Disclosure and/or Acknowledgements

- The speaker has $0 financial interest to report.

- The speaker would like the audience to be aware they have significant personal interest in educating students, researchers and staff about COI since:

Understand: Multiple Types of Research Conflict of Interest

Individual – Institution maintains policies for personal/financial interests of employees, students and trainees. Framework is responsive to state, federal or other requirements. UNC CH definition of COI and federal FCOI definitions.

Organizational – Type 1) FAR 9.5 optional clause for federal contracts; overlapping projects which could create financial benefit. Can also be applied to grants. Review required. **Type 2)** UG 200.318.c.2 requires Institution to have organizational COI code for procurements with related entities; review if needed upon procurement request.

Institutional – No federal definitions or regulations. Required for IRB accreditation. Used when Institution owns equity, intellectual property and could financially benefit (immediate or future) from situation, especially as result of direct treatment research.

RAMSeS: COI Coverage versus Flow Down

Individual COI Coverage by UNC Chapel Hill:
- UNC employees, staff, students
- UNC HCS on specific grants
- Independent Contractor Investigators
- Research Collaborators (unless covered by primary employer), adjuncts
- As required by NIH and NSF
  - Sub-awardees: Only if they <u>DO NOT HAVE</u> a COI policy registered at NIH or FDP Clearinghouse (NSF)

Flow Down of individual COI requirements :
- All sub-awardees as required by sponsor
- Flow down for NIH and NSF if they have their own COI policy

NOTE: Flow Down of organizational COI requirement goes to sub-awardee or Independent Investigator!!!

IRBIS or RAMSeS: Wrong Sponsor

Q: The wrong sponsor [or email or person name] is listed on my COI Disclosure form. It's not NIH [or email or name] but should be listed as supported by Department funds [or x or y]. Please correct.

A: The COI disclosure form is populated by data entered into the IRB application or RAMSeS file. Or the UNC directory. The data must be corrected in those locations. The COI Office cannot correct those errors.

Q1: Our ICi has taken the Research COI Training (we have the email) but they are still getting a reminder notice.

A1: The individual has been listed with @company. com email in the IPF but has taken the training with @gmail.com email address as their identifier. Contact coi@unc.edu where the office can request ITS to sync the records, but it make take 2-3 days.

2023 SYMPOSIUM
FOR RESEARCH ADMINISTRATORS

Q2: Our ICi is listed with their @xxx.edu email. Why are they under UNC's COI Policy?

A2: There's always a problem to be resolved when an IC or ICi is listed with an @xxx.edu address. At best, the COI Office cannot tell if the work is being done under another university's oversight AND if the individual should fall under the other University's COI policy. Or if they need to fall under UNC's COI Policy.

<u>As best practice and standard</u>, any IC or ICi should be listed with a personal email, not the university one, if they are doing the work in their personal capacity. Even IF the external person says it's fine.

Items Needed for Research COI Completion

Research COI Training ≠ Research COI Disclosure

In accordance with federal regulations, BOTH are required.

2023 **SYMPOSIUM**
FOR RESEARCH ADMINISTRATORS

IRBIS or RAMSeS: No longer at UNC

Q: Person ABC has left the University but is still getting COI disclosure/training reminders. Please make them stop as it's driving the PI crazy.

A: The COI disclosure form is populated by data entered into the IRBIS or RAMSeS file. The data must be corrected in that location (IRB application, IPFs or Awards). The COI Office cannot update the personnel listing or correct any error related to person's name.

Common Places to Stumble

5 Business days to OSR:

IFP is not submitted in a timely fashion

Data Check:

Who is named on the Sub Proposal/ emails match?

Data Check:

Was the right "Emmet Smith" chosen on the personnel list?

Manage:

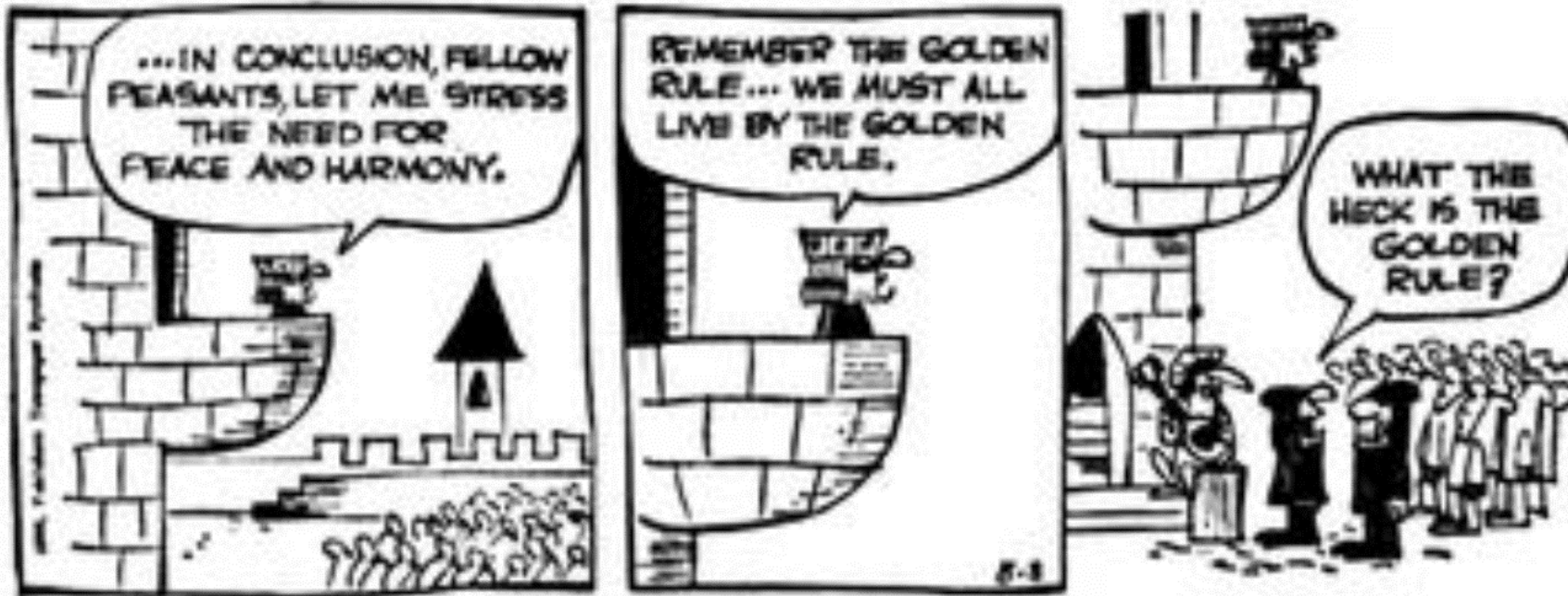COI disclosures OR trainings are not completed

Know:

Subs assume their COI policy is sufficient

RAMSeS: Sponsor COI Standards

Q: We noticed the sponsoring agency has a different COI definition of YYYY that's different from NIH. What happened to "harmonization"?

A: As stated by a federal agency, harmonization does not equal uniformity. As various agencies are creating their COI requirements, they are including some differences. The COI Office, along with ORIS, is adding sections (or creating additional questions to the standards) that will only appear when Entity is listed as a Sponsor or Prime Sponsor. Please enter correctly!

May 3, 1965

Procurement COI in the News

May 2015: The National Science Foundation has suspended millions of dollars in research grants to UConn after revelations that two UConn professors used more than $250,000 in grant money for no-bid purchases of equipment from a company they control.

In two of three purchase requisitions, faculty members with a stake in the company .... signed a form that included the statement: "I certify ... that I have no financial or other beneficial interest in the vendor."

Feds Freeze Millions In Grants To UConn After Conflict-Of-Interest Probe

By **Matthew Kauffman** and **Dave Altimari**

MAY 1, 2015, 5:05 PM

The National Science Foundation has suspended millions of dollars in research grants to UConn after revelations that two UConn professors used more than $250,000 in grant money for no-bid purchases of equipment from a company they control.

The professors, founders of Aquatic Sensor Network Technology LLC, a marine sensor and communication technology firm in Storrs, used NSF funds to purchase 15 specialized acoustic modems from their company, according to a report by the state Auditors of Public Accounts.

In two of three purchase requisitions, faculty members with a stake in the company, known as AquaSeNT, signed a form that included the statement: "I certify ... that I have no financial or other beneficial interest in the vendor." The faculty members told the auditors that they did not read the portion of the form they signed that indicated they had no financial conflict. They also blamed time constraints and mistakes for an earlier failure to disclose their interests in the company, on forms filed when they were seeking NSF funding.

The acoustic modems, purchased between April and August of 2013, cost $253,500, the auditors reported.

In a Dec. 19, 2014, letter to Jeff Seemann, UConn's vice president for research, a federal official said seven NSF grants to the university had been frozen, pending either corrective action or the termination of the grant awards. The grants, all related to underwater communication and exploration, are worth more than $4.6 million. Principals with AquaSeNT are principal investigators or co-principal investigators in each of the grants.

"NSF has determined that suspension of the referenced awards is reasonable to protect the interests of the government," NSF Grants Officer J. Christopher Robey wrote. "NSF has

Upcoming Changes

Requirement for Personal Identifier such as ORCiD ID is appearing in some agency RFPs:

> *(d) Persistent Identifiers (PIDs) for Key Personnel*
>
> **All key personnel are required to have a persistent identifier (PID)**, such as ORCID iD (Open Researcher and Contributor Identification; https://orcid.org/) **in place before an award will be made.**

For example, on eRA Commons, field is visible for anyone with a profile.

COI Office

Can Do:
- Provide clarification on COI Policy, procedures and questions on the forms
- Provide analysis on COI requirements in RFPs
- Teach you where & how to check any COI status for your study
- Sync COI training for duplicate PIDs

Can NOT Do:
- Add or Inactivate Personnel from Ramses IPF or Award (OSR) - also true for IRBIS
- Change Emails or PIDs (ITS)
- Change titles on a COI Disclosure (OSR and OHRE
- Add Sponsors to a COI Disclosure (OSR add to IPF, then re-issue COI disclosure)

Key Websites and Contact Information

COI Website: https://iirm.unc.edu/coi/

Disclosures: Activities, Interests and Relationships: **air.unc.edu**
        All COI disclosures and External Activities for Pay

Research COI Training: coi-training.unc.edu, https://apps2.research.unc.edu/coi-training/

Email: coi@unc.edu or Phone: 919-843-9953

Compliance Line - contact anonymously
https://ethicspolicy.unc.edu/report-a-concern/ or call 866-294-8688

Questions?

The University of North Carolina at Chapel Hill