# OFFICE OF RESEARCH COMPLIANCE, INTEGRITY AND SAFETY

ANNUAL REPORT 2021

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Office of Research Compliance, Integrity, and Safety

The Office of Research Compliance, Integrity, and Safety (ORCIS) at NIU helps researchers and the University as a whole, achieve and maintain ethical principles and maintain compliance with federal, state and university regulations governing research.  In FY21 ORCIS contributed to the NIU community in a meaningful and dedicated manner. The compliance boards handled 915 applications, and approximately 2205 individuals took online training. As NIU’s research portfolio continues to grow ORCIS is adapting to best serve our outstanding faculty and student researchers.

COMPLIANCE

Compliance aspects of ORCIS are managed by Dr. Patricia Wallace, the Research Compliance Coordinator, and Lene Scherer, the Research Compliance Analyst. The two work together and 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 FY21, the Compliance group assisted with 832 unique submissions to the Institutional Review Board (IRB), which deals with human subjects research. Of these, 335 were considered initial submissions, 172 were continuations of existing records, 184 were amendments to existing records, and 141 were final reports (to close a protocol record). The breakdown is as follows:

* Initial Submissions (New proposals)
	+ Exempt: 111
	+ Expedited: 182
	+ Full Board: 11
	+ Collaborative Agreements: 13
	+ Screening Forms: 18
* Continuation Submissions (Proposals that require additional time)
	+ Administrative Review: 185
	+ Member Review: 10
	+ Full Board Review: 11
* Amendment Submissions (Proposals with changes)
	+ Administrative Review: 96
	+ Member Review: 112
	+ Full Board Review: 5
* The applicants are a mixture of faculty, graduate students, and undergraduate students. Every submission is analyzed and sorted into the proper review category by the staff. Notices of expiration dates and required renewals are also monitored and sent out.

**TRAINING**

In FY21, the compliance office offered approximately 13 training sessions.

The breakdown is as follows:

* Authorized Departmental Reviewer (ADR) trainings
	+ General sessions (online recording): 1
	+ Individual sessions: 0
	+ Department Sessions: 0
	+ Total trained: Approximately 100
* In-Person in class trainings
	+ Classroom trainings: 0
	+ Total trained: 0
* Online custom presentations
	+ Virtual classes: 11
	+ Total trained: Approximate 250
* New IRB Member trainings: 1
* Citi Online trainings
	+ IRB Member training: 51
	+ Initial/Refresher IRB training: 827

**ELECTRONIC SUBMISSIONS**

At the start of FY21, the Compliance Office had just moved the IRB application process to an online system. Throughout the year, the office provided documents, small online sessions, and individualized training to help users navigate the new system. Several brief videos were created and added to the website to help users with specific components of the submission process.

**COVID-19 EFFORTS**

Due to the pandemic, all face-to-face research was stopped during much of FY21. The Compliance team created guidance for the transition of face-to-face research to online research. When restrictions were lifted, they also provided guidance on resuming protocols and an online application for that process. Twenty-eight researchers submitted requests to conduct face-to-face data collection using guidance provided by RIPS.

**PAYMENT UPDATES**

ORCIS completed the process of updating the policy regarding research participant payments in FY21. The final draft of the policy was submitted to the policy library at the end of FY21. The updated policy provides more detailed information about the process of paying research participants including special circumstances, such as anonymous data collection and returning unused funds. In addition, efforts were made to amend the types of payments that could be reimbursed through university funds. The updated policy allows for reimbursement of gift card payments in addition to cash and electronic payments.

**EXTERNAL RESEARCH PROCEDURE**

In consultation with legal counsel, ORCIS is working on creating guidance to help external researchers who are seeking permission to access NIU students, staff, or faculty to serve as research participants. Between 5 and 10 requests are made each year, so clear guidance will be helpful for the external researchers and for any NIU contacts attempting to assist the external researchers.

**PROFESSIONAL DEVELOPMENT**

In FY21 the Compliance Coordinator attended the virtual Compliance and Law Track of the Society for Research Administrators Annual Conference (Oct 2021) as well as the AAAS Science and Technology Policy Forum (October 2021). The Compliance Coordinator also prepared for and passed the Certified IRB Professional Certification exam in April 2021 and now has the CIP credential demonstrating an advanced level of knowledge, understanding, and experience in human research administration.

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 54 unique submissions. The breakdown is as follows:

The breakdown is as follows:

* Initial Applications: 6
* Continuations: 22
* Triennials: 7
* Amendments: 12
* Final Reports: 7

Applicants are mainly faculty members. NIU has two animal laboratories where most of this research is preformed; however, eleven of the protocols are for field animal research. ORCIS analyzes and processes every application. They also provided notice of all expirations and required renewals.

**INSPECTIONS**

The USDA preforms one un-scheduled inspection yearly. ORCIS assists the inspector by providing all of the files, touring the facilities, and answering questions. The IACUC also preforms two semi-annual inspections.

**REPORTING**

ORCIS is responsible for all required animal reporting, this includes filing papers with the DEA, USDA, FDA, and our OLAW assurance.

**TRAINING**

In FY21 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 CITI Training. The breakdown is as follows:

* IACUC annual member training: 7
* Online CITI trainings completed: 18
* Annual training online session: 16

**FOIA ASSISTANCE**

NIU received one FOIA requests involving animal research, most were for records that ORCIS houses. We worked with General Counsel, the researchers, and the FOIA department at NIU to respond to these requests as required by law.

RESEARCH INTEGRITY

ORCIS responsibilities for research integrity involves several different topics. ORCIS responsibilities evolve as new requirements regarding research 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 denied 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 FY21:**

* A total of 376 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, SPA, and Procurement.
* 48 people and companies were screened against Restricted Parties Lists in an ad-hoc scenario. (Partner screening occurs daily; Ad hoc screening occurs once.)
* A total of 18 travel applications were assessed for export control concerns
* No funding opportunities involved an export control assessment
* Six contracts were reviewed for export control issues

**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. Three agreements were screened in FY21.

**CONFLICTS OF INTEREST**

Institutions receiving Public Health Services (PHS) funding must monitor their Principal Investigators for possible Conflicts of Interest through a proactive policy. In FY20 ORCIS received twelve disclosures from eleven PHS funded projects. The training is required every four years and ORCIS offers this training through the CITI online modules. In FY21, 24 individuals took the training.

In FY21 ORCIS began an overhaul of the university wide Conflicts of Interest policy. This is a joint effort with General Counsel and the Provosts’ offices. The new policy is still in draft form but a significant portion of the work was done in FY21, the new policy will allow for more disclosures and will protect the institution and researchers. It is a strong goal of ORCIS to see the policy activated in FY22.

**FOREIGN INFLUENCE**

The federal government has a growing concern for foreign influence and theft of intellectual property by foreign states. The government 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 government guidance. ORCIS represents NIU on the Academic Security & Counter Exploitation Program and attended several professional development sessions on this offered by a number of organizations including the FBI.

**RESPONSIBLE CONDUCT OF RESEARCH**

ORCIS is responsible for monitoring and providing training in the Responsible Conduct of Research (RCR). This service is provided two different ways. The first is traditional trainings direct from ORCIS. This includes mandated trainings by students who receive funding from NSF grants. In FY21, twenty-seven graduate students required RCR training and completed the course.

**The training comprises:**

* Classroom sessions:
	+ - One session for Graduate Professionalism involving approximately 20 individuals
		- Four sessions for Graduate Ethics Chemistry involving approximately 60 individuals
* Online:
	+ Citi – 132 Individuals

The second way ORCIS 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 FY21, ten training sessions were offered.

The training topics and individuals served follow:

* Mentoring – 51 attendees
* Collaborative Research – 56 attendees
* Animal Care and Use - 14 attendees
* Conflicts of Interest - 40 attendees
* Peer Review – 48 attendees
* Authorship and Publication – 46 attendees
* Research Misconduct - 58 attendees
* Data Management – 45 attendees
* Human Subjects – 25 attendees
* Laboratory Safety – 71 attendees

Additional attendees may have been present, but their attendance is not counted if they are not participating. We have seen a marked uptick in attendance, the last two academic years:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2017 - 2018** | **2018 - 2019** | **2019 -2020** | **2020 - 2021** |
| FALL SEMESTER | 148 | 113 | 195 | 209 |
| SPRING SEMESTER | 94 | 123 | 136 | 245 |
| TOTAL # / Unique Students | 242 (137) | 236 (97) | 331 (159) | 454 (182) |
| % INCREASE / DESCREASE |  | - 2.5% (-29%) | +40% (+63%) | +37% (+14%) |
| TRANSCIPT NOTATION # |  |  | 1 + 5  | 2 + 5 |

Attendance (and participation) at the six core topics over the course of two years earns a graduate student transcript notation. Seven graduate students received the transcript notation in FY21. This is transitioning to seven topics 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 which is fulfilled by Shannon Stoker. In FY21 there were no allegations of research misconduct. While this number should be celebrated, it is still a requirement ORCIS stay up to date on rules and regulations regarding research misconduct so NIU is prepared for any allegation. 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. NIU is also a member of the subcommittee on education.

**PROFESSIONAL DEVELOPMENT**

Attended the Society of Research Associates International national conference in October 2020

Attended National Science, Technology, and Security Roundtable in July 2021

Attended the Federal Bureau of Investigation roundtable on Foreign Influence in May 2021

Attended the Senate hearing on foreign influence April 2021

Attended the International Workshop for Universities by the Centre for Science and Security Studies March 2021

SAFETY

**LABORATORY SAFETY**

NIU has two hundred and twenty teaching and research laboratories on the DeKalb campus. The laboratory safety team includes the Laboratory Safety Manager, Michele Crase, and the Laboratory Safety Officer, Jim Gable. Laboratory Safety includes chemical, biological, radiological and physical hazards present in the 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**

ORCIS houses the Laboratory Safety Committee (LSC). The committee comprises representatives from the administration, staff, and faculty. The LSC implement policies and procedures related to laboratory safety. The group met five times in FY21 and finalized one new policy, the Field Work Safety Policy. The LSC is responsible for reviewing and developing recommendations for accidents, in FY21 there was three minor accidents, one near miss and a case of vandalism reviewed. The LSC also hears requests related to safety in the laboratory, in FY21 there was one, concerning Chemical fume hoods in Davis Hall. Capital Improvement related to safety were also heard and evaluated by the LSC.

**TRAINING**

 Three virtual general Laboratory safety training sessions were offered in FY 21.

Approximately 350 individuals were trained.

For general laboratory safety the training breakdowns as follows:

NIU Online:

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

CITI Online Trainings:

* Citi: 99

Most of these trainings are for a mixture of faculty, graduate, and undergraduate students. Topic specific training follows:

* Bloodborne Pathogen for Physical Therapy, Audiology and Engineering Technology students, online with approximately 75 attendees
* Radiation Safety Refresher training online for approximately 20 attendees. attendees.

**WASTE DISPOSAL**

NIU operates under the Academic Laboratory Rule Subpart K. In FY21 ORCIS completed the following disposals:

Hazardous Waste: 4649 pounds

Nonhazardous Waste: 1458 pounds

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

While a portion of Compliance, the IBC is managed by the Laboratory Safety Manager. 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 as follows:

* Initial Applications: 3
* Continuations: 21
* Triennial reviews: 2
* Amendments: 1
* Final Reports: 1

This committee is mandatory to perform this research at NIU.

**RADIATION SAFETY**

NIU research utilizes radioactive materials and x-ray machines. This requires compliance with the state regulatory agency Illinois Emergency Management Agency (IEMA). ORICS is also responsible for monitoring and testing instruments. In FY21 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: 27 people monitored
* Badges and rings utilized: 216

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

**LASER SAFETY COMMITTEE**

There is some research done involving lasers at NIU. The Laser Safety Committee meets each 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 FY21 the Lab Safety Officer inspected 200 labs. They found approximately 50 violations, of which over 98% were addressed and fixed.

**EXTERNAL INSPECTIONS**

Lab Safety assists with federal and state inspections, both announced and unannounced. There were no external audits in FY21.

**PROFESSIONAL DEVELOPMENT**

 Attended training and certification for shipping dangerous goods such as chemicals and biologics. The laboratory safety manager also attended Radiation and Nuclear in the Public Consciousness training, controlling threats on campus training, and a session on the FBI response efforts to the COVID-19 pandemic.

**OUTREACH**

Beyond the responsibilities enumerated above, ORCIS is also a presence on campus. In FY21 Dr. Wallace taught three adjunct psychology courses. Dr. Wallace and Ms. Stoker also served on the Presidential Commission on the Status of Women, Dr. Wallace served on the Institutional Animal Care and Use Committee, and Ms. Stoker served on the Supportive Professional Staff Council as well as the SRAI Research Integrity subgroup. Dr. Wallace attended several social justice workshops on campus, served on a dissertation committee in the department of psychology, served as a judge for the Conference for Undergraduate Research and Engagement, and participated in an invited round table at Elon University.

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 FY21 has been a team effort.

ORCIS’ goal is always to support research and ensure NIU is complaint with all state and federal regulations. In FY22 the office hopes to strengthen their online presence, including logging all laboratory inspections in Info Ed, update the Conflict of Interest policy campus wide, and foster a culture of safety. We hope to expand our external presence by increasing the outside organizations we represent NIU in. Our main goal will be to follow our mission statement:

*Our mission is to assist the NIU research community by advancing the highest standards of ethics, integrity, compliance, and safety in research endeavors. We strive to promote the best practices through training and oversight with the goal of supporting research at NIU*.