Research Regulatory Affairs

Research Security and Export Controls

11/24/2025

PURDUE UNIVERSITY

1

Today's Discussion

What we will cover:

- Who RSEC is
- Sanctions and Export Controls
- Research Security
- Key Takeaways

PURDUE UNIVERSITY

2

Who are we?

Research Security and Export Controls (RSEC)

Kate Stoan
Senior Director

Steph Schmidt
Executive Assistant

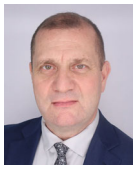
Karan Hustedt-Warren
Associate Director
Research Security

Ross Meyers
Export Controls
Program Manager

Keona Sherrill
Senior Export
Controls Analyst

Michelle Parks
Export Controls
Analyst

Tad Mitchell
Research Security
Program Manager



Brian Bussell
Research Security
Analyst

Amanda Eldridge
Research Security
Program Coordinator

PURDUE UNIVERSITY

Regulatory Responsibilities

Research Security and Export Controls (RSEC)

Sanctions and Export Controls

Provides a framework for how we engage internationally to:

- Protect U.S. national security;
- Advance U.S. economic interests; and
- Achieve U.S. foreign policy objectives.

Research Security

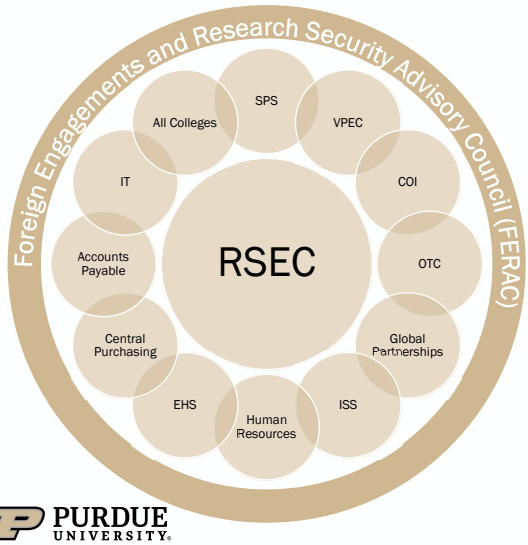
Provides a framework to protect the research enterprise against:

- The misappropriation of research and development;
- Foreign government interference; and
- Reputational and funding risks.

PURDUE UNIVERSITY

Program Design

Research Security and Export Controls (RSEC)



Our researchers serve Purdue's mission best when they are in the lab and in the classroom.

Foreign Engagements and Research Security Advisory Council (FERAC)

- Chaired by our Research Integrity Officer
- Assesses tricky situations to recommend Purdue's strategic approach on certain international activities

RSEC is dovetailed into almost every administrative unit to flag, analyze, and mitigate risks.

PURDUE UNIVERSITY

5

RSEC Goals

Helping Purdue's researchers navigate evolving regulations

- ✓ Safeguard Purdue's research intellectual capital from potential threats.
- ✓ Provide clear and actionable guidance.
- ✓ Integrate reporting processes and procedures.

PURDUE UNIVERSITY

6

Sanctions and Export Controls

FACR, ITAR, EAR, and others

Kate Stoan, Senior Director for Research Security & Export Controls

PURDUE UNIVERSITY

The Importance of Compliance

Sanctions and Export Controls

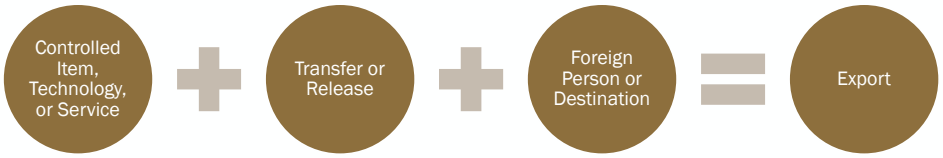
- Export Controls exist to protect U.S. national security, to advance U.S. economic interests, and to achieve U.S. foreign policy objectives.
- Need to act responsibly toward the research enterprise and the broader society we serve.
- Important to maintain trust with our students, faculty, donors, and the Indiana taxpayer.
- Penalties for violations are severe and include fines, jail time, loss of export privileges, loss of government contracts, and reputational damage. Penalties can be levied against individuals and the University.
- RSEC holds responsibility for ensuring Purdue maintains compliance with these regulations. By building pathways to compliance, we make it easier for our faculty to engage in controlled research.

PURDUE UNIVERSITY

What are Export Controls?

Sanctions and Export Controls

- Federal regulations that govern the transfer of certain items, technology, and services to persons abroad and in the U.S.
- Exports can occur via email, phone or in person conversations, visual access, etc.
- In some cases, express written permission in the form of an export license is required from the U.S. government. Failure to secure a license when one is required is considered an "export control violation."

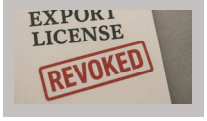


PURDUE UNIVERSITY

9

Key Terms

Sanctions and Export Controls

Export	Deemed Export	Foreign Person	Export License	Exceptions/Exemptions
An actual shipment or transmission out of the United States, including the sending or taking of an item out of the United States, in any manner.	Releasing or transferring export controlled technology to a Foreign Person in the United States.	Any person who is not a U.S. citizen by birth or naturalization, U.S. permanent resident, or has special status (e.g., refugee or asylum holders).	Specific authorization from the U.S. government to engage in an otherwise prohibited activity. Applications can be returned without action, denied, granted with provisos, granted, or revoked at any time.	An otherwise prohibited activity that is authorized if a very specific set of criteria are met. There are recordkeeping requirements associated with the usage of these, and they are self-electing.
				

PURDUE UNIVERSITY

10

Regulating Bodies

Sanctions and Export Controls

	Department of the Treasury	Department of State	Department of Commerce
Empowered Agency	Office of Foreign Assets Control (OFAC)	Directorate of Defense Trade Controls (DDTC)	Bureau of Industry and Security (BIS)
Regulations	Foreign Assets Control Regulations (FACR)	International Traffic in Arms Regulations (ITAR)	Export Administration Regulations (EAR)
Scope	Services of value to and from certain countries, regimes and other parties on which economic and trade sanctions have been issued.	Permanent and temporary exports, and temporary imports of: ○ Defense articles ○ Defense services ○ Technical Data	Permanent and temporary exports, reexports, and retransfers (in-country) of: ○ Commodities ○ Software ○ Technology
Control List	OFAC Sanctions Lists	United States Munitions List (USML)	Commerce Control List (CCL)
Classifications	Sanctions Programs: Cuba, Iran, North Korea, and Global Terrorism (i.e., Taliban / Afghanistan)	USML Categories	Export Control Classification Numbers (ECCN)
Restrictiveness	Typically restrictive, and typically complex in application; depends on individual sanctions program	Most restrictive, but relatively straightforward in application	More permissive, but more complex in application
Restricted Parties: These may be foreign or domestic individuals, companies, or organizations that the U.S. government has designated as acting contrary to the national security or foreign policy objectives of the United States. All these Departments issue publicly available lists which are updated regularly.			

There are other regulations (NRC, DOE, FTR, etc.). These are the primary ones that impact research.

PURDUE UNIVERSITY

11

Most university activity is not subject to these regulations, but some of it is.

Purdue performs classified, export controlled, and other sensitive research.

12

Technology Not Subject to the Regulations

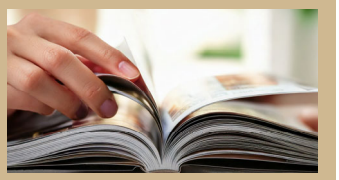
Export Controls

Published Information

Information available to the public without restrictions upon its further dissemination

Information presented at conferences open to the public

Includes patents available at any patent office.



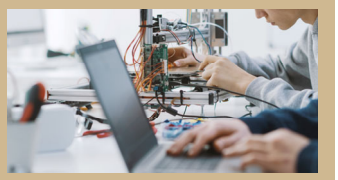
Educational Information

Information released by instruction in a catalog course or associated teaching laboratory of an academic institution.

General scientific, mathematical, or engineering principles.

Fundamental Research

Basic and applied research in science and engineering, **the results of which** ordinarily are published and shared broadly within the scientific community…



PURDUE UNIVERSITY

Technology Subject to the Regulations

Export Controls

Receipt of confidential or proprietary information

Information with restrictions upon its dissemination

Typically covered by an NDA or the confidentiality section of a sponsored research agreement

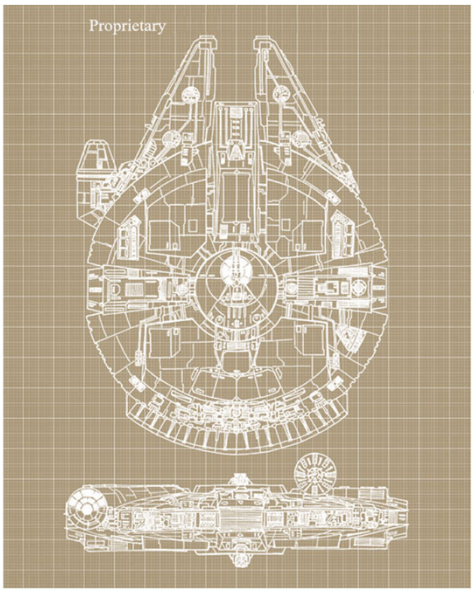
Access or dissemination restrictions on research results

Research results that the sponsor holds as their proprietary information (work-for-hire)

Requirements for research results to be **approved** by the sponsor prior to publication

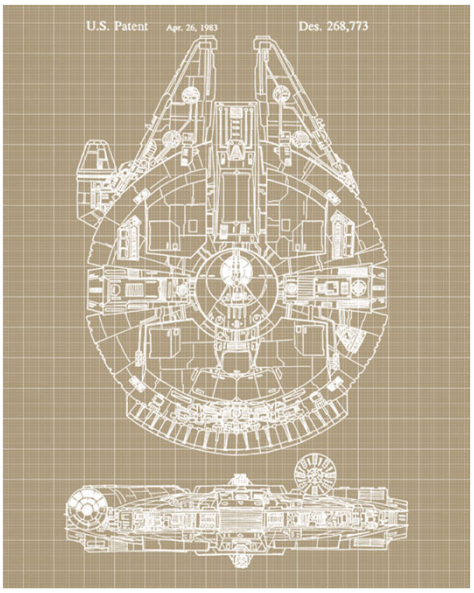
Restrictions on research staff based on citizenship for national security reasons

PURDUE UNIVERSITY



Subject to export controls

Not subject to export controls



PURDUE UNIVERSITY

15

When we act like a university, we are treated like one.

When we act like a business or a defense contractor, we are regulated like one.

Limits to Fundamental Research

Export Controls

Physical Exports
Shipping or hand-carrying physical items containing controlled software and technology.

Financial Transactions
Financial transactions with restricted parties or entities

Proprietary Information
Faculty may work with export controlled technology during the course of a Fundamental Research project

Certain Activities
Export controlled activities such as "activities of U.S. persons", "technical assistance" or "defense services".

Sanctions, Embargoes, and Boycotts
Other transactions involving embargoes or sanctioned parties or people in sanctioned geographies

PURDUE UNIVERSITY

17

Activities of U.S. Persons

15 CFR § 744.6

No U.S. person may, without a license from BIS, 'support':

- The design, development, production, and operation of:
  - Chemical or biological weapons in or by any country
  - Nuclear explosive devices in or by certain countries
  - Missiles in or by certain countries
  - Advanced node integrated circuits to some countries
- The design, development, production, shipment, or transfer of a whole plant to make chemical weapons precursors for toxic chemical agents;
- A 'military-intelligence end use' or a 'military-intelligence end user,' in certain countries.

'Support' = engaging in some way when you know the activity lends itself to one of these end-use, even if an "export" isn't occurring.

PURDUE UNIVERSITY

18

Defense Services

22 CFR § 120.32

- The furnishing of assistance (including training) to foreign persons, whether in the United States or abroad in the design, development, engineering, manufacture, production, assembly, testing, repair, maintenance, modification, operation, demilitarization, destruction, processing, or use of defense articles;
- The furnishing to foreign persons of any technical data controlled by the ITAR whether in the United States or abroad; or
- Military training of foreign units and forces, regular and irregular, including formal or informal instruction of foreign persons in the United States or abroad or by correspondence courses, technical, educational, or informational publications and media of all kinds, training aid, orientation, training exercise, and military advice.

PURDUE UNIVERSITY

19

Export Controls Program

We want to ensure that all exports performed by Purdue are intentional, deliberate, and facilitated by an export compliance professional.

- Exports of Physical Articles:
  - International Shipping: All physical shipments to destinations outside the U.S.
  - International Travel: Hand-carries of Purdue items are exports
- Exports of Controlled Technical Data, Technology, and Software
    - Foreign Person access on campus
    - Cloud Platforms
    - Remote Access
  - Technology Control Plans: Implemented to safeguard this information and to ensure that when these things happen, we are aware and can facilitate that export.

PURDUE UNIVERSITY

20

Program Design

Sanctions and Export Controls (RSEC)

While we sit within the Office of Research, we have responsibilities throughout the entire university.

FERAC: Chaired by Dr. Jamie Mohler

Cross functional partnerships to mitigate risks:

- Faculty Outreach
- Security Briefings and Training
- Technology Control Plans

PURDUE UNIVERSITY

21

Technology Control Plans

Technology Control Plans (TCPs) are part of our internal security procedures used to describe and document the steps necessary to ensure that all exports of information are intentional, deliberate, and facilitated by an export controls professional to ensure compliance.

Noncompliance with TCPs are subject to an escalating scale of disciplinary measures including, but not limited to, the ability to continue to conduct controlled research.

TCPs are living documents!

PURDUE UNIVERSITY

22

Know Your Customer

Supplement No. 3 to Part 732

Various requirements of the EAR are dependent on a person's knowledge of the end-use, end-user, ultimate destination, or other facts relating to a transaction or activity.

- Decide whether there are red flags
  - The other party is reluctant to offer information or evasive about the end-use of a technology
  - The technical capabilities do not fit the other party's line of business
  - The technology requested is incompatible with the technical level of the country showing interest
- Do not self-blind
- Ask questions and reevaluate
- Refrain from certain transactions

PURDUE UNIVERSITY

Research Security

NSPM-33, CHIPS & Science Act, & Federal Agency Requirements

Karan Hustedt-Warren, Associate Director for Research Security

PURDUE UNIVERSITY

What is Research Security?

"…safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign government interference." (NSPM-33)

- Emphasis on **affiliations** and **associations** to protect **federal research funding**
  - Applicable to ALL federally funded research

Click or scan for Purdue's policy

PURDUE UNIVERSITY

Research Security Requirements

Flowing to Research Institutions via Federal Agency

NSPM-33 (2021)	CHIPS and Science Act (2022)	OSTP / NSPM-33 Final Rule (2024)
Directed federal agencies to: • Require the usage of digital persistent identifiers • Standardize disclosure requirements • Enhance vetting and compliance Put research institutions on notice to: • Implement research security programs that embed: 1) cybersecurity, 2) foreign travel security, 3) research security training, and 4) export controls training	Passed to: • Boost U.S. competitiveness • Fund NSF Research Security Office • Designate NSF as the lead agency • Prohibit federal agencies from funding participants of Malign Foreign Talent Recruitment Programs (MFTRPs) • Increase disclosure requirements • Require research security training	Directed federal agencies to: • Expand disclosure requirements • Implement requirements for research institutions to provide research security training, export controls training, foreign travel security, and cybersecurity • Implement requirements for research institutions to certify to a Research Security Program within 18 months

PURDUE UNIVERSITY

26

Key Concerns

How is U.S. government research funding being used?

1. National Security
2. Strategic Economic Competition
3. Maintaining Trust

Scan or click to check out the 2024 Critical and Emerging Technology List

PURDUE UNIVERSITY

***Even though a lot of focus on CETs, its important not to forget all the things that are already controlled. CETS are high risk gray areas, but we are also seeing increased restrictions and regulations being imposed with legal consequences at record speed. ***

27

International Engagement Risk-Levels by Country

Lower Risk		Moderate Risk		Higher Risk		*Comprehensive Sanctions*
Low		Medium		High		
Australia Canada United Kingdom	Argentina Austria Belgium Bulgaria Croatia Czech Republic Denmark Estonia Finland France Germany Greece Hungary Iceland India Ireland Italy Japan South Korea Latvia Lithuania Luxembourg Mexico Netherlands New Zealand Norway Poland Portugal Romania Slovakia Slovenia South Africa Spain Sweden Switzerland Turkey	Albania Brazil Serbia Ukraine Malta Singapore	Algeria Andorra Angola Antigua and Barbuda Aruba Bangladesh Barbados Belize Benin Bhutan Bolivia Bosnia & Herzegovina Botswana Brunei Burkina Faso Burundi Cameroon Cape Verde Chad Chile Colombia Comoros Congo (Republic of the) Costa Rica Cote d'Ivoire Curaçao Djibouti Dominica Dominican Republic Ecuador El Salvador Equatorial Guinea Ethiopia Fiji Gabon Gambia The Ghana Grenada Guatemala Guinea GuineaBissau Guyana Honduras Indonesia Jamaica Kenya Kiribati Kosovo Lesotho Liberia Macedonia Madagascar Malawi Malaysia Maldives Mali Marshall Islands Mauritania Mauritius Micronesia Monaco Montenegro Morocco Mozambique Namibia Nauru Nepal Niger Nigeria Palau Panama Papua New Guinea Paraguay Peru Philippines Rwanda Saint Kitts & Nevis Saint Lucia Saint Vincent and the Grenadines Samoa San Marino Sao Tome & Principe Senegal Seychelles Sierra Leone Sint Maarten Solomon Islands Sri Lanka Surinam Swaziland Tanzania Thailand The Bahamas Timor Leste Togo Tonga Trinidad & Tobago Tunisia Tuvalu Uganda Uruguay Vanuatu Vatican City Western Sahara Zambia	Taiwan Bahrain Egypt Israel Jordan Kuwait Oman Pakistan Qatar Saudi Arabia United Arab Emirates	Afghanistan Armenia Azerbaijan Cambodia Central African Republic Congo (DRC) Cyprus Cyprus Eritrea Georgia Haiti Iraq Kazakhstan Kyrgyzstan Laos Lebanon Libya Moldova Mongolia Myanmar Nicaragua Somalia South Sudan Sudan Syria Tajikistan Turkmenistan Uzbekistan Vietnam Yemen Zimbabwe Venezuela	Belarus **China** **Hong Kong** **Macau** **Russia**	**Cuba** **Iran** **North Korea**

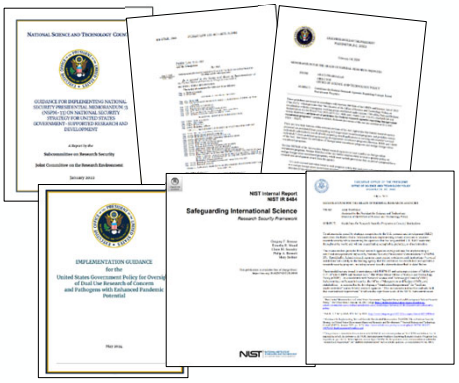
Highest Research Security Risk

PURDUE UNIVERSITY

28

Disclosure Requirements

- ✓ ***Safeguarding of fundamental research*** –Report engagement in malign foreign talent program, U.S. restricted entities, foreign patents, funding from a country of concern
  - ✓ ***Disclosure and transparency*** – Requires faculty to register with ORCID (digital object identifier) and maintain an accurate federal CV, outside activity disclosure
  - ✓ ***Disclosure of foreign financial gifts and contracts*** – Requires Purdue to report financial gifts and contracts received from international parties.



In addition to federal requirements there are also ***new Indiana laws and EOs*** *that will limit engagement with strategic competitors and require additional reporting by Purdue.*

PURDUE UNIVERSITY

29

Research Security Program

Current State of Key Components

Research Security Training	International Travel	Cybersecurity	Export Controls Training
• DOE = May 2025 • USDA = July 2025 • NSF = Oct 2025 • NIH = Oct 2025 • DoD = TBD 2025	• No federal agency requirements have been rolled out yet	• Draft guidance issued fall 2025	• Addressed through Export Controls Program • Additional information embedded in Research Security Training
✓ Within 12 mo of proposal ✓ Annual recertification ✓ All covered/key personnel	✓ International travel reporting and approval in risk mitigation plans (some include personal travel)	✓ Research Security Plans require a cybersecurity program consistent with Dept of Commerce guidance.	✓ Already a key component of any export controls program

Critical Trends to Watch:

- ➢ Incoming risk assessment letters requiring immediate institutional response
- ➢ Mandated Risk Mitigation Plans (RMPs) with strict deadlines
- ➢ Expanding Research Security Plan obligations from sponsors

Risk of funding loss due to non-compliance or delayed action!

PURDUE UNIVERSITY

30

How do we meet these requirements?

- ✓ Annual Training
- ✓ Outreach
- ✓ Briefings
- ✓ Travel guidance
- ✓ Consultations
- ✓ Risk assessments
  - ✓ Partner with other compliance teams and administrative units

Collaboration is key!

Take the Training!

annual certification

PURDUE UNIVERSITY

Malign Foreign Talent Recruitment Program (MFTRP)

CHIPS and Science Act of 2022

1 **Is there compensation** in any form- including recognition or awards- or with the promise of future compensation from a country other than the U.S.?

2 **Is the program from a country of concern** as defined by the U.S. federal government - China, Iran, Russia, North Korea?

3 Indicators that the program is "malign" in nature are below:

- Transfer IP, data or other nonpublic information without authorization
- Recruit others to participate in the program
- Hold a position in a foreign country
- Engage in work for or in another country that overlaps with U.S. federal funding
- Unable to terminate the contract
- Apply for or receive funding from a sponsoring foreign government with the sponsoring foreign organization as the recipient
- Conceal program participation
- Have a conflict of interest or commitment

PURDUE UNIVERSITY

Scan or click to learn more

Foreign Recruitment Programs

Executive Order 25-64

Purdue = State Educational Institution (SEI)

> 13. All SEIs shall include in their employment manuals or policies a prohibition against their faculty and employees taking part in any foreign recruitment program by a foreign adversary nation, including but not limited to the China's Thousand Talents Program.

Broadens the prior MFTRP prohibition in 3 ways:

- Applies to <u>all</u> employees of Purdue, not just key personnel on federally funded research;
- Applies to programs sponsored, not only by China, Iran, Russia, and North Korea, but also to those sponsored by Cuba and Venezuela;
- Prohibits talent recruitment programs, regardless of whether or not they are "malign" in nature.

<u>Research Security Program (I.A.6)</u>
<u>Foreign Adversary Nations, Interim (III.B.7)</u>

PURDUE UNIVERSITY

33

Federal Agency Funding Process

PURDUE UNIVERSITY

34

Federal Agency Research Security Risk Assessments

Agency	Risk Factor 1	Risk Factor 2	Risk Factor 3	Risk Factor 4	Co-authorship considered in risk assessment?	How far back?
DoD (incl DARPA)	Foreign Talent Recruitment Program participation	Funding from FCOC	Patent applications or patents filed outside the U.S., particularly in FCOC	Association or affiliation with entities on entity lists	Yes	Some factors from 10/10/2019 (Griffin Letter) others from 08/09/2022 (signing of CHIPS)
U.S. Army	Foreign Talent Recruitment Program participation	Affiliation with denied entities	Funding from strategic competitors	Affiliation, association, or collaboration with strategic competitors	Yes, and also participant as a panelist at foreign conferences	Not specified
DOE	Foreign Talent Recruitment Program participation – foreign funding sources, certain concerning behaviors associated with patenting	Foreign ownership or control, criminal or regulatory issues, the supply chain for any sensitive equipment/supplies, and ties to entities on specified lists	Risk factors tied to date of activity or relationship	Technology considerations – emerging or critical technologies	Yes, not stated in policy but verbally DOE has stated they may look at co-authors	Not clearly specified but 2019
NIH	Foreign Talent Recruitment Program participation	Undisclosed foreign funding, particularly from FCOC	Undisclosed affiliations with foreign institutions or entities, particularly with FCOC	N/A	No, if not directly related to NIH-funded work	5 years
NSF (Quantum / AI only)	Active appointments and positions with or research support from U.S. proscribed parties and party to MFTRP	Nondisclosures of appointments, activities, and sources of research support	Potential foreseeable national security applications of the research	N/A	N/A	Undisclosed information will be examined from January 2022 (NSPM-33 implementation guidance issued)

PURDUE UNIVERSITY

Created courtesy of Vanderbilt and further adapted by Northwestern & Purdue.
Recommend verifying with agencies' matrices.

Disclosure Requirements

Purdue Disclosure Requirements (Internal)

1) Reportable Outside Activities
2) Conflict of Interest

Federal Disclosure Requirements (External)

1) NSPM-33 Implementation Guidance
2) Common Forms
3) NSPM-33 Implementation Guidance Pre-and Post-Award Disclosures Table

NSPM-33 Implementation Guidance Pre- and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending (Other) Support
May 20, 2024

Type of Activity	Biographical Sketch	Current & Pending (Other) Support	Facilities, Equipment & Other Resources	Project Reports	Post-Award Information Term & Condition	Disclosure Not Required
Postdoctoral scholars, students, or visiting scholars who are supported by an external entity, and whose research activities are intended for use on the project/proposal being proposed			✓			
Postdoctoral scholars, students, or visiting scholars who are supported by an external entity, whose research activities are not intended for use on the project/proposal being proposed and have an associated time commitment		✓		✓*	✓*	
Travel supported/paid by an external entity to perform research activities with an associated time commitment		✓		✓*	✓*	
Startup company based on non-organization-licensed IP		✓		✓*	✓*	

PURDUE UNIVERSITY

Program Design

Research Security

While we sit within the Office of Research, we have responsibilities throughout the entire university.

FERAC: Chaired by Dr. Jamie Mohler

Cross functional partnerships to mitigate risks:

- Faculty Outreach
- Security Briefings and Training
- Risk Mitigation Plans
- Research Security Plans

PURDUE UNIVERSITY

37

Cost of high-risk engagements and/or noncompliance

Removal from Project

Debarment

Administrative Actions

Civil & Criminal Liability

Reputational Damage

PURDUE UNIVERSITY

38

Key Takeaways

What you need to do

- ✓Notify us before engaging with anyone in Cuba, Iran, or North Korea
- ✓Follow university processes
- ✓Reach out if you have a TCP, RMP, or RSP with prior institution

We don't want to disrupt your work.
If we reach out, we need something from you, and you likely need something from us.

PURDUE UNIVERSITY

39

QUESTIONS

PURDUE UNIVERSITY

40

Research Regulatory Affairs

Human Research Protection Program and the IRB

11/24/2025

PURDUE UNIVERSITY

Research with Human Subjects I.C.1

Purdue Policy

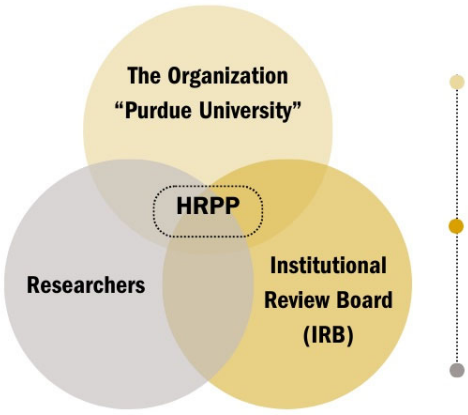
All Research involving Human Subjects conducted at or by Purdue University must be guided by the ***highest ethical standards and adhere to applicable federal, state, and local laws and regulations.***

.

The overarching ethical principles of respect for persons, beneficence and justice, as articulated in the Belmont Report and codified in the Common Rule (45 CFR part 46), must be upheld at all times during the design and conduct of Research involving Human Subjects.

Purdue University's ***Human Research Protection Program (HRPP)*** *implements measures to cultivate Purdue's commitment to protect human participants in Research.*

A Human Research Protection Program (HRPP) is More Than the Institutional Review Board (IRB)



The Organization "Purdue University"

- Purdue policies
- Safety
- Contracts and sponsors
- Data security and access
- Managing conflicts of interest

Institutional Review Board (IRB)

- Promote and uphold ethical research principles
- Review per the Common Rule
- Apply expanded sponsor regulations
- Assigning review type

Researchers

- Responding to concerns from participants
- Reporting unanticipated events
- Updating documents
- Mentoring and training research team

Protections are distributed responsibilities

HRPP

Key Functions of the HRPP

- Provide regulatory expertise and guidance
- Support the IRB
- Provide education for investigators
- Facilitate collaborative research with external IRBs (sIRB/reliance/multisite studies)
- Maintain regulated records
- Conduct post-approval monitoring of research
- Facilitate ancillary reviews
- Integrate the diverse elements of that make up the HRPP

The Institutional Review Board (IRB)

The Purdue IRB

A key component of HRPP, the Purdue University Institutional Review Board (IRB), is charged with ethical review of proposed research with human subjects.

One committee with 15 members, 5 alternates

- Faculty from different colleges at Purdue
- Licensed Physicians
- Non-affiliated members and non-scientist members
  - Three Community Based
    - Child Advocate
    - Prisoner Representative
- HRPP Staff- Certified IRB Professionals (CIP)

Convened Committee

- Meets twice monthly
- Rolling submission deadline

The Institutional Review Board (IRB)

Convened Committee Review

- Greater than minimal risk studies (GTMR)
  *Minimal Risk- "The **probability and magnitude** of **harm or discomfort** anticipated in the research are not greater in and of themselves than those **ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests**."*
- Involves research that is not listed in federally defined expedited categories
  - Examples: Investigational medical devices, VO2 Max, radiation exposure
- Expedited review criteria are not met for approval
- Local policy requires committee review
  - Research with prisoners

The Institutional Review Board (IRB)

Does your research qualify for expedited review?

Must be no greater than minimal risk

Involve only procedures listed in one or ore <u>expedited review categories</u>

- *Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture…"*
- *"Prospective collection of biological specimens for research purposes by noninvasive means…"*
- *"Collection of data through noninvasive procedures"*
- *"Research on individual or group characteristics or behavior…"*

Reviewed and approved by an IRB member or Chair on a rolling basis

Exempt from IRB Review

Exempt doesn't mean what you think it does…

- Exempt from IRB review, approval, and oversight
- Must have an exempt determination made by the HRPP or IRB
- All activities must fit into one or more exempt categories and be no greater than minimal risk
- Exemption does not lessen the ethical obligations to subjects and the investigator may still be required to:
  - ✓ obtain informed consent
  - ✓ protect confidentiality and privacy
  - ✓ minimize risks
  - ✓ address problems or complaints
- Exemption Examples: Research on normal educational practices, surveys, interviews, focus groups, secondary data analysis, benign behavioral interventions

Trust the process

From Pre-Review to Approval

- Verification of personnel and training
- Administrative Pre-review by a Protocol Analyst
  - ➢ Clarifications requested
- Review by an IRB member or designated staff member
  - ➢ Clarifications requested
- Processing the final decision and determination letter

PERA IRB Module

Purdue Excellence in Research Administration (PERA)

Replaced Cayuse as IRB submission and management system October 2025

- PERA Training Website- videos and guides on how to use/navigate the system.
- Protocol details are put into Word document and appendices found in PERA IRB Library, along with consent templates.
  - Must log in to PERA to access, within the module.
- SmartForm Questions for reporting and HRPP/IRB office staff assignment purposes
  - Use the help text
  - Use the PERA Training Website resources

PERA IRB Module - Resources

PERA Library- Templates for Protocol and Consent

IRB > Library

Library

Standard Operating Procedures | General | Worksheets | Checklists | Templates

Name	Document
HRP-502a - Non-Exempt Consent Form TEMPLATE	HRP-502a - Non-Exempt Consent Form TEMPLATE
HRP-502b - Exempt Research Information Sheet TEMPLATE	HRP-502b - Exempt Research Information Sheet TEMPLATE
HRP-502d - Sample Assent Form	HRP-502d - Sample Assent Form
HRP-502e - Deception Debrief Consent Form TEMPLATE	HRP-502e - Deception Debrief Consent Form TEMPLATE
HRP-503a - Protocol - Non-Exempt Research	HRP-503a - Protocol - Non-Exempt Research
HRP-503b - NHSR Protocol TEMPLATE	HRP-503b - NHSR Protocol TEMPLATE
HRP-503c - Protocol - Exempt Research	HRP-503c - Protocol - Exempt Research
HRP-503e-Protocol-External-IRB-Site-Supplement-2	HRP-503e-Protocol-External-IRB-Site-Supplement-2
HRP-593-Appendix-A-Adults-with-Impaired-Decision-Making-Capacity	HRP-593-Appendix-A-Adults-with-Impaired-Decision-Making-Capacity
HRP-593-Appendix-B-Children	HRP-593-Appendix-B-Children
HRP-593-Appendix-C-Deception	HRP-593-Appendix-C-Deception
HRP-593-Appendix-D-Devices	HRP-593-Appendix-D-Devices
HRP-593-Appendix-E-Drugs	HRP-593-Appendix-E-Drugs

PERA IRB Module - Resources

PERA Library- Worksheets and Checklists

IRB > Library

Library

Standard Operating Procedures | General | Worksheets | Checklists | Templates

Name	Document
HRP-308 - WORKSHEET - Pre-Review	HRP-308 - WORKSHEET - Pre-Review
HRP-310 - Worksheet - Human Research Determination	HRP-310 - Worksheet - Human Research Determination
HRP-311 - Worksheet - Engagement Determination	HRP-311 - Worksheet - Engagement Determination
HRP-312 - Worksheet - Exemption Determination	HRP-312 - Worksheet - Exemption Determination
HRP-313 - Worksheet - Expedited Review	HRP-313 - Worksheet - Expedited Review
HRP-314 - Worksheet - Criteria for Approval	HRP-314 - Worksheet - Criteria for Approval
HRP-314a - Worksheet - Criteria for Consent	HRP-314a - Worksheet - Criteria for Consent
HRP-315 - WORKSHEET - Advertisements	HRP-315 - WORKSHEET - Advertisements
HRP-316 - WORKSHEET - Payments	HRP-316 - WORKSHEET - Payments
HRP-318 - WORKSHEET - Additional Federal Agency Criteria	HRP-318 - WORKSHEET - Additional Federal Agency Criteria
HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent	HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
HRP-324 - WORKSHEET - Contracts	HRP-324 - WORKSHEET - Contracts

Reliance with other IRBs

Multi-Site Research and Single IRB

- When investigators from different institutions conduct collaborative, non-exempt human subjects research, it is possible for one IRB (the sIRB) to lead the review and approval process and maintain oversight of the research.
- Reliance agreement – also known as an IRB Authorization Agreement (IAA)
  - Formal, written agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical (IRB) review and a participating institution relying on the ethical (IRB) review.
  - Study-specific
- Regulations require a single IRB (sIRB) for domestic, non-exempt research – with a few exceptions. If you have federally funded, non-exempt human subjects research projec, it's subject to sIRB requirements!

irbreliance@purdue.edu
https://www.irb.purdue.edu/resources-and-guidance/reliance.php

Data and Material Transfer

The agreement or the approval; which comes first?

Before submitting to the IRB, know if the provider requires a formal agreement for Purdue to use the data/materials for your research.

- You may be asked to upload a draft or fully signed agreement to the PERA IRB submission or to upload confirmation from the provider that an agreement is not needed.
- You may be asked to provide the informed consent that was used to originally collect the data.
- Processing of agreements and review of IRB submission can happen in parallel.

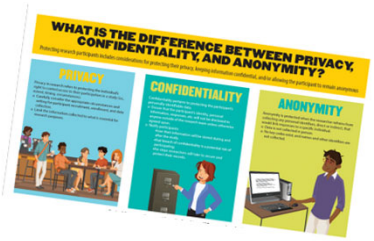
All agreements must be signed by either Purdue Sponsored Programs Services (SPS) Contracting or Purdue Office of Legal Counsel (OLC).

Tips

- Start early!
- View our review metrics to help plan
- Ensure your entire study team is up to date with CITI Training for Human Subjects Research
- Have site permissions and approvals in place before submitting.
- Mentor your graduate students through the entire process, beginning with the protocol

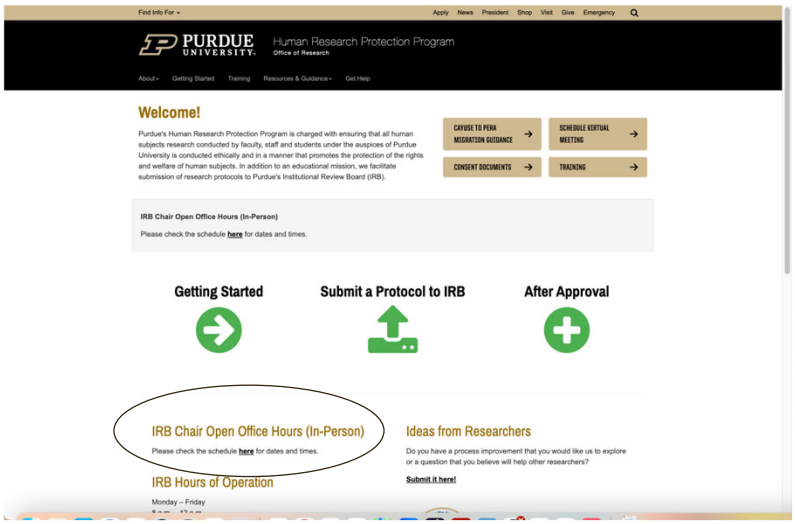
Review available resources on our website:

- Considering Privacy, Confidentiality, and Anonymity
- Deception and Debriefing
- Compensation
- International Research
- PERA Library



Resources for Assistance

IRB Chair Office hours in Wang Hall

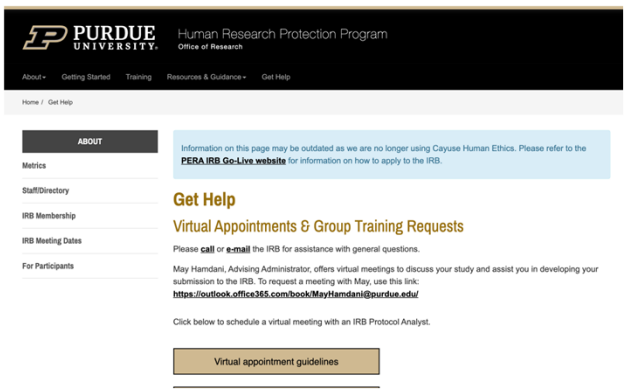


We are here to help!

Email Questions

- irb@purdue.edu
- irbreliance@purdue.edu

Virtual Meetings with HRPP Staff



QUESTIONS

PURDUE UNIVERSITY