Human Research in the Global Sphere: Export Controls & Research Security including Foreign Influence

Sponsored by the IRB

18 September 2024

Export Controls & International Compliance (ECIC)

Your ECIC team . . .

We are here to help you navigate the fluid regulatory landscape and get to a yes wherever possible!

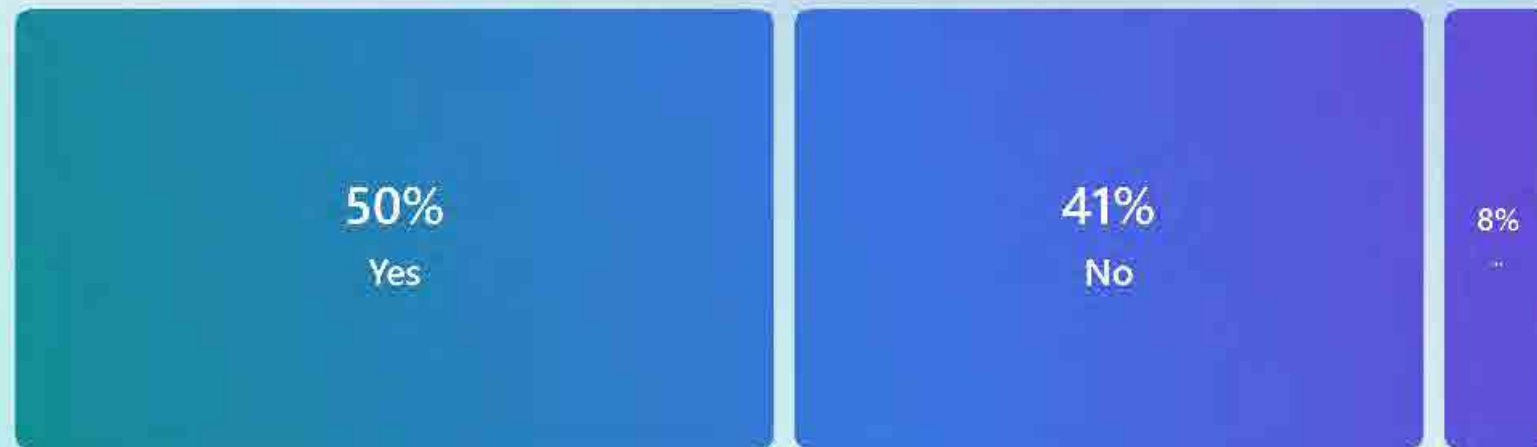Mary Kate Clifford
Assistant Director

Sylvia Garcia
Analyst

Kristin Thoma
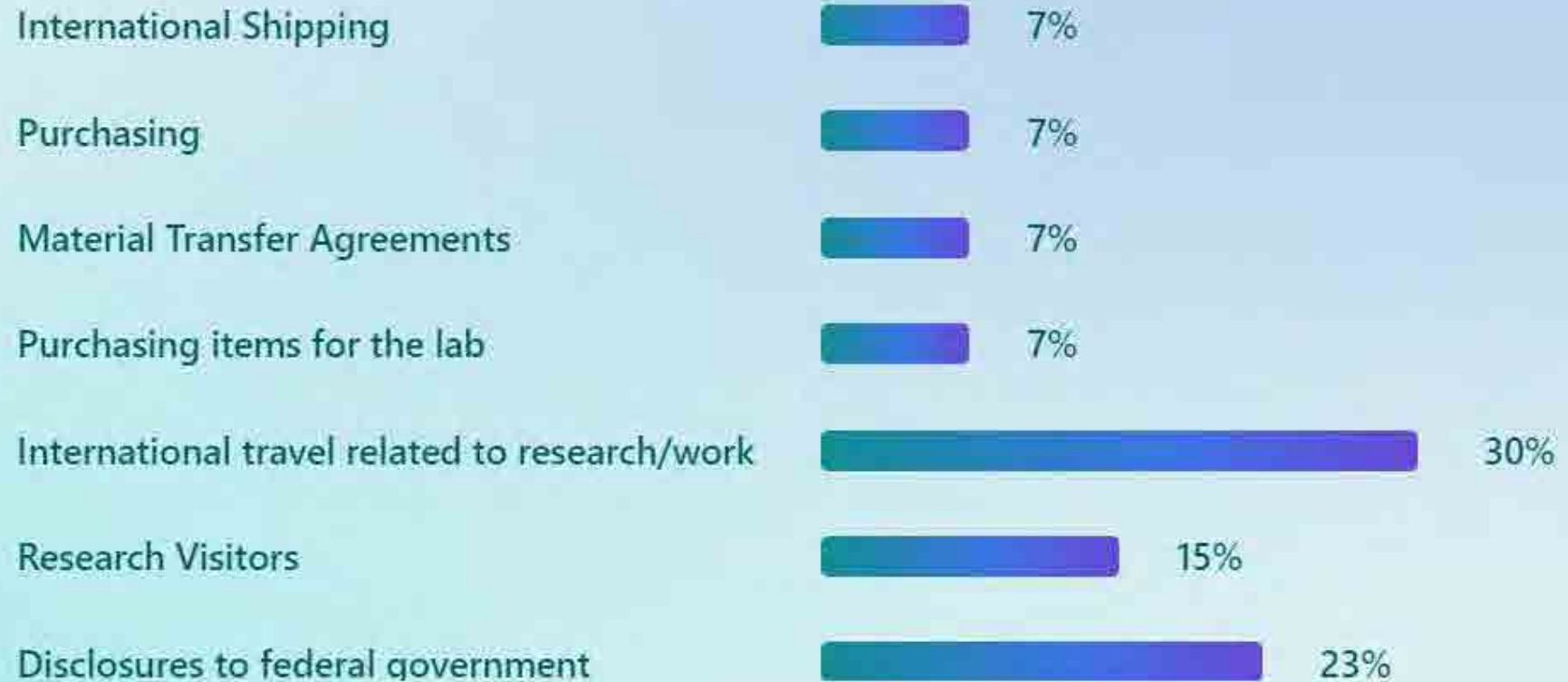Analyst

Amy Weber
Senior Director

Are you or anyone you work with involved in any of the following:

International Shipping — 7%

Purchasing — 7%

Material Transfer Agreements — 7%

Purchasing items for the lab — 7%

International travel related to research/work — 30%

Research Visitors — 15%

Disclosures to federal government — 23%

What best describes your role?

100%

Staff

Discussion Guide

Export Controls & Research

Foreign Influence & Malign Talent Programs

Importance of Disclosures

Resources – Who can help with questions?

Export Controls & Research

Export controls are U.S. laws and regulations that regulate and restrict the release of critical technologies, information, and services to foreign nationals, within and outside of the United States, and foreign countries for reasons of foreign policy and national security.

Restrict access to technology for U.S. national security

Further U.S. foreign policy interests

Prevent terrorism, weapons proliferation, narcotics trafficking, etc.
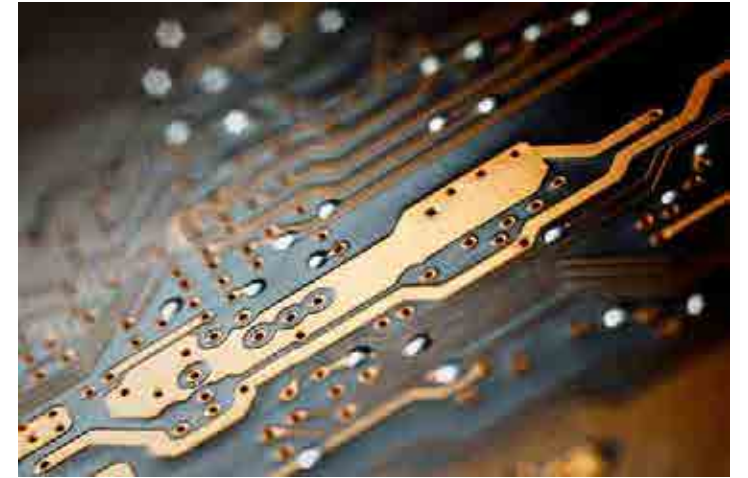
Satisfy multilateral obligations

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WHO
Regulations impacting people, organizations, universities with which you collaborate.

WHERE
Countries involved in traveling, shipping, or other activities.

WHAT
Regulated items, data, materials, equipment, and research.

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How can an export occur?

Under the regulations, an export can occur in ==two ways==:

1. by the ==physical movement== of a controlled item outside the United States, or
2. by the transfer of controlled data or item, whether outside or inside the United States, to a foreign national. This second transfer is defined as a ==deemed export==.

Technology

Hardware

Software

Data

Substances

U.S. persons or entities under the export control regulations:

- U.S. citizens

- U.S. permanent residents

- U.S. protected persons including asylees

- Business entities incorporated to do business in the U.S.

U.S. Agency	Regulates	Regulation
State	Military and Space Critical Technologies	International Traffic in Arms Regulations **(ITAR)**
Commerce	Dual Use Technologies (**Commercial and Military**)	Export Administration Regulations **(EAR)**
Treasury	Sanctioned Countries & Individuals	Office of Foreign Asset Controls **(OFAC)**

Export Control & International Compliance Considerations

OFAC & Military End Use Countries
Highly sanctioned and embargoed, and military end use countries pose some of the most significant risks. Contact Export Control with questions.

Travel
Travel outside the U.S. can trigger the need for a license -depending on multiple factors.

Collaborators and Visitors
Working with some global partners (individuals, universities, organizations) is restricted. Conduct Restricted Party Screenings in advance.

Shipping & Purchasing
Notify the ECIC before the export of certain items outside the U.S. & when purchases involve end user statements

Malign Foreign Talent Recruitment Programs
Individuals applying for or receiving federal funding cannot be MFTRP members

How do you know if something may be export controlled?

- Project agreement includes a:
  - publication restriction
  - foreign person restriction
  - technology readiness level (3 or higher)
  - funding source level (solicitation)
  - information security restriction

- MTAs, particularly those to military end use or OFAC sanctioned countries

- Research with potential military end-use

- Equipment has an export-control user agreement

- Shipping or hand carrying items outside the U.S.

- Work involves an entity that is a Restricted Party

- Work involves an OFAC sanctioned or heavily embargoed country

International Shipping

High export control risk for universities
- Decentralized shipping processes
- Lack of training/education – timing
- High number of global partnerships
- Increased number of restricted entities
- Enforcement action by government

Enforcement action by federal government

THE DAILY PRINCETONIAN
NEWS

Princeton fined $54,000 for prohibited ex animal pathogens

Indiana University (June 2024)

o Commerce Department settlement with Indiana University (IU).

o 42 export violations involving IU's stock center, an office of the university's biology department that supplies fruit flies (genetically modified with toxins) to research institutions around the world.

o IU lost its export control privileges for certain biologics for one year, plus other admin penalties.

Princeton University (Feb. 2021)

o 37 export violations for sending animal pathogens from the U.S. to research institutions around the globe without the required export licenses.

o Voluntary disclosure reduced the penalties.

o $54,000 fine, plus internal and external audit/monitoring.

NU's close call

- Research/student attempted to ship chemicals to a restricted party (Chinese university on the BIS entity list).

- Shipment did not leave the U.S.

- Student reached out to the ECIC for assistance.

- ECIC conducted a review – PI and team had not shipped any other items to this entity.

- ECIC advised them of the services it provides, shared resources and recommended training.
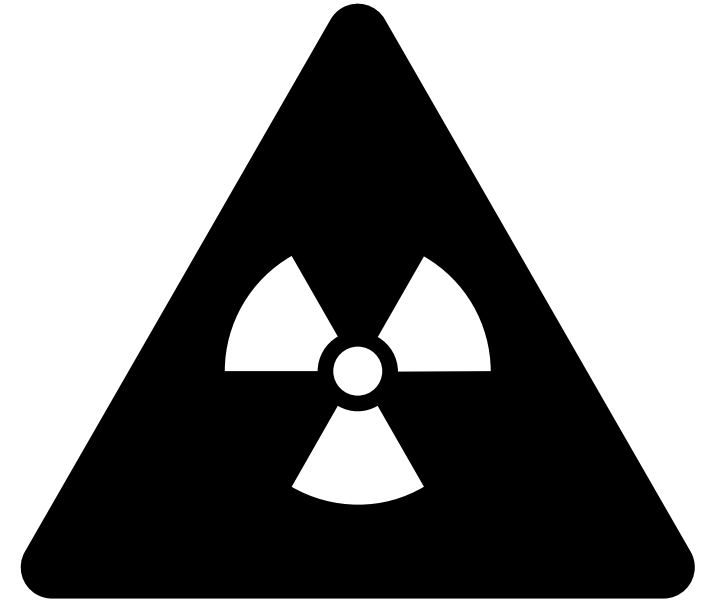
Outbound International MTAs –
Review Criteria (Started Sept 1, 2024)

1. **High Risk Countries:** All outbound from high-risk countries of concern (OFAC and Military end use countries)
   i. OFAC: Cuba, Iran, North Korea , Syria, and certain regions of Ukraine (Crimea, Donetsk, Luhansk, and Sevastopol).
   ii. Military end use countries: Belarus, Myanmar/Burma, Cambodia, China (including Hong Kong), Nicaragua, Venezuela

2. **Biologics or hazardous materials:** All outbound biologics or hazardous materials regardless of country

3. **Critical Technologies:** All outbound for critical technologies regardless of country (Reference: White House Critical Technology List)

Next steps – we need your help

Complete and submit a questionnaire for all outbound MTAs – starting Sept 1, 2024. Reference link: https://services.northwestern.edu/TDClient/30/Portal/KB/ArticleDet?ID=2265

If the MTA needs further review, SR will create an ancillary review for the ECIC team.

The ECIC will review and work with the research team to determine if an export control license is needed.

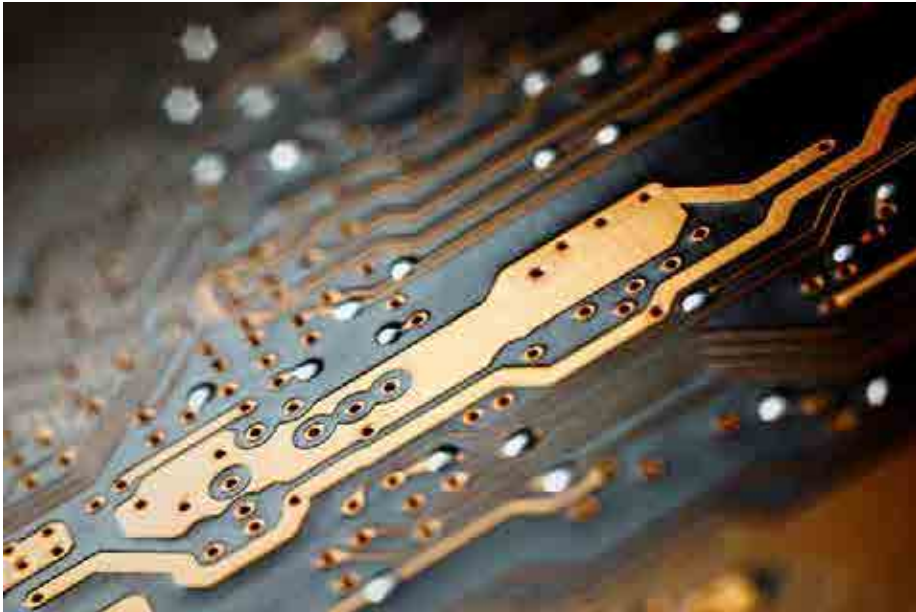# High risk countries

Military End Use Countries

- Belarus

- Myanmar/Burma

- Cambodia

- China (and Hong Kong)

- Russia

- Venezuela

OFAC (comprehensively sanctioned)

- Cuba

- Ukraine (certain areas)

- Iran

- North Korea

- Syria

Critical & Emerging Technology

Advanced Computing

Advanced Engineering Materials

Advanced Gas Turbine Engine Technologies

Advanced and Networked Sensing and Signature Management

Advanced Manufacturing

Artificial Intelligence

Biotechnologies

Clean Energy Generation and Storage

Data Privacy, Data Security, and Cybersecurity Technologies

Directed Energy

Highly Automated, Autonomous, and Uncrewed Systems (UxS), and Robotics

Human-Machine Interfaces

Hypersonics

Integrated Communication and Networking Technologies

Positioning, Navigation, and Timing (PNT) Technologies

Quantum Information and Enabling Technologies

Semiconductors and Microelectronics

Space Technologies and Systems

(Reference: White House Critical Technology List)

Export Control Questions

WHAT?
What are you sending?

- Scientific name
- Lay person description
- Amount/size
- Chemicals – hazardous?
- Biologicals – pathogenic?

WHAT FOR/WHY?
What is the purpose of the shipment?

- What will they be doing with the items?
- Is it an ongoing collaboration?
- Is there a known or expected military end use?

WHO/WHERE?
Who are you sending the items to?

- Recipient
- Employer/Institution
- Complete address

Identify ECCN → Determine Level of Control → Research License Requirements → Conduct Restricted Party Screening

Additional Questions

WHERE FROM?

Where was the sample obtained from?

↓

MATERIAL TRANSFER AGREEMENTS

FUNDING?

Is this project federally funded? If so, who is the sponsor?

↓

REQUIREMENTS/ DISCLOSURES

Classification

1C351 Human and animal pathogens and "toxins", as follows:

a. Viruses identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

    a.13. Ebola virus;

Ebola Virus 1C351.a.13

Classification

1C353 Genetic elements and genetically-modified organisms, as follows:

b. Genetically modified organisms, as follows:

  b.1. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c or 1C354;

  b.2. Genetically modified organisms that contain nucleic acid sequences coding for any of the "toxins" controlled by 1C351.d or "sub-units of toxins" thereof.

Shipping and hand carrying items outside of the U.S. or its territories

- Any physical shipment or hand carry outside the US is considered an "export"

- International shipments may need a license

- Even temporary exports (e.g., equipment taken abroad for research and returning to the U.S.) are subject to regulations

- Laptops containing technical data or proprietary information could trigger licensing requirements

- Encrypted drives may be problematic at customs

- **Export Controls** can facilitate hand carry documentation upon request

Plan ahead, review travel guidance, and take a clean laptop, if possible.

[Link](#) **to export control travel guidance.**

Take steps to safeguard your research

- Request Restricted Party Screenings on your international collaborators.
  - The ECIC team can assist with conducting screenings.

- Traveling with a "clean" laptop is recommended.
  - A "clean" laptop does not include proprietary or sensitive information, including unpublished information that might be subject to confidentiality restrictions. Contact your department IT team or NUIT for assistance.

- Limit what you take abroad;

- Ask for an export control review if you need to take research items abroad;

- Keep information in your possession or locked in a secure location;

- Use the Northwestern VPN (where allowed; some countries ban the use of VPN software); and

- Encrypt your device.

What is OFAC?

The Office of Foreign Asset Controls **(OFAC)** administers economic sanctions primarily against countries and groups of individuals to accomplish foreign policy and security goals.

Activities that <u>very likely</u> need a license:

- Conferences (even virtual)
- Research
- Joint publications
- Payments
- Remote or online classwork
- Software use (in many cases)

- **Cuba**
- **Belarus**
- **Ukraine** **(certain areas)**
- **Iran**

- **North Korea**
- **Syria**
- **Russia**

Military end use rule applies to designated entities in the following countries:

- Belarus
- Burma
- Cambodia
- China (and Hong Kong)
- Russia
- Venezuela

Case study

Facts: You are doing a global human subject study with multiple countries including Cuba, Iran, Syria, and parts of Russia and maybe Crimea.

A. Go for it – better to get input from all over the world!

B. Forget it – it sounds too risky

C. Reach out to the export control team for guidance and help.

What word(s) do you think of when yo hear the phrase "foreign influence?"

17 responses

interference

data breach

regulations

spies

demand

dangerous

funding

money

unlawful

politics

elections

conflict

superpowers

corruption

malign intent

hacking

against national interest

11

Research Security – Foreign Influence & Malign Foreign Talent Recruitment Programs

Improper fforeign interference and malign foreign influence

Foreign interference and foreign influence are malign activities by another country to interfere or influence U.S. policies or activities, or to benefit the foreign government.

Some foreign countries seek to illegally acquire U.S. academic research to advance their scientific, economic, and military development. Saving significant time, money, and resources while achieving generational advances in technology.

These malign activities deprive victimized parties of revenue and credit for their work and use U.S. funding to advance their technology goals.

The malign efforts can come in many forms, including overt theft, plagiarism, elicitation, and the commercialization of early-stage collaborative research.

What Federal Agencies Observed (2018-19)

Disruption of the peer review process and inappropriate sharing of grant applications during peer review process.

Conducting the same, or similar, research at two institutions (aka having a "shadow lab") and/or having the same project supported by both U.S. federal funds and foreign funds.

Incomplete disclosure of relationships with foreign governments or other institutions to sponsors and the investigator's home institution.

What constitutes foreign interference?

- Undisclosed sources of foreign research support

- Undisclosed conflicts of interest

- Violations of peer review integrity rules

- Overcommitment and dishonesty

- Malign Foreign Talent Program participation

Institutional Responsibility

Cleveland Clinic - $7 million settlement

- Alleged mismanagement of 3 grants
- Allowed employees to share passwords to NIH's reporting system

Stanford - $1.9 million settlement

2015-2020: 16 grant proposals failed to disclose current or pending funding from foreign sources for 11 Stanford researchers

Research Security Regulations

NSPM-33 requires all federal research funding agencies to strengthen and standardize disclosure policies. Standardization requires full disclosures of collaborations and other sources of support. Requires institutions receiving more than $50M to have a Research Security Program.

The **CHIPS and Science Act** contained several Research Security provisions and requirements, including a malign talent program prohibition for covered individuals receiving federal money and an institutional certification requirement.

Research Security (NSPM-33) Working Group

Export Controls & International Compliance

Sponsored Research

Risk and Compliance

Cyber (NUIT & RIT)

Buffett Institute for Global Affairs

Training

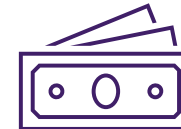International Relations

OGC

Human Resources

Alumni Relations & Development

Office of the Provost

Financial

Government Relations

Research Working Group Mission Statement

International collaborations are critical to creating breakthrough advances, and Northwestern **highly values global research partnerships**. The Research Security Working Group will lead and coordinate Northwestern's readiness for federal agencies' implementation of NSPM-33 within that context, **focusing on our core values of openness in research, integrity, collaboration, and innovation**.

The team will develop a research security program while maintaining our commitment to a diverse academic and research community.

Policy on Discrimination, Harassment, and Sexual Misconduct:

Policy on Discrimination, Harassment, and Sexual Misconduct: Northwestern prohibits discrimination and harassment on the basis of race, color, religion, creed, national origin, ethnicity, caste, sex, pregnancy, sexual orientation, gender identity, gender expression, parental status, marital status, age, disability, citizenship status, veteran status, genetic information, reproductive health decision making, height, weight, or any other classification protected by law (referred to as "protected statuses or protected characteristics") in the educational programs or activities Northwestern operates, including but not limited to matters of admissions, employment, housing, or services. Prohibited discrimination based on sex includes sexual misconduct, including but not limited to, sexual harassment, sexual assault, sexual exploitation, stalking, and dating or domestic violence. Such conduct violates Northwestern's values and disrupts the living, learning, and working environment for students, faculty, staff, and other community members.

Job postings for relevant grant projects must not include inappropriate language, criteria, or qualifications (e.g., "U.S. Citizens only" or "U.S. person only") and job candidates should not be screened on such bases. Conditional job offers should include language about the need to pass background checks including vetting by federal agency sponsors. Lastly, seeking, where possible, to reassign any person not approved by the federal government under foreign person restrictions.

JULY 09, 2024

White House Office of Science and Technology Policy Releases Guidelines for Research Security Programs at Covered Institutions

Today, the White House Office of Science and Technology Policy issued

Cybersecurity	Foreign Travel Security	Research Security Training	Export Control (EC) Training
• Implement a cybersecurity program **one year** after publication of the final NIST cybersecurity resource (IR 8481: Cybersecurity for Research)	• Implement federal foreign travel security training to covered individuals (CI) within **1 year of availability** and at least every 6 yrs. • Organizational record of CI international travel when agency determines security risks warrant travel reporting for an R&D award	• Implement research security training; certify CI completion • Option A: NSF training modules • Option B: Non-federal training that covers: (1) Improper transfer of USG-supported R&D; (2) importance of International research & talent	• Provide EC training to CI working with controlled technology • Option A: Govt. training (BIS, DDTC) • Option B: Non-fed training with U.S. EC and compliance requirements & processes for reviewing foreign sponsors, collaborators, and partnerships

General consensus: Appreciation for flexibility, concern about agency latitude

Assumes minimum windows for agency and institutional implementation

Jan. 2027 is a possible end point

Source: COGR

July 9, 2024

OSTP releases Guidelines for Research Security Programs at Covered Institutions to heads of federal agencies.

January 8, 2025

Within 6 months of the date of OSTP Guidelines, federal agencies shall submit to OSTP & OMB plans for updating their policies to address the Guidelines in their research security program standards.

January 2025-July 2025

Federal agencies shall implement their updated policies no later than 6 months after finalized plans are submitted to OSTP & OMB.

January 2025-July 2026

Covered institutions shall have no more than 18 months after the effective date of agency plans to implement their requirements.

Institutional Certifications

Certifications that universities/institutions have:

- A **research security program**, including:
  - Cybersecurity and foreign travel security
  - A research security training program for all covered individuals (CI), and export control training for CI who perform R&D involving export-controlled technologies
- Training on foreign travel security to CI engaged in international travel at least once every six years and some sort of travel registry
- Non-discrimination safeguards to protect the rights of researchers, students, and research support staff
- The means for certification has not yet been identified

New law impacting the research community

Engagement in a "malign" foreign talent recruitment program from a *country of concern* precludes you from applying of receiving federal research dollars.

Foreign talent recruitment program

A foreign talent recruitment program is any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to an individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue.

What is different?

Broader and new definitions	• Foreign talent recruitment program definitions have changed – much broader
Funding restrictions	• "Malign" foreign talent recruitment program participants = no federal funding
Certain organizations are a high risk	• Denied entity lists and DOD 1286 list
Focus on activities	• Focus on activities, characteristics, and behaviors – what are you doing?

Is My Talent Program Malign?

1 Are you being paid or receiving any form of compensation (i.e. recognition, awards, money, funding, reimbursement, land, etc.) from a country other than the US (including the promise of future compensation of any kind?

2 Is the program from China, Iran, Russia, or North Korea?

3 Contact the Export Controls & International Compliance team if you are asked to engage in or are participating in any of the following activities:

3 Contact the Export Controls & International Compliance team if you are asked to engage in or are participating in any of the following activities:

- Recruit others (trainees, researchers, speakers, etc.) to participate in a talent program with a foreign entity.

- Hold a position, an appointment,* a laboratory, or a company in a foreign country

- Engage in a contract/agreement where termination is not an option or is difficult

- Unauthorized transfer of (IP) intellectual property), materials, data, or other nonpublic information

- Engage in work for or in another country that overlaps with U.S. Federal dollars

- Apply for or receive funding from a sponsoring foreign entity where you did NOT engage Sponsored Research

- Omit a recipient affiliation, or being told/required to make ommisions

- Conceal program participation in any way

*Simply holding a position or appointment does not constitute a "malign" talent program but if it's with a country of concern it maybe problematic

Engagement in a "malign" foreign talent recruitment program from a *country of concern* precludes you from applying of receiving federal research dollars

Countries of concern are currently defined by the U.S. federal government.

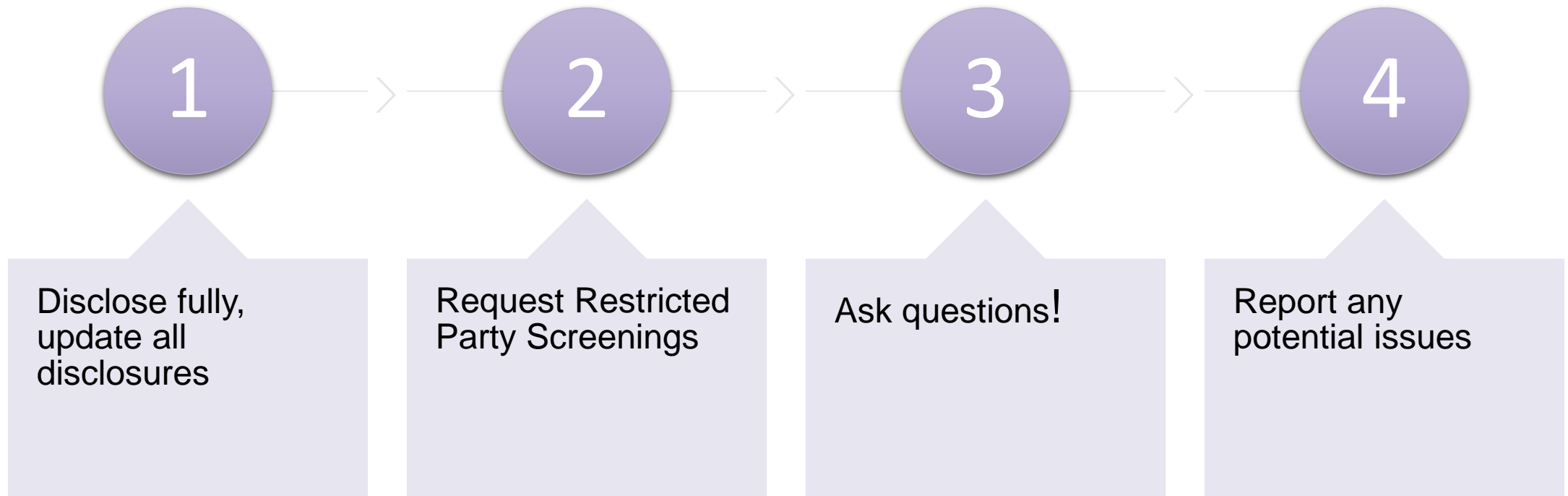| China | Iran | Russia | North Korea |

Northwestern | RESEARCH

Restricted Party Screenings

- Visual Compliance is a third- party vendor tool used to identify denied parties.

- **Restricted party examples:** Bureau of Industrial Security (BIS) entity list, DoD 1286 List, OFAC sanctioned entities or individuals, or those barred by other U.S. government lists or other countries.

- Northwestern screens the following:
  - Research visitors
  - International shipments that go through Research Safety
  - Formal partners where there is a Sponsored Research agreement
  - Vendors processed by Procurement & Payment Services

- **The ECIC will screen any collaborator upon request**.

Importance of Disclosures

What can you do to avoid inadvertent missteps?

1

Disclose fully, update all disclosures

2

Request Restricted Party Screenings

3

Ask questions!

4

Report any potential issues

Relationships

- Appointments
- Affiliations
- Collaborators
- Leading or performing research elsewhere
- Talent program participation

Funding

- <u>All</u> sources of funding available to your program
- Funding for similar work from other sources – both foreign and domestic

Resources

- Other research space
- Funded visitors
- Materials / equipment – even if provided "in-kind"

Activities

- Research outside of primary institution
- Investments* (e.g., startups)
- Some travel
- Consulting / paid speaking*

Disclosing

What to Disclose?

Significant Financial Interests

When to Disclose?

Training

Disclosing for Researchers

Reviewing

Research Requirements

Management Plans

Policies & Guidelines

Committees

Forms

Contact Us

HOME > DISCLOSING > **DISCLOSING FOR RESEARCHERS**

Disclosing for Researchers

Key personnel on sponsored projects make disclosures to funding agencies as well as in their Northwestern conflict of interest disclosure. Sometimes there is overlap between the two. The table below shows common types of activities and interests and where they must be disclosed.

Researchers looking for information on Current & Pending/Other Support should review the **guidance** *provided by Sponsored Research. See also guidance on* **Protecting Against Improper Foreign Influence in Research** *from the Office for Research.*

Disclosure Requirements for Federal Awards and per Northwestern Policy

Type of Entity or Activity	Conflict of Interest Disclosure (eDisclosure)	Biographical Sketch	Current & Pending (Other)	Facilities, Equipment, & Other Resources*	Project Reports**

Mitigation Plans

Contact the Export Controls & International Compliance team for assistance if you receive a letter requesting a mitigation plan.

exportcontrols@northwestern.edu

🌐	1. Foreign Talent Programs
🚫	2. Denied Entities
💵	3. Foreign Funding
🏛	4. Foreign Institutions
🛡	Patents filed outside U.S. first

Research Security Proposal Risk Reviews & Mitigation

DoD, DOE, NSF, and NIH have matrices/process in place

Table 1: Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions

Factors for Assessing a Covered Individual's Associations, Affiliations, Collaborations, Funding, and the Policies of the Proposing Institution that Employs the Covered Individual

	Factor 1: Foreign Talent Recruitment Programs	Factor 2: Funding Sources	Factor 3: Patents	Factor 4: Entity Lists

NSF TRUST

Trusted Research Using Safeguards and Transparency

Northwestern Research | EXPORT CONTROLS & INTERNATIONAL COMPLIANCE

Rating	Factor 1: Foreign Talent Recruitment Program[4,5]	Factor 2: Foreign Funding[6,7]	Factor 3: Affiliation with Foreign Institutions or Entities[6,8]
Mitigation measures required. **Contact recipient institution for more information.**	Indicators of active (ongoing) participation in a malign foreign talent recruitment program (MFTRP) meeting any of the criteria in Sec. 10638(4)(A)(i)-(ix) of the CHIPS and Science Act of 2022. [Note: this factor/rating is automatically disqualifying]	Indicators of undisclosed or incompletely disclosed active (ongoing) funding from a Foreign Country of Concern (FCOC) or an FCOC-connected entity	Indicators of an undisclosed or incompletely disclosed active (ongoing) affiliation with an institution or entity located in or connected to a Foreign Country of Concern (FCOC).

What we need to conduct a review/risk assessment:

Names of the institutions (universities, companies, labs, etc.):

Names of the individuals (and their employer):

Nature of the activity (meeting, conference, research exchange, etc.):

Formal or informal collaboration (SR agreement, MTA, other, none):

Compensation (by whom and what services will you be providing):

Items to be shared: (data, materials, substances, equipment, technology, other):   If yes, has it been published?

IF TRAVEL related, provide the below:

Dates for travel:

Funding for the travel (NU, federal agency, personal, other):

[Research Security Website link](#)

Northwestern | EXPORT CONTROLS & INTERNATIONAL COMPLIANCE

When to contact the ECIC team

When should you contact the ECIC team?

- Shipping/exporting something outside the U.S., particularly if it meets ones of three high risk criteria

- Working (virtually or abroad) with a sanctioned country

- Reviewing an agreement and you find a publication restriction

- Purchasing equipment that requires and export control certification

- Traveling abroad on university business with Northwestern equipment

- Performing work under an RFP/Agreement/Contract that is marked "Export Controlled"

- When you have a question related to improper foreign influence or research security

- You suspect a violation of export control laws or regulations has occurred

- Anytime you have a question!

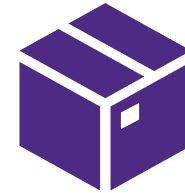# Export Controls & International Compliance Core Services

Export Clause Reviews

Equipment Purchases

International Shipping

Restricted Party Screenings & Talent Plan Reviews

International Travel

Sanctioned Countries Engagement

License Applications

Training

It takes a village

Export controls and research
security is a team sport!

Who can help you?

- [Sponsored Research](#) – Current & Pending Support Updates and Sponsor Qs

- [Conflict of Interest](#) – Northwestern COI disclosures

- [Office of General Counsel](#) (OGC) – If a federal enforcement agency contacts you.

- [Export Controls & International Compliance](#) – General questions including is my talent program "malign?"

CONTACT US

- Questions – email us: exportcontrols@northwestern.edu

- Website Resources:
  - Export controls website: https://exports.northwestern.edu/
  - Research security website: https://researchsecurity.northwestern.edu/

- Frequently Asked Questions (FAQs) & Guidance
  - International Collaboration FAQs Link
  - Disclosure matrix and FAQs
  - Foreign Talent Program Guidance
  - Restricted Party Screening – Denied Entity FAQs
  - International Shipping FAQs
  - International Travel Guidance

- Training – Export Controls & Research Security

- Export Control Policy

Comments | Questions

Office for Research

email: **exportcontols@northwestern.edu**

Export Controls & International Compliance website

Research Security website

Protecting our values while meeting federal regulatory requirements

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