

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

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Session Speakers

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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

Objectives

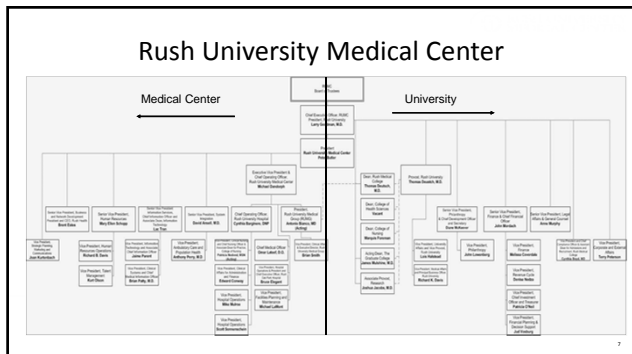
- Describe how Research Compliance as a Shared Governance in a small research program
- Describe the interplay of research compliance in responsible offices
- Address one challenge of shared governance and how to mitigate risk

Rush Research Compliance Background




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



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

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

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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)

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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

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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

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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

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Application of the 7 Elements-

4. Monitoring and Auditing-ORC

- Education Quality and Improvement Program – EQulP
 - 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*



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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

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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

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Application of the 7 Elements-

5. Reporting Mechanisms and Investigating-ORC

- Awareness Campaign
- Research Integrity Officer (RIO)



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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



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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

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Application of the 7 Elements-

6. Disciplinary Guidelines-ORC

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



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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

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Application of the 7 Elements-

7. Response and Prevention-ORC

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



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Application of the 7 Elements-

Response and Prevention- *Shared*

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

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Future Path: Enterprise Risk Management

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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

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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

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Thanks very much for your time and attention!

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