



# **TURAC 2024<sup>+</sup>**

**Connection • Collaboration • Cohesion**

## **Research Compliance Checklist and Export/Research Security**

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.”*





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## **Research Compliance Checklist and Export/Research Security**

**Cliff Fredericks & Nancy Henderson, ASU**

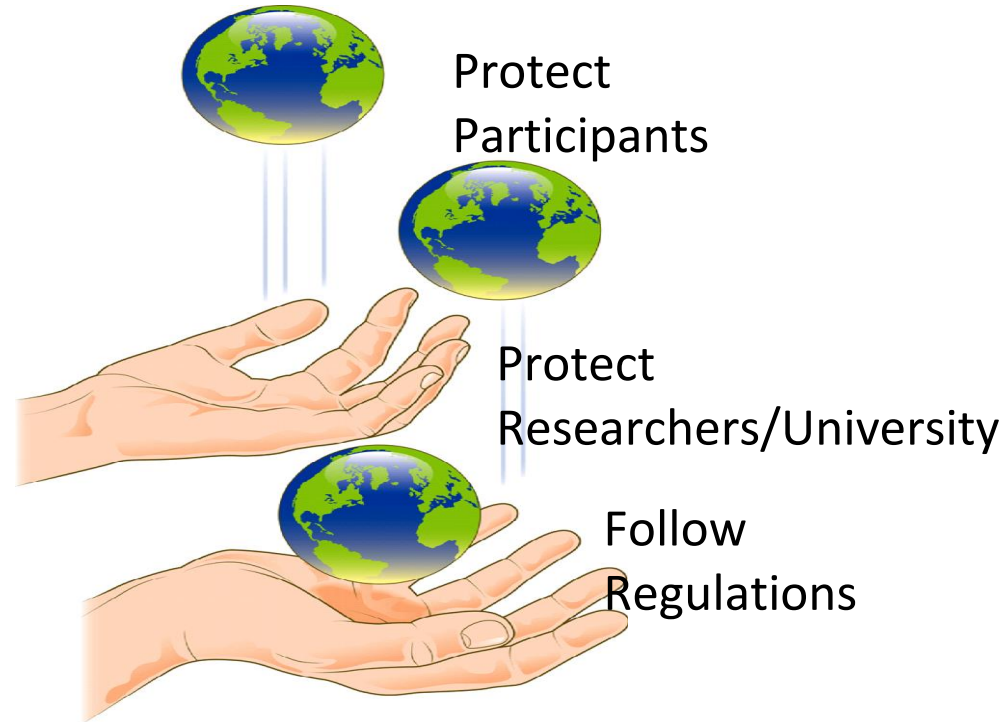
April 17, 2024

## Overview

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# Role of Research Compliance

Ensure support for **compliance** with **Local, State, and Federal Regulations** through ethical and responsible conduct of Research.



## Research Compliance Areas:

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Human Subjects Research - Oversees, supports and ensures compliance for research involving human subjects

Biosafety - Oversees, supports and ensures compliance for research involving biological materials.

Animal Care and Use - Oversees, supports and ensures compliance for research involving animals.

Conflict of Interest - Oversees, supports and ensures compliance with all university, sponsor, ABOR, federal, state, local laws and regulations with respect to researcher financial or other relationships with outside entities to ensure that such interests do not create situations that are, or appear to be, in conflict with the values of free and unbiased inquiry.

## Research Compliance Areas:

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Responsible Conduct of Research - Oversees, supports and ensures compliance with federal requirements and ASU's commitment to maintain the highest ethical conduct of research by faculty, staff and students.

Scientific Diving – Oversees, supports and ensures compliance for personnel that engage in underwater research activities involving diving.

Research Security & Export Controls – Oversees, supports and ensures compliance with federal government requirements governing the export, transfer or sharing of certain commodities or information for reasons of national security or protections of trade.

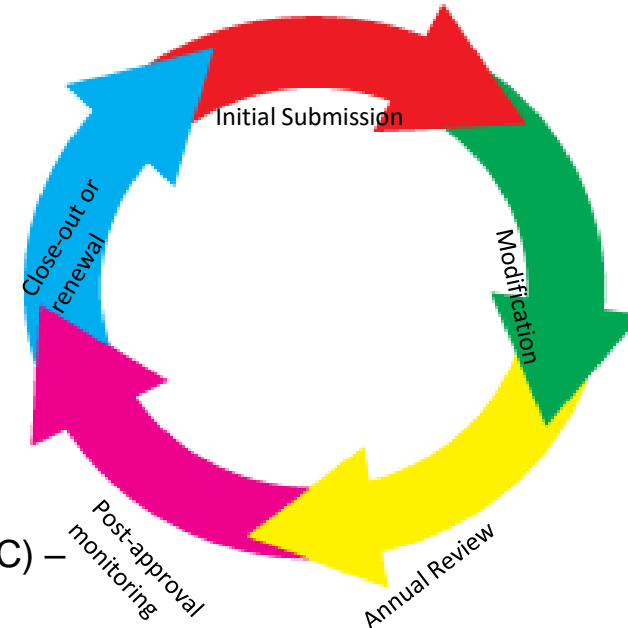
## Overview – Compliance Committees

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- Institutional Review Board (IRB) – Human Subjects
  - Social Behavioral and Bioscience boards at ASU
- Institutional Animal Care and Use Committee (IACUC)-Animals
- Institutional Biosafety Committee (IBC) – Biosafety

### Common Elements to IRB, IACUC and IBC:

- Submission of protocols to the committees
  - Review processes
    - Full Committee Review
    - Designated Review
    - Administrative Approvals
  - Modifications
    - Locations
    - Study Design or Scope
    - Materials
- Intellectual Property and Institutional Review Committee (IPIRC) – addresses issues related to intellectual property management and reviewing conflict of interest disclosures related to research in which an investigator has disclosed significant financial interests that could affect the design, conduct, or reporting of his/her research and to recommend and implement management strategies designed to reduce, manage or eliminate perceived conflicts.



# Human Subjects Research

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## What is Human Subjects Research?

Research - a **systematic** investigation, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable** knowledge”

Human Subject - “a living individual about whom an investigator conducting research obtains data through **intervention** or **interaction** with the individual or **identifiable private information**”

Conduct of HSR governed by federal regulations (HHS, 45 CFR 46) and Institutional policies.

**Institutional Review Board (IRB):** Review proposed **research** involving **human subjects** to ensure ethical treatment of subjects and protection of rights/welfare.

- Three Review Types - Full Board, Expedited, Exempt
- Two Boards at ASU - Bioscience and Social Behavioral
- Some sponsors require IRB approval at proposal time; PIs can request Just in Time (JIT) letter from IRB - signifies approvals will be in place before HSR
- IRB Approval must be in place prior to initiating research activities and expenditure of funds. Changes to HSR may require additional approval.
- Specific IRB training requirements for study team members.
- ABOR Policy 1-118 Tribal Consultation, and your institutional policy, for HSR (and non-HSR) that involves Native American Tribes.

Contact your Institution IRB Administrator for more information.





## Animal Research

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- Governed by Federal regulations under the Animal Welfare Act and the Public Health Service (PHS) Policy
- Cephalopods per AAALAC accreditation
- Must have **Institutional Animal Use and Care Committee (IACUC)** approval
  - Prior to Investigation and expenditure of funds
  - PIs can request a Just in Time (JIT) letter before research begins if sponsors required
- All investigators must be appropriately trained by education and experience
- Approval for 3 years
- Contact your Institution IACUC Administrator for more information.



**It is a privilege and not a right to work with animals!**

## Biological Research

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*All research involving recombinant or synthetic nucleic acid molecules, biohazardous materials, or the use of infectious agents must be registered with the IBC whether exempt from federal regulation or not.*



Governed by federal requirements NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES) and Institutional policies.

Biohazardous materials include, but are not limited to:

- Recombinant and/or synthetic nucleic acid molecules
- All human and nonhuman primate blood, blood products, tissues, and body fluids
- Human cells, tissues, and bodily fluids
- Microorganisms, microbial toxins, or other biological agents that can infect and/or cause disease in humans, animals, or plants
- Select agents or toxins
- Transgenic animals, plants or insects

### trans·gen·ic

/transˈjenɪk, tranzˈjenɪk/

adjective BIOLOGY

relating to or denoting an organism that contains genetic material into which DNA from an unrelated organism has been artificially introduced.

**Institutional Biosafety Committee (IBC)** approval before conduct of research/expenditure of funds. Approval periods range from 1 year to 5 years – the more risk, the shorter the approval.. Specific training requirements.

Contact your Institution IBC Administrator for more information.

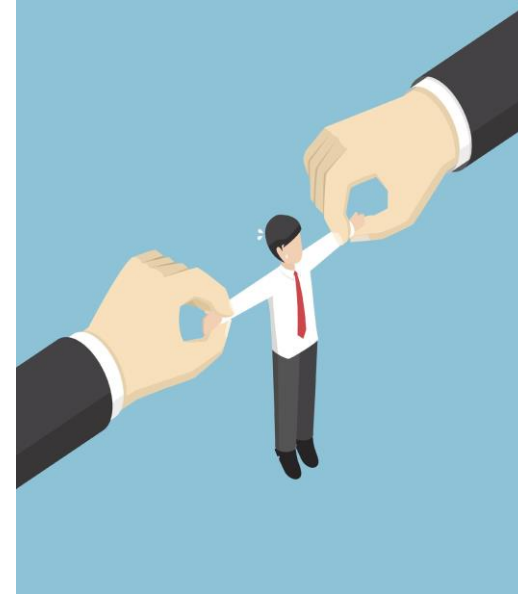
**SAFETY IS THE UTMOST CONCERN – Personnel, Animals, Environment**

# Conflict of Interest

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## ABOR 3-901 Conflict of Interest

- All regents and board and university employees must comply with Arizona conflict of interest laws.
- A regent or employee who has, or whose relative has a substantial interest in any contract with, sale to, purchase from, service for or decision by the board or university **must**:
  - disclose the substantial interest to their university
  - keep disclosures current and update whenever the disclosed interest or relationship changes
  - **must** also refrain from participating in any manner in the contract, sale, purchase or decision.
- The term “substantial interest” is a legal term and not a relative term. Substantial as a relative term refers to quantity. Substantial interest in legal terms is any pecuniary (money) or proprietary (ownership) interest, direct or indirect, other than a remote interest.
  - ASU ACD 204-08 remote interest examples: non profit corporation non-salaried officer, landlord/tenant of another party, attorney of contracting party, non profit cooperative marketing association, insignificant stock ownership.



## Conflict of Interest - Research

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- A conflict of interest with respect to research is a situation in which an individual, or the individual's spouse or dependent children, has a financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting, purpose or funding of research.
- Federal sponsors (e.g. NSF, Public Health Service (PHS) (including NIH), and DOE) require investigators to disclose significant financial interests.
- "Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). For what SFI does not include see [NSF PAPPG Chapter IX Grantee Standards, Section A. Conflict of Interest Policies](#)
- Disclose per your Institutional policies and procedures
- Regulations **require** disclosure at proposal submission and at least every (1) year thereafter. Report changes within thirty (30) days of the change.
- Contact your Institution COI Administrator for more information.



## Conflicts of Interest

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# Federal and ABOR Policies

- NSF PAPPG 23-1 Chapter IX.A. Conflict of Interest Policies
- 42 CFR Part 50 PHS Promoting Objectivity in Research
- Public Health Service (PHS) COI Regulations
- DOE Interim COI Policy Requirements for Financial Assistance (FAL 2022-02)
- [ABOR 3-901 Conflict of Interest](#) - Arizona Board of Regents policy on conflicts of interest
- [ABOR 204-08 Conflict of Interest](#) - policy on financial conflicts of interest for faculty and academic professionals
- [ABOR 6-909.10 Technology Transfer Policy](#) - Arizona Board of Regents policy on intellectual property

## Responsible Conduct in Research

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- Ethics training in the Responsible Conduct of Research
- RCR topic areas include: Animal welfare, COI, Data Management, Human Subjects, Mentor/Trainee Responsibilities, Peer Review, Responsible/Safe Lab practices, Safe Research Environments, Research Misconduct, Research Security
- For undergraduates, graduate students, postdoctoral researchers, and NSF funded investigators and senior personnel (as of July 31, 2023) when working on sponsored projects
- ASU's RCR plan consists of three phases:
  - **Phase 1:** Online training via the Collaborative Institutional Training Initiative (CITI) for undergrad and grad students, postdoctoral researchers, and NSF funded investigators and senior personnel
  - **Phase 2:** Attendance at a minimum of one RCR workshop by postdocs
  - **Phase 3:** Continuing education led by PI
- Contact your Institution RCR Administrator for more information.



## Scientific Diving

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**Federal definition:** “Diving performed solely as a necessary part of a scientific, research, or educational activity by employees whose sole purpose for diving is to perform scientific research tasks.” Does not include tasks associated with commercial diving such as rigging heavy objects underwater, inspection of pipelines, construction, demolition, cutting or welding, or the use of explosives.

OSHA 1910 Subpart T, Commercial Diving Operations, Appendix T, Guidelines for Scientific Diving. - Scientific Diving is exempt from OSHA Commercial Diving requirements when:

1. The Diving Control Board consists of a majority of active scientific divers and has autonomous and absolute authority over the scientific diving program operations.
2. The purpose of the project using scientific diving is the advancement of science; therefore, information and data resulting from the project are non-proprietary.
3. The tasks of a scientific diver are those of an observer and data gatherer. Construction and trouble-shooting tasks traditionally associated with commercial diving are not included within scientific diving.
4. Scientific divers, based on the nature of their activities, must use scientific expertise in studying the underwater environment and, therefore, are scientists or scientists in training.

## Scientific Diving

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ASU maintains an institutional membership in the [American Academy of Underwater Sciences](#) (AAUS), which has established standards and certification requirements for scientific diving.

Under ASU policy [RSP207](#) and federal regulations, all research and related activities involving underwater diving for which ASU is a responsible participant, regardless of whether the activity will receive funding or not **must** adhere to these standards.

Contact your Institution Scientific Diving responsible party (Diving Control Board, Diving Safety Officer) for more information.



# International Research, Research Security and Export Controls

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# Research Security

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Over the past years higher education has experienced increased activity and scrutiny related to issues of foreign influence in academia. Many federal agencies have issued new requirements and guidance and Congress has signed new legislation on now we have to change how the research community performs internationally.

The federal government has placed the burden on universities to take measure to strengthen protections of U.S.-supported research and development against foreign government interferences and exploitations.

The university system is decentralized resulting in challenges when developing and implementing compliance programs, coordinating operations and representing the institutional perspective.



# The Solution

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Create a team of individuals authorized to centralize institutional research compliance activities which would enable the university to focus on compliance efforts and to reduce faculty time spent on administrative tasks.

The Institutional Compliance & Regulatory Affairs (ICRA) team was created approximately one (1) year ago to address these issues.

ICRA provides support in the following areas:

- Export Control
- Research Security
- Misconduct in research
- Foreign influence
- Institutional Certifications
- Responsible Conduct in Research



# Responsibilities as Employees of Public Institutions

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We are public universities, and we are public servants.

Everything we do as part of our job is potentially discoverable and is something that government agencies and law enforcement can subpoena.

This includes travel records, emails, financial interactions, texts on a device that you receive university support for, or that has university encryption (phones, laptops) - any transactions, particularly with an international partner.

By far the best thing we can do to make sure we are never in any danger of having our actions misinterpreted is to completely disclose and all interactions we have or intend to have with international organizations.



**OPENNESS AND TRANSPARENCY ARE KEY!**

# Export Control and Research Security

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Why do we have Export Controls?

Objective – to protect U.S. national security and foreign policy interests by:

- Preventing terrorism
- Restricting exports of goods and technologies that may contribute to military potential of foreign adversaries
- Protecting loss of goods and key technologies that could affect the U.S. economy

## What is an Export?

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### Definition:

- An export under the regulations is any shipment, transmission or transfer of controlled physical items, information or software, or technical data to foreign persons in the US or abroad without an export license or exemption.
- Transmission including by phone, fax, email and conversation are considered an export to the home country of a foreign person.

# Export Control Laws

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United States Export Controls governed by 3 principal sets of regulations

- **U.S. Department of Commerce**
  - Export Administration Regulations (EAR) – dual use (civilian or military) technology
- **U.S. Department of Treasury**
  - Office of Foreign Assets Control (OFAC) – sanctioned countries controls
- **U.S. Department of State**
  - International Traffic in Arms Regulations (ITAR) – military

# Export Control and Tri-University Researchers

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We are public universities, and we are public servants.

Most research activities (over 90%) performed are fundamental in nature and are not controlled by the export regulations.

Applies to both funded and unfunded research.

Application of export controls is specific to the project.

Export controls are the law of the land and we must ensure that we can demonstrate due diligence in protecting what needs to be protected.

Consequences of non-compliance with export control laws and regulations can be severe. Criminal and Civil penalties – prison time and monetary fines.





# Changing times

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August 2018 - NIH issues letter to grantees on foreign influence concerns

March 2019 - Dept. of Defense issued memo for the protection of Intellectual Property

June 2020 - NSF updates disclosure requirements

July 2020 - NSF shared first details on foreign influence investigations

January 2021 - NSPM-33 posted for strengthening research security

May 2021 - NIH conflict of interest disclosure requirements updated

## Context: In the News

November 2022 - •Ohio State University pays over \$875,000 to resolve allegations of failure to disclose professor's Foreign Government support.

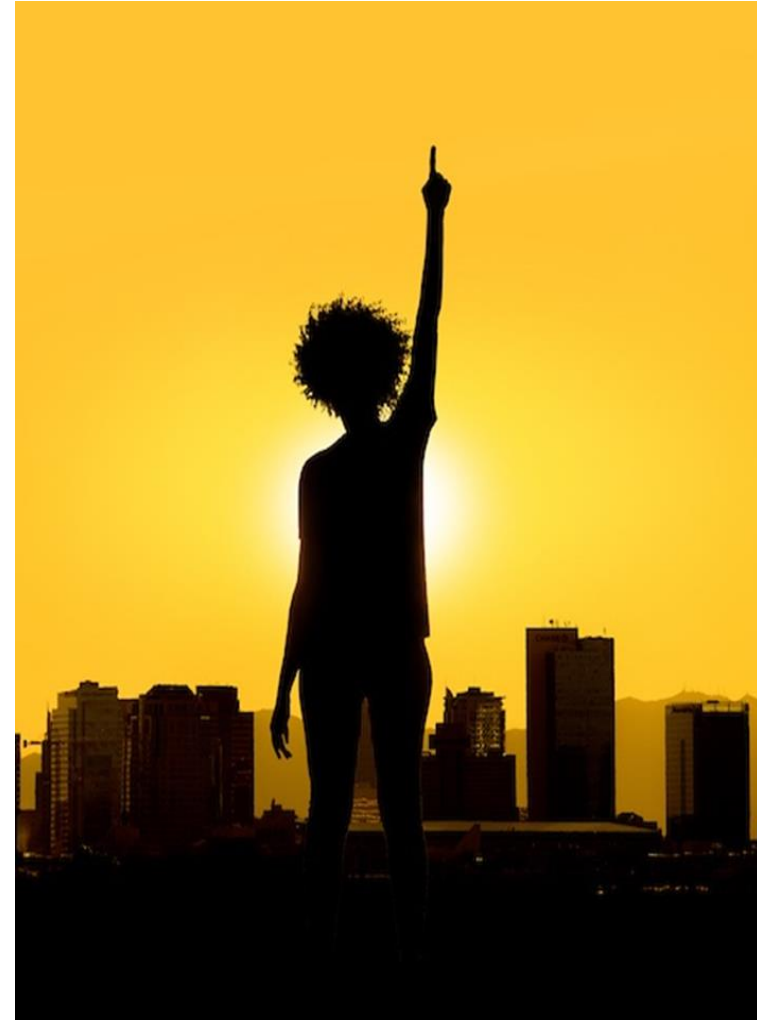
June 29, 2023 – University of Oklahoma Professor and wife sentenced to prison for federal grant fraud.

October 02, 2023 – Stanford University agrees to pay \$1.9 Million to the DOJ to resolve allegations of failure to disclose foreign research support in federal grant proposals.

# Best practices

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- Ensure reporting of all external funding relationships to research sponsors and ASU. This includes financial interests in any foreign entities. Contact the Office of Research Integrity and Assurance (ORIA) at [Research.Integrity@asu.edu](mailto:Research.Integrity@asu.edu).
- Appointments or positions at other institutions, inside or outside the US, need to be disclosed and approved.
- At time of proposal development, include descriptions of foreign collaborators. Review funding announcements for required disclosure information.
- Report Conflicts of Interest (COI) in MyDisclosures ERA COI portal.
- Ensure agreements are in place for material transfers, data sharing, and sharing of confidential information.



# Resources

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Emails and links:

- Export Control Questions:

[export.control@asu.edu](mailto:export.control@asu.edu)

- Export Controls and Security:

<https://researchintegrity.asu.edu/export-controls-and-security>

- Export Controls and Security: regulations and resources:

<https://researchintegrity.asu.edu/export-controls-and-security/regulations-and-resources>

- International Collaboration and engagement:

<https://researchadmin.asu.edu/resources/international-research-global-collaborations/international-engagement/>



## Who Can Help Me with Compliance – Finding the Right Folks



Knowledge Enterprise

### Research Integrity and Assurance



Human Subjects

Animals

Biosafety

Conflicts of Interest

Export Controls

Responsible Conduct

Scientific Diving

About

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## About the Office of Research Integrity and Assurance

The Office of Research Integrity and Assurance is dedicated to the mission of moving research forward while complying with regulations and protecting the safety of participants and personnel. Utilizing their unique talents, skills, and perspectives, the team maintains a dynamic and innovative approach to ASU's philosophy of compliance as a service.

Contact us by e-mail at [research.integrity@asu.edu](mailto:research.integrity@asu.edu) or by phone at 480-965-6788.

<https://researchintegrity.asu.edu/about>

# QUESTIONS



# Thank You!

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

