



TURAC 2024⁺

Connection • Collaboration • Cohesion

Institutional Management of Conflicts of Interest

April 17, 2024

Land Acknowledgement Statement

“Arizona State University, Northern Arizona University, and the University of Arizona collectively acknowledge that the campuses are situated on the ancestral lands of twenty-two federally recognized tribes located across Arizona. These universities collectively honor the past, present, and future generations of Native Americans, who have lived here for millennia and will forever call this place home. Committed to diversity, the institutions integrate Indigenous knowledge into their practices and strive to cultivate sustainable relationships with Native Nations through education, partnerships, and community service.”






Institutional Management of Conflicts of Interest

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AGENDA

- Why are we here?
 - The Institution perspective
 - The Faculty perspective(s)
 - The Research Administrator perspective
 - Discussion
- 

Why are we here?



Conflicts of interest have the potential to inappropriately bias (or appear to bias) the design, conduct, and reporting of research.

The goal:

Protect the integrity and objectivity of research by ensuring research is free from bias resulting from a researcher's conflict of interest

A laboratory scene featuring a scientist in the foreground, a student in the middle ground, and another student in the background. The scientist, wearing a light blue shirt with colorful embroidery and purple gloves, is focused on a glass jar containing a plant specimen under a lamp. The student in the middle ground, wearing a white lab coat and safety glasses, looks on intently. The student in the background, wearing a grey sweatshirt and glasses, holds a blue book. The setting is a well-lit laboratory with bookshelves in the background.

A SCENARIO

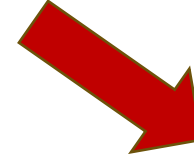
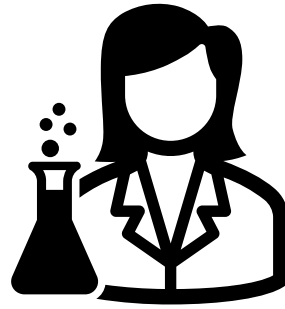
A faculty member approaches you and asks to meet about the budget for an NIH proposal they are working on. During the meeting, the faculty member mentions that they're excited about some consulting they just started doing on the side with a private company.

The First Thing to Know about “COI”

- COI is about **disclosure** of outside activities and interests
- **Disclosure** is made by the investigator to the institution and the sponsor
- Federal sponsors and institutions generally provide several opportunities for the investigator to **disclose**



Primary Disclosure Obligations



NAU
NORTHERN
ARIZONA
UNIVERSITY

A THE UNIVERSITY
OF ARIZONA®

ASU ARIZONA STATE
UNIVERSITY

NSF

NIH

NASA

DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

DEPARTMENT OF ENERGY
UNITED STATES OF AMERICA



THE INSTITUTION PERSPECTIVE

Permissible & Encouraged

- No prohibitions against engaging in outside activities or having outside financial interests....
- So long as they are disclosed and, if necessary, appropriately managed!
- Caveat! In some cases, conflicts cannot be managed and instead need be eliminated

Institutional Responsibilities

- Policies and procedures
- Designated official(s)
- Training and education
- Manage financial conflicts of interest and conflicts of commitment
- Report to sponsors as required
- Maintain records
- Enforce polices

Only the institution's designated official(s) can determine whether a conflict exists!



THE FACULTY PERSPECTIVE



National Science Foundation Innovation Corps (I-Corps) Training



NSF I-Corps Program

The I-Corps program develops and nurtures a national innovation ecosystem built upon fundamental research and the development of technologies, products, processes, and services that benefit society.

This FREE 5-week I-Corps regional training program provides a hands-on, high-impact, and fast-paced opportunity for innovators to learn to commercialize their technology or idea.



Check out our website here!

Contact the NAU Program Director at Cristy.Salanga@nau.edu with any questions.

Teams will participate in a fully virtual training which is an assumption/hypothesis-testing, customer-focused discovery process to gather important insights needed to maximize the impact of your innovation.

- Hands-on experiential learning based on a customer-focused business model curriculum
- Quickly learn how to assess if there is a market and customer for your idea and develop a compelling value proposition
- Receive personalized feedback from expert entrepreneurial instructors
- Teams that complete the program will be eligible for a \$3,000 small grant to pursue customer discovery and minimum product development

- Not all faculty have, or have even considered having, outside arrangements
- Universities benefit when faculty are not siloed!
 - Funding agencies encourage expansion of funded research into entrepreneurial efforts
 - **Desert and Pacific Regional I-Corps Hub includes all three Universities in Arizona system!**



UC San Diego



UNLV



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- When outside arrangements exist, the COI process may not be something a faculty has ever thought about
 - Why are disclosures necessary?
 - When are disclosures necessary?
- Ultimately the faculty will be the one who makes the decision to disclose
- **Transparency and trust** guides the process

Faculty DO

Transparency and Trust require Give and Take

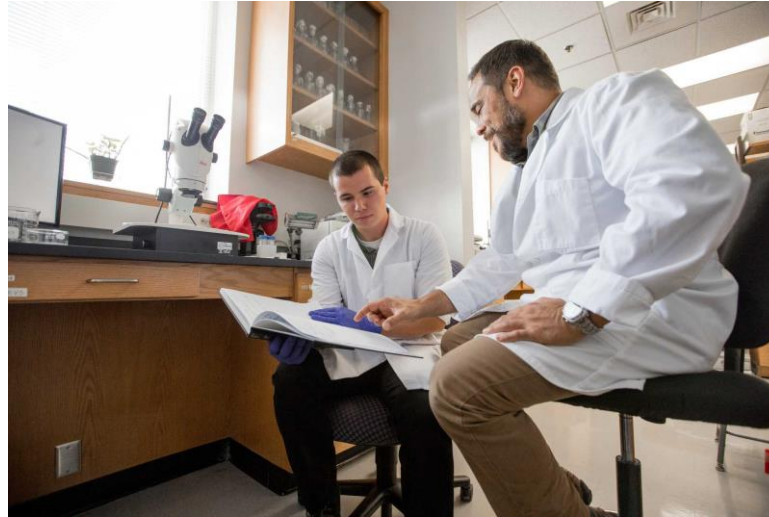
- Have intimate knowledge of their work, and how it overlaps with others
- Have an ability to readily recognize opportunities for their work to be applied
- Have an appreciation that these opportunities can be nuanced, fleeting and often time sensitive



Faculty DO NOT

- Always have an objective understanding of where conflicts are, nor the means to assess them
- Always have an appreciation that university and sponsor both have a stake in the game
- Usually appreciate that the COI process is about implementing/managing structure of relationship and not about modifying their behavior
- Regularly understand expectations on COI from the sponsor

Faculty Mindset



- **Faculty are Team Players**
 - Goal is **transparency and trust**
- **Often Unaware of Requirements to Disclose**
 - May authentically not know rules
 - May underappreciate their own potential for COI
 - May not be in a position to objectively assess COI
 - Unclear on how to disclose to a sponsor

COI Disclosure and Management Can Be Perceived as Punitive

- Perception that COI disclosures will lead to punitive actions
- Perception that disclosing at all will slow the submission or research
 - University is vested in the long-term success of the work
- Perception that sponsors may not care or be aware
 - Review and evaluation of proposals done by real people!
 - PM's know and care about what is in their portfolio



“It’s easier to ask for forgiveness than it is for permission.”

- Comfortable to invoke this as the easy way out
 - COI disclosures makes sure all parties are comfortable with a mutual relationship
 - Sponsor empowered to take measures if it feels the COI is unmanageable (or if it results in a black eye)



A photograph of a man and a woman in an office setting. The man, on the left, has curly dark hair and is wearing a light-colored, patterned button-down shirt. He is smiling and looking towards the woman. The woman, on the right, has dark hair and is wearing a light-colored, textured sweater. She is seen from the back/side, looking towards the man. In the foreground, a laptop is open, showing some colorful graphics. The background is a plain office wall with a framed document. The overall lighting is soft and indoor.

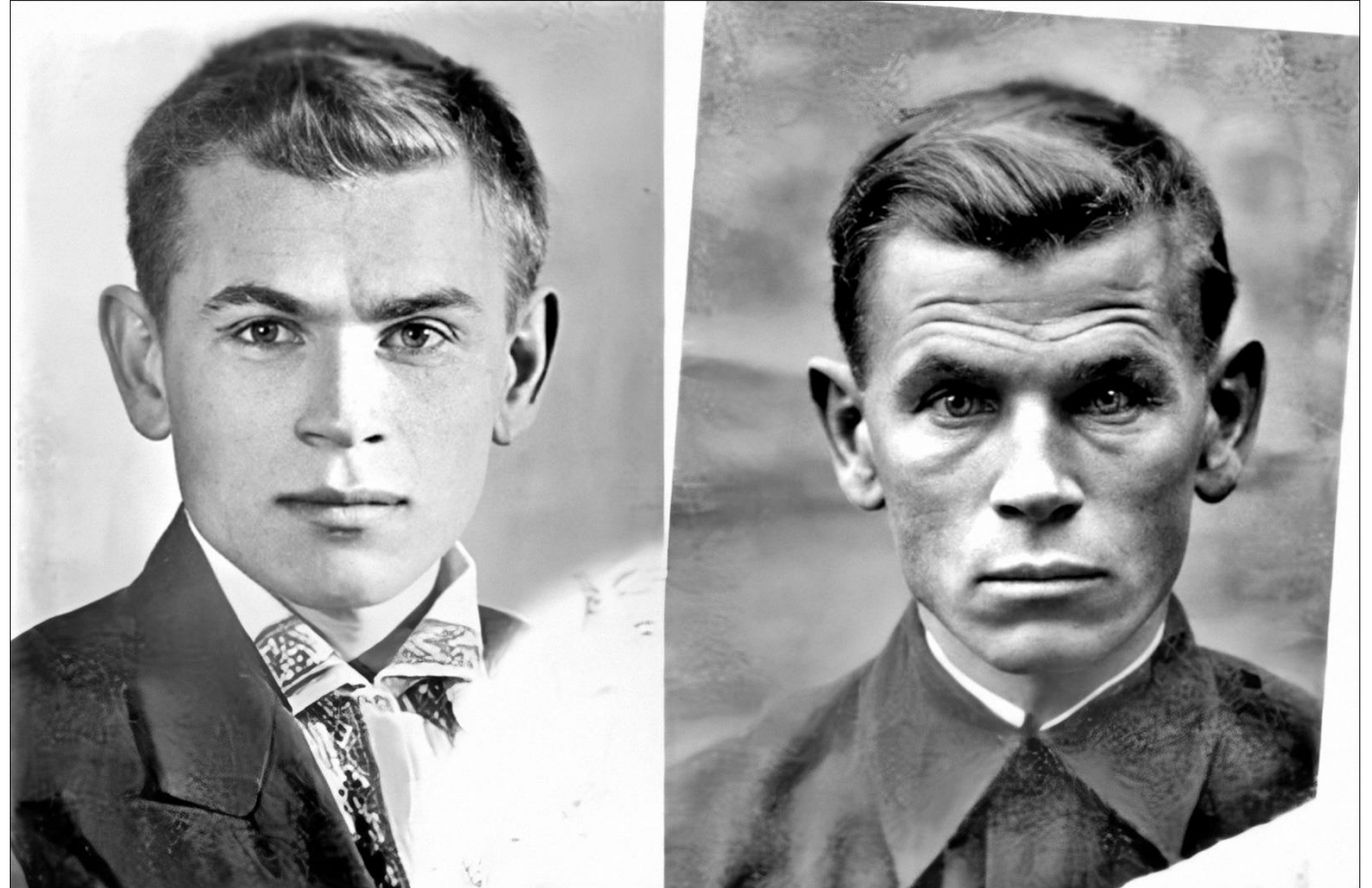
THE RESEARCH ADMINISTRATOR'S PERSPECTIVE

What do you know about being an RA, Brent?

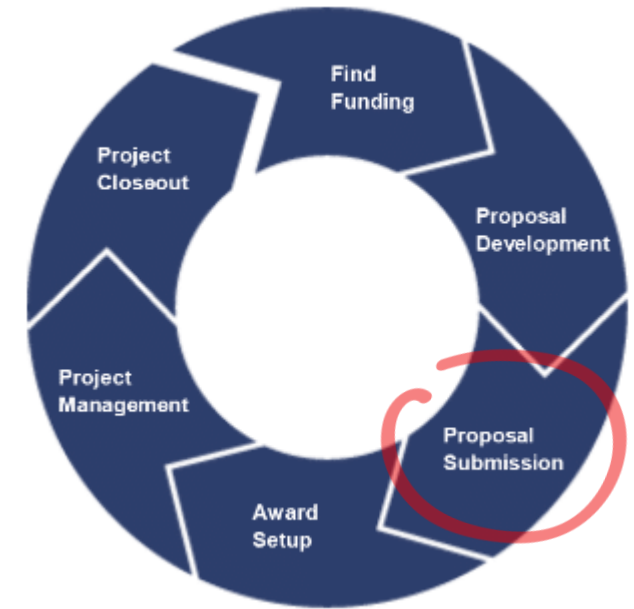
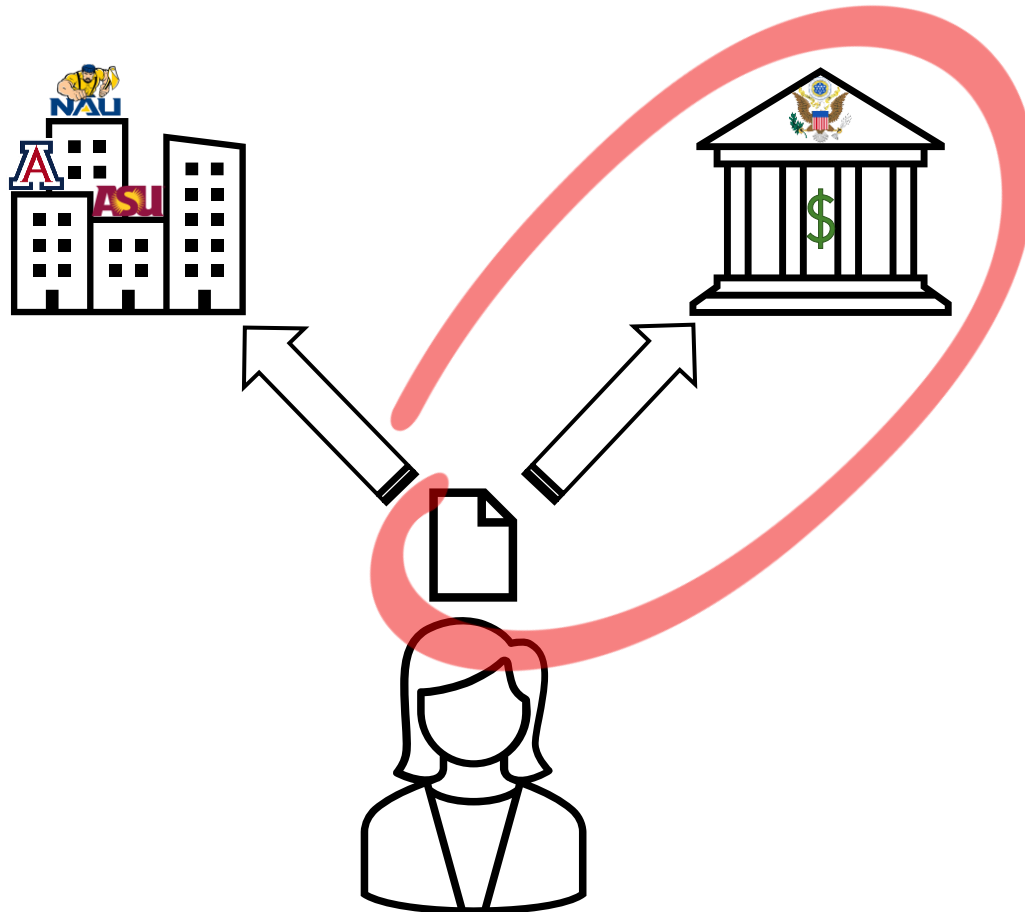
- Pre-Award RA > RA Manager: University of Nebraska Medical Center (2 years)
- Pre-Award RA: ASU College of Health Solutions (3 years)
- Pre-Award RA > RA Manager: ASU College of Engineering (5 years)

...left January 2023

New RAs and the Battle Hardened RAs



Scope:



Disclosure

- Examples of information all investigators are asked by federal sponsors to **disclose**:
 - Business Positions
 - Outside Employment
 - Outside Appointments
- REGARDLESS of involvement in the project



Disclosure... Where?

- Biosketch
- Current & Pending (Other) Support
- Facilities, Equipment & Other Resources (sometimes!)



Recap!

Investigators are asked to **disclose**

- Business Positions
- Outside Employment
- Outside Appointments (etc.)

Within

- Biosketch
- Current & Pending (Other) Support

REGARDLESS of involvement
in the project



Where is the requirement?

NIH

- SF424 (R&R) Application Instructions
- NIH Disclosure Table

NSF

- PAPPG
- NSF Disclosure Table

DOE

- Funding Opportunity Announcement

Other Federal Sponsors

- NSPM-33 Disclosure Table
- Funding Opportunity Announcement



Where else?

- Funding Opportunity Announcements
- Common Forms Instructions
 - NSF is Steward



Anywhere
else?



Yeah, but
**WHO
DETERMINES
COI?**

NOT:

- Pre/Post-Award RA
- Investigator
- Project PI
- School Director, Deans, etc.



Yeah, but still:
WHO
DETERMINES
COI?

- Personnel designated by the institution
- Institutional Official
- Conflict of Interest Administrator (COIA)



Woah! You
forgot about
us...

POST Award

- IF COI is determined, a management plan will be implemented
- A management plan monitor will be assigned (usually a faculty member)
- Post-Award RAs may – as needed – assist the plan monitor or COIA
- Investigators are asked to disclose during the period of performance



So you say...

Investigators are asked to disclose during the period of performance

- Sponsor Project Reports
- Per Sponsor Requirements



Curious... what's in a management plan?

- Disclosure to
 - Project Team Members
 - Human Subjects
 - Journals
- Refrain from
 - Financial Approvals
 - Contractual Actions



Is there
anything else
I should know?

- Go easy on faculty and be **helpful!**
- At ASU, there's up to **3** separate institutional disclosure requirements
+
Funding Proposal Disclosure
(biosketch, current/pending support, etc.)
for EACH funding proposal



How can I be helpful as an RA?

- Know *your* institution's resources
- Know your institution's COIAs
 - Teams chat them and say hi!
- Understand **federal** disclosure requirements - BRUSH UP!
- Know that there is also institutional disclosure requirements
 - Learn the means and methods to assist!



How can I be helpful as an RA?

For example...

- Create an email template that you can send to faculty asking for assistance:
 - Institutional Disclosure Resources
 - Institutional Disclosure Means & Methods
 - Federal Grant Disclosure Resources
 - Federal Grant Disclosure Means & Methods
- Advise “When in doubt, **DISCLOSE!**”



REMEMBER!

The COI process is about establishing a **partnership of trust between investigators, universities and sponsors**

- Research Administration on both sides can help
- Everyone benefits when conflicts – or the potential for conflicts – are disclosed and addressed as early as possible!

A laboratory setting where a scientist with a beard and glasses, wearing a light blue shirt with colorful embroidery and purple gloves, is focused on a glass jar containing a plant specimen. He is working under a bright lamp. In the background, two students, a man in a white lab coat and safety glasses, and a woman in a grey sweatshirt, are observing the work. The scene is set in a well-lit lab with bookshelves in the background.

RETURN OF THE SCENARIO

A faculty member approaches you and asks to meet about the budget for an NIH proposal they are working on. During the meeting, the faculty member mentions that they're excited about some consulting they just started doing on the side with a private company.

- How would you counsel the faculty member?
- Do they need to disclose? If so, where?
- By when do they need to disclose?
- What are your local resources?

Thank You!

**Be sure to complete all 3
TURAC surveys for a chance
to win a **\$25 gift card!****

