Welcome Packet

Research Compliance
https://researchcompliance.asu.edu/

Welcome to Research Compliance

We're delighted to welcome you to the Office of Research Compliance, part of ASU's Knowledge Enterprise. Our office was created to better serve the research community while aligning closely with the broader Academic Enterprise.

Our key responsibilities include:

- Monitoring applicable federal laws, regulations, and guidance.
- Reviewing and updating programs, processes, and training to ensure compliance.
- Providing training for faculty, staff, and research support personnel.
- Conducting audits to evaluate compliance within university research activities.
- Supporting compliance committees that address regulatory and ethical aspects of research.

The Office of Research Compliance brings together activities that uphold ASU's commitment to conducting ethical, responsible, and legally compliant research. This integration combines the expertise and responsibilities of two former units: Institutional Compliance and Regulatory Affairs (ICRA) and the Office of Research Integrity and Assurance (ORIA).

We look forward to supporting you in a meaningful and enriching experience—both in your professional growth and in fostering a strong culture of compliance.

This packet will help guide you through your Research Compliance journey.

The Office of Research Compliance

This office was established to strengthen support for the research community, foster a culture of compliance and ensure alignment with the broader goals of the Academic Enterprise. It administers key research compliance committees and oversees the development and implementation of training programs that promote the responsible conduct of research across the university. Contact Research Compliance if any of the following will be used or apply to your research:

- Human Subjects Research Compliance - Oversight of IRB-regulated research involving human participants.
- Animal Research Compliance - Oversight of IACUC-regulated research involving animal subjects.
- Biosafety Research Compliance - Oversight of research involving biohazards, recombinant DNA, and DURC.
- Conflict of Interest Compliance- Management of financial and personal conflicts in sponsored research.
- Conflict of Commitment Assistance - Support units and investigators completing pre-approval requests and advising units on current and pending/other support disclosure requirements.
- Responsible Conduct of Research (RCR) Training - Administration of federally mandated ethical research training programs.
- Scientific Diving Compliance - Oversight of OSHA-regulated scientific diving activities.
- Radiation Safety Support - Coordination of research radiation compliance with EHS partners.
- Native American Cultural Review - Facilitation of tribal research approvals in alignment with ABOR policy.
- Research Misconduct - Oversight and investigation of research misconduct allegations.
- Research Security & Export Control Compliance - Oversight of federal compliance related to export controls and foreign influence in research.
- Organizational Conflicts of Interest (OCI) - Guidance on organizational conflicts in sponsored research proposals.
- Institutional Certifications - Management of institutional certifications required for research compliance.

For general information and resources related to research compliance, please visit our website:
https://researchcompliance.asu.edu/

Human Subjects Research Compliance (RIA)

- Ensures compliance with all research involving human subjects, in accordance with federal regulations.
- Reviews research studies, advises researchers, conducts Institutional Review Board (IRB) meetings, provides training, and maintains IRB records.

All ASU and research involving humans as subjects **must** be reviewed and approved by ASU's IRB before implementing studies, including recruitment and screening activities. The role of the IRB is to review proposed research involving human subjects to ensure that subjects are treated ethically and that their rights and welfare are adequately protected. The IRB is supported and administered through the Office of Research Compliance.

What activities are considered human subject research requiring review?

IRB review is required if the study involves human subjects and meets the definition of research.

A human subject is defined as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information." This definition can include the collection of data using online surveys, social media, analysis of secondary data/archived data, interviews, etc.

Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

How do I submit to the IRB?

Studies are submitted electronically via ERA (https://era.oked.asu.edu), an online portal where an investigator can upload their protocol (summarizing their procedures) and supporting materials (consent forms, recruitment materials, survey instruments/ interview questions, site permissions, etc.)

Step by Step instructions can be found on the IRB website: researchcompliance.asu.edu/human-subjects/protocol- submission. Human subject forms and templates can be found at: researchcompliance.asu.edu/human-subjects/forms

What are the training requirements?

- Study teams involved in human subjects research must complete an IRB course at www.citiprogram.org Researchers conducting clinical trials must complete Good Clinical Practices (GCP) course in addition to the IRB course.
- Training requirements are outlined within researchcompliance.asu.edu/human-subjects/training is good for 4 years for the IRB course and 3 years for the GCP course.

How long does it take to obtain IRB approval and begin my research?

Approval times may vary depending on the type of research that is being proposed. The convened IRB meets monthly at ASU for the highest-risk studies. Submissions that meet the criteria for exempt or expedited review are reviewed on a daily basis. Please be prepared to start early if you are working on a deadline.

Contact: asuirb@asu.edu or call (480) 965-6788 Additional information can be found on our website at researchcompliance.asu.edu/human-subjects

Animal Research Compliance (RIA)

- Oversees research involving animals under federal regulations.
- Reviews animal use protocols, advises researchers, collaborates with the Department of Animal Care (DACT) and Environmental Health & Safety (EHS), supports Institutional Animal Care and Use Committee (IACUC) meetings, and maintains IACUC records.

ASU's Animal Care and Use Program provides animal housing, husbandry, and veterinary care; trains researchers on safe and ethical procedures; and ensures compliance with federal, state, and university regulations. The IACUC oversees a compliant and humane animal care and use program that supports the research and teaching programs of our researchers, instructors, and students; as well as activities and events on campus involving animals.

ASU's Position on the Importance of Animal Study in Research

ASU conducts research of vital interest to society and the health and welfare of individuals. Some of that research is devoted to advancing health care and finding cures for diseases such as cancer, diabetes, Alzheimer's, Ebola, and heart disease. Animal research has played a major role in virtually every major medical advance in the last century and remains integral to biomedical progress. A study by the Department of Health and Human Services (DHHS) concluded that animal research has helped increase the life expectancy of humans by 20.8 years. Animal research is also crucial for advances in veterinary medicine and wildlife conservation, both of which depend on improvements in our understanding of animal behavior, ecology, physiology, pathology, nutrition, and stress responses. Millions of people and a similar number of animals would suffer or die unnecessarily if animal research were to cease.

Many Americans support the need for animal research aimed at medical advances. It is not possible to eliminate animal research altogether and still produce new or improved treatments for disease, including those for cancer, AIDS, and other diseases that the public at large have established as priorities. Similarly, the use of animals in research has been paramount to understanding animals in nature and thus enhancing efforts to conserve the planet and the species with which we share it. Man's influence on the planet cannot be eliminated, but, through a better understanding of the world around us derived in part from studies involving animal subjects, these impacts can be modified to minimize the negative effects.

How do I submit an IACUC protocol? How long does it take to obtain IACUC approval and begin my work?

The protocol forms can be downloaded from our website: researchcompliance.asu.edu/animals/forms. Email the completed forms in MSWord format to IACUC@asu.edu. A pre-review will be conducted by IACUC office staff to verify training requirements have been met and that the protocol is complete. The veterinarians on campus will then work directly with you during their review to address any questions, comments, or concerns they have. A member of the IACUC will be assigned as a reviewer before the meeting as well, and they too will work directly with you to address any questions, comments, or concerns they have.

The IACUC meets once a month to review protocols, and the submission deadline is 3 weeks before the meeting. With extensive reviews before the meeting, and by having the PI/lab representative present at the meeting, we strive to have protocols approved at the meeting, or shortly thereafter.

What are the training requirements?

To use any live vertebrate animals or cephalopods at ASU, all faculty, staff, graduate students, and undergraduate researchers must achieve certification in animal care and use training program (Level I Basic and Level II Species specific training; valid for 4 years) and receive clearance from the Occupational Health and Safety Program (on an annual basis).

Contact: Email IACUC@asu.edu, or call 480-965-6788 and select the option for animals. Information can also be found on our website at researchcompliance.asu.edu/animals.

Biosafety Research Compliance (RIA)

- Manages compliance for research involving recombinant or synthetic nucleic acid molecules, biohazards, select agents, toxins, and Dual Use Research of Concern (DURC).
- Conducts protocol reviews, advises researchers, collaborates with EHS Biosafety Officers, conducts training, supports Institutional Biosafety Committee (IBC) meetings, and maintains IBC records.

The Institutional Biosafety Committee (IBC) is responsible for the review and oversight of research or teaching conducted under the auspices of Arizona State University that utilizes recombinant or synthetic nucleic acid molecules, biohazards or infectious agents, select agents or toxins, or dual use research of concern (DURC).

The IBC has established and implemented policies and procedures to provide for the safe and ethical conduct of research and teaching activities involving all biohazards and to facilitate compliance with the National Institutes of Health's Guidelines for Research or Synthetic Nucleic Acid Molecules, and other universities, sponsor, federal, state, and local laws and regulations.

The IBC is supported and administered through the Research Compliance Office. Environmental Health & Safety's (EHS) Biosafety and Biosecurity unit supports the IBC through training, expertise, and laboratory inspections. In working together, we are committed to supporting ASU's culture of safety.

Does my research require an IBC disclosure?

Research involving the following materials will require an IBC disclosure:

- Human, animal, and plant pathogens including bacteria, bacterial toxins, parasites, fungi, viruses, rickettsia, prions.
- Select agents or toxins.
- All human or non-human primate blood, blood products, tissues, and certain bodily fluids.
- Cultured human cells and potentially infectious agents these cells may contain.
- Infected animals, their tissues, and bodily fluids.
- Recombinant or synthetic nucleic acids as defined by the NIH Guidelines on section I-B.
- Transgenic or genetically modified animals.

How do I submit an IBC disclosure?
Disclosures are submitted electronically via ERA (https://era.oked.asu.edu), an online portal where an investigator inputs information related to their proposed research, and upload accompanying documents as necessary. The accompanying documents can be downloaded at researchcompliance.asu.edu/biosafety/forms.

How long does it take to obtain IBC approval and begin my research?
Approval times may vary depending on the type of work that is being performed. The IBC meets on the second Thursday of every month to review IBC disclosure submissions. Plan to work closely with the Research Compliance IBC Staff, EHS, and the Committee to secure approval. Turnaround times for disclosure approvals vary but are usually around a month. Be prepared to start early if you are working on a deadline.

Contact: Email IBC@asu.edu, or call 480-965-6788 and select the option for biosafety. Information can also be found on our website at researchcompliance.asu.edu/biosafety.

Conflict of Interest (COI) Compliance (RIA)

- Ensures compliance with federal COI regulations for sponsored research.
- Reviews financial disclosures, manages potential conflicts, advises researchers, conducts training, supports Intellectual Property Institutional Review Committee (IPIRC) meetings, and maintains compliance records.

The COI policies, processes, and systems to declare financial or other relationships with outside entities ensure compliance with all university, sponsor, ABOR, federal, state, local laws and regulations and are effective in not creating situations that are, or appear to be, in conflict with the values of free and unbiased inquiry.

I completed all COI training and disclosure requirements at my previous institution. Do I have to redo everything at ASU?
Yes. Investigators must complete the ASU-specific training and disclosure requirements.

How often do I have to complete the disclosure process and training if required?
Regulations require disclosure at the time of proposal submission, at the time of award, and within 30 days of any changes to financial interests or outside business activities. COI training for investigators receiving sponsored project funding is required at least every four (4) years.

How do I make a disclosure?
There is a single reporting system through the Enterprise Research Administration System (ERA) called "MyDisclosures". Reminders to complete and/or update your Disclosure profile are sent by ERA when a project is awarded, but new disclosures can be added at any time.

How do I access COI Training?
COI training can be found at https://researchcompliance.asu.edu/coi/training-information/. The system will automatically record training completion for our records.

How do I get cleared for conflicts of interest to start spending on an award?
Before an award is cleared for activation, the compliance team will review financial disclosures and verify COI training for all investigators. Reminders with instructions will be sent to investigators regarding any outstanding requirements.

Contact: COI@asu.edu

Responsible Conduct of Research (RCR) Training Program (RIA)

- Administers RCR training in alignment with federal requirements for ethical research conduct.
- Provides online and in-person training, sponsors workshops, and maintains records for NSF-funded personnel, postdocs, and students.

Fostering a culture and expectation of responsible and ethical conduct of research is a critical component in the advancement of knowledge through research and scholarship. It is also a key element in the maintenance of public trust in the research enterprise. ASU is committed to the highest quality education for all students and scholars, and RCR instruction is essential to producing the best scientists and researchers for the future.

Who has to take RCR training?
All students and postdocs on sponsored research projects must complete RCR training. The National Science Foundation requires all investigators and senior personnel to receive awards to complete RCR training as well.

How is the RCR training requirement satisfied?
Students and postdocs can log into CITI to complete online training. Postdocs must also attend a workshop and complete ongoing training with their PI.

If I have taken RCR training at another institution, does that satisfy the ASU requirement?
No. Some CITI training modules, however, may be transferable. CITI Support can assist with account affiliation.

Is IRB training the same as RCR training?
No. RCR training is distinct from IRB training. IRB focuses on human subject protections and related policies, while RCR covers broader topics, meeting the federal RCR training requirements.

Contact: RCR@asu.edu

Research Security & Export Control Compliance (ICRA)

- Oversees export control and research security compliance.
- Oversee compliance with federal regulations related to undue foreign influence in research, including disclosures and risk management.
- Conducts screening, manages Technology Control Plans, reviews foreign travel, international collaborations, and reviews for international material transfers for export controls and prepares export control related proforma invoices related to international shipping.
- Provides export control training and liaises with government agencies.
- Manages Facility Security Clearance and Insider Threat Program requirements, including security briefings, foreign ownership control reporting, and coordination with law enforcement.

Protecting ASU research activities from misappropriation of research to the detriment of national or economic security, violations of export control regulations and research integrity, and undue foreign influence in research.

ASU's Research Security position can be found here.

What is ASU's Research Security Program?
As a *Covered Institution,* Arizona State University's Research Security Program aligns with the requirements of National Security Presidential Memorandum 33 (NSPM-33) and the Office of Science and Technology Policy (OSTP) *Guidelines for Research Security Programs at Covered Institutions* (July 9, 2024). ASU's Research Security Program addresses risks related to cybersecurity, research security training, export controls processes and training, and foreign travel security.

Who has to take Research Security training?
Research Security training is critical to protecting federally funded research activities from misappropriation of research to the detriment of national or economic security, violations of research integrity, and undue foreign influence in research. Annual Research Security Training for all "covered individuals" or "Senior/Key Personnel" on DOE, NSF, NIH, NASA, and USDA proposals, and other federal proposals/awards as required is mandatory. Covered individuals will be required to certify completed research security training within the 12 months prior to the proposal submission date and recertify annually in awards (as required by the sponsor). ASU Research Compliance currently offers Research Security training that meets federal training requirements, and we encourage you to take this **now.**

The instructions on how to access Research Security training are below:

1. Log into your CITI account with your ASURITE at CITI Program
2. After you're logged in, scroll down to "Add a Course."
3. Select the **Research Security** category.
4. Choose **"Research Security Training (Combined)"** to complete the 1-hour training.

What are export controls?
Export control regulations are federal laws that restrict the export of information, goods, technology and services to foreign nationals, within and outside of the United States, and to federally sanctioned countries and countries of concern. In addition to assisting with licenses that may be required for items carried/information shared during foreign travel, the KE Research Compliance Export Control Team members work directly with researchers to ensure project activities align with applicable federal export laws and regulations. If export

controls are found to apply to ASU research activities, they assist researchers with the development of required technology control plans (TCP), monitor TCP implementation for compliance, and provide export control training and guidance to TCP personnel. For more information see Research Security and Export Controls.

What are best practices related to foreign relationships and activities?
ASU faculty and staff who have such collaborations are required to be transparent and provide full disclosure of all funded and unfunded collaborations and affiliations as required by federal and state agencies, as well as ASU's policies. Refer to International Research and Global Collaborations and the International Research Compliance, and Security Checklist for all things related to international engagements.

Contact: export.control@asu.edu

Additional Research Compliance Areas

Scientific Diving Compliance (RIA)

- Verifies compliance with OSHA regulations for underwater research.
- Supports the Diving Control Board (DCB), provides guidance, and hosts program information on the Office of Research Compliance website.

Radiation Safety Support (RIA)

- Supports radiation safety compliance for research involving radiation, governed by OSHA and federal rules.
- Reviews compliance in collaboration with EHS Radiation Safety Office (RSO) and Radiation Safety Committee; records are maintained by RSO.

Native American Cultural Review (RIA)

- Facilitates compliance with ABOR Policy 1-118 for IRB studies involving Native American communities.
- Coordinates with ASU's Office of American Indian Initiatives (OAII), tracks approvals, and hosts relevant information online.

Combating Trafficking in Persons (CTIP) (RIA)

- Provides resources and guidance on federal CTIP compliance for research projects.
- Offers plan templates and advice as needed; Principal Investigators (PIs) and units manage compliance.

Code of Business Conduct and Ethics (RIA)

- Shares resources on ASU's Code of Business Conduct and Ethics, as required by ASU policy and federal regulations.
- Maintains access to manuals and policies on the Office of Research Compliance website.

Organizational Conflicts of Interest (OCI) (RIA)

- Advice on organizational conflict of interest matters related to sponsored research proposals and compliance with sponsor requirements.

Research Misconduct (ICRA)

- Oversees allegations of research misconduct in accordance with federal regulations.
- conducts investigations and manages reporting requirements.

Institutional Conflicts of Interest (ICRA)

- Manages potential conflicts between the university's institutional interests and its research activities.

Institutional Certifications (ICRA)

- Manages various institutional compliance certifications required for research activities.

Contact: research.integrity@asu.edu