Research Security and Export Control Regulations

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Research Security and Export Controls in a University Setting

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

Export Control/Research Security/Classified Research



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Export Control Regulations

U.S. laws that regulate the export of strategically important products, software, services, and technical data to <u>foreign persons</u> and <u>foreign countries</u> 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 <u>controls</u> 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

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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"	Non-US Persons Defense services for foreign persons & sponsors
EAR 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	Specially Designated Nationals list (SDN) Comprehensively Sanctioned: Cuba, Iran, North Korea, and Syria

Export Control Compliance

Key Definitions

Term	Definition
U.S. Person	 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	 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 onsite 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

<u>Does not include</u>: 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

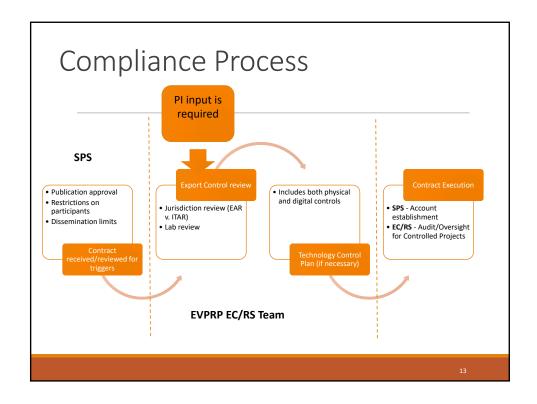
Examples:

- 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

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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 <u>responsible</u> <u>person</u> (most cases a principal investigator)
- *Faculty do not sign NDAs as the contractual party Contract SPS Contracting for assistance



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

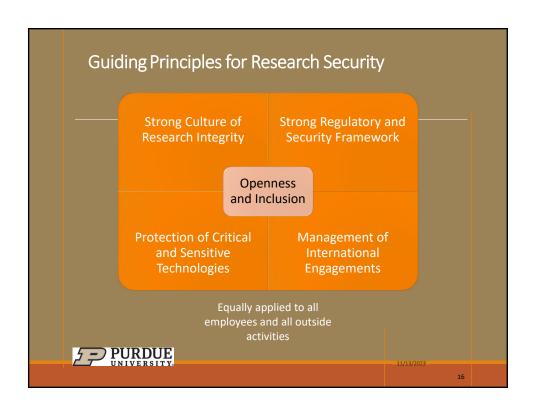
Research Security Program: New Federal Requirement

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



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 Al 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
- •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 exportcontrols@purdue.edu
- Telephone: (765) 494 9806
- Website: https://www.purdue.edu/research/oevprp/regulatory-affairs/export-controls/
- Elizabeth Wagner, Senior Director, Research Security and Trade Compliance wagne366@purdue.edu

Managing Your Award: Research Regulatory Affairs

lanthe "Cookie" Bryant-Gawthrop, MS, CRA, CIP Senior Director, Research Regulatory Affairs

Regulatory Acronyms

- HRPP Human Research Protection Program
- IRB Institutional Review Board
 - Human subjects surveys, existing datasets, Biomedical or Behavioral Research
- IACUC Institutional Animal Care and Use Committee
 - · Vertebrate Animals
- IBC Institutional Biosafety Committee
 - synth./recomb. nucleic acids, unfixed human blood, biohazards
- RCR Responsible Conduct of Research
- FCol Financial Conflict of Interest



General Regulatory Responsibilities for PIs



- Keep up with sponsor-specific regulatory requirements;
- Apply to committees applicable to the research, tell them about any changes;
- Train staff and keep records of training;
- Review and assistance with study design for students and staff;
- Maintenance of study data and records.

Regulatory Training

- Each area requires relevant training prior to approval of a research protocol
- Most areas require training through the CITI Program (CITI) www.citiprogram.org
- CITI refers to the name of the program, several courses are offered in topics like Human Subjects research, Biosafety, etc.
 Research teams may need to take more than one course to complete the correct requirement.



Responsible Conduct of Research (RCR) Training

- RCR topics include authorship, mentoring, peer-review, conflicts of interest, plagiarism, data management, and reproducibility of research results.
- Effective July 1,2020 all researchers at Purdue, system-wide, are required to complete RCR training according to the Purdue University Responsible Conduct of Research <u>Standard</u>, (S20).
- Training consists of an online course and a research field-specific component.
 Please see https://www.purdue.edu/research/regulatory-affairs/integrity/responsible-conduct.php for details, FAQs, changes, and contacts.

Financial Conflict(s) of Interest

- The EVPR Office, through its FCOI staff assists and helps researchers manage research-related FCOIs.
- When an FCOI is identified, EVPR works with the Investigator and their Department Head/Oversight Manager to draft and execute a management plan.
- The process is dependent on investigator disclosure of financial interests at the time of proposal or protocol submission to sponsors and/or the IRB.
- Examples- Company ownership, start-up companies, stock interest.

The Organization "Purdue University" The Purdue University" Institutional Review Board (IRB) The Organization "Purdue University" Institutional Review Board (IRB) Researchers Review Board (IRB) Protections are distributed responsibilities 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) Penote and uphold ethical research principles Penote por the Common Rue Assigning review type Researchers Researchers Researchers Protections are distributed responsibilities Adding documents Mentioning and training research team

Research with Human Subjects

- · There are four types of review conducted based on risk to the participant:
 - <u>Full Board</u> meets twice per month, deadlines for agenda
 - Expedited review occurs without full board convening, rolling review basis
 - $\bullet \quad \underline{\text{Limited Exempt}} \text{possibly sensitive exempt, rolling review}$
 - Exempt review occurs with designated office staff, rolling review
- Purdue HRPP/IRB uses the Cayuse system for all protocol submissions.
 - First time Cayuse users must register for Cayuse access allow 48 business hours for system sync.
- Consider all elements of study design, training, collaboration, agreements, etc. <u>before submitting</u> a <u>protocol for review</u>.

Resources and Guidance are Available! Training and Tools If you are epigaged in human religant research, all study personnel who research will subject, participate in an intervention with subject, so who access referencion about subjects and received processing and subjects and received processing and p

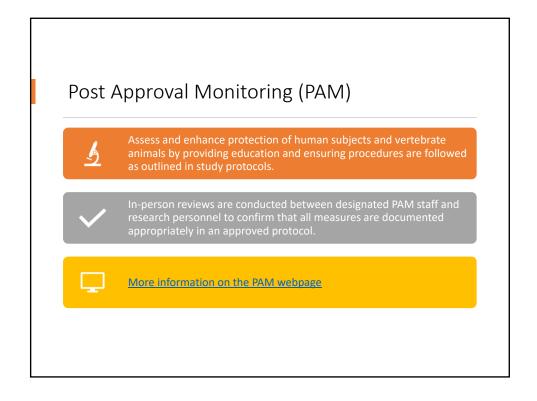
Research with Vertebrate Animals

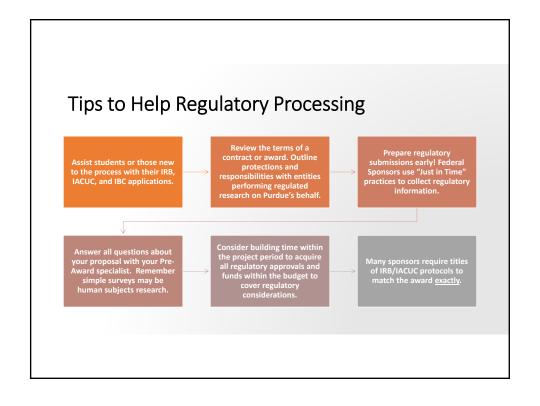
- The Institutional Animal Care and Use Committee (IACUC) oversees all review of research conducted with vertebrate animals as required by the US Dept. of Health & Human Services Office of Laboratory Animal Welfare (OLAW).
- The Purdue Laboratory Animal Program (LAP) provides veterinary care, housing, and other required practices to ensure animal well being in research, testing and teaching.
- IACUC applications are submitted through the COEUS Lite system. Proper qualifications and training are required prior to authorization to conduct research with vertebrate animals.
- There are two types of review conducted by the IACUC based on risk
 - Full Committee Review- meets once per month
 - Designated Review in office on a rolling basis by IACUC members or

Research with Biohazards, Recombinant or Synthetic Nucleic Acids

- Research involving biohazardous materials, recombinant or synthetic nucleic acids (regulated by NIH Guidelines) requires review by the Institutional Biosafety Committee (IBC).
- An IBC protocol requires a PI to detail proper use, training containment, and disposal procedures.
- Training and lab inspections are required prior to a protocol approval. Build this into the timeline for review.
- Provide detailed information about the laboratory procedures. Protocols are specific to each research lab and must be submitted by and signed by the PI.









Research Regulatory Affairs Website	See: https://www.purdue.edu/research/regulatory-affairs/
Human Research Protection Program/IRB	www.irb.purdue.edu irb@purdue.edu
Biosafety, Recombinant DNA	Biosafety Officer, Joshua Brown brow1422@purdue.edu https://www.purdue.edu/research/oevprp/regulatory-affairs/biosafety-and-rdna
Vertebrate Animals	Idsnider@purdue.edu Lisa Snider, IACUC Administrator https://www.purdue.edu/research/oevprp/regulatory-affairs/animal-research/
Research-Related Conflicts of Interest	fcoi@purdue.edu https://www.purdue.edu/research/oevprp/regulatory-affairs/conflict-of-interest,
Responsible Conduct of Research Training;	RCRTraining@purdue.edu https://www.purdue.edu/research/oevprp/regulatory-affairs/researcher-training





Sponsored Program Services

Contracting

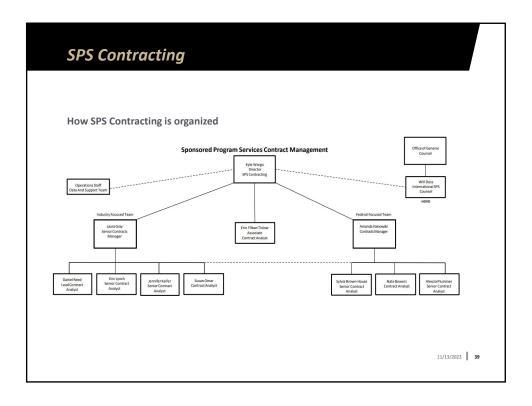
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Proposal is Awarded

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'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
- $\bullet \quad \hbox{Collaborate with other University staff as appropriate including:} \\$
 - o 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
- $\bullet \quad \text{Maintain up-to-date records in COEUS negotiation on all agreements initiated, in-process and completed} \\$
- $\bullet \quad \text{Negotiate the terms and conditions of an agreement to ensure compliance with all laws and University policies}\\$
- Assure all regulatory requirements and export control issues are identified and necessary internal approvals are obtained



Role of a Contract Application as follows:

- √ Regulatory/IRB
- ✓ Export Control
- ✓ Information Assurance
- ✓ Private Business Use
- √ Risk Management
- ✓ Dean/Department Head

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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
- $\bullet \quad \hbox{Often contain requirements that the confidential information be marked} \\$
- NDA Info Sheet found here: https://www.purdue.edu/business/sps/contractmgmt/NDA/contractingNDA.html
- MTA: Material Transfer Agreements
- Set terms under which proprietary materials are transferred to Purdue or from Purdue for use by another research institution
- MTA Info Sheets found here: https://www.purdue.edu/business/sps/contractmgmt/agrtemplates.html



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
- Subcontracts
- Government
 - Federal funding is significant and we routinely receive awards from numerous federal agencies for research work
- · We also receive state funding for research



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Agreements not related to Sponsored Research

Many agreements are not related to sponsored research and are handled in other parts of the University. Here are some examples:

- Purchasing of goods, even when the goods are purchased with funds brought into the University under a grant or research agreement. Purchasing agreements are handled by Procurement.
- Recharge agreements for conferences, services agreements for digital education, facilities
 use agreements, business associate agreements, student internship and affiliation
 agreements, study abroad agreements, gifts of software licenses, sponsored student class
 project agreements (non-core agreements). These are handled by the Office of Legal
 Counsel.
- Agreements for licensing Purdue-owned intellectual property, including commercial evaluation licensing agreements, and patent prosecution agreements are handled by Purdue Research Foundation/Office of Technology Commercialization, which manages the University's intellectual property assets.



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/



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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 Contracting's departmental email.
- 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 priority (the red exclamation point) 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.



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

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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

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 the COEUS Negotiation Record or the assigned Contract Analyst
- Best contact for new questions and agreements: spscontr@purdue.edu



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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
 - o Includes any unique restrictions or special requirements
 - o 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:
 - o Regulatory (Animals & Human Subjects)
 - Export Control



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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 executed.
 - NTP is a line of credit established to allow a project to begin prior to receipt of a fully executed award
 - Your Business Office will work with you and your department to approve the backing of the NTP.
 - Your Business Office will work with SPS to get you an account number

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



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:

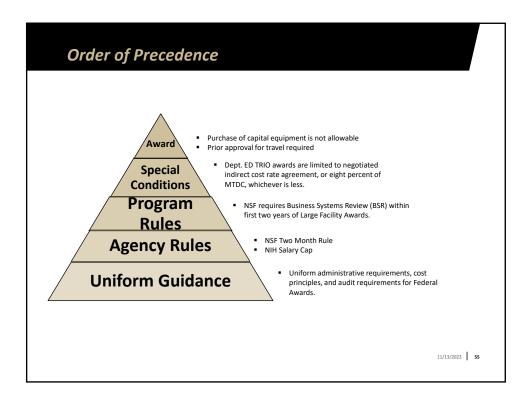
- Serve as resource for faculty, researchers, and business offices
- · Provide guidance on sponsor specific guidelines and regulations
- Ensure all regulatory requirements and export control issues are identified and contain appropriate disclosures and approvals
- Review award document for requirements 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

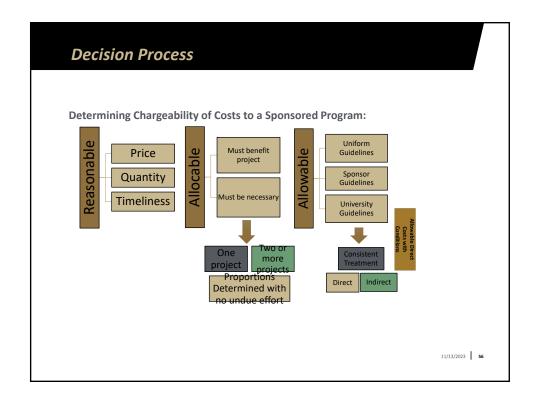
Post Award Email: spsacctmgmt@purdue.edu



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Post Award Services - Business Office Proposal submission Day to day account Proposal budget management Dashboards/balances Current & Pending Grant projections Monitors expenditures Effort Reporting SPS **Business** Fiscal oversight Procurement Center Office Pre Award Employment Center Manages Faculty Allocations SPS (discretionary, startup) Administers awards Just In Time Requests **Post** Sponsor reporting (financial, property, patent) Assist with Technical Report Submission **Award** Award setup Award closing Billings Subcontract monitoring Provides guidance on allowability for each sponsor award Audits/reviews PURDUE UNIVERSITY. 11/13/2023 54





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.



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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



https://www.purdue.edu/business/sps/preaward/menu/1.gett ingstarted/pi_role/pi_expectation.html

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
 - o 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

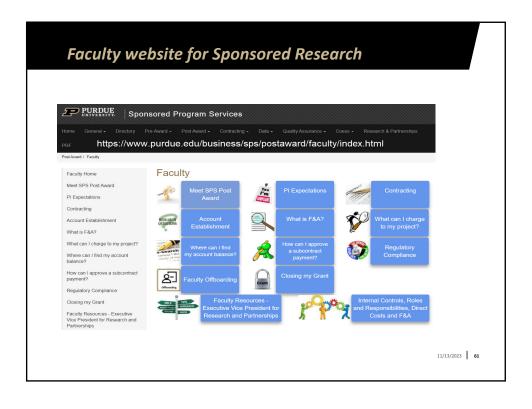


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Technical Reports

- 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







Areas within Post Award

Ken Sandel

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Kyle Wargo

Director, Contracting 49-40382 kwargo@purdue.edu



Susan Corwin

Director, Post Award 49-41052

scorwin@purdue.edu

