OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Research Compliance Services

Research Compliance Committee Quarterly Meeting

September 26, 2025 – Meeting Summary

Participation: The meeting saw strong engagement with 30 RCC Members and 94 members from the broader research community in attendance, representing at least 42 unique units across the institution.

The Research Compliance Committee (RCC) has undergone a significant transformation with a streamlined structure designed to enhance research compliance across our institution. This quarterly meeting highlighted critical regulatory updates, new training requirements, and strategic initiatives that will shape our research landscape in the coming year. The committee's refreshed approach emphasizes collaboration, efficiency, and proactive compliance management.

Streamlined RCC Structure

Four interconnected components: Steering Group, Membership Body, Link subcommittees, and broader research community

Critical Compliance Changes

New annual COI disclosure, DOJ Bulk Data Rule, NIH biospecimen restrictions, and mandatory security training

Enhanced Resources

Updated website, Member SharePoint Site, and Annual Compliance Summit for ongoing support

Key Regulatory Updates & Compliance Changes

Several significant regulatory changes are taking effect that require immediate attention from the research community. The transition to annual Conflict of Interest disclosures represents a major shift from project-specific submissions, promising to reduce administrative burden while maintaining rigorous oversight. The new DOJ Bulk Data Rule introduces critical restrictions on data sharing with countries of concern, particularly affecting human genomic research and sensitive personal data.

1 Annual COI Disclosure Launch

Beginning early 2026, replacing multiple project-specific submissions. Expected to significantly reduce disclosure volume and streamline management plans. More details: **FAQ on Annual Disclosure Process**

2 DOJ Bulk Data Rule Implementation

Restricts sharing of sensitive data including human genomic data, biometric identifiers, and personal health information with designated **countries of concern**. Full rule: **Federal Register Notice**

3 NIH Biospecimen Policy

New **NIH policy** effective September 24, 2025, prohibits NIH-funded human biospecimens from being shared with restricted countries.

4 Research Security Training

Required under the **CHIPS and Science Act**. Mandatory annual 20-minute training module for all federally funded researchers, tracked through Carolina Talent system.

5 Clinical Research Policies & ICH GCP E6(R3) Updates

New policies are in effect for cGMP oversight, delegation of clinical tasks, and investigator management of investigational drugs. These aim to enhance regulatory compliance and operational efficiency.

The FDA adopted the **ICH Good Clinical Practice (GCP) E6 (R3)** guidelines in September. Researchers are encouraged to review them; however, re-training is only required when existing GCP training is due. NIH-funded investigators and clinical trial staff must complete GCP training every three years. For more details: **UNC Approach to ICH E6(R3) Good Clinical Practice Training**

6 Drone Compliance

The American Security Drone Act, effective December 2025, prohibits the use, delivery, and procurement of drones from specified restricted companies and countries. A comprehensive list of these restricted entities will be published on **sam.gov** Consequently, drones containing components from these manufacturers will be deemed ineligible for federally contracted research. For specific guidance pertinent to campus operations, researchers should consult **UNC-Chapel Hill's Unmanned Aircraft Systems Policy**.

RCC Subcommittee Initiatives

The RCC's four Link subcommittees are driving innovative projects to enhance research compliance and reduce administrative burden. These collaborative efforts focus on policy awareness, communication efficiency, process improvement, and risk management. Each Link is developing practical tools and frameworks that will benefit researchers across all disciplines and career stages.

Policy Link

Developing a research policy awareness campaign and designing frameworks for researcher listening sessions to capture valuable feedback for strategic improvements.

Learning Link

Building a centralized Research Communication Directory to map institutional channels, reduce duplication, and strengthen collaboration across units.

Process Improvement Link

Designing a process improvement roadmap to identify challenges, prioritize solutions, and create sustainable improvements that promotes compliance and reduces administrative burden.

Risk Management Link

Developing a two-part initiative to improve UNC-Chapel Hill's ability to manage international research risks by mapping responsibilities and providing researchers with a quick-reference tool.

Action Items & Next Steps

1 Access RCC Resources

Utilize the updated **RCC website** and **Member SharePoint Site** for the latest compliance updates, resources, and collaboration opportunities.

2 Complete Required Training

Take the new **research security module** in Carolina Talent and stay current with GCP training requirements for clinical research staff.

3 Prepare for Changes

Watch for announcements about the COI Program update and participate in upcoming webinars to understand new annual disclosure processes.

4 Engage & Share

Join Link subcommittee initiatives, bring RCC information back to your unit, and share questions or ideas at **RCS@unc.edu**.

Next RCC Quarterly Meeting: January 30, 2026. Mark your calendars and continue monitoring the RCC website for ongoing updates and resources.