



SOCIETY OF
RESEARCH
ADMINISTRATORS
INTERNATIONAL

Clinical Trials: **Governance,** **Compliance, and Audit Readiness** for **Research Administrators**

CODE™ in Action: Managing Emerging Risk

1

Dr. Rashonda Harris, MBA, CRA
Research Finance & Compliance Leader
Purple Sheep Consulting

The question is whether it's governed.





Where AI Shows Up

- Recruitment
- Data analysis
- Monitoring

The CODE™ Framework



When CODE™ is strong, compliance is defensible.

AI Risk Through CODE™

AI risk emerges when:

- Competence is low
- Oversight is unclear
- Documentation is missing
- Execution is uncontrolled



RISK Breakdown

(Competence Risk)



CODE™ Breakdown

(Oversight Risk)

“Who approved its use?”



CODE™ *Breakdown*

(Documentation Risk)



CODE™ Breakdown

(Execution Risk)

HOW IS IT BEING USED IN PRACTICE?





AUDIT EXPOSURE

What Auditors Will Ask



- Validation?
- Documentation?
- Decision logic?

Governance Through CODE™

- Competence → training + understanding
- Oversight → approval structures
- Documentation → audit trails
- Execution → controlled use





Bottom Line.....

Thank you!



Dr. Rashonda Harris
LinkedIn

