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A Roadmap of Faculty External Affiliations: Investigating Disclosures and Understanding Impact

Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, ECoP (EAR), DACAW
Associate Vice President, Research Support & Regulatory Management

Meredith Brown Noto, MBA, MA, CHRC, EXCS
Associate Director, Conflict of Interest and Export Control

Vince Snoddy, MBA
Regulatory Monitoring Analyst, Conflict of Interest

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Disclaimers

- The presenters have no outside interests that are relevant to this talk.



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Session Objectives

- Describe faculty relationships and affiliations with external entities
- Identify scope of relationships and implement appropriate oversight
- Develop open communication and reporting among UTSW disclosers and departments



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Background: Risks of External Affiliations

- Institutional risks
 - Conflicts of Commitment
 - Conflicts of Interest
 - Export Control
 - Research Security
- Research funding and award risks
- Legal risk
 - False Claims Act
 - Stark Law/Anti-kickback
 - Other violations



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Increasing Attention to External Affiliations

- Concerns that international collaborations and international funding sources could result in resource overlap, conflict of commitment, or inappropriate use of resources
 - Federal funding requires recipient institutions to disclose all financial resources available to researchers (“Other Support”)
 - Federal funding agencies perform analyses at both pre-and post-award phases to determine other sources of funding
 - NIH also reviews for any component of the research to be performed outside of the U.S.
 - New legislation prohibits certain external affiliations such as participation in malign foreign talent programs

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Institutional Perspective

- Key stakeholders include:
 - Faculty with outside activities and external affiliations (or considering them)
 - Administration and research support staff
 - Federal agencies
 - University of Texas System



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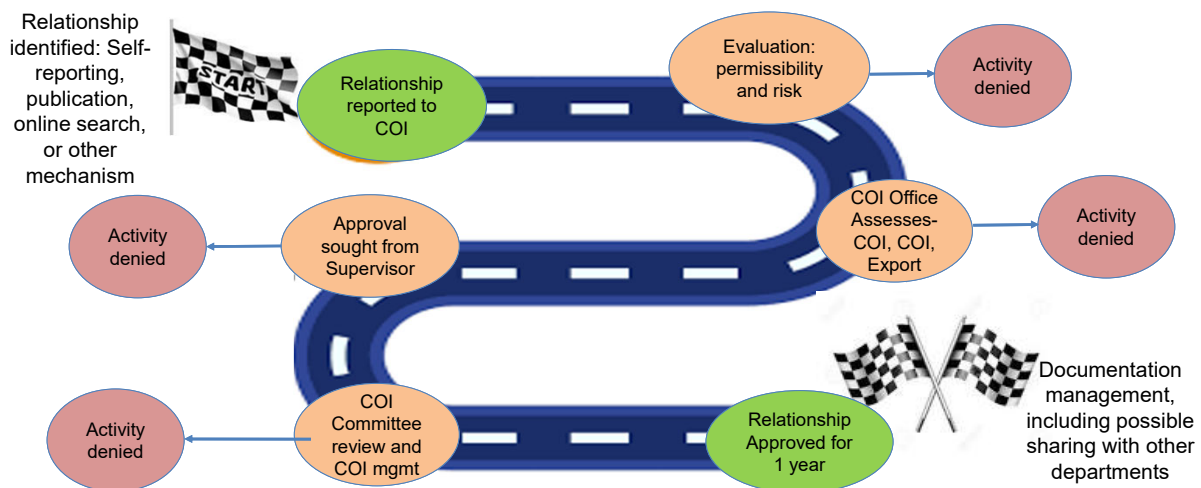
Key Definitions

- External
 - These are outside of the home institution, assumes one's "primary loyalty" is to the primary employer
- Relationship
 - Connection between an individual and another individual or entity in which a service or expectation is created, managed, and exists in addition to the individual's primary employment
- Affiliation
 - Connection between an individual and another individual or entity in that is less formal than a relationship, exists in addition to the individual's primary employment, and in which there is a reputational link between the individual and the entity
- Outside Activity
 - Compensated or uncompensated activity that does not necessarily constitute employment or affiliation, such as consulting

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Roadmap Example: Outside Activity



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Understanding the Relationship Ahead

- Ensure flexibility on forms to ask new questions in emerging areas
- Collect and manage supplemental documentation, like agreements with outside entities
- Processes for accommodating requests and documenting decisions
- Consider both the benefits and risks to external affiliations under review
 - Escalate risks posed by specific external affiliations
- Coordinate reporting requirements with other departments as needed
- Do not be afraid to ask more questions!

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Outside Activity	Risks	Key Information to Evaluate Risk
Consulting	<ul style="list-style-type: none"> • Various types of consulting; term may colloquially be used inappropriately • May conflict with institutional responsibilities or research 	<ul style="list-style-type: none"> • Do supporting documents including scope of services align with other information collected? • Is compensation and time commitment appropriate and consistent with standard practices?
Founder of a “Start-up” using Institutional IP	<ul style="list-style-type: none"> • Commitment to institutional responsibilities • Use of institutional equipment, supplies, talent • Opportunity to conflict with research or institutional responsibilities 	<ul style="list-style-type: none"> • What is the role in the “start-up?” • Where is the “start-up” incorporated? What is the physical address (campus or off-campus)? • Do direct reports also have a role or financial interest? • Does the primary or other institution(s) have a financial interest in the “start-up?” • What is the connection/overlap to the research or institutional responsibilities?
Board of Directors	<ul style="list-style-type: none"> • Participation in funding decisions for companies sponsoring research • Fiduciary responsibility may conflict with institutional responsibilities or research 	<ul style="list-style-type: none"> • What are responsibilities (e.g. leadership activities, funding decisions, research direction, grant review)? • Is the entity funding any of the discloser’s institutional research or that of direct reports? • Is compensation appropriate?

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Outside Activity	Risks	Key Information to Evaluate Risk
Prior or pending employees (moving institutions)	<ul style="list-style-type: none"> • Network/system access • “POI/Systems Credentials”- retaining credentials may lead to inappropriate affiliations on publications • Managing outside activity approvals that began at the prior institution 	<ul style="list-style-type: none"> • What is the length of time that access will be retained and for what purpose? • Will an appointment or affiliation be maintained after departure? • Will early access be granted prior to start date and to which systems? • What external activities and affiliations will new hires bring with them?
External Faculty appointments	<ul style="list-style-type: none"> • Often unclear responsibilities, may conflict with commitments to primary institution • Opportunity to exceed commitment limits/effort • Affiliations in publications • Honorary or volunteer titles may be misleading • Inconsistent information in Other Support, CV, and institutional reporting 	<ul style="list-style-type: none"> • What are the responsibilities for the appointment (teaching/mentoring students, research support, funding, grants)? • What is the term of the appointment? • Is the appointment compensated? • What obligations does discloser have to the prior institution? • Is info found across other platforms consistent (e.g. Other Support, Orcid, CV/Resume, institutional disclosure)?

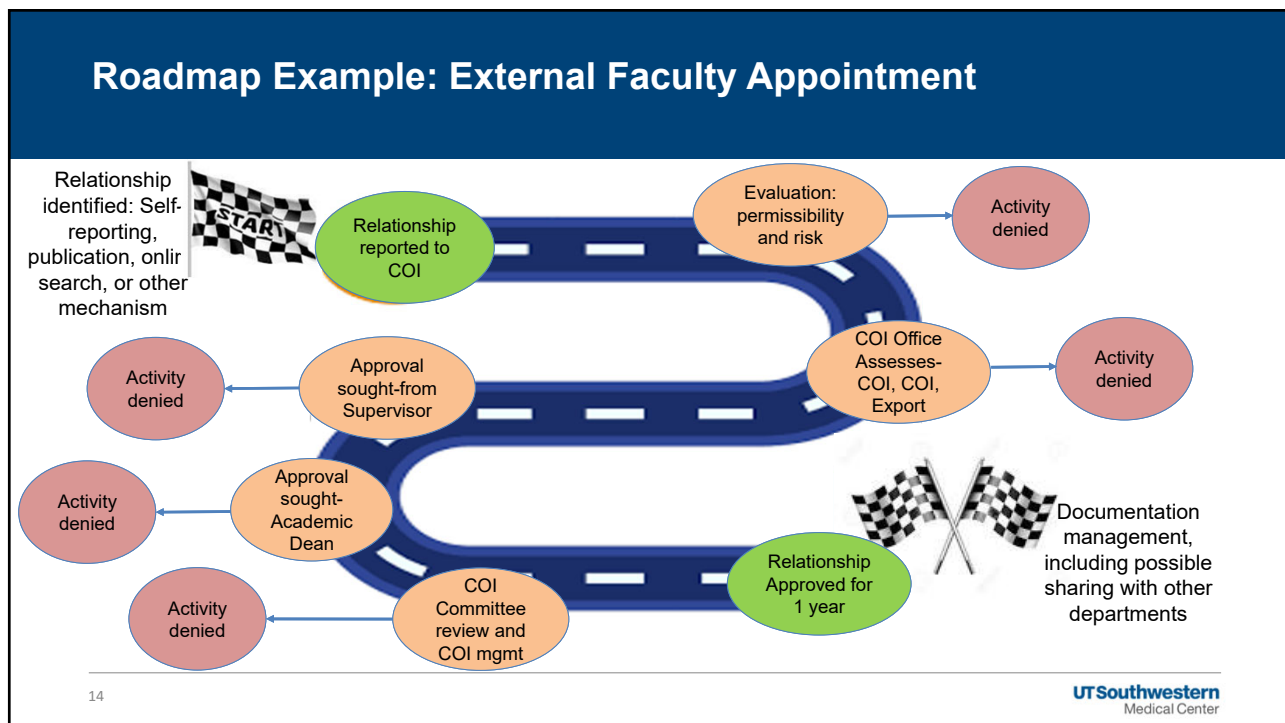
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Outside research as an individual w/without formal agreements	<ul style="list-style-type: none"> • Opportunity for overlap with federally funded research • Use of primary institution resources and time • Sources of funding and outside commitments • Inappropriate sharing of information • Disagreements over IP ownership 	<ul style="list-style-type: none"> • Is the “research” really research? • Does the home institution allow and have safeguards for outside research? • Is there an international component? • Will the research be performed on-site or at the outside entity (should this require an inter-institutional agreement)? • What are the implications for reporting on Other Support and other documents? • Is there inappropriate sharing of data and results? • What is the chance of competing claims to intellectual property?
Research collaborations	<ul style="list-style-type: none"> • Scientific expectation to collaborate may result in missing risky collaborations (export control, FGTRP) • Few institutions have mechanisms to review 	<ul style="list-style-type: none"> • Who is the collaborator and what is the relationship to institutional research? • Is there an international component? • Is there a reputational risk upon publication of research? • Does the institution have a mechanism for COI, Export Control and research security assessment?

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Outside Activity	Risks	Key Information to Evaluate Risk
Foreign Government Talent Recruitment Program	<ul style="list-style-type: none"> • Ineligible for federal funding with malign programs • Requirement to report to relevant federally funding agencies immediately • Inappropriate influence over institutional activities and research • Research transparency • Lack of reciprocity • Coercive or deceptive recruiting • Theft of intellectual property • Non-disclosure of conflicts • National and economic security 	<ul style="list-style-type: none"> • Has this been reported appropriately on Other Support and related documents, and what are the implications to existing awards? • What is the name of the Talent Program and the country of sponsorship? • Could this be a malign foreign government talent recruitment program? • What services, affiliations, and other promises are part of program participation? • Are there signs of inducement, coercion, deception, opaque legal language, or are agreements in a language not comprehended by the Signer? • Does the institution have sufficient risk tolerance to accept individuals with active foreign government Talent Recruitment Program participation?

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Roadmap Example: External Faculty Appointment

- Disclosure collected annually during the open submission period
- Additional approvals required:
 - Supervisor, Department Chair, and Dean approval required
 - Collection of appointment letters
 - Export control screening of international institutions
 - Use of tracking tool and system reporting to document and manage process

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Roadmap Example: External Faculty Appointment

- Additional operational steps
 - Process external faculty appointment reports each Spring and Fall
 - Creation of specialized templates for review requests
 - Use of e-signature tool to collect formal electronic signatures
- Record retention requirements
 - Upload appointment approvals to faculty records
 - COI Office
 - Office of Faculty Affairs

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Metrics and Reporting of Outside Activities

- Use disclosure system automated reports to monitor Statement status and COI Office assessment progress
- Prepare and send Conflict of Commitment reports to Department Chairs bi-annually
- Consolidation of Research activities, Outside interests, Personal agreements and Management plans information on a central user platform
- Export Control determinations, and personal agreements and Management Plans information on a Central user platform

History	Research	Account Detail	COI Summary	Roles	COI Documents	EC Summary	
COI Training Completion Date: Tuesday, January 10, 2023 COI Training Expires: Monday, March 1, 2027 Last COI Statement Submission: Wednesday, April 26, 2023 Statement State: In Review Please u Statement Name: 2023 STATEMENT OF FINANCIAL INTERESTS							
Entity Name	U.S. Entity	Activity/Interest Type				Entity State	
"Aura Biosciences, Inc"		Consulting or Scientific and Medical Advisory Board Service				QAE Approved	

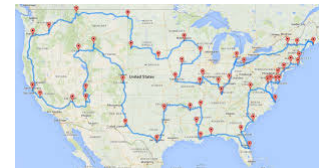
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Keys to Success

- Create standard operating procedure/processes
- Prepare reports, tools and standard templates required for task execution and tracking
- Collect the same basic information for all activities
- Some activities, like external faculty appointments, may occur on different timelines than a typical disclosure period
- Automate, and integrate platforms, as much as possible
- Do not be afraid to say, "No!"



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Questions?

Session Presenters

Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, ECoP (EAR), DACAW

Associate Vice President, Research Support & Regulatory Management

Assistant Professor, Psychiatry (Ethics Division)

UT Southwestern Medical Center

Stacy.Pritt@utsouthwestern.edu

Meredith Brown Noto, MBA, MA, CHRC, EXCS

Associate Director, Conflict of Interest and Export Control

Office of Research Support and Regulatory Management

UT Southwestern Medical Center

Meredith.Brown@utsouthwestern.edu

Vince Snoddy, MBA

Regulatory Monitoring Analyst

Conflict of Interest

Office of Research Support and Regulatory Management

UT Southwestern Medical Center

Vincent.Snoddy@utsouthwestern.edu