

Winter 2023

NU-RESearch Quarterly

A research compliance newsletter focused on raising awareness across the NU research enterprise

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2nd Research Institution Enters Into Settlement Agreement for Alleged Failure to Disclose Researcher's International Ties

By Jeff Seo

In November, the Department of Justice (DOJ) announced that The Ohio State University (OSU) agreed to pay \$875,000 to resolve civil allegations that it failed to disclose foreign support provided to an OSU researcher when it successfully applied for funding from the Army, NASA and NSF (DOJ Statement). While the details in the announcement are scarce, the DOJ implied that OSU failed to disclose to federal research sponsors that its researcher was participating in a foreign talent program and that the researcher was awarded a grant from a foreign natural science foundation. Based upon criminal indictments of individual researchers who allegedly failed to disclose similar involvement with foreign talent programs over the past several years, we can assume that here, the researcher involved may have disclosed such involvement to OSU, and that OSU may have neglected to relay the foreign collaboration to the respective sponsors in the form of a conflict of interest/commitment leading to the settlement with the institution, as opposed to an enforcable action directly against the unnamed individual.

Article continued on page 2.

Challenges with Researcher Collaboration in Russia

By Lissette Gilster

Russia's invasion on Ukraine has led the U.S. and country allies to impose extreme sanctions against Russia. The primary objective is to carry out severe consequences on Russia's economy and its ability to finance the war against Ukraine. The current geopolitical climate & sanctions also have a significant impact on Academic Research with collaborators in Russia. Special rules will apply under different sets of export control regulations. Some prohibitions are broad while others can be targeted sanctions. Although the majority are targeted towards the Russian government and its President, along with his inner circle and oligarchs, the sanctions are having a negative affect on other activities as well.

Article continued on page 3.



SPECIAL POINTS OF INTEREST

- The CHIPS & Science Act
- Important updates on Federal Grant Application Requirements
- Changes to NIH Data Management and Sharing Policy
- RCR Requirements and available training opportunities this semester

3 THINGS FACULTY NEED TO KNOW ABOUT THE CHIPS & SCIENCE ACT

By Amanda Humphrey

As most in the research community already know, the recently passed CHIPS & Science Act provides increased basic research funding for the National Science Foundation (NSF) and the Department of Energy (DOE). However, there are 3 facts about the bill you should know:

- 1. In addition to students and post docs, all faculty and senior personnel on NSF grants will be required to take Responsible Conduct of Research Training (RCR) every 4 years beginning July 2023. Research Compliance will provide more information in the near future, including dates and topics (section 10337).
- 2. The CHIPS Act identifies countries of concern and prohibits individuals from holding talent awards from a country of concern while also receiving federal funding. If you have a talent award from Iran, North Korea, Russia or China, please reach out to Research Compliance. This section also emphasizes that beneficial international collaborations continue to be supported (section 10632).
- 3. NSF is directed to establish a requirement for reproducibility and replicability in the form of required data management plans and repositories. Requires that data, software, and code resulting from NSF funded research to be made available. We will track this emerging requirement and communicate more information as it becomes available (section 10344).

There is a thorough summary of the CHIPS Act created by The Council on Government Relations (COGR), of which Northeastern is a member, available here. The government's summary is available here.

We're moving! Mid-February, NU-RES will pack its bags and head over to our new home in Belvidere! Mailstop is 130 BV



2ND RESEARCH INSTITUTION ENTERS INTO SETTLEMENT AGREEMENT FOR ALLEGED FAILURE TO DISCLOSE RESEARCHER'S INTER-NATIONAL TIES

Continued from page 1.

This is only the second reported civil settlement with a research institution since the start of the China Initiative (which no longer goes by such name). Hence, it's clear that the DOJ made the effort to not identify the foreign country in which the OSU researcher was involved. The other research institute that entered into a similar settlement agreement was Van Andel Research Institute (VARI) in 2019 (DOJ Statement). This announcement provides more details as to the alleged failures of the NIH grantee when it was supposedly aware of its researchers' long-term involvement with Chinese foreign talent programs, yet neglected to disclose or update NIH with the information.

In addition to the prosecutions of individual researchers, these institutional settlements highlight the significance of disclosures of external, international commitments. Northeastern's <u>Policy on External International Engagements</u> is designed to mitigate these risks by proactively reviewing pending international commitments and ensuring that federal sponsors are updated if and when such commitments commence. Additional information can be found on our <u>Compliance Site</u>.



CHALLENGES WITH RESEARCHER COLLABO-RATIONS IN RUSSIA

Continued from page 1.

What are some current restrictions towards Russia? The U.S. export regulations have taken severe actions, which prohibits both import and export of goods, services, and technology (with a few exceptions for humanitarian support). The U.S. has also implemented controls to block financial transactions with a significant portion of the Russian financial system, which includes many banks and subsidiaries.

What about research with a collaborator in Russia? Although not all research is prohibited, in the current geopolitical climate, research with collaborators in Russia should be reviewed carefully. If you have current research or are considering research collaboration with a person/entity in Russia, please contact the <u>Export Control Office</u> will need to assess applicable controls for individual research efforts, as some services and/or exchange of data may require an approved export license before collaboration can take place.

The White House issued a <u>statement</u> on June 11, 2022 discussing the Guidance on Scientific and Technology Cooperation with Russian Federation. The U.S. government has taken active measures to limit bilateral research, as well as, "wind down" research collaborations. Further, it said, U.S. agencies and labs "have been advised to curtail interaction" with the leadership of Russian government-affiliated universities and institutions, "as well as those who have publicly expressed support" for the war. The U.S. recognizes that many Russians, inside and outside of Russia, are opposed to Putin's war of choice in Ukraine. While some, including in the scientific community, have bravely stood up in defiance, the Russian government's measures to restrict freedom of expression have made it far more difficult for Russians to express their opposition to this unjust war without fear of retribution.

For more information on the sanctions, please visit <u>OFAC Russia Related Sanctions</u>, <u>BIS Russia-Belarus</u> and <u>DDTC Summary of Changes -Russia</u>.

CELEBRATION & FOND FAREWELL: NAN REGINA

By Curtis Van Slyck

Best wishes to Nan Regina, who is retiring from Northeastern after 20 years of dedicated service, effective February 3. As Director of the Human Research Protection Program, Nan is an invaluable member of the NU Research community, her reassuring presence steering the IRB through years of tremendous growth and change, serving as a beacon of knowledge and support for faculty and student investigators.

Nan has dedicated her career to the advancement of science, education, and the safety of research participants. We are tremendously grateful for Nan's commitment to NU and the wealth of knowledge she now passes on to the next generation of IRB staff.

Please stay tuned for details on how you can show your appreciation to Nan for her years of service and celebrate her career.

LOOKING FORWARD... WELCOME NEW IRB MEM-BERS & STAFF

It is a bittersweet time as we say goodbye to Nan and celebrate her next adventures. It is also an exciting time to share the growth of the office leadership, team, and IRB membership. Our inaugural Executive Director, Anita Balgopal, joined us in July 2022 and the inaugural Assistant Director, Rae Mwangi, joined the team in November 2022. Combined, Anita and Rae bring over 30 years of human subject research protection leadership experience.

In addition, the IRB and administrative office have doubled in size to address the growing research portfolio and support the breadth and depth of human subject research. For a full list of current board members and staff, please visit the HRPP website.

Serving on a compliance committee can be a great way to support your colleagues and help to uphold the highest ethical standards in research. If you are interested in learning more about how to get involved, contact Research Compliance.

We hear you! Please continue to provide comments and feedback to the <u>IRB Satisfaction Survey</u> on how the office can support your research efforts.



DATA MANAGEMENT & SHARING POLICY 2023

By Tessa Seales

NIH has released information for a new Data Management & Sharing Plan (DMSP) in effect on/after January 25, 2023. This is a plan describing how scientific data will be managed, preserved, and shared, considering any potential restrictions or limitations. Once the new DMSP goes into effect, the 2003 Data Sharing Policy will end.

Visit Northeastern University Libraries for more information on <u>Data Management Plans</u>.

For information on how DMS Plans will affect NSF, check out the CHIPS article on page 2.

DO YOU REMEMBER?

REFLECTING ON SIGNIFICANT EVENTS INFLUENCING THE RESEARCH COMPLIANCE LANDSCAPE

THE YALE SETTLEMENT OF 2008 AND LESSONS LEARNED

By Jeff Seo

Approximately fourteen years ago, the U.S. Department of Justice (DOJ) announced that it had entered into a settlement agreement with Yale University (Yale) for the sum of \$7.6 million to resolve allegations related to false claims arising from federal research grants. Following an investigation that spanned 2.5 years, covering billions of dollars of federal grants and contracts across almost every major federal research sponsor awarded since 1999, Yale reportedly produced approximately a million files in response to the DOJ's requests for documents.

The two primary allegations leading to the settlement involved inaccurate time and effort reporting in the form of researchers claiming 100% salary during summer months when evidence suggested that effort was made on non-research endeavors, as well as for charging certain research expenses on the wrong grants. In particular, the DOJ took issue with what is commonly referred to as "cost transfers," when expenses are moved from one award to another. While cost transfers are normally permissible, auditors frown upon what is described as "late cost transfers" when volumes of research expenses are transferred towards the end of a grant's term, sometimes in order to spend down balances remaining or risk returning any unspent funds.

Without admitting liability, Yale invested resources in research administration for new systems and processes including better means by which researchers were updated on

time and funds spent on grants, new positions dedicated towards research administration and compliance, and required training for its researchers.

Yale was certainly not the first or the last university to experience legal adversity with managing federal research funds. In fact, Northeastern would enter into its own settlement agreement in 2016 following selfdisclosure to the National Science Foundation. What distinguishes Yale's set of circumstances is the breadth of the investigation across multiple sponsors, the length of the investigation (2+ years) and the obvious inconvenience and distraction associated with such, and that the major allegations could have applied to almost any grantee resulting in similar findings. Despite adversity, Yale navigated the experience as successfully as one could expect, laying out a blueprint for others that may experience a similar event, demonstrating that cooperation and accountability are keys to resolving such intense scrutiny.

UPCOMING RCR REQUIREMENT CHANGES MANDATED BY NSF EFFECTIVE JULY 2023

By Morgan Fielding

Currently, NSF institutions are only required to provide RCR training and education to undergraduates, graduates and postdoctoral researchers who receive NSF funds, which includes salary or stipends to conduct research on NSF-funded projects. It does not specify the content of the training. Northeastern currently suggests the completion of <u>CITI training</u> most closely related to the discipline or to attend a single, live RCR workshop via the <u>Calendar</u> to fulfill the current requirement.

Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 USC 18620-1), as amended and will go into effect for new proposals submitted or due on or after July 31, 2023, requires that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, postdoctoral researchers, faculty, and other senior personnel supported by the proposed research project. Such training must include: Mentor training and mentorship; Training to raise awareness of potential research security threats; and Federal export control, disclosure, and reporting requirements

Full PAPPG (NSF23-1) and Summary of Changes

CHANGES TO NIH APPLICATIONS IN 2023

By Michael Marino

For applications with due dates on or after January 25, 2023, there will be updated application materials, known as Forms-H. You can read a full list of the <u>Significant Changes</u> to the forms online.

One of the most significant changes to be aware of relates to the Implementation of the NIH Policy for Data Management and Sharing (DMS Policy). This policy effects all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes: Extramural (grants), Extramural (contracts), Intramural research projects, and Other funding agreements.

The DMS Policy does not apply to research and other activities that do not generate scientific data, for example: training, infrastructure development, and non-research activities.

Data sharing plans and genomic data sharing plans will no longer be submitted to the "Resource Sharing Plan (s)" field. A new "Other Plan(s)" field will be added to FORMS-H to collect a single PDF attachment of a DMS Plan. NIH program staff will review the DMS Plan, unless sharing data is integral to the project design and specified in the FOA.

Researchers can request direct costs to support the DMS Plan and if they do so they must be indicated as "Data Management and Sharing Costs" in budgets. A brief summary of the DMS Plan and a description of the requested Data Management and Sharing Costs must be included within the budget justification attachment.



UPCOMING RCR SES-SION SUBJECT MAT-TER FOR SPRING 2023

- 1. Wellness & Self-Care for the Researcher lead by Suzanne Garverich, MPH, Program Director Institute for Health Equity and Social Justice Research and Amy Ferrell, Ph.D., Director and Professor School of Criminology and Criminal Justice
- Managing Conflict and Strengthening Professional Relationships in Research lead by Diane Levin, University Ombudsperson – Office of the Provost and Kimberly Wong, Graduate Ombudsperson – Graduate Affairs
- 3. Animal Care and the IACUC Function lead by Sean Sullivan, Director Division of Laboratory Animal Medicine (DLAM)

An updated <u>Calendar</u> will soon be available for the start of the Spring 2023 semester.

HUSKY HEROES

CELEBRATING THOSE WHO CONTRIBUTE ABOVE AND BEYOND TO THE UNIVERSITY'S RESEARCH MISSION

By Wilson Mazile

Jennifer Moreno

Our featured NU-RES Husky Hero for this winter issue is Jennifer Moreno! Jennifer is a Veterinary Technician at the Division of Laboratory Animal Medicine (DLAM). She has been working at Northeastern for nearly 14 years and is a prime example of a phenomenally dedicated member of the NU-RES community. This section will highlight an interview with Jennifer and why she is our featured NU-RES Hidden Hero for this issue.

What is your background? Where were you before you started working here at Northeastern?

After high school, I went to UMass Boston, but after two semesters, I felt like it was not for me anymore. So, I stopped and initially started working in retail. My parents worked in animal research at other universities, and my father knew my current supervisor, Sean Sullivan. Since I was a kid, both my parents have worked in this field, and I even have aunts and uncles working in animal research right now, so it is like a whole family thing. Thus, when I came in for an interview for a job with Sean, I got it. Next March, it will be 14 years since I started working as a Veterinary Technician here at Northeastern University. I recently passed the exam to become an AALAS certified Laboratory Animal Technologist (LATG), which was my goal!

Could you briefly describe your current role here at Northeastern University?

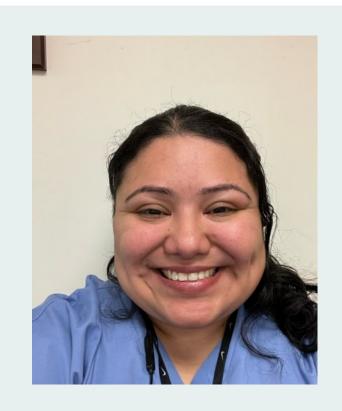
My current role in DLAM is as a Veterinary Technician. I do health monitoring for all the animals in our facilities. We ensure that all the animals are healthy and well taken care of, you know, basic animal husbandry. That involves daily care of our research animals, cleaning and sanitizing their cages, monitoring their health and well-being (such as general appearance, and behavior), and just all standard compliance procedures for animal husbandry and safety. I also train PIs and students on proper handling of the animals before starting their experiments to ensure they follow procedures correctly and ethically.

Could you briefly describe your typical day-to-day on the job?

I usually start the day at the ISEC facility by checking on all the animal rooms and the animals to ensure that rooms are operating properly, and all the animals are well. I check basic environmental conditions such as humidity, temperature, and pressure for all the animals. Then, I will work with PIs and students on a technical training scheduled for that day or go over specific procedures related to their research.

What are hobbies you like to do outside of work?

Outside of working with animals, I am a more introverted person. I like gaming, reading, and collecting trading cards. I like going out with friends and stuff, but I mostly enjoy doing my own thing.



What is something you are proud of, and in what ways do you believe your work tends to go unnoticed by the broader Campus Community?

As I mentioned, I have been working here for nearly 14 years and have seen significant growth in the University's Animal Research program. For example, when I first started, we only had a few facilities, and then, within just two years of me being here, we started expanding much further up until the opening of ISEC. As DLAM has grown, so has my role, responsibilities, and even my knowledge in handling various types of animals. It has been amazing to see such an expansion of our division. We have been continually upgrading our program, including our caging systems. In the business of animal science, everything is constantly evolving. Every year, we are improving in some way. At DLAM, you can see that things every year are changing and getting better everyday. The research being done with the help of the animals is meaningful and helps our humanity and animals in some way. A lot of excellent research within most scientific fields goes unnoticed by the public, but we must do this research to improve knowledge and our society.

What does it mean to you to be working at Northeastern University? How would you describe the overall impact that individual Northeastern entities like yours have brought to the University?

I love my job! I like coming in every day and the work we do here. It does not even feel like a job anymore; this work gives me passion and joy daily. I like being involved with animal husbandry and working with animals more than only being in an office. In terms of an overall impact on the University, our work here at DLAM helps researchers at Northeastern with their projects and trains them in essential procedures when handling laboratory animals so that everything in their research and findings is done correctly. That is a duty that is essential in science and in promoting best practices.

CHANGES TO NSF APPLICATIONS START-ING IN JANUARY 2023

By Michael Marino

NSF has released the updated <u>NSF Proposal & Award Policies & Procedures</u> Guide (PAPPG) and it is effective for proposals starting January 30, 2023.

Significant changes that you should be aware of include the following (*italicized items will be covered in an upcoming training session being developed by NU-RES Compliance*):

- Revisions to incorporate Research.gov as the replacement for FastLane for proposal preparation and submission.
- ◆ Information about the use of Broad Agency Announcements (BAAs) and the BAA Management System (BAAM).
- Revisions to certification for Responsible and Ethical Conduct of Research (RECR) for proposals submitted on or after July 31, 2023.
- Use of Concept Outlines as a submission type and the Program Suitability and Proposal Concept Tool (ProSPCT).
- Requirement to provide a certification regarding Safe and Inclusive Working Environments for Off-Campus and Off-Site Research.
- Revisions to Biographical Sketch and Current and Pending Support formats to include certifications from the individual (as required by the 2021 National Defense Authorization Act, Section 223) regarding information being accurate, current, and complete.
- Requirement for NSF program officers to request updated Current and Pending Support information prior to making a funding recommendation, in accordance with the NSPM-33 Implementation Guidance.
- Requirements for use of SciENcv for the Biographical Sketch and Current and Pending Support documents.
- ♦ Implementation of Build America, Buy America statutes.
- New sections on Research Security and Scientific Integrity.

CHARGING COMPUTER DEVICES ON FEDERAL AWARDS

By Jeff Seo

In an NSF audit report dated July 5, 2022, NSF auditors questioned approximately \$43,000 in costs claimed on its awards to West Virginia University (WVU). Among those charges was \$235 for AirPods. The report acknowledged that the AirPods may have been useful to listening to webinars (the knowledge of which was utilized in the NSF project). However the AirPods were not used "exclusively" for the NSF award in question, and were used for general work such as online meetings and unrelated webinars. The finding is a typical one when computing devices are examined by federal auditors. Whether the devices are AirPods, IPads, or laptops, auditors generally find that they fail to meet the two elements as outlined in the Uniform Guidance (2 CFR 200.20; 200.453). First, the computing device must be "essential" or necessary to perform the work on the project. In general, incidental use for other purposes are acceptable, however, grantees must be prepared to demonstrate the essentiality of these devices.

Another common reason why charges for computing devices are questioned is the allocability and allowability of the charges. As evidence against allowability, auditors tend to question the timing of the purchases of computing devices regardless if the devices were budgeted and approved. If computing devices are purchased towards the end of a project, auditors naturally question how the devices could have benefitted the project when purchased with only so many days remaining in the project period. Therefore, even if a computing device is deemed "essential" for a project, allowability/allocability principles require additional consideration such as timing and whether the device might be used for multiple projects. If the device is intended for multiple projects, then we may have an obligation to document an appropriate cost allocation methodology across multiple projects. If you have any questions, please don't hesitate to contact us.

OVERVIEW OF NSPM-33

By Tessa Seales

What is NSPM-33?

National Security Presidential Memorandum 33 (NSPM-33) directed federal funding agencies to strengthen protections of U.S. Government-supported R&D against interference and misappropriation, while maintaining the open environment that fosters new research and innovations that benefit the U.S. and the world.

Why is NSPM-33 required?

As research, innovation and discovery continue to develop, there is an increased need to protect U.S.-funded scientific research from misuse of the open university research environment and intellectual property theft.

How is NU impacted by NSPM-33?

As a qualifying research institution, NU has one year from date of issuance of the formal requirement to comply. Issuance of formal requirements is expected to take place in early to mid-2023.

Currently NU-RES Research Compliance has been working with other University groups to ensure that the University is working to meet all NSPM-33 requirements, including becoming a full member of the DPI service ORCID.



ANIMAL ACTIVISTS USE OF FOIA

By Jeff Seo

As reported in a September 2022 article appearing in the Report on Research Compliance (Vol. 19 Number 9), the People for the Ethical Treatment of Animals (PETA) sent letters to NIH, the Office of Laboratory Animal Welfare (OLAW), Duke University and Vanderbilt University seeking accountability for violations of the Animal Welfare Act and/or the NIH guidelines for animals used in research. The letters purportedly asked the respective universities to modernize and transition away from animal models after citing allegations of neglect of various species used in research.

PETA reportedly obtained correspondence between federal oversight agencies (USDA and OLAW) and federal grantees through the Freedom of Information Act (FOIA). This practices has been applied by activists for decades, sometimes to identify and target individual investigators involved in animal research. Each federal agency has its own process to manage FOIA requests. Most offer the subject of the FOIA request the opportunity to seek redactions under limited grounds, the most relevant of such include exemptions for protected trade secrets or proprietary information and personal records that could invade one's privacy. Ultimately, the federal agency has the discretion to accept or reject the redactions requested.

