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
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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

<table>
<thead>
<tr>
<th>Office of Research Affairs</th>
<th>Human Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsored Projects Administration (SPA)</td>
<td>Code of Conduct</td>
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<tr>
<td>Effort Reporting</td>
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<td>Grants and Contracts</td>
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<td>IRB</td>
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<td>Medicare Coverage Analysis</td>
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<td>IACUC</td>
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<td>Biohazard</td>
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<td>Dual Use Research Concern (DURC)</td>
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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)

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
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

Application of the 7 Elements-

Education and Training-Shared

<table>
<thead>
<tr>
<th>Research Affairs</th>
<th>Medical Center/University</th>
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</thead>
<tbody>
<tr>
<td>Research Operations Technology</td>
<td>New Employee Orientation</td>
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<tr>
<td>New Coordinator Orientation</td>
<td>Annual Mandatory Training</td>
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<tr>
<td>Animal Care &amp; Use</td>
<td>Colleges</td>
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<td>Monthly Education Sessions</td>
<td>Corporate Finance</td>
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<td>Corporate Compliance</td>
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<td>Communications</td>
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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

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
Application of the 7 Elements-

Monitoring and Auditing - *Shared*

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<tr>
<td>IRB</td>
<td>Clinical Trials Billing Monitoring</td>
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<td>Sponsored Projects</td>
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<tr>
<td>Administration (SPA)</td>
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<tr>
<td>Clinical Research Core</td>
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5. **Reporting Mechanisms** and Investigating - *ORC*

- Awareness Campaign
- Research Integrity Officer (RIO)
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

Application of the 7 Elements -

Reporting Mechanism and Investigations - Shared

<table>
<thead>
<tr>
<th>Corporate Compliance</th>
<th>Office of Legal Affairs</th>
<th>Human Resources</th>
<th>Office of the Provost</th>
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<tbody>
<tr>
<td>Audit Committee</td>
<td>General Counsel</td>
<td>Employee Orientation Exit Interviews</td>
<td>Investigation Outcomes</td>
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<tr>
<td>Corporate Compliance Committee</td>
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<td>Prohibition Against Retaliation Hotlines</td>
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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

<table>
<thead>
<tr>
<th>Medical Center/University</th>
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<tbody>
<tr>
<td>Provost</td>
<td>Code of Conduct Employment</td>
<td>Sanctions for Non-compliance</td>
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<tr>
<td>COIIIR Committee</td>
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<tr>
<td>IRB</td>
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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

Application of the 7 Elements -

Response and Prevention - Shared

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<tr>
<td>IRB/Other ancillary committees Departments/Divisions</td>
<td>Hotline</td>
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Future Path: Enterprise Risk Management

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
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

Thanks very much for your time and attention!