Enterprise Solutions:
Effective Corrective Action and Prevention Plans (CAPA) Following Internal Audits of Clinical Research Trials

UT Southwestern Medical Center
Office of Compliance

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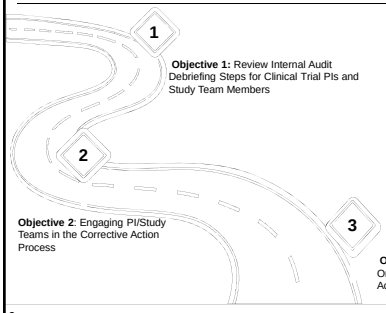
Session Objectives



Objective 1: Review Internal Audit Debriefing Steps for Clinical Trial PIs and Study Team Members

Objective 2: Engaging PI/Study Teams in the Corrective Action Process

Objective 3: Strategies for Evaluating the Organizational Effectiveness of Corrective Action Planning

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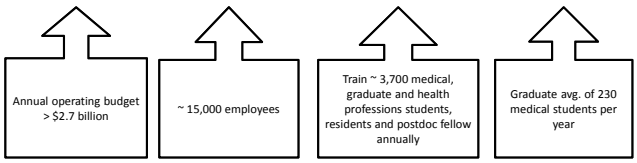
MEDICAL CENTER MEDICAL



PROFILE PROFILE PROFILE

Research Footprint

Federal, foundation, individual, and corporate sponsorship → ~ $422.6 million per year in funding → ~5700 research projects

Home to many nationally and internationally recognized physicians and scientists.

- 6 Nobel Laureates
- 23 National Academy of Sciences members
- 19 National Academy of Medicine members

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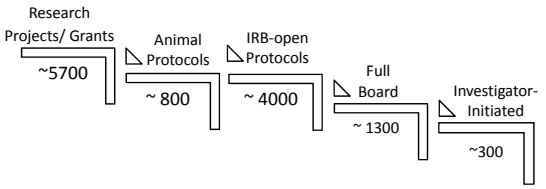
Research Footprint



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Polling Question: What is your role in your Research Compliance Program?

A. Compliance Officer

B. Legal Counsel

C. Compliance Administrator/Specialist

D. Billing Compliance

E. Other

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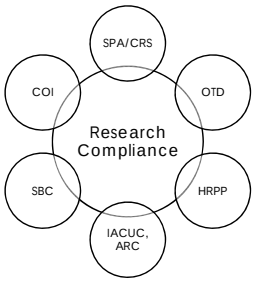
Research Compliance Offices



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Research Systems & Tools

- Velos
- eIRB
- eCOI
- e-Grants

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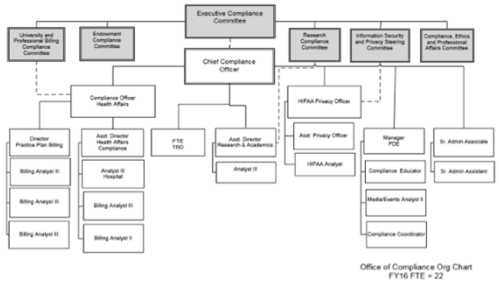
Office of Compliance Reporting Structure



Office of Compliance Org Chart
FY16 FTE = 22

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Human Subject Research Oversight

ECC

RCC | UPBCC

SBC (Radiation Safety) | IRB X 4 (HRPP) | Tech Dev Committee | COI

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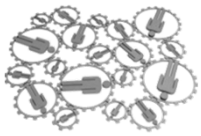
Polling Question: How is Your Research Compliance Program Structured?

Where does your program currently reside:

A. Office of Compliance
B. Internal Audit
C. Research Administration
D. The Medical School
E. Other



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Research Compliance Activities

Office of Compliance

- **Quarterly QA review of full board, approved, IIS**
- Conflicts of Interest
- Fiscal Management – Cost transfer, effort reporting transition
- **Quarterly clinical research billing compliance review**
- Export Control Analyses & Screenings

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Research Compliance Activities – Monitoring

Research Operations

Sponsored Program Administrations	Clinical Research Services	Research Administration
• UG thought leader • Monthly financial review/reconciliation • Pre-closeout readiness reviews	• VELOS trial and subject enrollment validations • Coverage analysis	• COI disclosures, management plans • CMS open payments

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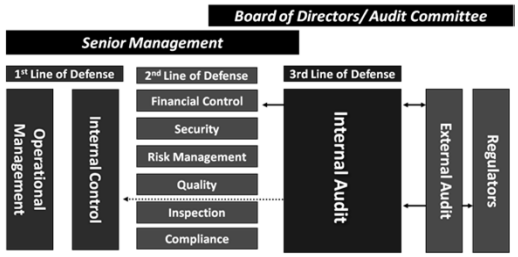
Three Lines of Defense



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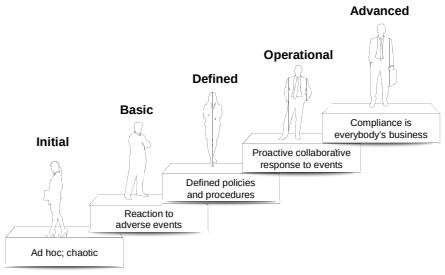
Optimizing Resources: Program Maturity



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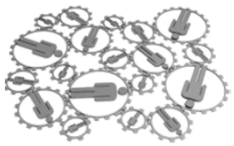
Polling Question: How Mature is Your Research Compliance Program?

A. <5 years

B. 5-10 years

C. 10+ years

D. Don't know



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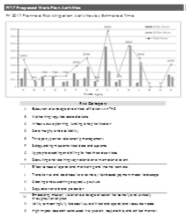
Annual Risk Assessments



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Compliance: Auditing and Monitoring

Element of an effective compliance program is to conduct periodic auditing and monitoring of the organization's adherence with regulatory guidance and established written standards.

Audit and Review Types:

Baseline/Probe	• High level review to determine whether a compliance issue exists
Routine	• Evaluate ongoing compliance adherence
Follow-up	• Enlarge sample based on error rates identified during a routine audit
Requested	• Requested review by Leadership and/or Clinical Department
Focused	• For cause review

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AUDIT PROCESS

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Auditing and Monitoring: Compliance Risk Areas

Risk Level	Examples of Study Types
High (Full Board)	IND/IDE, Phase 1, UTSW Lead Coordinating Site, Investigator-Initiated
Moderate (Full Board)	Phase 2, Phase 3, Pediatrics
Low (Expedited, Exempt, or Registration)	Prospective or retrospective data and/or specimen collection, including interventional and/or treatment studies, repository or registry studies
Lowest (Studies Already Monitored)	High, moderate, or low risk studies monitored by external sponsors/CROs or internal groups, e.g. SCCC CRO or Office of Research Protections

*Categories
1. Eligibility
2. Informed Consent Process and Documentation
3. Essential Documentation filed in Regulatory Binder
4. Investigational Product - Management & Accountability
5. CRF and Source Verification
6. Protocol Compliance
7. Safety Monitoring - Adverse Events & Data
8. Privacy and Deidentification of Data
9. Appropriate Record Storage and Retention
10. Recruitment Strategies
11. Study Population
12. Sponsor Monitoring

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Monitoring: Exceptions and Ratings

Major Exception - Generally 1) significantly compromises the integrity of the study or the safety of the subject, 2) violates or significantly deviates from Federal or UTSW requirements or policies or 3) represents cumulative minor deficiencies of the same nature.

Minor Exception - Occurs when the protocol is not followed exactly, but the data remain usable and valid or is a less serious deviation from Federal regulations or UTSW policies.

Exceeds Expectation	• **<5 minor deficiencies noted**
Meets Expectation	• **<5 major deficiencies noted**
Does Not Meet Expectation	**If any of the following is noted:** • **5 or more major deficiencies noted per subject chart reviewed** • **Single life-threatening major deficiency** • **Concern for misconduct or fraud**

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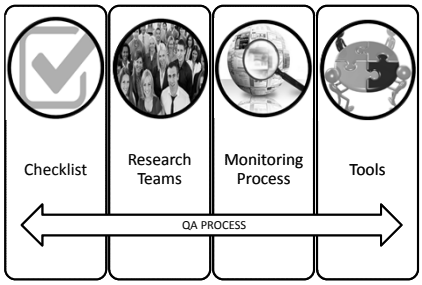
QA Process



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Auditing and Monitoring: Checklist, Resources, and Dashboards



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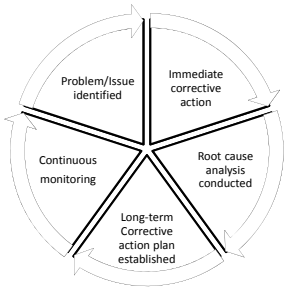
Corrective Action Plan Assessment Flow



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CAPA Planning

- Debrief
- Study Team
- Operational Stakeholders
  - HRPP
  - CRS
  - Other Departments

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Reporting Serious/Continuing Non-Compliance

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Elements Of CAPA Plan

1. Specific areas requiring compliance attention;
2. Additional training requirements;
3. Ceasing problematic process;
4. Change in procedures;
5. Repaying overpayments;
6. Reporting to the appropriate governmental authorities;
7. Further review and/or investigation;
8. Determining whether the problem is systematic;
9. Disciplinary action; and
10. Notice to journals, publishers, or other media services concerning issues of research integrity.

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Recurring Exceptions

- Informed Consent Template & Process
- Data Mgmt – Sharing & Disclosures
- Claim Direction – RSH vs SOC
- Coverage Analysis & Protocol
- Clinical Research Documentation
  - Source Docs
  - Epic
- Study Set Up – Double Blinded Protocols

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Organizational Engagement: Advocating Change

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Rules of Engagement: Executive Trust

- Finding ways to connect with President, EVP, VPRA
  - –Tone at the Top: Culture of Compliance
  - –Executive Leadership Team- Dedicated Quarterly Meetings for Compliance
  - –Meaningful Data: Compliance Dashboards, Real-time Auditing and Monitoring
  - –Study Team and Principal Investigator Rounding and Town Hall Meetings
- Compliance - Valued Addition to Operations
  - Research Administration and Services
  - Sponsored Program Administration
  - Health System Affairs- University Hospital and Ambulatory Services

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Compliance: The Change Agent

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Understanding the Marriage: Operations vs. Compliance

Risk Mitigation

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Compliance Program: Mission, Vision and Value

Each day our patients, students, and the public count on us to deliver the very best in patient care, state-of-the-art research, and outstanding medical education. As a University, we strive to meet and exceed these goals. By fostering a culture of compliance with established policies and standards, we reassure the community of our commitment to adhering to all applicable laws, rules, and policies.

Daniel K. Podolsky, M.D.
President, UT Southwestern Medical Center

Source: UT Southwestern Medical Center, Standards of Conduct (2013)

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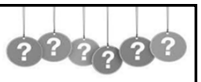

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