

SPONSORED PROGRAM SERVICES

CONTRACTING & POST AWARD

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November 19, 2024



Sponsored Program Services

Contracting

Proposal is Awarded

What happens next?

- Sponsoring Agency sends a Notice of Award or Agreement
- Agreement is reviewed and negotiated by an SPS Contract Analyst to ensure that:
 - The University can meet the obligations as written within agreement.
 - The award truly reflects the University's understanding of the activity
 - Any contract/agreement entered into by the University is compliant with State and Federal law, and with University policy

SPS Contracting

- SPS Contracting's **Service-Level Agreement** can be found at the link below. The SLA details the services provided by Contracting and provides expected timelines for our contract negotiations.

<https://www.purdue.edu/business/sps/contractmgmt/index.html>

- Contract Analysts provide services which include, but are not limited to:
 - Answer questions on University contracts and contract negotiation issues
 - Draft Contract Agreements
 - Collaborate with other University staff as appropriate including:
 - Regulatory and Compliance, Export Control, Risk Analysis, Office of Legal Counsel, and others
 - Read and review all contract documents and prepare red-lines for sponsor review
 - Maintain up-to-date records in COEUS negotiation on all agreements initiated, in-process and completed
 - Negotiate the terms and conditions of an agreement to ensure compliance with all laws and University policies
 - Assure all regulatory requirements and export control issues are identified and necessary internal approvals are obtained

SPS Contracting

Role of a Contract Analyst

- Obtain approvals as follows:
 - ✓ Regulatory/IRB
 - ✓ Export Control
 - ✓ Research Security
 - ✓ Private Business Use
 - ✓ Risk Management
 - ✓ Dean/Department Head
 - ✓ Tech Transfer

SPS Contracting

Types of SPS contracts

- **NDA: Nondisclosure/Confidentiality/Proprietary Agreements**
 - Keep certain information confidential for a certain period of time
 - Can be unilateral or mutual
 - Typically for preliminary discussions before a research agreement
 - Often contain requirements that the confidential information be marked
 - **NDA's should be submitted to SPS Contracting in the new PERA system. The pdf NDA Info Sheet is no longer needed as all those questions are built into the PERA submission process.**

- **MTA: Material Transfer Agreements**
 - Set terms under which proprietary materials are transferred to Purdue or from Purdue for use by another research institution
 - **Similar to NDAs, MTAs need to be submitted to SPS Contracting in the new PERA system as well. The pdf MTA Info Sheet is no longer needed as all those questions are built into the PERA submission process.**

SPS Contracting

Types of SPS contracts

- **Traditional Agreements**
 - Basic Research
 - Testing
- **Applied Research Agreements**
 - Up-Front Commercial Non-Exclusive License
 - Up-Front Exclusive License
- **Master/Strategic Alliance Agreements**
- **Government**
 - Federal funding is significant and we routinely receive awards from numerous federal agencies for research work
 - We also receive funding for research from State of Indiana agencies

SPS Contracting

Non-Core Agreements handled by the Office of Legal Counsel

- Facility Use Agreements
- Equipment Use/Transfer Agreements
- Technical Assistance Agreements
- Student Affiliation Agreements
- Academic Subscription or Content Agreements
- Study Abroad/Student Exchange/Recruitment Agency Agreements
- International MOUs and Collaboration Agreements
- Editorship Agreements
- Visiting Scholar/Scientist Agreements
- Business Associate Agreements
- Student Capstone Projects and associated NDAs
- Purdue Online and Purdue Global
- Data Mine Agreements
- Software User/License Agreements (Procurement)

When routing items to the Office of Legal Counsel, please use their New Matter Intake Form found here: <https://www.purdue.edu/legalcounsel/>

SPS Contracting

Request Contracting Service

- When a faculty member is working with Pre-Award, Pre-Award will request Contracting's involvement at the appropriate time. When in doubt, ask your Pre-Award specialist about the next step.
- When the agreement does not involve Pre-Award -- such as confidentiality agreements, material transfer agreements, unfunded collaborations, and MOUs -- the faculty member should send an email request to spscontr@purdue.edu or submit in PERA.
- Contracting's departmental email is: spscontr@purdue.edu. The phone number is (765) 494-3863.
- When using Contracting's departmental email box, you should expect:
 - Your email will be answered by Contracting Support with an acknowledgement or more detailed response within 24-48 hours. If you have not received a response, please call our general line (765) 494-3863 for assistance.
 - If you have an urgent item, please state the timeframe clearly in your email. If the timeframe is urgent, mark your email as high priority and put "URGENT" in the subject line.
 - Please include as much helpful information and contacts in the body of the email and provide all relevant attachments to assist Contracting in providing a timely review and response.

SPS Contracting

Signature delegation

- Legal entity is the Trustees of Purdue University (we just use “Purdue University”)
- Under our bylaws, authority to sign for certain matters is delegated
- Contract Analysts have been delegated authority under defined parameters to sign contracts
- Business managers, faculty members cannot sign these contracts on behalf of Purdue University. However, faculty are often asked to **acknowledge** their responsibilities for confidentiality agreements and material transfer agreements
- There is a separate learning session on Signature Delegation

Intellectual Property

What does the ownership of IP impact?

- Licensing Revenue or IP Fees for PI, Department and University
- Right to Publish
- Right to pursue related research
- Private Business Use

SPS Contracting

Additional Resources and Information

- SPS Contracting website:
<https://www.purdue.edu/business/sps/contractmgmt/index.html>
- Best source of information for an active negotiation will be in PERA and the Assigned Owner of that Agreement will be the best SPS point of contact.
- Best contact for new questions and agreements: spscontr@purdue.edu

Sponsored Program Services

Post Award

Post Award

Award is fully executed – Now what happens?

- Post Award sets up the grant and sponsored program accounts
 - Send Notice of Award to PI, Co-PI's and business offices
 - Includes any unique restrictions or special requirements
 - Foreign restrictions
 - Financial Conflict of Interest certification (must be in order prior to starting research)
 - Training & travel disclosures (if applicable)
 - Compliance Items that need approvals:
 - Regulatory (Animals & Human Subjects)
 - Export Control

Need an account before the award is fully executed?

Notice to Proceed (NTP)

Notice to Proceed (NTP) will allow you to start research before award is received or fully signed.

- Your Business Office will work with you and your department to approve the NTP
- Your Business Office will submit a request to SPS Post Award
- SPS will review the request and communicate any risks as applicable
- SPS will create a grant and charging accounts

IMPORTANT: Compliance approvals and Conflict of Interest (COI) disclosures must typically be in order prior to start of research.

Post Award Services - SPS

Provides support for all sponsored awards through dedicated award set-up, subcontracting, billing and account management teams

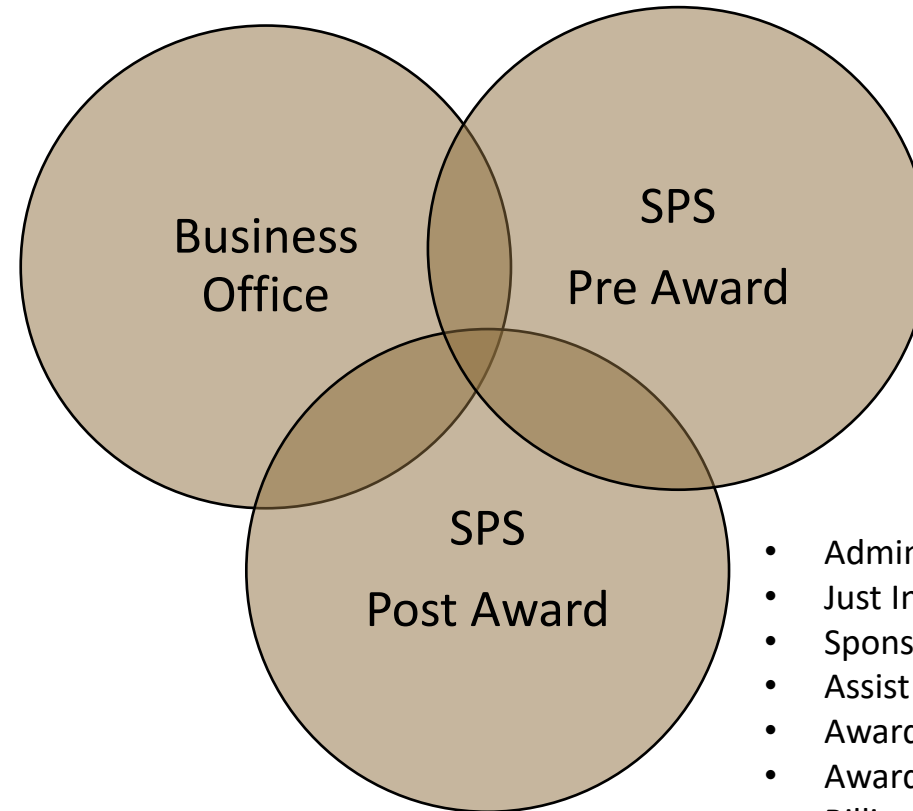
Services include, but are not limited to:

- Serve as resource for faculty, researchers, and business offices
- Provide guidance on sponsor specific guidelines and regulations
- Ensure all regulatory requirements and export control issues are identified and contain appropriate disclosures and approvals
- Review award document for requirements and highlight key issues for faculty and business offices
- Work with partnering institutions to secure all subcontract documentation
- Prepare and submit invoices, financial, invention and property reports
- Assist with electronic submission of technical reports

Post Award Email: spsacctmgmt@purdue.edu

Post Award Services – Business Office

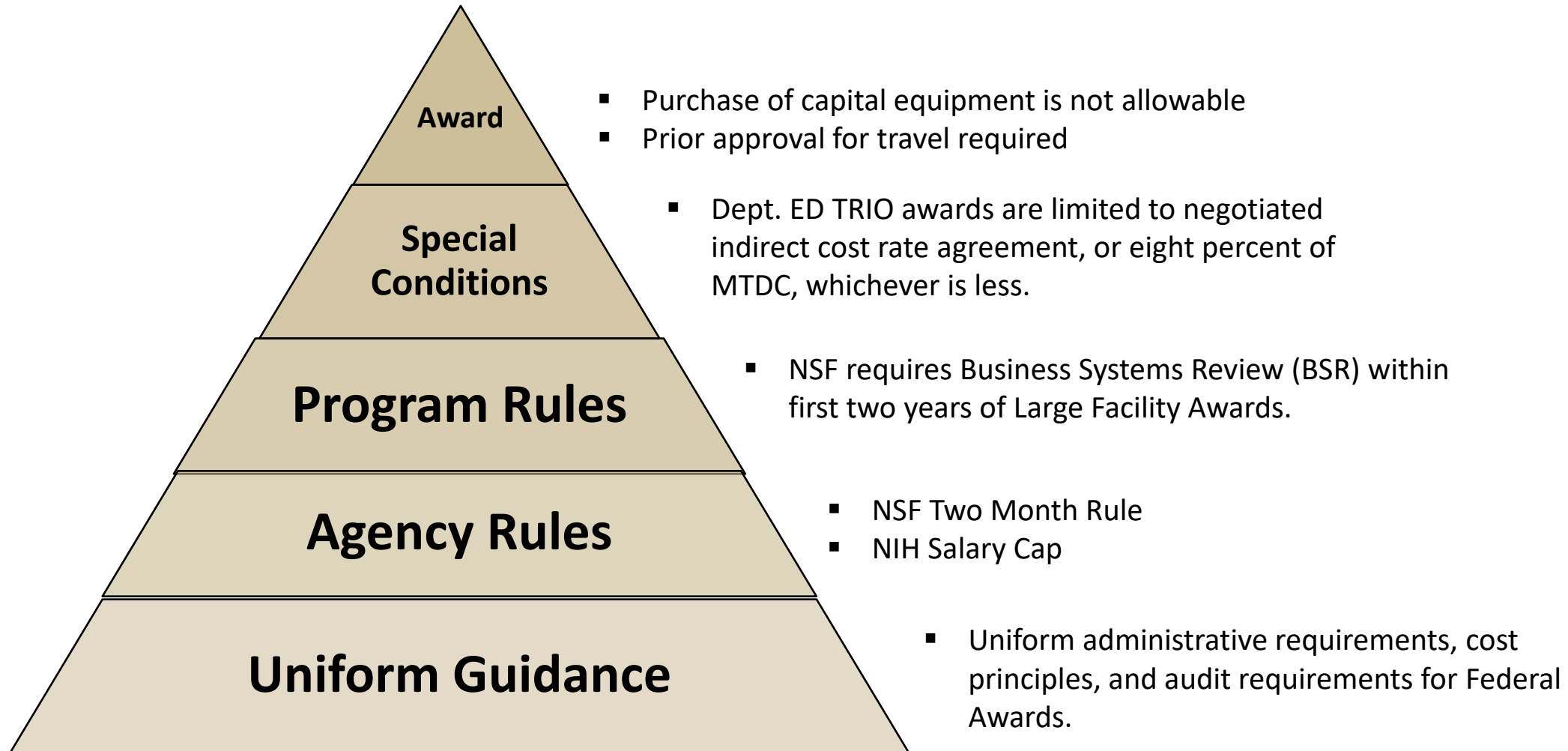
- Day to day account management
- Dashboards/balances
- Grant projections
- Monitors expenditures
- Effort Reporting
- Fiscal oversight
- Procurement Center
- Employment Center
- Manages Faculty Allocations (discretionary, startup)



- Proposal submission
- Proposal budget
- Current & Pending

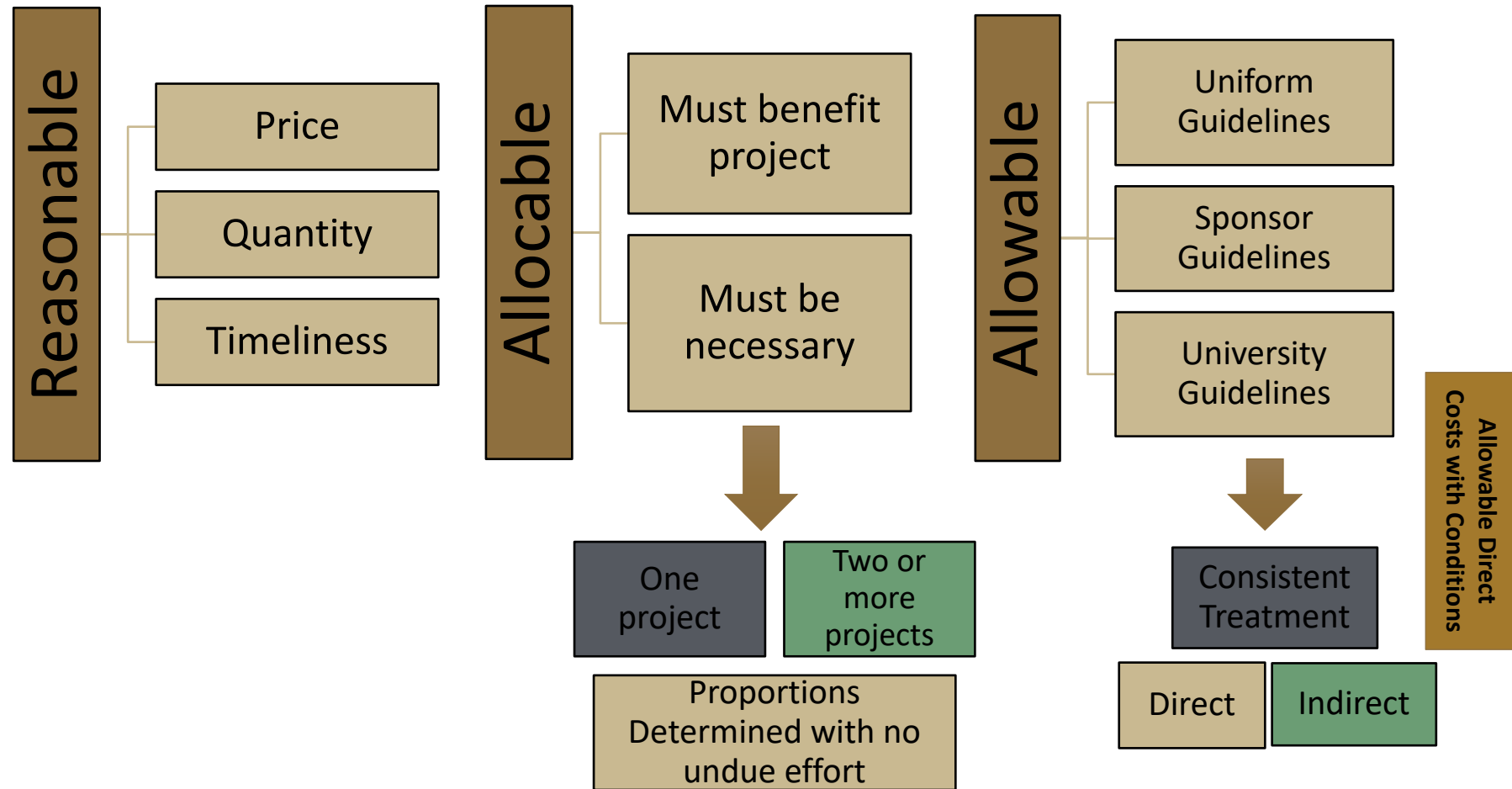
- Administers awards
- Just In Time Requests
- Sponsor reporting (financial, property, patent)
- Assist with Technical Report Submission
- Award setup
- Award closing
- Billings
- Subcontract monitoring
- Provides guidance on allowability for each sponsor award
- Audits/reviews

Order of Precedence



Decision Process

Determining Chargeability of Costs to a Sponsored Program:



Managing the Award – Prior Approvals

Items that may require prior approval:

- Change in Scope
- Changes in Key Personnel
- New/Additional Subcontracts
- Foreign Travel
- Capital Equipment
- PI absence exceeding 3 months
- PI reduction of effort exceeding 25%
- Extension of time
- Expenditure variances (per sponsor or award terms)
- Foreign national restrictions/Foreign components

Your Business Office will work with you and SPS on what is needed for a prior approval request submission. SPS will submit the request to the sponsor.

Role of the Principal Investigator (PI)

- Direct the work
 - Within project period
 - Within budget authorized by sponsor
 - Oversight of subrecipients work
 - Approval of subrecipient invoices certifies that the subrecipient is meeting project deliverables/objectives
- Determine Staffing
 - Project should be staffed according to budget unless something has changed
- Communicate with Business Office
 - Work closely with business office if changes to budget categories are needed; sponsor prior approval may be required

Role of the PI - Audits/Monitoring Visits

Terms and Conditions of the Award allow auditors the right of access to all University records associated with a project

- PI Responsibilities:

- Scientific records and data
 - Regulatory material (if applicable)
- Programmatic reports & approvals
- Maintain for THREE years after completion/submission of final report
- May be contacted by auditors regarding certification of effort and other items

Technical Reports

- Principal Investigators are responsible for the timely submission of all technical reports
 - Due dates are in award document
 - Contact SPS Research Administration Specialist with questions
 - NSF requiring a Current & Pending be sent with the RPPR
 - Outside Activity reported (summer)
 - Working at a Federal lab
- Why be timely?
 - Proper stewardship
 - Requirement (as part of terms & conditions)
 - Incremental or future funding may depend upon receipt of the report

Award Header – Status Workflow

Grants > UAT JS - [redacted] NIH R01 Detailed S2S

Help

Active

UAT JS - [redacted] NIH R01 Detailed S2S

AWD00000163 Funding Award

Next Steps

- [View Award](#)
- [Printer Version](#)
- [Create Award Modification](#)
- [Create Subaward](#)
- [Request Award Modification](#)
- [Create Continuation](#)

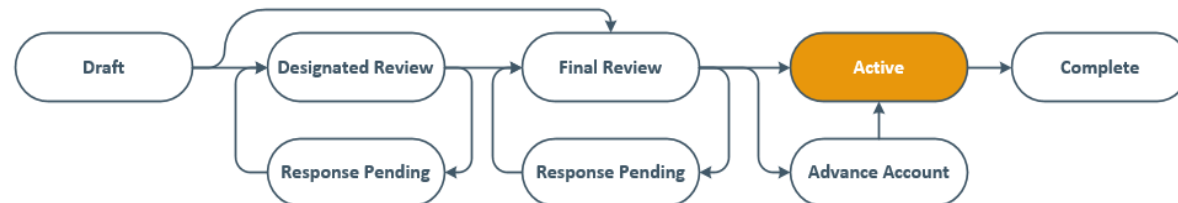
- [COI Disclosure Status](#)
- [Complete](#)
- [Set Award Relationships](#)
- [Upload Award Documents](#)
- [Manage Deliverables](#)
- [Manage Relationships](#)
- [Manage Tags](#)
- [Create Agreement](#)

PD/PI:	[redacted]	Award Date:	7/13/2024
Specialist:	Cori Mellady Test	Start Date:	2/1/2025
		End Date:	1/31/2031
Designated Reviewer:		Sponsor Award #:	123456
Award Approver:	Suzanne Payne		
Approving Dept/Div/Institute:	Biomedical Eng-PWL		
Administrative Contact:	Cori Mellady Test		
Direct Sponsor:	National Institutes Of Health		
Prime Sponsor:			
Current Total Project Period Commitment:	\$1,945,221		
Current Total Award Amount To Date:	\$400,182		

Awarded Funding Proposals:

ID	Name	Principal Investigator	Status
FP00000510	UAT JS - [redacted] NIH R01 Detailed S2S	[redacted]	Awarded

Grant Number:	
Grant Value:	\$400,182.00



Post Award – Grants Module/Awards

Agreements are linked on the award

Modifications	Totals	Funding Allocations	Deliverables	Subawards	Child Awards	Related Projects	Reviewers	Correspondence	History	...
Related Projects										
Filter by ? ID <input type="text" value="Enter text to search"/> <input type="button" value="Q"/> <input type="button" value="+ Add Filter"/> <input type="button" value="X Clear All"/> <input type="button" value="⚙"/>										
ID	Name	Owner	Organization	Project Type	Project Status	Modified Date				
SRA00000037	5-15 SRA Test w/o FP	Kyle Wargo	Sponsored Program Services	Agreement	Active	5/15/2024 4:14 PM				
SUB00000078	Michigan SUB (AWD00000175)	Marcella Britton	SPS-PWL	Agreement	Clarification Requested	9/8/2024 12:00 AM				

Post Award – Grants Module/Awards

Ancillary Reviews

Modifications	Totals	Funding Allocations	Deliverables	Subawards	Child Awards	Related Projects	Reviewers	Correspondence	History	...
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Contacts

Name	Organization	Phone	Email
Sarah Abney	Human Research Participation Prgrm-PWL		peratest@purdue.edu
Cynthia Sanders	SPS-PWL	7654963653	peratest@purdue.edu
Nan Kong	Biomedical Eng-PWL	7654962467	peratest@purdue.edu
Jenny Siemers Test	Sponsored Program Services		mcardio@hcg.com
Madaline Foglesong	SPS-PWL	7654962177	peratest@purdue.edu

Reviewers

The following people will review this Award

Designated Reviewer:

Award Approver: Suzanne Payne

Ancillary Review

Review Type	Person	Organization	Required	Completed	Accepted
Budget - Award	[REDACTED]		yes	yes	yes
IACUC Congruency Review	[REDACTED]		no	no	
Subaward	[REDACTED]		no	no	

Post Award – Grants Module/Awards

Listing of all attachments

Modifications	Totals	Funding Allocations	Deliverables	Subawards	Child Awards	Related Projects	Reviewers	Attachments
Name								
01.01.2025 - T&C.pdf								
05.15.2024.pdf								
10.10.2025 - mods.pdf								
12.12.2024 - mod.pdf								
5.16.2024 - Terms & Conditions Testing.pdf								
5.16.2024 - TESTING_NOA.pdf								
5.16.2025 - TESTING_NOA.pdf								
5.23.2024 - AWARD.pdf								
5.23.2024 - ONR TERMS & CONDITIONS - Addendum.pdf								
5.23.2024 - ONR TERMS & CONDITIONS - General T&C.pdf								
5.23.2024 - TERMS & CONDITIONS.pdf								
Amendment - 9.16.2024.pdf								
AWARD - 5.16.2024.pdf								
Mod 1.pdf								
Mod 2.pdf								
Modification 01 - 9.16.2024 - Sponsor Mod No. P0001.pdf								
Modification 01 - 9.16.2024.pdf								
Modification 02 - 09.16.2024 - Internal.pdf								
Modification 02 - 09.16.2024.pdf								
Modification 03 - 12.22.2024 - Sponsor Mod No. P0002.pdf								
Modification 03 - 12.22.2024.pdf								
Modification 04 - 01.31.2025.pdf								
Modification 05 - 06.30.2025.pdf								
Modification 06 - 10.31.2025.pdf								
Modification 12 - 10.1.2026.pdf								
Terms & Conditions - 05.16.2024.pdf								
Terms & Conditions - 06.30.2025.pdf								
Terms & Conditions - 09.16.2024.pdf								
Terms & Conditions - 5.16.2024.pdf								

Post Award – Grants Module/Awards

Research Account Dashboard



PURDUE EXCELLENCE IN RESEARCH ADMINISTRATION (PERA)

Dashboard

Admin

Agreements

Facilities

Grants

IACUC

Page for Jessica Lawrence

Create ▾

Recently Viewed

Recent

Pinned

PAR100000005: PAR19-

My Inbox

My Reviews

Research Account Dashboard

My Inbox

Filter by ?

ID



Enter text to search



+ Add Filter

✕ Clear All

ID

Name

Date Created

▾ Date Modified



PERA - Research Account Dashboard

Research Account Dashboard



PURDUE EXCELLENCE IN RESEARCH ADMINISTRATION (PERA)

Dashboard

Admin

Agreements

Facilities

Grants

IACUC

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Recently Viewed

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PAR100000005: PAR19-

My Inbox

My Reviews

Research Account Dashboard

My Inbox

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✕ Clear All

ID

Name

Date Created

▾ Date Modified



Research Account Dashboard

Summary Account List

Grant Details

Sponsored Program Details

Faculty Allocations Details

Grant Accounts

Data as of 9/3/24

HELP ?

User

Sponsor	Grant	Lead PI	Type	Sponsored Program	Project Start	Project End	Co-PI	Budget	Expenses	Commitments	Available Balance	% Expended		
Energy, U.S. Department Of	Grant Number - Grant Title	Name	Sponsor	Account Number - Sponsored Program Title	10/01/19	09/30/24	Name	\$24,781.90	\$1,987.11	\$0.00	\$22,794.79	8%		
Indiana Soybean Alliance			Sponsor		08/01/23	05/31/24		\$171,331.00	\$171,331.01	\$0.00	\$-0.01	100%		
			Sponsor		10/01/23	09/30/24		\$70,000.00	\$39,848.84	\$0.00	\$30,151.16	57%		
			Sponsor		10/01/23	09/30/24		\$100,000.00	\$49,732.92	\$0.00	\$50,267.08	50%		
			Sponsor		08/01/24	12/31/24		\$30,000.00	\$0.00	\$0.00	\$30,000.00	0%		
National Science Found..			Sponsor		08/15/24	07/31/29		\$0.00	\$11,267.96	\$0.00	\$-11,267.96	0%		
								\$0.00	\$11,267.96	\$0.00	\$-11,267.96	0%		
Grand Total								\$396,112.90	\$274,167.84	\$0.00	\$121,945.06	69%		

Faculty Allocations

Data as of 9/3/24

Type	Fund	Lead PI	Account	Expiration Date	Budget/Carryforward	Income/Net Transfers	Expenses	Commitments	Available Balance	% Expended
Discretionary	21030000	Name	Account Number - Title	12/31/99	\$9,255.19	\$498.00	\$6,747.03	\$0.00	\$3,006.16	73%
				12/31/99	\$8,415.34	\$0.00	\$0.00	\$0.00	\$8,415.34	0%
Restricted	21010000			06/30/24	\$-1,603.34	\$0.00	\$-1,603.45	\$0.00	\$0.11	100%
				21020000	12/31/99	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
36010000	12/22/23			\$1,011.60	\$0.00	\$0.00	\$0.00	\$1,011.60	0%	
	12/23/24			\$1,529.12	\$0.00	\$0.00	\$0.00	\$1,529.12	0%	
	12/17/23			\$1,011.28	\$0.00	\$0.00	\$0.00	\$1,011.28	0%	
	12/15/24			\$0.00	\$0.00	\$2,184.81	\$0.00	\$-2,184.81	0%	
	53010000			12/31/99	\$31,246.59	\$0.00	\$19,394.11	\$0.00	\$11,852.48	62%
				08/11/24	\$39,197.00	\$0.00	\$0.00	\$0.00	\$39,197.00	0%
Startup	21030000	08/11/24	\$43,237.00	\$0.00	\$1,652.83	\$0.00	\$41,584.17	4%		
		08/11/24	\$20,474.29	\$0.00	\$7,167.11	\$0.00	\$13,307.18	35%		
				12/31/24	\$49,000.00	-\$458.29	\$44,053.86	\$0.00	\$4,487.85	90%
Grand Total					\$202,774.07	\$39.71	\$79,596.30	\$0.00	\$123,217.48	364%

Faculty website for Sponsored Research



Sponsored Program Services

Home General ▾ Directory Pre-Award ▾ Post Award ▾ Contracting ▾ Data ▾ Quality Assurance ▾ Coeus ▾ Research & Partnerships

PRF

<https://www.purdue.edu/business/sps/postaward/faculty/index.html>

Post Award / Faculty

Faculty Home

Meet SPS Post Award

PI Expectations

Contracting

Account Establishment

What is F&A?

What can I charge to my project?

Where can I find my account balance?

How can I approve a subcontract payment?

Regulatory Compliance

Closing my Grant

Faculty Resources - Executive Vice President for Research and Partnerships

Faculty



Meet SPS Post Award



PI Expectations



Contracting



Account Establishment



What is F&A?



What can I charge to my project?



Where can I find my account balance?



How can I approve a subcontract payment?



Regulatory Compliance



Faculty Offboarding



Closing my Grant



Faculty Resources - Executive Vice President for Research and Partnerships



Internal Controls, Roles and Responsibilities, Direct Costs and F&A

SPS Post Award Areas

SPS Teams based by Tasks/Functions

- Account Management
 - Main Point of Contact
- Award Setup
- Subawards
- Launch/JIT
- Finance (Billings & Closeout)

<https://www.purdue.edu/business/sps/postaward/contacts.html>



Welcome to Post Award Services

Our mission and structure

Post Award is committed to provide timely, accurate, and courteous assistance to our faculty, external sponsors and other University personnel. We assist our customers in exercising good fiscal management practices for the administration of externally funded sponsored programs at Purdue University during the lifecycle from establishment to closeout. We provide expertise to interpret guidelines and promote compliance with sponsor and University policies.

Our service-level agreement

Post Award Research Administrators provide services which include but are not limited to:

- Award establishment, management, and closeout
- Administrative and financial assistance for faculty, researchers, and business offices
- Guidance on sponsor specific guidelines and regulations
- Invoicing sponsors, drawdown letter of credit and follow up on collections of past due invoices
- Work with partnering institutions to secure all necessary subcontract documentation if the documentation is not collected during the Pre-award process.
- Collaborate with other university staff as appropriate
- Prepare and submit financial and property reports and assist with electronic submission of technical reports
- Review budgets, cost sharing and related documentation

Areas within Post Award

Ken Sandel

Senior Director, SPS

49-41063

sandel@purdue.edu

Susan Corwin

Director, Post Award

49-41052

scorwin@purdue.edu

Kyle Wargo

Director, Contracting

49-40382

kwargo@purdue.edu

QUESTIONS?



Schelly Decker
Sr. Operations and
Outreach Analyst

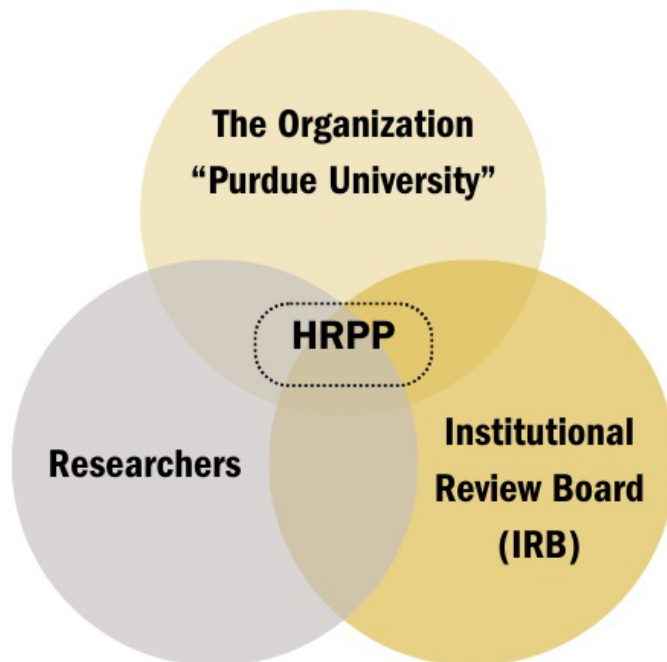
November 19, 2024

**PURDUE
UNIVERSITY**

The HRPP implements Purdue's commitment to:

- Protecting human research subjects
- Applying **Belmont Report** principles:
 1. Respect for Persons: voluntary informed consent
 2. Beneficence: do no harm, maximize benefits, minimize harm
 3. Justice: fairness

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



Protections are distributed responsibilities

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

KEY FUNCTIONS OF THE HRPP

- Provide regulatory expertise and guidance
- Provide education for researchers
- Support the IRB
- Facilitate collaborative research with external IRBs
- Maintain regulated records
- Conduct post-approval monitoring of research

FULL COMMITTEE REVIEW

Purdue's Full Board meets twice monthly, submission deadline 2 weeks before meeting.

1. Greater than minimal risk studies
2. Does not fall into a category of expedited review
3. Expedited review criteria are not met for approval
4. Local policy requires full board

[Purdue IRB Meeting Dates and Membership](#)

REVIEW PROCESS – EXPEDITED REVIEW

Does it qualify for Expedited review?

- Research that is no greater than minimal risk
 - *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.
- Fits into one or more expedited review categories per the regulations

REVIEW PROCESSES - EXEMPT RESEARCH

Exemption does not lessen the ethical obligations to subjects and the investigator may still be required to:

- obtain informed consent
- protect confidentiality
- minimize risks
- address problems or complaints

Exemption Examples:

- Surveys, interviews, focus groups, secondary data analysis, benign behavioral interventions

BASIC CRITERIA FOR IRB PROTOCOLS

- Knowing the study population
 - Identifying vulnerable or special populations
- Recruitment process
 - How to minimize coercion or undue influence
- Consent process
 - All participants must be willing to participate and give their consent
 - In most non-exempt studies, a consent document is required. It outlines the risk, procedures, duration, and other important factors that must be considered before participating in the research.
- Risks and risk mitigation
 - Study design elements geared to reduce the probability and magnitude of a potential risk
- Managing links to study subjects
 - How to protect the confidentiality of subject data

FORMS AND FORMATTING

Recruitment Material

- E-mail, phone, social media, [flyers](#), advertisements
 - Exact title of study submission
 - IRB #
 - Name of Principal Investigator
 - Contact information of PI or another member of the study team

[Guide to Recruitment](#)

FORMS AND FORMATTING

Consent Document/Form

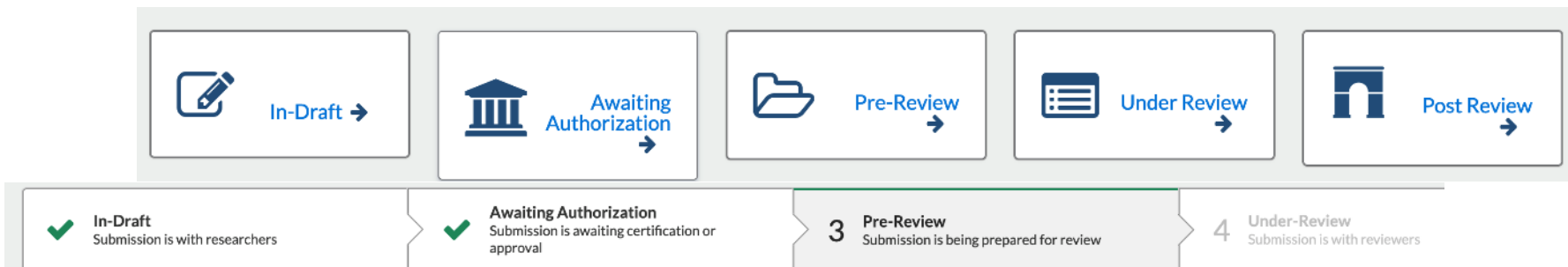
- All non-exempt research protocols
- Obtain participant consent before enrollment
- Exempt information sheet for exempt research, [follow this template](#)
- Written at an [8th grade reading level or lower](#)
- Required elements-follow templates
- What needs to go in a Consent Form

<https://www.irb.purdue.edu/resources-and-guidance/forms.php>

REVIEW PROCESS

The processing includes all the following:

- Verification of personnel and training
- Pre-review by a protocol analyst
- Review by an IRB member or designated staff member
- Response to revisions (both by the HRPP and investigators)
- Processing the final decision and determination letter



PI RESPONSIBILITIES

- The PI is responsible for every aspect of the research study, from its design, through its implementation, and the maintenance of study data and records.
- The PI may assign responsibilities to other members of the research team, but **accountability rests with the PI.**

EXTERNAL COLLABORATIONS

- External Sites and/or External Collaborators-
what do we need in the IRB application?
- Well, it depends...
- Letter of Collaboration if you're doing the
research on-site somewhere (school,
daycare, health facility, etc.)

EXTERNAL COLLABORATIONS

Non-Exempt Research

- When researchers from different institutions conduct collaborative human subjects research, it is possible for one IRB to lead the review and approval process.
- Reliance agreement – also known as a deferral or an IRB Authorization Agreement (IAA)
- Federal sponsors require a single IRB (sIRB) for non-exempt research – with a few exceptions

<https://www.irb.purdue.edu/reliance/>

EXTERNAL COLLABORATIONS

Exempt research

- Another IRB/HRPP exempted the study
 - Submit an exempt collaboration application in Cayuse
 - Upload their determination memo and application
 - What are you doing? Keep the application focused on your/Purdue's role in the study.
- Exempt Submission at Purdue
 - What are they doing?
 - Do they work at an institution/site with an IRB?
 - If yes, then we want their IRB/HRPP to provide their own exempt determination or document that they accept Purdue's exemption
 - If no, then we need an [Independent Investigator Acknowledgement Agreement \(IIA\)](#)


INFOGRAPHICS HELP US HELP YOU!

WHAT IS THE DIFFERENCE BETWEEN PRIVACY, CONFIDENTIALITY, AND ANONYMITY?

Protecting research participants includes considerations for protecting their privacy, keeping information confidential, and/or allowing the participant to remain anonymous.

PRIVACY

You as a researcher have to protect the individual's right to control access to their personal or identifiable data. Carefully consider the appropriate disclosures and actions for participant recruitment, assessment, and data collection. Let the informed individual know what is essential for research purposes.



CONFIDENTIALITY

Confidentiality pertains to protecting the participant's personally identifiable data. Information, including name, identity, address, telephone number, and other identifying information, is not to be shared with anyone outside the research team or its authorized agents.

- Notify the individual.
- Share their information only as needed during and after the study.
- What level of confidentiality is the potential risk of sharing?
- Also, appropriate actions will take to secure and protect their records.



ANONYMITY

Anonymity is a process of or from the researcher retains from collecting any personal data from their study or protocol, that would be identifiable to a specific individual. Data is not collected in a way that is identifiable to the individual, and names and other identifiers are not collected.



RESEARCH STUDY PARTICIPANTS NEEDED

[Insert Study Title]

Receive [insert allowable compensation] for your participation. You may be eligible to participate if: [Insert eligibility criteria]

Consider adding your inclusion/exclusion criteria to the recruitment flyer if your study requires a target population based on age, health, socioeconomic status, or other defined criteria. This could assist the potential participants to understand the study better.

For more information contact: [Insert Contact Information]

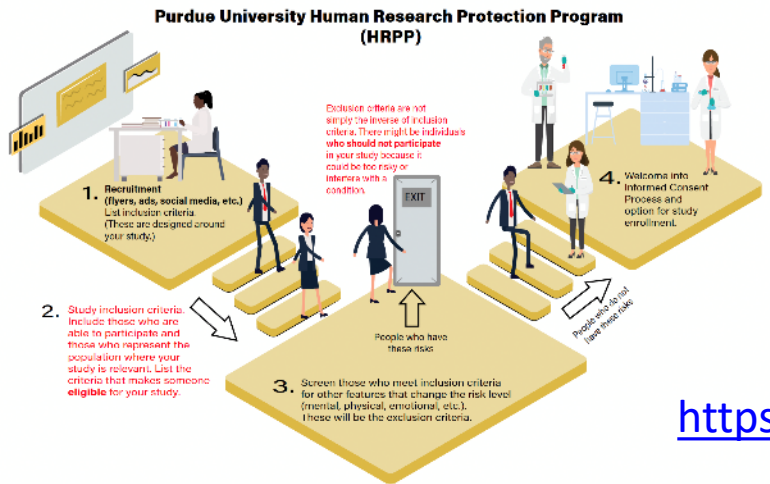
Purdue University IRB protocol number _____
 IRB Protocol Expiration date _____
 Principal Investigator _____

The IRB approval number and PI name should be displayed on the recruitment flyer. This allows quick tracking for the IRB and for study participants inquiring with questions or concerns.

Describe to the IRB application who receives flyers and how researchers communicate with people interested in participating in the study. Be certain to address any policy concerns that may arise from a person's interest in the study (e.g. topics that may be sensitive or require disclosure of a condition).

Considering the use of long-ways tabs to advertise to potential participants, be certain to include the title of the study (or a distinctive name) along with the contact information for the research team.

Understanding Study Inclusion and Exclusion Criteria in Human Subjects Research Protocols



<https://www.ird.purdue.edu/training/>

Review available resources:

- [Considering Privacy, Confidentiality, and Anonymity](#)
- [Deception and Debriefing](#)
- [Compensation](#)
- [International Research](#)
- [Consent Form Template](#)

TIPS

- Start early!
- View our [review metrics](#) to help plan
- Use the guidance in the Cayuse application
- Ensure your entire study team is up to date with [CITI Training for Human Subjects Research](#) before submitting
- PI review prior to certification

TIPS

- Schedule one-on-one meeting with HRPP Staff
- Schedule a class or group training
- Open Office Hours
- Virtual Monthly Trainings – Cayuse and basics.

CONTACT INFORMATION

Human Research Protection Program Purdue University

www.irb.purdue.edu/contact

irb@purdue.edu

Virtual Appointments & Group Training Requests

Please **call** or **e-mail** the IRB for assistance with general questions or help with the Cayuse IRB system.

May Hamdani, Advising Administrator, offers virtual meetings to discuss your study and assist you in developing your submission to the IRB. To request a meeting with May, use this link:

<https://outlook.office365.com/book/MayHamdani@purdue.edu/>

Click below to schedule a virtual meeting with an IRB Protocol Analyst.

Virtual appointment guidelines

Schedule a virtual meeting for
assistance with protocol development †

Schedule training for a class or large group †

† Requires Purdue career account authentication

Research Security and Export Control Regulations

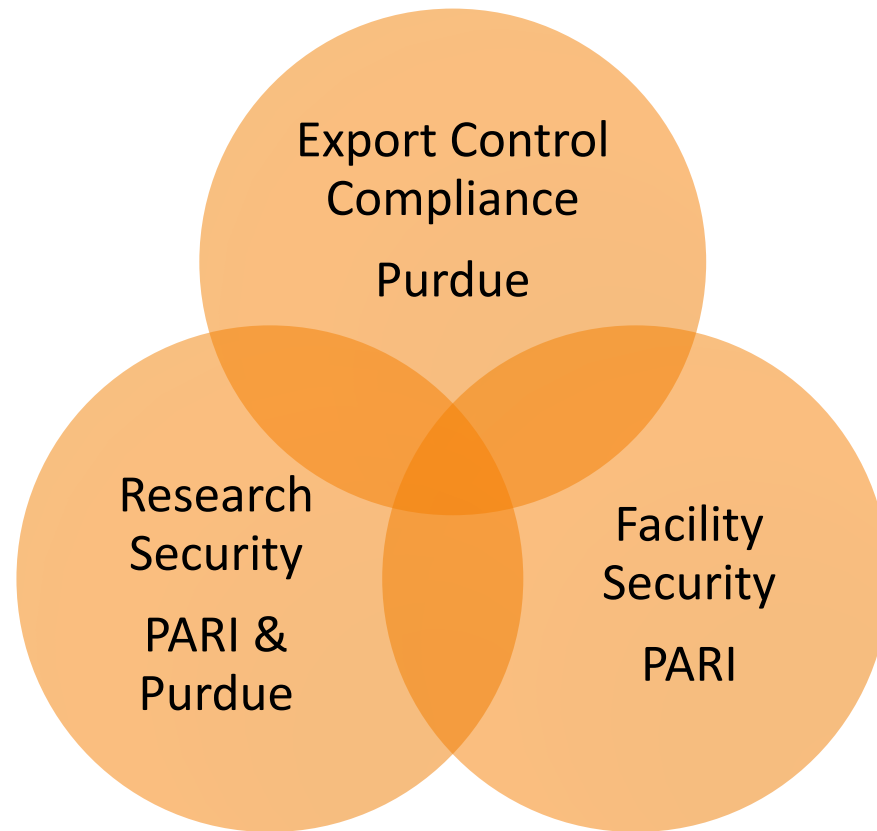
ELIZABETH WAGNER

*SENIOR DIRECTOR, RESEARCH SECURITY
AND EXPORT CONTROLS*

Research Security and Export Controls in a University Setting

1. Controlled Research (national security, proprietary, confidential)
2. Contract reviews, master research agreements, international MOUs and agreements
3. Managing Controlled Research (Technology Control Plans)
4. International Shipping
5. International Visitors
6. International Travel
7. International Research Collaborations
8. Performing Research outside of the US (ex. archeological dig in Sudan)
9. Export classification of physical items, software
10. Undue foreign influence (NSPM-33 Research Security Program)
11. Cybersecurity
12. Investigations and Mandated Federal Reporting
13. Export Licenses
14. Outreach and training for researchers and labs
15. Guidance on regulatory requirements and changes
16. Participation/hosting of national & international conferences

Export Control/Research Security/Classified Research



Export Control Regulations

U.S. laws that regulate the export of strategically important products, software, services, and technical data to foreign persons and foreign countries for reasons of foreign policy, US economic interests, and national security.

Applicable to physical export and sharing of information (technical data or technical information about controlled technology)

Inherent Conflict

PURPOSE OF RESEARCH

To create and disseminate knowledge for the betterment of society.

Purdue's mission statement:

To be globally recognized and at the forefront of innovation in higher education for empowering students and creating a seamless transition for all.

INTENT OF THE EXPORT CONTROL REGULATIONS

U.S. Government **controls** export of sensitive equipment, software and technology to promote:

- National Security Interests
- National Economic Interests
- Foreign Policy Objectives
 - Regional Stability
 - Human Rights considerations
 - Prevent Proliferation of weapons and technology to sponsors of international terrorism
- Comply with International Commitments

International collaboration is central to Purdue University

NECESSARY TO SOLVE THE PROBLEMS, CHALLENGES AND OPPORTUNITIES FACING HUMANITY

Knowledge and expertise is diverse and dispersed

We are part of a global community of researchers

In fact:

- Purdue is active in hundreds of countries worldwide
- 1740 international faculty and staff from 83 nations
- 4th in the US for international student enrollment at a public institution (2020)

Export Control Compliance

Legal/Regulatory Basis for Controls

Jurisdiction	What's Controlled	Federal approval requirements
<u>ITAR</u> 22 C.F.R. Parts 120-130	Defense articles, technical data, and defense services USML - 19 Categories ranging from Explosives and propellants to Toxicological Agents "Specially Designed for..."	<ul style="list-style-type: none">• Non-US Persons• Defense services for foreign persons & sponsors
<u>EAR</u> 15 C.F.R. Parts 700-799	Dual Use commodities and related technology typically for commercial use CCL – 9 Categories ranging from nuclear to telecommunications (Organized by ECCN) (All technology not controlled by another Jurisdiction)	Depends on the commodity and reason for control. (CCL - ECCN) Note: EAR99 – Catch all
<u>OFAC</u> 31 C.F.R. Parts 500-599	Support for and business with the subjects of the various sanctions	<ul style="list-style-type: none">• Specially Designated Nationals list (SDN)• Comprehensively Sanctioned: Cuba, Iran, North Korea, and Syria

Export Control Compliance

Key Definitions

Term	Definition
U.S. Person	<ul style="list-style-type: none">• US Citizen, or• Lawful permanent resident (green card holder);• Any federal, state, or local government entity in the U.S.• Any individual who is granted status as a “protected person” under 8 U.S.C.
Foreign Person	<ul style="list-style-type: none">• Any individual who is not a U.S. citizen; or• Any individual who is not a U.S. permanent resident alien (Green Card holder); or• Any individual who is not a protected individual (e.g. refugees, or have political asylum); or• Any foreign corporation/business/organization/group not incorporated or organized under U.S. law; or• Foreign government and any agency or subdivision of foreign governments (e.g. diplomatic missions)
Export	Shipment outside the U.S. of export controlled technology or technical data, software/code or equipment. This includes physical items, software, oral, visual, or written disclosure of export controlled technology or technical data.
Deemed Export	The release of controlled technology to foreign persons in the U.S. are "deemed" to be an export to the person's country or countries of nationality. NOTE: Disclosure may be via email, telephone, websites, face-to-face discussions, training sessions, tours that involve visual inspections, etc.

Technology (EAR) vs. Technical Data (ITAR)

EAR - Part. 772

Technology means: Information necessary for the “development,” “production,” “use,” operation, installation, maintenance, repair, overhaul, or refurbishing (or other terms specified in ECCNs on the CCL that control “technology”) of an item.

Use: **Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.**

NOTE: If an ECCN specifies one or more of the six elements of “use” in the heading or control text, only those elements specified are classified under that ECCN.

Software separately defined

ITAR -Part 120.10

Technical data means: Information, other than software, which is required for the **design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles.**

Software directly related to defense articles.

Does not include: general scientific, mathematical or engineering principles commonly taught at universities or information in the public domain (note: fundamental research exclusion is in the definition of public domain)

Technology and Technical Data = Information

Fundamental Research Exclusion (FRE)

- Fundamental Research definition covers **most** university research
- Fundamental Research is basic and applied research the results of which are normally **published freely** in the scientific and engineering literature; must be **non-proprietary** in nature
 - Publication delay for sponsor review is allowable
- FRE Does not apply to
 - controlled inputs (like external confidential information)
 - Research that is subject to publication approval or dissemination controls
 - Informal arrangements to hold information in confidence

Examples of Controlled Information

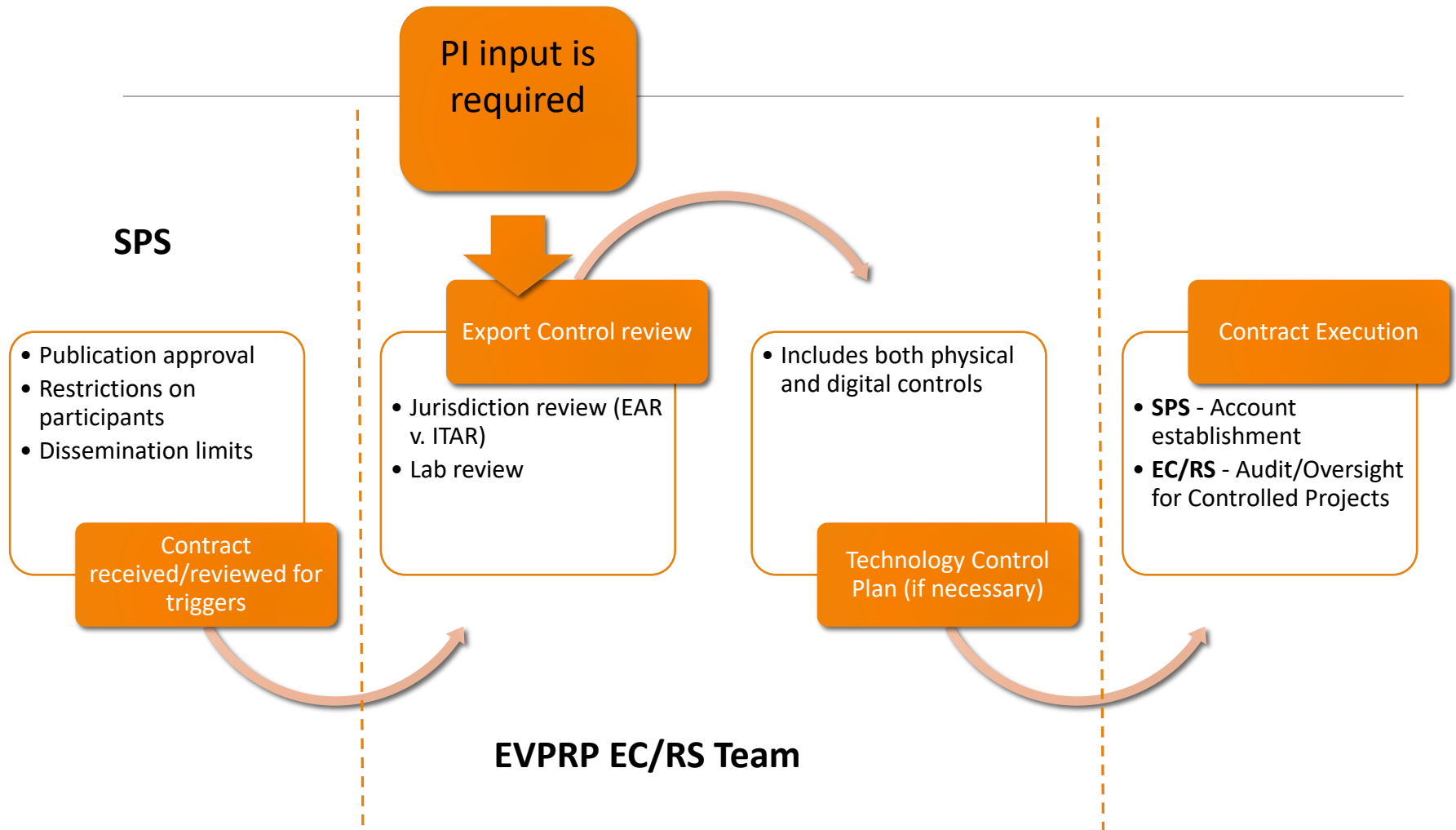
Examples:

- Inputs received from third parties – industry (through a Non-Disclosure Agreement or project agreement)
- Controlled information from the federal government
- Project Agreements with dissemination limitation and publication restrictions
- Results of industry research with unique Intellectual Property ownership or publication approval terms

Confidential Information

- Starts with a Contractual Obligation*
 - An Institutional Obligation – Purdue is the legal party
 - Nondisclosure Agreement (Confidentiality Agreement)
 - Industrial or Government Contract
- Responsibility of compliance is delegated to the responsible person (most cases a principal investigator)
- ****Faculty do not sign NDAs as the contractual party – Contract SPS Contracting for assistance***

Compliance Process



The government cares deeply about research security

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.

Expect increasing and lasting:

- Enforcement activity

- Requirements and expectations

Research Security Program: New Federal Requirement

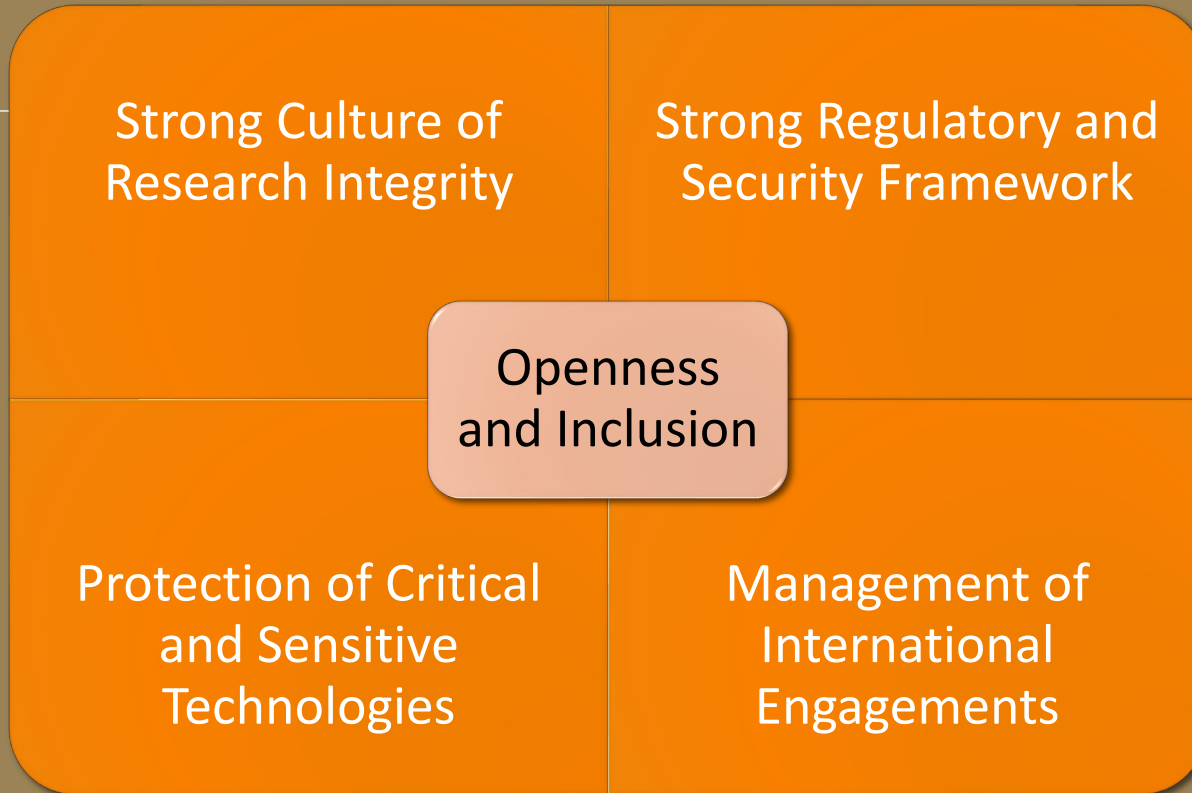
New Program Requirements for Fundamental Research

Four Basic Elements:

- Cybersecurity Training and Processes
- Foreign Travel Security
- Export Control Training
- Research Security Training
- New Disclosure and Reporting Requirements

See the [NSF site](#) for all of the elements

Guiding Principles for Research Security



Equally applied to all employees and all outside activities

New Faculty Considerations

- **How likely is technology in my field to be controlled by these regulations?**
 - The Research Security/Export Control Team can help you with this!
Semiconductors and AI have federal export control regulations.
- **How likely am I to seek funding from sponsors who will assert dissemination/participation controls?**
 - Department of Defense
 - Nuclear Regulatory Commission/Department of Energy
 - Industry
- **What do I do if I want to avoid research subject to these controls?**
 - Stay within the fundamental research exclusion (FRE)
 - Avoid publication approval requirements
 - Be clear with new funding sources
- **How to do controlled research – how will I limit access to only approved students and researchers?**

New Faculty Considerations

- **When will the new Research Security regulations start?**

- These are being implemented by each federal agency and NSF is leading the effort. Full implementation will be one year from final rule (expected soon!)

- **New requirements for travel reporting**

- These will be via Concur, implementation next year.
- Please reach out with questions you have related to travel. If you will be traveling to China, Russia, Iran or North Korea, please reach out for specific guidance on restrictions and reporting requirements.

- **New requirements and forms for disclosures**

- SciENCv and new Common Forms
- https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp

- **Foreign Talent Recruitment Programs: What you need to [know!](#)**

- **ORCID: Digital Persistent Identifier**

- **We will be launching our outreach program in January!**

Contact Information

- [Email – rsec@purdue.edu](mailto:rsec@purdue.edu)
- Telephone: (765) 494 – 0702
- Website: <https://www.purdue.edu/research/oevprp/regulatory-affairs/export-controls/> and <https://www.purdue.edu/research/oevprp/regulatory-affairs/research-security/>
- Elizabeth Wagner, Senior Director, Research Security and Trade Compliance
wagne366@purdue.edu