SPONSORED PROGRAM SERVICES
POST AWARD

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Director, Post Award

November 10, 2020

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Proposal is Submitted

Now what?

- Agency sends Notice of Award
- Award is reviewed and signed by a SPS Contract Analyst to ensure that:
  - The University can and should 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

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SPS Contracting

- Services include, but are not limited to:
  - Read and review entire contract, including all attachments
    - Funding Agreements (Federal, State, Industrial/Non-profit)
    - Confidentiality Agreements (NDA's, CDA's)
    - Material Transfer Agreements (MTA's)
    - Equipment Transfer/Loan Agreements
    - Miscellaneous Agreements (MOU, LOI, LOA's, Etc.)
  - Identify terms not matching proposal (project term, deliverables, etc.)
  - Contact Proposal Specialist or PI for clarification/ verification
  - Ensure export control review is complete
  - Identify contractual terms **not** in compliance with University policy, federal requirements, state requirements, and state and federal law
  - Present redline to sponsor and negotiate
  - Contracting Email: spscontr@purdue.edu

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SPS Contracting

What Contracting Handles

- Contracting administers agreements, usually funded, related to sponsored research activity, engagement and instruction. Contracting's three groups handle the following:
- **Industrial Team.**
  The Industrial Team handles research agreements with industrial sponsors, including private sponsors and nonprofit sponsors such as foundations. The Industrial Team analysts are experts in explaining Purdue's various alternatives for intellectual property rights, shown under the Industry Contracting Models. The Industrial Team also handles subcontracts from industrial sponsors to the university, material transfer agreements, and confidentiality agreements.
- **Government/International/Miscellany Team.**
  The GIM Team handles grants and awards from federal and state government, including when there is a subaward by another university recipient to Purdue University. This team handles agreements and understandings governing international collaborations. The GIM team also handles "miscellaneous" agreements which cover activities that directly support research for example, equipment loan and transfer agreements, visiting scholar agreements, data use and data transfer agreements, and other similar engagements.
- **Strategic Contracts Group**
  The Strategic Contracts Group, formed in 2017, will handle industrial and governmental agreements that are either complex and/or are with a Purdue Strategic Partner. These include master agreements, strategic memoranda of understanding, research agreements with complex intellectual property issues, consortium agreements, and some complex federal agreements, such as intellectual property management plans and partnership intermediary agreements. The group will have two Lead Analysts, who act as leaders to shepherd the agreement through Purdue's processes.

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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. These are handled by the **Office of Legal Counsel**. Requests should be sent to legalcounsel@purdue.edu.
- 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.

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SPS Contracting

Request Contracting Service

- When a faculty member is working with PreAward, PreAward will request Contracting's involvement at the appropriate time. When in doubt, ask your PreAward specialist about the next step
- When the agreement does not involve PreAward -- 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 box is: **spscontr@purdue.edu** and our general line is (765) 494-3863. To reach a particular analyst, please see the directory or the organization chart. **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 1 day during normal volume and 2 days during high volume. Typically, the response will let you know who your assigned contract analyst will be so you may work directly with the analyst. 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.

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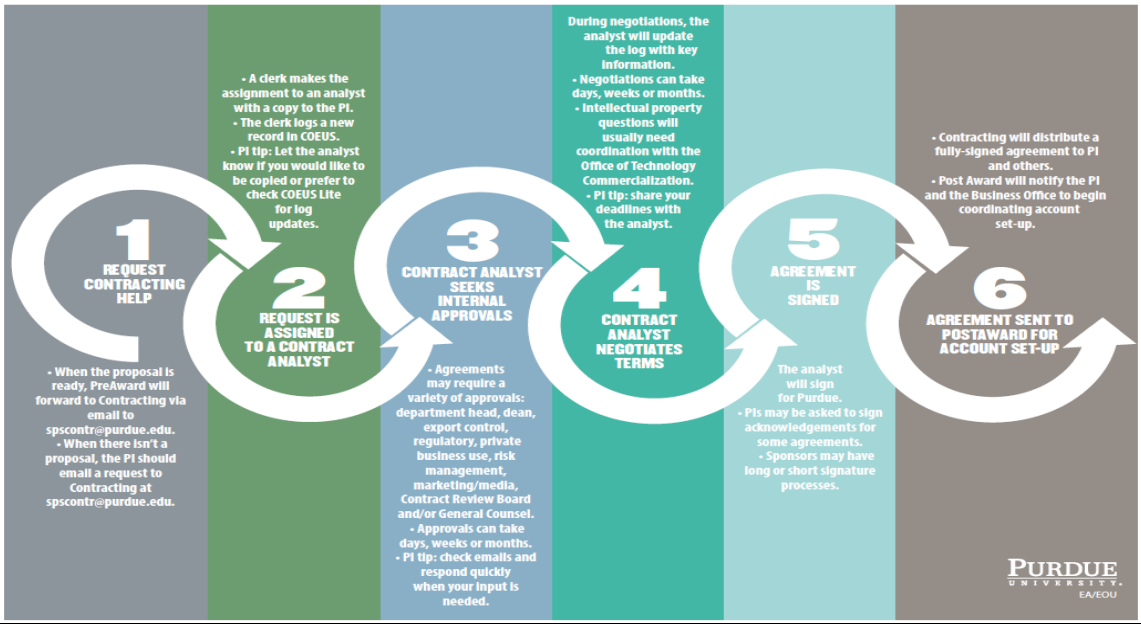
SPS Contracting



Communication is Key

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Post Award

Award is fully executed

- Reviews the file for Regulatory/Compliance approvals
- Communicates with PI and Business Office
- 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

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

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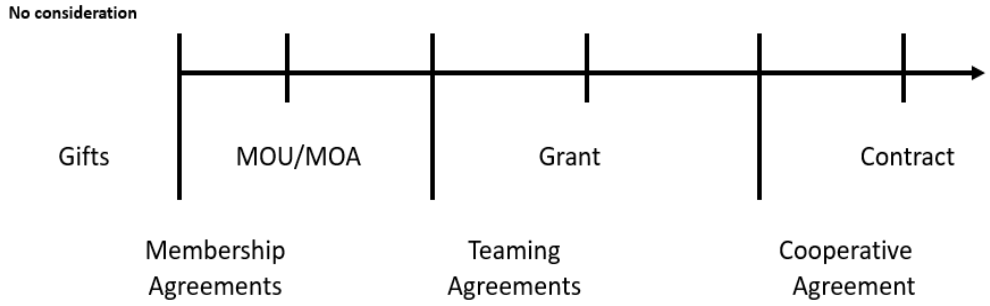
Difference in Awarding documents

Spectrum of Sponsor Influence



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Post Award

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
  - Business Office will work with SPS to get you an account number

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

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Important information in Award

- Start/End Dates
- Award Amount
- Approved Budget
- Agency Contacts
- Payment Terms
- Notation of Special Restrictions/Conditions
- Cost Sharing
- Limitations on Spending, Prior Approvals
- Required Reports (Technical, Fiscal)
- Intellectual Property Rights & Requirements (Industrial)
- Licensing Royalty Rights (Industrial)
- Publication Rights (Industrial)

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Award Establishment

Awarded budget may be divided internally into multiple sponsored program accounts:

- Multiple Investigators
- Unique categories (tasks, projects, sub-projects) & reporting requirements
- Incremental funding
- Specific budgetary restrictions
- Cost share

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Post Award

PI's First Point of Contact: Departmental Business Office

- Human Resources
- Purchasing
- Account Numbers (Startup/Discretionary funds)
- Travel
- Account Management
- Projections

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Role of the Principal Investigator (PI)

As PI, what is my role in allocating costs?

- Must assure charge is:
  - Reasonable and necessary
  - Incurred within the project period
  - Allowable in accordance with sponsor guidelines
  - Allocated on the basis of benefit to the project

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Role of the Principal Investigator (PI)

- Direct the work
  - Within project period
  - Within budget authorized by sponsor
- 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

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Managing the Award

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

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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

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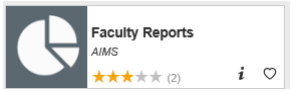
GM AIMS Reports

GM AIMS provides:

- Real-time tracking of grant budgets and expenditures
- Expenditure details such as PO numbers, vendors and item descriptions
- Information on technical reports
  - When due
  - Where & how to send
- Balance trends charts
- Projection tool to estimate future balances
- GM AIMS is accessible via the GM AIMS Faculty Portal



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Award Terms & Conditions

Terms and Conditions of 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)
  - 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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Areas within Post Award

Sponsor Specific Areas

- NSF/DHHS
- Other Federal
- Non-Federal
- Ag Field Office

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

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Post Award Services

Support is provided through sponsor specific areas which include: NSF/DHHS, Other Federal, and Non-Federal

Services include, but are not limited to:

- Award establishment, management, and closeout
- 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
- Facilitate the establishment of agreements with and the payment of sub recipients
- Manage collection of sponsor income, including draws under the federal letters of credit
- Prepare and submit financial and property reports
- Assist with electronic submission of technical reports

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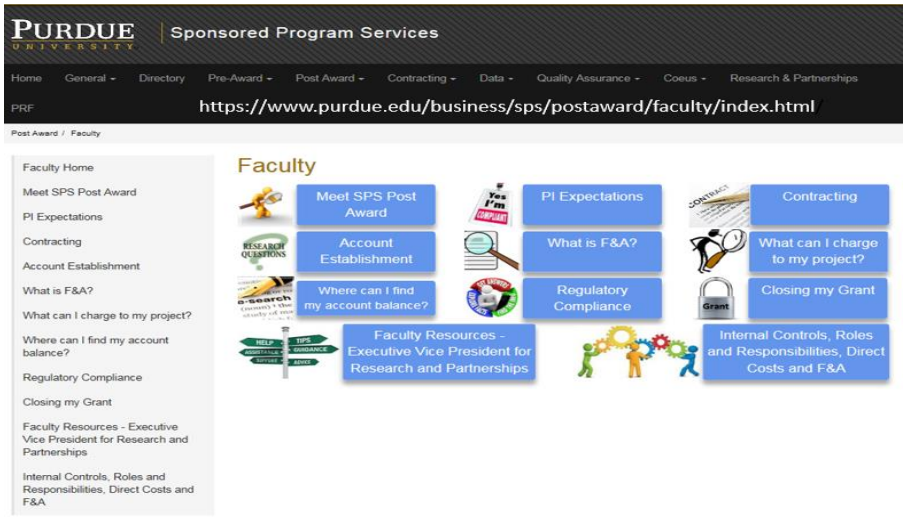
Faculty website for Sponsored Research



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Areas within Post Award

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QUESTIONS?

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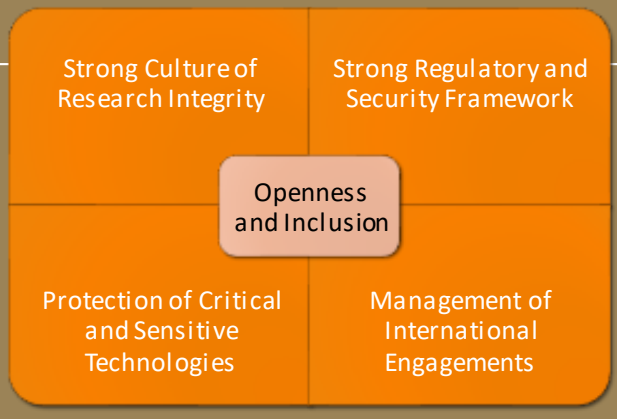
Research Information Assurance and Export Control Regulations

MARY DUARTE MILLSAPS

DIRECTOR, RESEARCH INFORMATION ASSURANCE

Guiding Principles for Research Security



Equally applied to all employees and all outside activities

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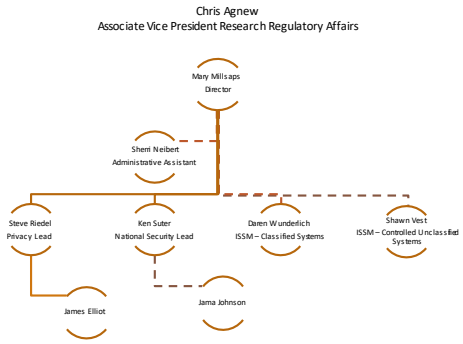
Export Control/Information Assurance Office (EC/IAO)



Export Control/Information Assurance Office (EC/IAO)

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 and national security.

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

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Inherent Conflict

PURPOSE OF RESEARCH

"The creation, **dissemination**, preservation and application of knowledge for the betterment of our global society" -

- pulled from the mission statement of UCLA

INTENT OF THE EXPORT CONTROL REGULATIONS

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

- National Security 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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Export Control Compliance

Legal/Regulatory Basis for Controls - part 2

Jurisdiction	What's Controlled	Federal approval requirements
ITAR 22 C.F.R. Parts 120-130	Defense articles (and technical data) or Defense services USML - 19 Categories ranging from Explosives and propellants to Toxicological Agents **"Specially Designed for…"**	• Non-US Persons • Defense services for foreign 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***
OFAC 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	• Any US Citizen, or lawful permanent resident (green card holder); • Any **corporation, society** or other **entity** incorporated or organized to do business in the U.S. • Any federal, state, or local government entity in the U.S.
Foreign Person	• Everyone else, including foreign students here are student visas (J and F) and foreign employees on non-immigrant visas types (e.g. H1B or O). • Foreign corporations, societies or entities.
Export	is defined very broadly to include an oral or written disclosure of **information** about, visual inspection of, or actual shipment outside the U.S. of **controlled** technology or technical data, software/code or equipment to a foreign person.
Deemed Export	Any disclosure of information or release of **controlled** technologies to a foreign person in the U.S. is deemed to be an "export" of that information or technology. NOTE: **Any method of disclosure may apply: email, telephone, websites, face-to-face discussions, training sessions, tours that involve visual inspections**

Technology (EAR) vs. Technical Data (ITAR)

EAR - Part. 772	ITAR -Part 120.10
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.	*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.**
Use: **Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing**.	Software directly related to defense articles.
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.	**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)
Software separately defined	

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

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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 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***

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Information Assurance Considerations

Safeguarding access and use of such information

- Good rule of thumb: Need to Know
- Consider digital controls

Impact of Export Control Regulations

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Confidential Information

Key Points	
Who	Determination of **who will have access** • Limit to those who truly have a **need to know** • Keep track • Make sure all with access understand the requirements
What	**Identification** of what is confidential - BE CLEAR! (e.g. technical specifications, business plans)
Why	Identification of the **purpose or reason** it is being shared • Limit use to the purpose, and nothing else
How	Proper Handling and Safeguarding of Confidential Information

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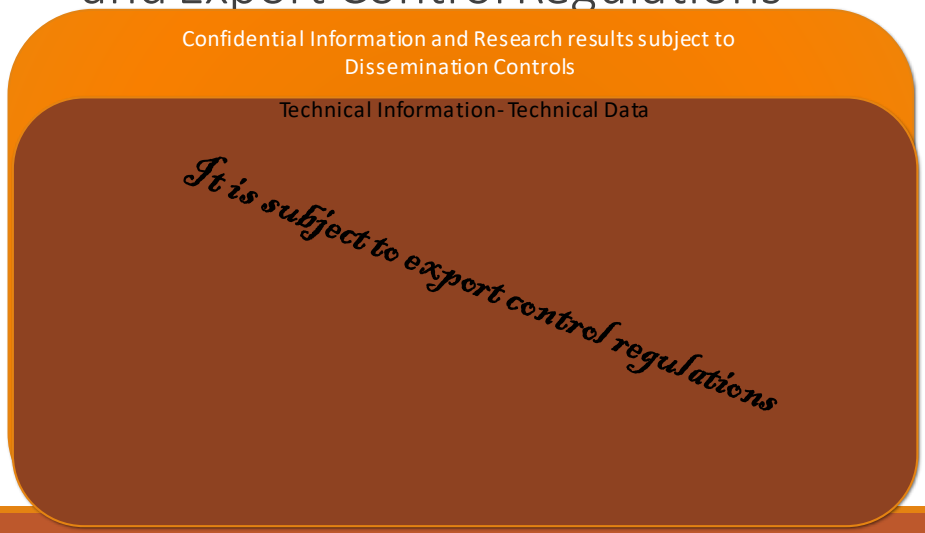
Nexus of Confidential Information and Export Control Regulations



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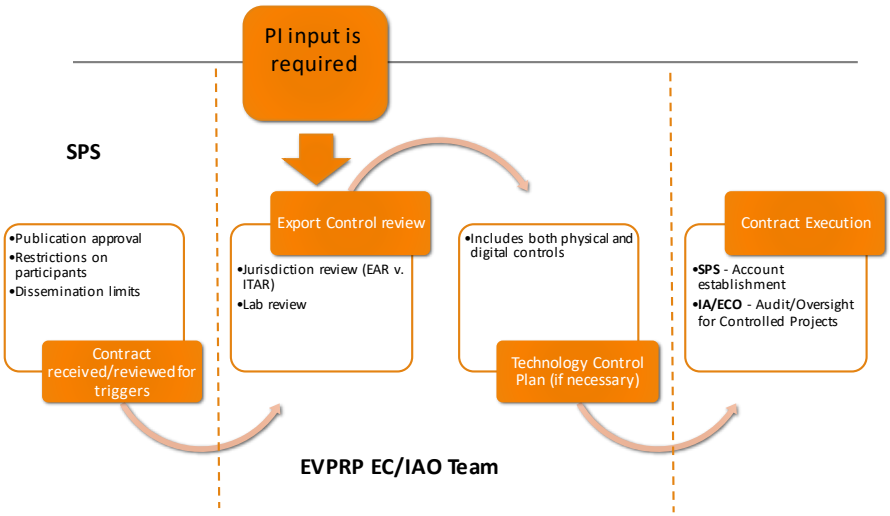
Compliance Process



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New Faculty Considerations

- **How likely is technology in my field to be controlled by these regulations?**
  - **The Information Assurance/Export Control Team can help you with this**
- **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
- **If I plan on including foreign students in my lab and I will do controlled research – how will I keep the effort segregated?**

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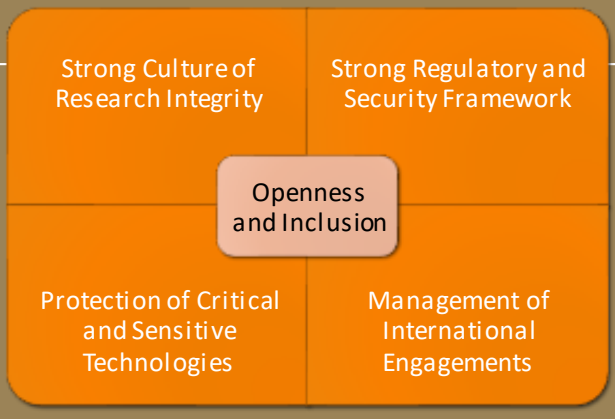
Guiding Principles for Research Security



Equally applied to all employees and all outside activities

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2/23/2021

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Contact Information

- Email - exportcontrols@purdue.edu
- Telephone: (765) 494–9806
- Website: https://www.purdue.edu/research/regulatory-affairs/export-controls-and-research-information-assurance/
  - (SHORT CUT: Google "Export" and "Purdue")

MANAGING YOUR AWARD: RESEARCH REGULATORY AFFAIRS

REGULATORY ACRONYMS

- IBC-Institutional Biosafety Committee
  - rDNA, unfixed human blood
- IRB- Institutional Review Board
  - Human subjects - surveys, existing datasets, Biomedical or Behavioral Research
- IACUC- Institutional Animal Care and Use Committee
  - Vertebrate Animals
- RCR - Responsible Conduct of Research
- FCoI - Financial Conflict of Interest

REGULATORY RESPONSIBILITIES

- Keep up with sponsor-specific regulatory requirements
- Apply to committees applicable to the research
- Train staff and keep records of training
- Principal Investigators are responsible for the research study from its design through its implementation, and the 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 Standard, (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 and contacts.

FINANCIAL CONFLICT OF INTEREST

- The EVPRP Office, through its FCOI staff assists and helps researchers manage research-related FCOIs.
- When an FCOI is identified, EVPRP 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.

RESEARCH WITH HUMAN SUBJECTS

- The Human Research Protection Program (HRPP) and associated IRB implements Purdue's commitment to protect participants in research.
  - There are three types of review conducted based on risk to the participant: Exempt (includes 2 tiers), Expedited, and Full Board.
- Purdue HRPP/IRB uses the Cayuse system for all protocol submissions. www.irb.purdue.edu, login with BoilerKey.
- Consider all elements of study design, training, collaboration, agreements, etc. before submitting a protocol for review. Helpful materials and contacts are found on the IRB website.
- Approved protocols are chosen for post approval monitoring procedures to ensure research protections and documentation requirements, are occurring as anticipated.

QUESTIONS TO HELP BEGIN THE IRB REVIEW PROCESS

- Is it Human Subject Research?
- Is it eligible for exemption (Common category- examples)
  - Exempt 2, surveys, interviews, observation of public behavior
  - Exempt 4, secondary Analysis (Affirm Permissible Access to Data)

  Note that exemption still requires submission of a protocol through Cayuse
- Does it qualify for Expedited review? (no greater than minimal risk).
  - Data collected by non-invasive procedures
  - Collection of data from voice, video, digital , or image recordings
- Does the potential risk to the participant or a vulnerable population require that the entire IRB to review the study?
  - Full board meets twice each month, submission deadline 2 weeks before meeting.
  - Deadlines and meeting dates appear on the IRB website and are strictly followed.

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 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 (Designated (in office on a rolling basis by IACUC members) or Full Board (meets once per month).
- Approved protocols are chosen for post approval monitoring procedures to ensure research protections and documentation requirements, are occurring as anticipated.

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.
- Sponsored research awards related to biohazards or rDNA research are not accessible until the IBC approval is complete.

REGULATORY CHECK POINTS OCCUR AT VARIOUS STAGES IN THE LIFETIME OF AN AWARD

- JIT- (Just In Time) Prior to Award Determination
  - Sponsor requests for IRB or IACUC approvals?
- Contract Terms
- Notices To Proceed (NTP)
- Account Set-Up
- Incremental fund distribution, Increase/Decrease
  - Verify work in progress reports or changes to procedures.
- Changes in Scope or PI
- No-Cost Extensions

GRANT TO PROTOCOL REVIEW PROCESS

GRANT/AWARD

Proposal submission contains full project scope and budget.

Sponsor (e.g. NIH, NSF) → Sponsor funds activity

Research Regulatory Affairs reviews and documents congruency between the activities.

PROTOCOL

Protocol application describes specific elements of research with humans/animals/ rDNA

Campus Committee (IRB, IACUC, IBC) → Committee provides determination

TIPS TO HELP REGULATORY PROCESSING

- Read the request for proposal (RFP) and note the requirements for your IRB, IACUC or other regulatory affairs commitments.
- Review the terms of a contract or award.
- Prepare regulatory submissions early! Federal Sponsors use "Just in Time" practices to collect regulatory information.
- Answer all questions about your proposal with your Pre-Award specialist
- Consider building time within the project period to acquire all regulatory approvals and funds within the budget to cover regulatory considerations
- Many sponsors require titles of IRB/IACUC protocols to match the award exactly.

HELPFUL LINKS

Research Regulatory Affairs Area	Website See https://www.purdue.edu/research/regulatory-affairs/
Human Research Protection Program/IRB	www.irb.purdue.edu irb@purdue.edu
Biosafety, Recombinant DNA	rwgolden@purdue.edu Robert Golden, Biosafety Officer
Vertebrate Animals	ldsnider@purdue.edu Lisa Snider, IACUC Administrator
Research-Related Conflicts of Interest	fcoi@purdue.edu
Responsible Conduct of Research Training	RCRTraining@purdue.edu