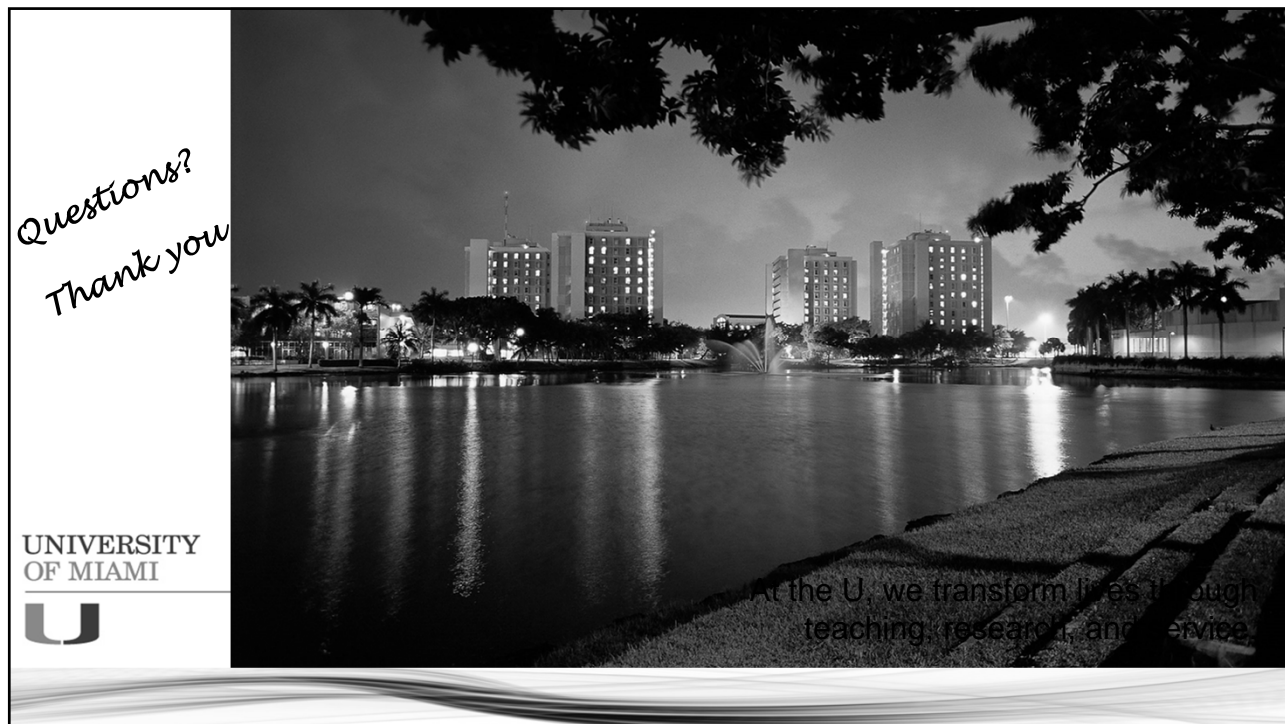


NON-COMPLIANCE IS RISKY



FINAL WORDS





CONTACT INFORMATION

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(RCQA)**

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