

An Integrated Model for Building and Maintaining an Effective Research Compliance Program in an Academic Research Center

Mary G. Keller, Rush University Medical Center
Colleen S. Sowinski, Rush University Medical Center

Session Speakers

Mary G. Keller, BSN, RN, CCRC

Colleen S. Sowinski, MBA, MPH, CCRP, CHRC

Clinical Research Auditors

Office of Research Compliance

Office of the Vice Provost for Research

Rush University Medical Center

Chicago, IL

Rush University Medical Center



Rush University Medical Center (RUMC) has been a part of the Chicago landscape for more than 170 years.

RUMC's main campus includes:

- 679 staffed bed academic medical center serving adults and children
- Health sciences university with over 2,200 students and \$130 million in annual research revenue
- Mixed medical staff model including Rush University Medical Group with 438 employed physicians
- 653 medical residents
- Single governance structure
- 10,000 employees

3

Objectives

- Describe how Research Compliance as a Shared Governance in a small research program
- Describe the interplay of research compliance in responsible offices
- Address one challenge of shared governance and how to mitigate risk

4

Rush Research Compliance Background



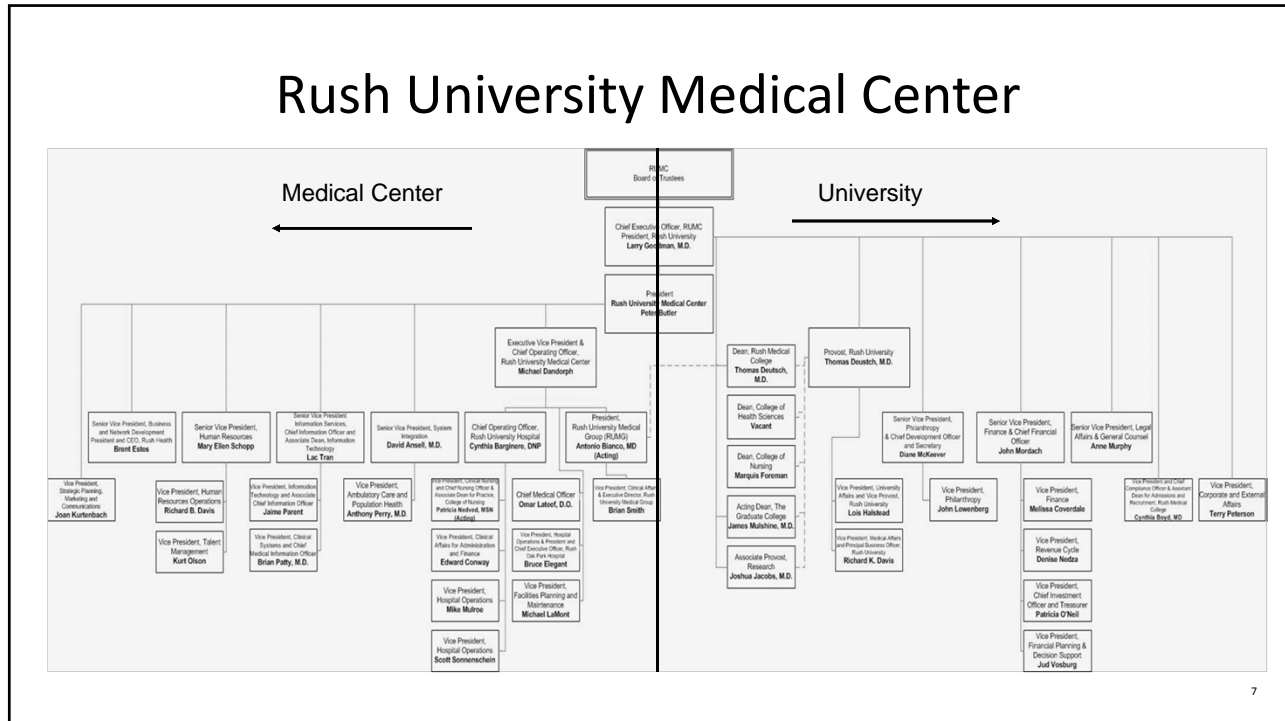
5

Research Compliance History

- Originally formed in Corporate Compliance- Research Compliance
 - 2003 - Clinical Trials Billing
- 2006 - Established the Office of Research Integrity- Research Affairs
- 2011 – Recast as Office of Research Compliance - Move back to Corporate Compliance
- 2016 - Current- Office of the Vice Provost

6

Rush University Medical Center



Application of the 7 Elements-

1. Standards and Policy/Procedures-ORC

- Education
- Reporting & Investigating Research Non-Compliance
- EQUiP: The Evaluation Quality Improvement Program
- Governmental & Sponsor Audits
- External Relationships & Conflicts of Interest
- Research Misconduct
- Authorship on Scientific and Scholarly Publications



Application of the 7 Elements-

Standards and Procedures-ORC-Continued

- Responsible for assessment of research polices – gap assessment
- AAHRPP- Human Research Protection Program (HRPP)
 - Consult and advise on IRB policies (ORC is also a component of HRPP)
- Hospital System
 - Rush University Medical Center (main campus)
 - Rush Oak Park Hospital
 - Rush Copley Medical Center
 - Rush Outpatient Chicago Loop location opening 2019

9

Application of the 7 Elements-

Standards and Procedures-Shared

Office of Research Affairs	Human Resources
Sponsored Projects Administration (SPA) Effort Reporting Grants and Contracts IRB Medicare Coverage Analysis IACUC Biohazard Dual Use Research Concern (DURC)	Code of Conduct

10

Application of the 7 Elements-

2. Oversight (Authority and Resources)-ORC

- ORC has direct reporting to Vice Provost for Research
 - Access to the Board of Governors (University)
 - Institutional Official for Research (IO)
- ORC has dotted line reporting to the Chief Compliance Officer
 - Reporting to Audit Committee of the Board of Trustees (quarterly and annually)
 - Annual Work Plan
 - Member of Corporate Compliance Committee
- ORC has dotted line reporting to Office of Legal Affairs
 - Audit Committee and research investigations (under privilege)



11

Application of the 7 Elements-

3. Education and Training-ORC

- Required:
 - CITI Program
 - Research Compliance Onboarding
 - Rush Research Portal Training
- LEAP
- Face-to-Face
- Departmental Education Sessions from Audit Findings



12

Application of the 7 Elements-

Education and Training-ORC - Continued

- ORC accepts the responsibility of developing compliance training as areas of need are identified
- Researcher training most effective with personal approach
- Use training to focus on key risk areas
- Essential to reinforce the importance of the compliance program

13

Application of the 7 Elements-

Education and Training-Shared

Research Affairs	Medical Center/University
Research Operations Technology New Coordinator Orientation Animal Care & Use Monthly Education Sessions	New Employee Orientation Annual Mandatory Training Colleges Corporate Finance Corporate Compliance Communications

14

Application of the 7 Elements-

4. Monitoring and Auditing-ORC

- Education Quality and Improvement Program – EQuIP
 - Standing work plan
 - Investigator Reviews: 5-10% of all studies with enrolled human subjects to be audited annually – *Routine Audits*
 - IRB/Ancillary Committee Review – Routine and For Cause
 - *Follow-Up Audits*
 - *Overtesting*



15

Application of the 7 Elements-

Monitoring and Auditing-ORC - Continued

- EQuIP Findings-Reports
 - Audit Committee
 - Institutional Official
 - Department Chairs
 - Research Affairs Leadership
 - IRB (when necessary)
- Identify trends

16

Application of the 7 Elements-

Monitoring and Auditing -*Shared*

Research Affairs	Corporate Compliance
IRB Sponsored Projects Administration (SPA) Clinical Research Core	Clinical Trials Billing Monitoring

17

Application of the 7 Elements-

5. Reporting Mechanisms and Investigating-ORC

- Awareness Campaign
- Research Integrity Officer (RIO)



18

Application of the 7 Elements-

Reporting Mechanisms and **Investigations-ORC - Continued**

- Investigations
 - Process for triaging investigations
 - Considerations for attorney client privilege should be given to high risk and/or sensitive matters
 - Team to conduct investigation (members as needed)
 - Investigations are confidential
 - Reporting to Leadership



19

Application of the 7 Elements-

Reporting Mechanism and Investigations-Shared

Corporate Compliance	Office of Legal Affairs	Human Resources	Office of the Provost
Audit Committee Corporate Compliance Committee Prohibition Against Retaliation Hotlines	General Counsel	Employee Orientation Exit Interviews	Investigation Outcomes

20

Application of the 7 Elements-

6. Disciplinary Guidelines-ORC

- Sanctions for non-compliant behaviors
- Sanctions for Conflict of Interest
- Sanctions for Research Misconduct



21

Application of the 7 Elements-

Disciplinary Guidelines -*Shared*

Medical Center/University	Human Resources	Office of Legal Affairs
Provost COIIR Committee IRB	Code of Conduct Employment	Sanctions for Non-compliance

22

Application of the 7 Elements-

7. Response and Prevention-ORC

- Education
- Policy & Procedure revision/refinement
- Respond promptly to detected offenses
- EQulP – CAPA – Follow-Up
- Communication



23

Application of the 7 Elements-

Response and Prevention- *Shared*

Research Affairs	Corporate Compliance
IRB/Other ancillary committees Departments/Divisions	Hotline

24



Future Path: Enterprise Risk Management

25

Enterprise Risk Management

- Internal Environment: Organizational tone and basis for how risks are viewed and assessed by the organization
- Objective Setting: Establish objectives that align & support the organization's mission and risk appetite
- Event Identification: Internal & external events affecting the organization's ability to meet objectives are identified
- Risk Assessment: Evaluation of the risks by assessing the probability and impact of the risk

26

Enterprise Risk Management-*Continued*

- Risk Response: Selected risk responses and development of corrective actions
- Control Activities: Establish and implement P&P to assist in effective execution of risk responses
- Information & Communication: Identifying, capturing & communicating relevant information in a manner & timeframe that allows personnel to carry out their responsibilities
- Monitoring: Monitor risk management processes & make modifications when needed

27



Thanks very much for your time and attention!

28