OFFICE OF RESEARCH COMPLIANCE,
INTEGRITY AND SAFETY

ANNUAL REPORT 2022



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# Office of Research Compliance, Integrity, and Safety

The Office of Research Compliance, Integrity, and Safety (ORCIS) helps researchers and the University as a whole, achieve and maintain ethical principles, while also maintaining compliance with federal, state and university regulations governing research.  In FY22 ORCIS contributed to the NIU community in a meaningful and dedicated manner. The compliance boards (IRB, IACUC, and IBC) handled 752 research applications, 56 in person training sessions were held, and over 1765 online trainings were completed. As NIU’s research portfolio continues to grow, ORCIS is adapting to best serve our outstanding faculty and student researchers.

# Compliance

Dr. Patricia Wallace, Research Compliance Coordinator, and Lene Scherer, Research Compliance Analyst mange research compliance for ORCIS. They are primarily responsible for human subjects research and animal research. Biosafety research falls into the compliance category as well but, will be addressed in the safety portion of this report.

## Human Subjects Research

### Applications

In FY22, the Compliance group assisted with 820 unique submissions for human subjects research to the Institutional Review Board (IRB). Of these, 327 were considered initial submissions, 168 were continuations of existing records, 183 were amendments to existing records, and 142 were final reports (to close a protocol record).

The applicants are a mixture of faculty, graduate students, and undergraduate students. Staff analyze every submission and sort them into the proper review category. Notices of expiration dates and required renewals are also monitored and sent to researchers.

#### Number and types of submissions included:

* Initial Submissions (new proposals)
	+ Exempt: 118
	+ Expedited: 171
	+ Full Board: 16
	+ Collaborative Agreements: 11
	+ Screening Forms: 5
* Continuation Submissions (proposals that require additional time)
	+ Administrative Review: 162
	+ Member Review: 4
	+ Full Board Review: 2
* Amendment Submissions (proposals with changes)
	+ Administrative Review: 74
	+ Member Review: 108
	+ Full Board Review: 1

### Training

In FY22, the compliance office offered approximately 15 training sessions.

#### Types and number of trainings included:

* Authorized Departmental Reviewer (ADR) trainings
	+ General sessions (online recording): 1
	+ Individual sessions: 0
	+ Department Sessions: 1
	+ Total trained: Approximately 100
* Student Trainings (approximately 250 trained)
	+ Online: 3
	+ In-person: 8
* Faculty Staff Trainings (approximately 30 trained)
	+ Online: 1
	+ In-person: 1
* New IRB Member trainings: 2
* Citi Online trainings
	+ Initial/Refresher IRB training (including IRB member training): 865
	+ Social and Behavioral Responsible Conduct of Research: 71
	+ Students (no more than minimal risk): 334

### Potential Non-Compliance

In FY22, there were 4 complaints raised of possible instances of non-compliance. Each allegation was assessed by the Research Compliance Coordinator, ORCIS Director, and Chair of the IRB. It was determined that none of the allegations rose to the level of serious noncompliance. Three were found to be compliant. One was found to be non-compliant and was advised next steps in accordance with the IRB’s determinations. It should be noted one of the complaints was a self-complaint.

### Policy Development

The external research recruitment policy was made effective. This is for external researchers who would like to utilize NIU students, faculty, or staff to collect research data. In the past, external researchers would directly contact departments, but now they are directed to a system that provides instructions for recruiting NIU participants.

### Additional Activities

The Research Compliance Coordinator (RCC) provided a presentation on research with human participants as part of the Responsible Conduct of Research graduate student program. The RCC also demonstrated the use of the InfoEd Data Management System as part of a day-long Chemistry program. In addition, the RCC is working to develop materials and processes that will facilitate the development of projects involving broad consent (creation of a consent process to allow identifiable data to be used for future projects).

### Professional Development

In FY22 the Research Compliance Coordinator attended the virtual PRIM&R Advancing Ethical Research Conference and served on the poster review committee for the 2022 PRIM&R Annual Conference.

## Animal Research

### Submissions

ORCIS houses the Institutional Animal Care and Use Committee (IACUC), which approves animal research preformed at NIU. This year the IACUC saw 50 unique submissions.

#### Number and types of submissions included:

* Initial Submissions: 5
* Continuations: 18
* Triennials: 4
* Amendments: 19
* Final Reports: 4

Applicants are predominantly faculty. NIU has 2 animal laboratories where most of this research is preformed; however, seven of the submissions are for field animal research. ORCIS analyzed and processed every application and provided notice of all expirations and required renewals.

### Inspections

The U.S. Department of Agriculture (USDA) preforms one un-scheduled inspection on an annual basis. ORCIS assists the inspector by providing all the files, touring the facilities, and answering questions. The IACUC also preforms two semi-annual scheduled inspections.

### Reporting

ORCIS is responsible for all required animal reporting, this includes filing papers with the Drug Enforcement Administration, USDA, Food and Drug Administration, and our Office of Laboratory Animal Welfare assurance.

### Training

In FY22, ORCIS offered a variety of annual training options to fulfill the training requirements of animal researchers and the members of the IACUC. Researchers are expected to participate in online Collaborative Institutional Training Initiative (CITI) Training.

Types of training and number of participants included:

* IACUC annual member training: 7
* Online CITI trainings completed: 51
* Annual online training session: 24

## Research Integrity

ORCIS is responsible for research integrity, and those responsibilities evolve as new research requirements arise from the federal government and other agencies. Shannon Stoker, Director of ORCIS, is responsible for research integrity policies and policy implementation.

### Export Control

Federal export control regulations pertain to the export, transfer or transmission of certain commodities, software, technology, and technical information from the United States to foreign destinations or to foreign nationals on U.S. soil.

Ensuring compliance involves several activities, including screening individuals against restricted parties lists, assisting faculty and staff who wish to travel abroad specifically if they carry NIU property, and assessing situations involving federal funding and nationalities.

#### In FY22:

* A total of 1688 people and companies were screened against restricted parties lists, although escalation review and administration lie with ORCIS, the screening is a joint effort between ORCIS, Sponsored Programs Administration (SPA), and Procurement.
* Approximately 500 people and companies were screened against Restricted Parties Lists in an ad-hoc scenario. (Partner screening occurs daily; ad hoc screening occurs once (annually?).)
* A total of 119 travel applications were assessed for export control concerns

Thirty-Six funding applications involved an export control assessment

### Data Management

The sharing of data between organizations calls for an agreement between parties. These agreements are screened by ORCIS and signed by the VP Research. Five agreements were screened in FY22.

This included signing NIU up for access to the All of Us Research program, a database of health information and statistics, which can potentially be used by a significant number of users.

### Foreign Influence

The federal government has a growing concern for foreign influence and theft of intellectual property by foreign states and has requested universities take a proactive role in combating this threat.

ORCIS is continuing to develop programs to educate the NIU community on the threat of foreign influence and is active in implementing guidance from the federal government. ORCIS represents NIU on the Academic Security & Counter Exploitation Program, which is a consortium of universities developing tools to combat undue influence. Further development of the program is an FY23 goal.

### Conflicts of Interest

Institutions receiving Public Health Services (PHS) funding must monitor their Principal Investigators for possible Conflicts of Interest (COI) through a proactive policy. In FY22, ORCIS received 13 disclosures from 13 PHS funded projects. The training is required every four years and ORCIS offers this training through the CITI online modules. In FY22, 15 individuals took the training, and The Department of Energy (DOE) recently expanded their requirements to mimic the PHS requirements and ORCIS is expanding the current COI to ensure compliance. Beyond the DOE, ORCIS is working with SPA to expand the COI program to researchers with all additional funding agencies to better protect the university and researcher. This is an FY23 goal.

### Responsible Conduct of Research

ORCIS is responsible for monitoring and providing training in the Responsible Conduct of Research (RCR). This service is provided 2 different ways. The first is traditional trainings direct from ORCIS, which includes mandated trainings for students who receive NSF grant funding. In FY22, ten graduate students who required RCR training completed the course.

#### Training types and number of participants included:

* In person:
	+ Classroom sessions:
		- Two sessions for Graduate Professionalism involving approximately 40 individuals
		- Four sessions for Graduate Ethics (Chemistry involving approximately 60 individuals
* Online:
	+ Citi – 95 Individuals

ORCIS also provides RCR training is in conjunction with the Graduate School. Both offices work together to provide a forum series opened to all but geared toward graduate students. In FY22, ten training sessions were offered.

#### Training topics and number of individuals severed are as follows:

* Mentoring – 34 attendees
* Collaborative Research – 18 attendees
* Animal Care and Use - 6 attendees
* Conflicts of Interest - 26 attendees
* Peer Review – 23 attendees
* Authorship and Publication - 29 attendees
* Research Misconduct - 39 attendees
* Data Management – 29 attendees
* Human Subjects – 20 attendees
* Laboratory Safety - 15

Additional attendees may have been present, but their attendance is not counted if they are not participating. Attendees participate by contributing to a message board about the topic. Attendance (and participation) in 6 of the ten topics listed above within 2years earns a graduate student transcript notation. Ten transcript notations were awarded in FY22.

### Research Misconduct

NIU strives for the highest level of research integrity. As mandated by the federal Office of Research Integrity, NIU has a Research Integrity Officer. This role is currently fulfilled by Shannon Stoker. In FY22, there were 3 allegations of research misconduct. After an initial review determined that none of the allegations fell under research misconduct, instead all were potential non-compliance with IRB policies. This resulted in 0 instances of research misconduct.

While this number should be celebrated, it is still a requirement that ORCIS staff stay current on rules and regulations regarding research misconduct so that NIU is prepared for any allegations. Time was devoted to ensuring policies and procedures are active and compliant with federal regulations. NIU is an active member in the Association of Research Integrity Officers.

### COVID-19 Efforts

ORCIS was responsible for all COVID-19 reporting at the Fermilab national laboratory, which required weekly reporting and coordination with Principal Investigators (PIs) and the President’s Office. Five PIs reported their presence at Fermilab over the course of ten weeks.

### Professional Development

The ORCSI director attended the Council on Government Relations conference June 2022 as well as the workshop series on Export Control Spring 2022, and

the workshop series on Responsible Conduct of Research topics Fall 2021.

## Safety

### Laboratory Safety

NIU has 220 teaching and research laboratories on the DeKalb campus. The laboratory safety team includes Dr. Michele Crase, Laboratory Safety Manager, and Jim Gable, Laboratory Safety Officer. Laboratory Safety includes chemical, biological, radiological, and physical hazards present in laboratory or field research. Various committees oversee portions of laboratory safety. Federal and state regulations require specific committees focus on specific hazards.

### Laboratory Safety Committee

Laboratory Safety Committee (LSC) is housed within ORCIS. , and is comprised of representatives from university staff, and faculty. The LSC met six times in FY22, and implemented policies and procedures related to laboratory safety.

The LSC also receives requests related to safety in the laboratory. In FY22, the LSC received one request related to fume hoods. As a result, the Fume Hood Task Force was initiated, and analyzed all fume hoods on campus and submitted a report with recommendations to the VPR in May 2022.

The LSC is responsible for reviewing and developing recommendations for accidents, in FY22 there was one minor accident reviewed and one major accident reviewed. The investigation for the major accident is mentioned below.

### Investigation

The major accident required an investigation, which was led by. ORCIS. During the investigation, ORCIS assembled a committee, conducted interviews, looked at best practices, examined the laboratory, and considered the lab’s history of incidents. Following the investigation, the committee drafted recommendations to limit future incidents, that was sent to the college.

### Training

#### General laboratory safety training includes:

 Hybrid in-person/remote trainings offered:

 Department Sessions: 5 sessions

* Biology: approximately 80 individuals
* Chemistry: approximately 50 individuals
* Physics: approximately 40 individuals
* Engineering: approximately 60 individuals
* Psychology: approximately 10 individuals
* Geology: approximately 30 individuals

 Classrooms:

* Chemistry (4 classes per year): approximately 80 individuals
* Engineering (4 classes per year): approximately 80 individuals

 Online Trainings:

Citi: 77

Training participants included faculty, graduate, and undergraduate students.

#### Training topics and number of participants included:

* Building Service Workers Lab safety awareness, online with 27 attendees
* Bloodborne Pathogen for Physical Therapy and Audiology Student, in person with approximately 80 attendees
* Radiation Safety Initial Training, in person with approximately ten attendees and online with 20 attendees.

### Waste Disposal

NIU operates under the Academic Laboratory Rule Subpart K, a specific regulatory area defined by the Environmental Protection Agency. In FY22 ORCIS completed the following disposals:

Hazardous Waste: 5728 pounds

Nonhazardous Waste: 7259 pounds

### Institutional Biosafety Committee (IBC)

IBC is housed within Compliance but is managed by the Laboratory Safety Manager and is mandatory to perform this research at NIU The Committee must review all research that uses recombinant DNA, any infectious substance, select biologic agents, human blood, bodily fluids, or any known biohazard. In FY21, the IBC saw 29 unique submissions.

Types of submissions included:

* Initial Applications: 1
* Continuations: 15
* Triennial reviews: 11
* Amendments: 1
* Final Reports: 2

### Radiation Safety

NIU researchers utilize radioactive materials and x-ray machines, which requires compliance with the Illinois Emergency Management Agency (IEMA). ORICS is responsible for monitoring and testing instruments. In FY22 the following radiation safety actions were taken:

* Leak testing: 16 radioactive sources tested
* Irradiator alarm testing: quarterly alarm tests
* Laboratory radiation: 32 surveys
* Instrument collaboration: 17 instruments
* Radiation safety dosimeter badges and rings: 12 people monitored
* Badges and rings utilized: 96
* Shipped 177 lbs. of low-level radioactive waste for disposal
* Shipped 50 lbs. of mixed radioactive waste for disposal

Radiation Safety also involved The Radiation Safety Committee (RSC), which approves applications for research involving radiation. Applications are reviewed every two years. Currently, six researchers are authorized to use radioactive material in their research. NIU has 9 x-ray machines that are monitored for state regulatory compliance.

### Laser Safety Committee

NIU researchers also conduct research that utilizes lasers. The Laser Safety Committee meets once a semester to review laser usage. The lasers are inspected by representatives of the committee annually. Currently nine class 3B or class 4 lasers are monitored for state regulatory compliance.

### Internal Inspections

In FY22, the Lab Safety Officer inspected 125 labs housed within the Departments of Biology, Chemistry Engineering, and Geology. The Lab Safety Officer found approximately 150 violations of which were addressed and fixed by the departments.

### External Inspections

ORCIS assists with announced and unannounced federal and state inspections. The Illinois Emergency Management, Radiation Safety inspected NIU’s FY22 Radiation Safety Program.

### Electronic Storage

With the impending removal of the safety module in the InfoEd system, all the IBC materials and processes were replicated in the Lab Animal (IACUC) module. To make this work, IBC became a separate board in the Lab Animal module. All of the IBC protocols were re-created in the Lab Animal module, and all of the batch communications, routing materials, and workflow setups were doubled to accommodate the extra board.

### Professional Development

Dr. Crase attended Annual Campus Safety, Health, and Environmental Management Association Meeting (Indianapolis).

Dr. Crase attended training and certification for shipping dangerous goods such as chemicals and biologics.

Dr Crase earned her PhD and taught UNIV 600 Hazard Analysis in Academic Research and Artistry.

### Awards

Director Shannon Stoker won a Presidential Award for Excellence in Spring 2022

The Laboratory Safety Committee led by Josh Schwartz, won a CSHEMA Award for Innovation for the Field Work Safety program in Summer 2021

## Outreach

Beyond the responsibilities enumerated above, ORCIS is also a presence on campus. In FY22, Dr. Wallace taught 3 adjunct psychology courses, and Dr. Crase taught a graduate course on safety, Dr. Wallace and Ms. Stoker also served on the Presidential Commission on the Status of Women.

Dr. Wallace presented research at the American Society of Criminology (Nov. 2021) and the Association for Psychological Science (May 2022) and published a paper in the Journal of Gender and Women’s Studies (Oct. 2021). Dr. Wallace completed the following training: ACUE micro-credential in Teaching for Equitable Learning, the Ultra Transition Academy for Blackboard, and LGBTQI+ Ally Training. Dr. Wallace also served as a judge for NIU’s Psychology Undergraduate Research Conference and the campus-wide Conference on Undergraduate Research and Engagement.

Ms. Stoker published the lead article “The Flexible Future” in the August 2021 NCURA Magazine. She also completed the NIU LGBTQI+ Ally Training and served as the Community Relations subcommittee chair for the Supportive Professional Staff Committee.

External to NIU, Ms. Stoker is on the Association of Research Integrity Officers, education subgroup emphasis writing committee and the Society of Researchers International subcommittee Research Integrity.

## Conclusion and Outlook

ORCIS assists the NIU research community in a wide variety of ways. As a small office with large responsibilities, ORCIS is cross trained and assists each other often. Everything accomplished in FY22 has been a team effort.

ORCIS’ goal is always to support research and ensure NIU is complaint with all state and federal regulations. In FY23, the office hopes to develop the new software for laboratory safety, increase knowledge about research security (undue influence), create a new broader conflict of interest program, and increase the user-friendly modality of review board applications.