Sponsored Program Services
POST AWARD

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Sponsored Program Services

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SPONSORED PROGRAM SERVICES
POST AWARD

- Sponsor Specific Areas
  - NSF/DHHS
  - Other Federal
  - Non-Federal
  - Ag Field Office

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Proposal is Submitted - What Now?

Agency sends Notice of Award

- Directly to SPS
- Directly to Faculty

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

- 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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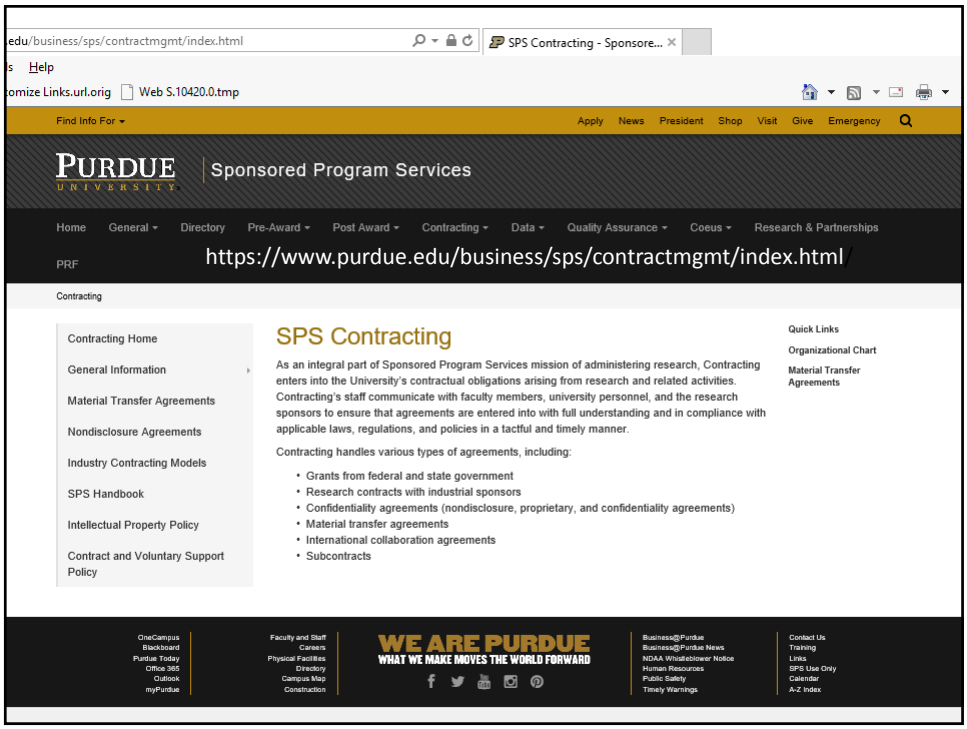

SPONSORED PROGRAM SERVICES

Contracting

Negotiate and process all contracts associated with sponsored programs

- 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

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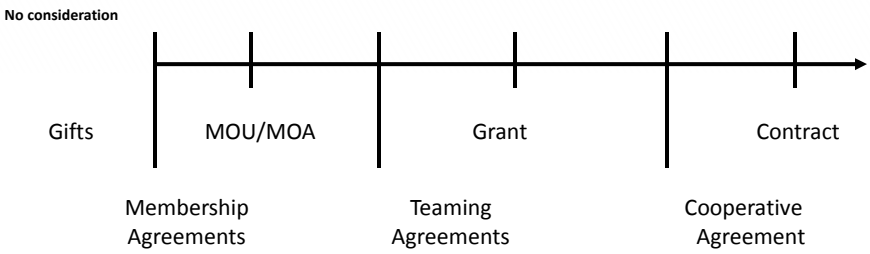
Types of Awards

Spectrum of Sponsor Influence



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SPS Contracting

Role of Contract Analyst

Contract Analyst ensures:

- 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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Award Arrives

What information is included?

- 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

Communication is Key

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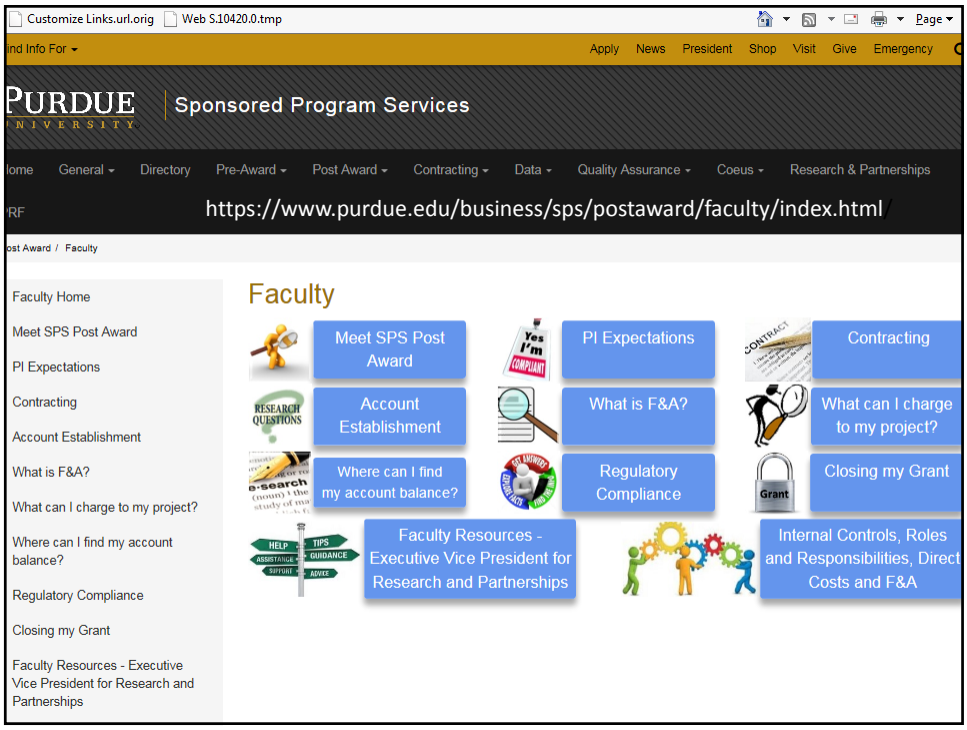

Sponsored Program Services

Post Award

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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Cost Allocation

Time to start spending!

First Point of Contact:
Departmental Business Office

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

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Award Establishment

Post Award

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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Cost Allocation

Roles of the Principal Investigator

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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Managing the Award

Roles of the Principal Investigator

- 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

Prior Approval

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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Managing the Award

Technical Reports

Principal Investigators are responsible for the timely submission of all technical reports

- Due dates are in award document
- Information available in Grants Management (GM) Account Information Management System (AIMS)
- Contact SPS Research Administration Specialist with questions

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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Managing the Award

Financial 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 https://www.purdue.edu/apps/account/cas/login?service=https%3A%2F%2Fwww.purdue.edu%2Fapps%2Faccount%2Fcasclient%2Flogin

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After Close-Out of Award

Record Retention

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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Sponsored Program Services

Contact Information

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Assistant Director, Ag Sponsored Programs
49-48464
sipleb@purdue.edu

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MANAGING YOUR AWARD: RESEARCH REGULATORY AFFAIRS

IANTHE "COOKIE" BRYANT-GAWTHROP
DIRECTOR, RESEARCH REGULATORY AFFAIRS AND HUMAN RESEARCH PROTECTION PROGRAM

PIS HAVE MANY REGULATORY

Keep up with sponsor-specific human/animal/rDNA/RCR requirements

Apply to committees applicable to your research

Train staff and keep records of training

Develop strategies that allow your research team to fulfill regulatory requirements

As a PI, you are responsible for the research study from its design through its implementation, and the maintenance of study data and records.

The Regulatory Affairs staff can assist you with the right path. Today, we will briefly cover regulatory requirements and how they relate to your proposals and awards for sponsored funds.

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REGULATORY ACRONYMS

IBC Institutional Biosafety Committee
- rDNA, unfixed human blood

IRB Institutional Review Board
- Human subjects, surveys

P(I)ACUC Purdue (Institutional) Animal Care and Use Committee
- Vertebrate Animals

RCR Responsible Conduct of Research
- RCR Training is required by some federal sponsors

FCoI- Financial Conflict of Interest

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REGULATORY TRAINING

Each area requires relevant training prior to approval of a research protocol
Most areas require training through the CITI Program (CITI), external to Purdue

CITI PROGRAM

the program, several courses are offered in topics like Human
ety, etc. You and/or your research team may need to take more
ete the correct requirement.

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SPONSOR SPECIFIC TRAINING…

Certain federal sponsors require RCR training (NSF, NIFA/USDA, some NIH) Requirements differ between agencies

Consists of online training course and may include discussion based learning (seminar, course, etc.)

NSF requires all trainees (postdoctoral fellows, graduate students and undergraduate students) to have training in RCR matters.

NIFA (USDA) requires all research personnel, including PIs and research staff to complete training.

Some NIH fellowship programs also require training in RCR matters.

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RESEARCH WITH HUMAN SUBJECTS

The Human Research Protection Program implements Purdue's commitment to protect participants in research.

An IRB is a committee that performs ethical review of proposed research with human subjects.

- An IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

Purdue has two Institutional Review Boards who review based on research area

- Social Science
- Biomedical IRB

Sponsors of research involving human subjects will require documentation of IRB approval at some point prior to an award.

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QUESTIONS TO HELP BEGIN THE IRB

Is it Human Subject Research?

- *A human subject is defined as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information about whom includes a subject's opinion on a given topic.*

Is it eligible for exemption? (Common category- examples)

- Exempt 1, educational practices in normal educational environment
- Exempt 2, surveys, interviews, observation of public behavior
- Exempt 4, pre-existing data

Does it qualify for Expedited review? (requires no greater than minimal risk).

- Data collected by non-invasive procedures
- Collection of data from voice, video, digital , or image recordings
- Research on individual or group characteristics or behavior

Does the potential risk to the participant require that the entire IRB meet and review the study?

- Full board meets monthly, submission deadline 2 weeks before meeting.

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SUBMITTING DOCUMENTS TO THE IRB

www.irb.purdue.edu

A step by step walk through of the forms and considerations to make when designing your IRB submission.

Getting Started

Submit a Protocol to IRB

After Approval

Forms and instructions to use after your study is approved by the IRB.

A link to the submission portal. Enter your Purdue Career Account to access. Then follow the directions to attach forms and submit directly to the IRB/HRPP staff.

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CLINICAL TRIALS

Some research with human subjects may be considered a clinical trial under recently revised definitions.

Trials funded by NIH require registration and updated results to be submitted to Clinicaltrials.gov

If your study could potentially be considered a clinical trial under this definition, additional training and record management requirements will apply.

- ***"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."***

Note- this applies to behavioral interventions, not just those of a biomedical nature.

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RESEARCH WITH VERTEBRATE ANIMALS

The Purdue Animal Care and Use Committee (PACUC) 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).

In addition, the Purdue Laboratory Animal Program (LAP) provides veterinary care, housing, and other required practices to ensure animal well being in research, testing and teaching.

PACUC applications are submitted through the COEUS system. Proper qualifications and training are required prior to authorization to conduct research with vertebrate animals.

Sponsors of research involving vertebrate animals will require documentation of IACUC approval at some point prior to an award.

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RESEARCH WITH BIOHAZARDS, SYNTHETIC OR

Research involving any of the biohazardous materials or those regulated by the NIH Guidelines requires review by the Institutional Biosafety Committee (IBC).

An IBC protocol requires a PI to detail the use, personnel, containment, and disposal procedures to protect the safety of the research team and surrounding community.

Apply to the IBC early. Training and lab inspections are required prior to a protocol approval.

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

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GRANT TO PROTOCOL REVIEW

Institutions can considered noncompliant for not validating congruence between what is funded and what IRB/IACUC approves

Congruence between the scope of work, model system, methods administered, strategy, etc. is required between the grant and the IRB/IACUC protocol.

Regulatory agencies currently see this as an obligation (though some changes may be coming).

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GRANT TO PROTOCOL REVIEW PROCESS

GRANT/AWARD

Proposal submitted → **Sponsor (NIH, NSF, I/F, etc).** → Sponsor funds activity

We review and document that these two items are congruent

PROTOCOL

Protocol application describes specific elements of research with humans/animals/ rDNA → **Campus Committee (IRB, IACUC, IBC)** → Committee provides determination

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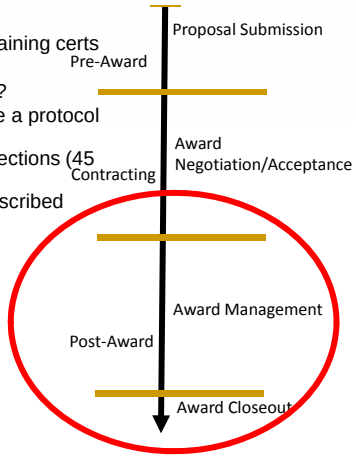
REGULATORY CHECK POINTS OCCUR AT

JIT- (Just In Time) Prior to Award Determination
- Is the sponsor asking for IRB/IACUC or approvals training certs

Contract Terms
- Is a sponsor trying to bind us to non-standard terms?
  - approving a protocol or mandating a date where a protocol must be approved
  - accepting alternate protections outside US protections (45 CFR 46, "Common Rule", DHHS regs, etc.)
  - Protect human research data in a particular prescribed manner

Notice To Proceed (NTP)
Account Set-Up
Incremental fund distribution, Increase/Decrease
- Review progress reports or changes to procedures.

Changes in Scope or PI
No-Cost Extensions
Unanticipated Human or Animal Charges



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FINANCIAL CONFLICT OF INTEREST

A Conflict of Interest(COI) is any interest, financial or professional that would bias, or appear to bias, objectivity in research, scholarship, and other professional activities.

Financial COI: Occurs when an individual's financial interest influences their professional actions, decisions, or judgment, in pursuing research, scholarship, other professional activities.

The EVPRP Office, through its FCoI staff assists and helps researchers manage research-related FCoI.

If necessary, the FCoI staff will assist the investigator in preparing a management plan.

The process is dependent on investigator disclosure of any interests at the time of proposal submission. Investigators answer questions from the online Proposal Disclosure Database (PDD).

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TIPS

Read the request for proposal (RFP) and note the requirements for your IRB, IACUC or other regulatory affairs commitments.

Don't skip reviewing the terms of a contract or award.

Prepare regulatory submissions early! Federal Sponsors use "Just in Time" practices to collect regulatory information. Many now require protections of human subjects/ vertebrate animals to be part of the proposal.

Answer all questions about your proposal with your Pre-Award center

Consider building time within the project period to acquire all IRB/IACUC approvals.

Federal sponsors may require titles of IRB/IACUC protocols to match the award exactly.

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HELPFUL LINKS AND CONTACTS

Research Regulatory Affairs Area	E-mail	Website
Human Research Protection Program/IRB	irb@purdue.edu	www.irb.purdue.edu
Biosafety, Recombinant/Synthetic Nucleic Acids	rwgolden@purdue.edu	http://www.purdue.edu/research/regulatory-affairs/biosafety-and-rdna/
Vertebrate Animals	ldsnider@purdue.edu	http://www.purdue.edu/research/regulatory-affairs/animal-research/
Research-Related Conflicts of Interest	fcoi@purdue.edu	http://www.purdue.edu/research/regulatory-affairs/conflict-of-interest/
Clinicaltrials.gov Registration	evprpregulatory@purdue.edu	https://www.irb.purdue.edu/clinical-trials/
Radiological and Environmental Management (REM)	https://www.purdue.edu/ehps/rem/ (Many areas fall under this single department)	

RESEARCH INFORMATION ASSURANCE AND EXPORT CONTROL REGULATIONS

MARY DUARTE MILLSAPS
RESEARCH INFORMATION ASSURANCE OFFICER

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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WHAT HAPPENS WHEN THERE ARE LIMITS

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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INFORMATION ASSURANCE

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

- 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)

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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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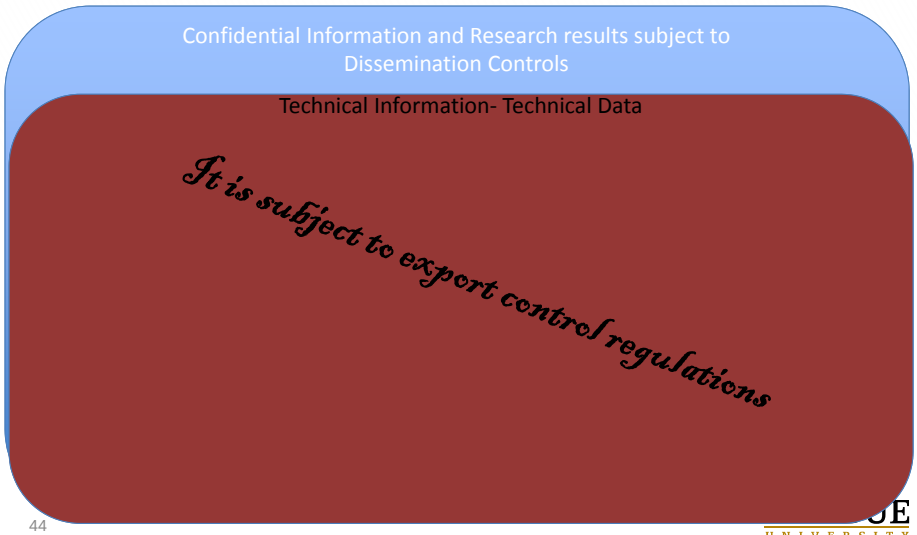
NEXUS OF CONFIDENTIAL INFORMATION



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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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EXPORT CONTROL COMPLIANCE

Legal Basis	Regulations	Cognizant Agency	Identification of controls
Arms Export Control Act (AECA) 1976	International Traffic in Arms Regulations (**ITAR**) 22 C.F.R. Parts 120-130	**Department of State** Directorate of Defense Trade Controls (DDTC)	U.S. Munitions List

Note: there are additional federal acts that some times impact Purdue activity (like the Atomic Energy Act of 1954) that may also need to be considered.

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EXPORT CONTROL COMPLIANCE

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) • **Cuba, Iran**, North Korea, Sudan and Syria

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EXPORT CONTROL COMPLIANCE

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**

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FUNDAMENTAL RESEARCH EXCLUSION

- 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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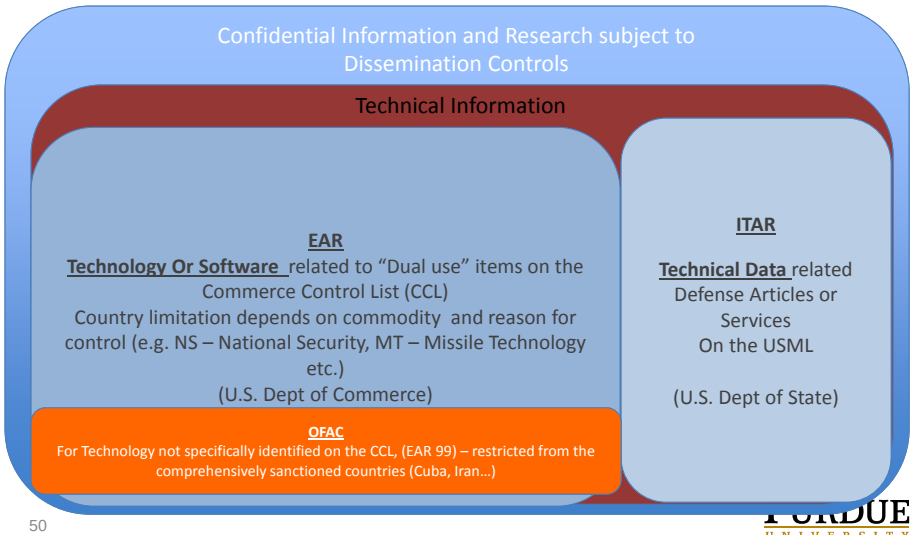

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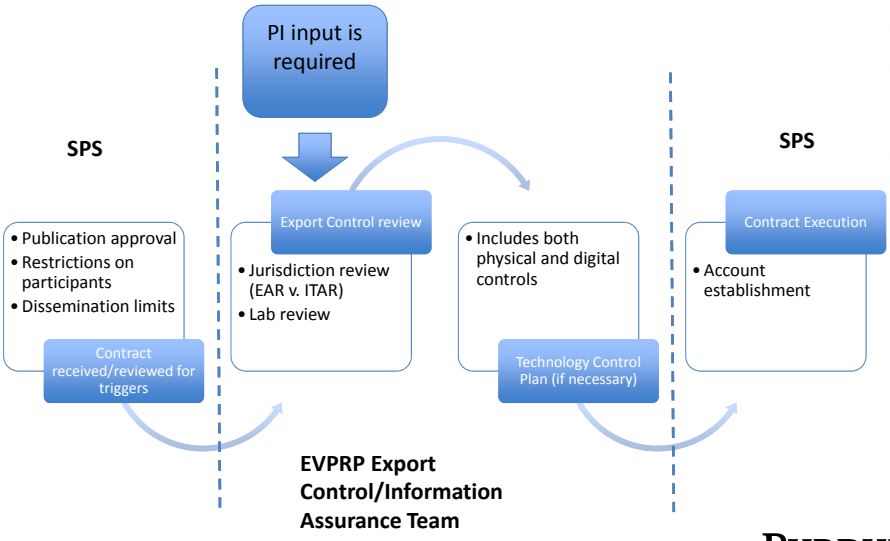
COMPLIANCE PROCESS



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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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NEW WEBSITE

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CONTACTS

Information/Export Control Team (within the EVPRP)

- exportcontrols@purdue.edu; 494 - 9806
  - Mary Millsaps – Research Information Assurance Officer
    - Steve Riedel
    - Ken Suter
    - Jama Johnson
    - Rene Celeste – Administrative support

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