

Compliance

A SHARED RESPONSIBILITY

Introduction

Compliance is a shared responsibility

- Primary – Principal Investigator
 - The Principal Investigator has primary responsibility for achieving the technical success of the project, **while also complying with the financial and administrative policies and regulations associated with the award**. Although Principal Investigator's may have administrative staff to assist them with the management of project funds, the **ultimate responsibility** for the management of the sponsored research award rests with the Principal Investigator. (From Dartmouth University)
- Institutional
 - Compliance offices
 - Training and Awareness
 - Monitoring and Close out
 - Sponsored Programs Services
 - Compliance with Sponsor requirements
 - Primary contact with Sponsors
 - Contractual and Financial Gatekeeper
 - Business Offices/Other Compliance Offices (like Radiological and Environmental Management (REM))

Grant to Protocol Review

Cookie Bryant Gawthrop

Navigating Grant to Protocol Congruence: Working Together to Meet Compliance Requirements



Have you ever wondered...

- What is “regulatory” review? What is the group reviewing?
- Where do regulatory and financial processes intersect?
- Who are the key players in the “regulatory” process?

Remember:

Institutional Review Board = IRB ---Humans

Institutional Animal Care and Use Committee = IACUC--- Vertebrate Animals

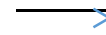
Institutional Biosafety Committee = IBC---Biohazards and Recombinant DNA

PROTOCOL

PI applies to the appropriate committee
Describes elements of their research with regulated elements (humans, animals, rDNA)



Appropriate Campus Committee (IRB, IACUC, IBC).



Committee reviews, provides revisions, approves or disapproves

**Do these match?*



GRANT/AWARD

PI submits proposal for funding.
Describes all elements of research aims. What they intend to discover, how they intend to get there. Elements beyond those that are regulated.



Sponsor (NIH, NSF, I/F, etc).



Sponsor determines if research activity is funded, what work will be funded, etc.

Grant to Protocol Review

- Institutions can be considered noncompliant for not validating congruence between what is funded and what IRB/IACUC approves
- What is Congruence?
 - Is the scope of work, model system, methods administered, strategy, etc. essentially the same in both the grant and the IRB/IACUC protocol
 - Helps take an administrative technical look at allowability costs
 - Can assist in minimizing risk to research participants
- Regulatory agencies see this as an obligation

OHRP and OLAW Protections at the Federal Level

- OHRP- Office of Human Research Protections within US Dept. of Health and Human Services (DHHS)
- OLAW-Office of Laboratory Animal Welfare within DHHS.
- These two agencies primarily govern the basis for humans and animals (respectively) in research activities.
- Purdue cannot receive federal funding without proper acceptance of basic protections for human subjects and animals = Federalwide Assurance (FWA) or Animal Welfare Assurance (AWA)
- Within the terms of these protections are terms to address congruence of funded awards.

Legal/Regulatory Framework

- OHRP regulations currently mandate review for congruency
- *“...An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB...”*
- OLAW regulations currently mandate review for congruency
- *“[PHS Policy](#) and the NIH Grants Policy Statement ([Part II, Terms and Conditions](#)) require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. This is not an explicit requirement for the IACUC to do a side-by-side comparison of an application/proposal and the IACUC protocol. However, institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application/proposal. Institutions are free to devise a workable mechanism to accomplish this end. One method to prevent inconsistencies between the information submitted to PHS and that on the IACUC protocol is to implement a procedure for direct comparison. Some institutions have delegated this responsibility to a particular office or position (e.g., sponsored programs or compliance office...”*



<http://www.sjsu.edu/research/irb/index.html>





Internal Infrastructure

- PI submits information about research project to committee (IRB, IACUC)
- IRBs and IACUCs are tasked with the human/animal participant protections stated in the PI's application
- The Research Regulatory Compliance team is tasked with reviews for congruency with sponsored funds
 - Must serve on the boards as voting members
 - Can look for status on both protocols and proposals
 - Updates are provided in COEUS, Image Now, and SAP (SAP updates are primarily for the BO to assist in ordering or payment compensation).

Hard Stops- Regulatory Reviews for Many Reasons

- 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



Course Corrections

- Situation: Incorrect statements on the Proposal Submission Form not painting the full regulatory picture.
 - **Correction**: SPS informs Regulatory. Ask if this is an issue. We can provide guidance, letters, or approvals to sponsor to assure them appropriate reviews will be done.
- Situation: SPS discovers accounts that were established without regulatory review
 - **Correction**: Discovered by periodic query or observant SPS staff- requests for routing. Special Review Tab in COEUS “pending” status. Direct our attention to grant files or route within system.
- Situation: Awards where regulatory charges were not anticipated in early stages, but evolved with the research.
 - **Correction**: Declared by PI or new GLs on account without regulatory documents. Business office inquiries. Route for review or direct to electronic grant file. SPS and EVPRP Regulatory will devise a working strategy.

What's related, But not in the grant to protocol review process--Why?

- Requirements are tightly controlled. Ordering, training, shipment, delivery are all defined through REM at the time materials are needed.
 - Radioactive Materials
 - Lasers
 - Controlled Substances
- HIPAA
 - Very rarely is the generation of Purdue research data truly subject to HIPAA regulations
 - Use of data obtained from a healthcare provider must still go through IRB in that capacity, it must be handled through the IRB still for proper review to be utilized in research.
 - It's possible that Purdue may be conducting a service where a contract is necessary

Take Home Messages

- Routing grants for Grant to Protocol Review (to Regulatory) keeps Purdue compliant with Federal Regulations
- The Research Regulatory Compliance team is reviewing for congruency
- PIs are responsible for submissions to the IRB/IACUC
- SPS must route files to Regulatory inboxes (Pre-award/Contracting) and queues (Post-award) to meet critical internal controls and course corrections. The final technical narrative/scope of work is always required.
- Some regulatory items do not require review for congruency because they may be related to safety, training, storage, or handling procedures in real time. Awareness to related departments promotes due diligence.
- If you don't know-ASK!



Other Opportunities to Learn

- www.purdue.edu/research (Integrity/Regulatory tab)
- Just in Time Information-
https://era.nih.gov/services_for_applicants/application_tracking_and_award/just_in_time.cfm
- Changes in Scope
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm
- CITI training (free to Purdue personnel)
 - www.citiprogram.org
- OLAW seminar archive presentation on congruence
 - https://grants.nih.gov/grants/olaw/educational_resources/webinar_06072012.htm

Examples

Exampleville Melanoma Study

This study is an incoming subcontract where a faculty member receives funds from a federally-sponsored prime recipient to study small molecules that may be useful in treatment of melanoma.

- Pre-award- Properly budgeted and collected the proposal documents. Marked proposal submission forms and Coeus for humans, animals, and biohazards.
- Contracting- Reviewed and approved subcontract terms and SoW
- Post-Award- Reviewed Documents, established account and routed file to Regulatory queue via Image Now (after noting that Special Review Tab in COEUS was flagged for regulatory review.)

What's Next?

What SPS Sees- Incoming Subcontract SoW

- **Aim One-** After identifying the candidate molecules, we will then forward promising results generated in vitro to an in vivo model. We will add 100 mg/kg of each drug in a rat model system for skin cancer. The 100 mg/kg dose will be given orally to rats. Skin cells will be collected by non-invasive procedures and tested through traditional biological assays to measure rates of inhibition of cancer cell growth. Once cells are harvested, they will be cultured in sterile lab conditions. We will utilize a lentiviral expression system with commercially available recombinant DNA plasmids.
- What congruency reviews are required?
- IACUC and IBC

What the IACUC Sees- One page of a protocol

**Purdue Animal Care and Use Committee (PACUC)
APPLICATION TO USE VERTEBRATE ANIMALS
IN RESEARCH, TEACHING, OR TESTING**

Principal Investigator/Project Director:

Protocol Title:

Coeus Protocol Number:

IACUC Protocol Electronic Submission Instructions:
http://www.purdue.edu/business/coeus/IACUC_Protocols/Investigator_Guide_IACUC/index.html

1. Justification for Animal Use and Species

- 1.1 How was it determined that alternatives (e.g., less painful/distressful animal procedure use of phylogenetically lower species or non-animal procedures) could not be substituted (i.e., why live animals must be used)? **"Alternatives" refers to methods, models, approaches that result in the reduction of the number of animals used, that incorporate refinements of procedures which result in the lessening of pain or to animals, or that provide for the replacement of animals with non-whole animal systems or the replacement of one animal species with another, particularly if substituted species is non-mammalian or invertebrate. There must be a written narrative description of the methods and sources which were consulted to determine the availability of alternatives (reduction, refinements, replacement).**

- 1.3 Indicate the scientific rationale for the number of animals to be used. How did you determine the number of animals required? Your explanation should include the numbers per group, number of groups, power analysis used, number of animals needed for training, etc. THE TOTAL NUMBER OF ANIMALS LISTED IN THIS SECTION MUST MATCH THE NUMBER GIVEN IN THE COUNT COLUMN IN THE SPECIES/GROUPS TAB OF COEUS.

- 1.3a Will you be maintaining a breeding colony as part of this protocol? YES ___ NO ___
If yes, please answer the following questions. If no, continue to question 1.4.
- a. How will the colony contribute to the overall objectives of your research and/or teaching activity?

- b. Please provide an explanation as to why animals from commercial vendor sources are not appropriate and this breeding colony is necessary.

What IBC Sees

- Biosafety Committee wants to ensure personnel are trained on the use of the materials they work with
- Recombinant DNA must be handled per NIH guidelines
- Biohazardous materials must be properly disposed
- Lab space must be regularly inspected by Biosafety Officer
- One page of an IBC application is included as an example of a few questions that PIs must address.

3. rDNA Description

"NIH Guidelines defines recombinant and synthetic nucleic acid molecules as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii) above .

Exempt from NIH Guidelines: Those synthetic nucleic acids that: (i) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (ii) are not designed to integrate into DNA, and (iii) do not produce a toxin that is lethal for vertebrates at an LD:50 of less than 100 nanograms per kilogram body weight.

Based on the description above, will this protocol utilize synthetic nucleic acid molecules?

Yes No

Source and Nature of the inserted DNA Sequences: _____

Vectors Used (viruses, plasmids, cosmids, or phage viruses): _____

Host Cell Used for Propagation or Expression: ~~Selected~~ - - - - -

Foreign Gene Expression (indicate the protein produced): _____

Describe/List the synthetic nucleic acid molecules used: _____

How will transgenic organisms be contained and/or destroyed? _____

4. Personnel: (Report personnel changes to the IBC office via email)

Name(s) of personnel who will be working with Risk Group II or above biohazardous or recombinant materials:

_____	_____
_____	_____
C J	C J

What SPS Sees

- **Aim Two-** Promising drug candidates will be evaluated in a number of samples obtained from Example University Hospital in Exampleville, Illinois. Briefly stated, we will enroll 40 participants for collection of a small skin biopsy to be excised from the left leg. Twenty of the participants will be healthy controls (no diagnosis of cancer) the remaining twenty will have a recent cancer diagnosis. Skin biopsy is widely used and presents no greater than minimal risk to participants. In addition, we will give enrolled participants a questionnaire to ask them about their overall health, smoking status, sun exposure, stress level, and nutritional choices. Each participant will be paid \$50 for their time; estimated to be approximately two hours. This study is already approved by our IRB under reference 1114943.
- What congruency review is needed?
- IRB and IBC

What the IRB sees/reviews

- <https://www.irb.purdue.edu/forms.php>
- Variety of forms which ones and how many are dependent on assessed risk level to the participant.
- Does not view entire grant/award
- PI must expand on protections to describe specific interactions with participants and their data.
- Example of part of a consent form follows. (A consent form is a key document to provide up front information about a study. It is one of many documents in an IRB application.
 - Are the grant and IRB documents congruent?

RESEARCH PARTICIPANT CONSENT FORM

Exampleville Melanoma Project Study 1114943

Dr. Fictional Smith and Dr. Sample Jones

Exampleville University

What is the purpose of this study?

The purpose of this study is to obtain biopsy specimens to use in the lab and collect data regarding the new drugs being developed to prevent and/or treat metastatic melanoma Example

What will I do if I choose to be in this study?

If you choose to be in this study you will be asked to donate a small piece of tissue from your right leg to be used for future research purposes. A small part of your skin will be cleaned and numbed with a local anesthetic. The technician will use a small device to extract a small cylinder of tissue. The amount of extracted tissue will be less than the size of a pencil eraser. The technician will then assist in bandaging the site.

How long will I be in the study?

The biopsy procedure is short. It is estimated that you will only spend about 30 minutes from the beginning to the end of this procedure.

What are the possible risks or discomforts?

The punch biopsy procedure may cause some temporary discomfort. Risks of infection at the site of extraction are possible. The technician will take all necessary precautions including the use of sterile procedures, sterile materials, and

Are there any potential benefits?

While there are no direct benefits to you, this small procedure will assist us in testing several new compounds for effectiveness in finding potential treatments for melanoma. These contributions could one day benefit society.

Will I receive payment or other incentive?

If you complete the biopsy procedure, you will be compensated \$15.

Are the Grant and Protocol Congruent?

- Not entirely!
 - Procedures to obtain biopsy are approved
 - No mention of questionnaire
 - Estimated time, compensation, and risk are not the same
- Research Regulatory Compliance Team will contact PI(s)
 - Is there another IRB protocol?
 - Were the grant aims modified?
 - Assist to provide instructions on how to modify application

Contacts

EVPRP Regulatory Team

Director, Research Regulatory Compliance
Sponsored Projects Regulatory Administrator

evprpregulatory@purdue.edu

Staff Info found at <http://www.purdue.edu/research/staff/index.php?id=4>

**Managing Financial
Conflicts of Interest in Research
A Team Effort (SPS/EVPRP)**

Voichita M. Dadarlat

**Office of the Executive Vice President for Research
and Partnerships**



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.
- ❑ Professional COI: May occur when an individual is an author of a publication or a participant in a research project and has conflicting professional roles/responsibilities in study (e.g., when a physician-researcher recruits research subjects from patient population).

FCOI regulations: Preserving Research Objectivity and Maintaining Public Trust in Research

- ❑ Public concerns about industry ties to academia, e.g., the Pharmaceutical industry and academic research or consulting activities.
- ❑ Gene therapy trials: Jessie Gelsinger died; researchers had financial ties to the industry supporting their work and questions were raised about the objectivity of their judgments because of their stake in the trial results.
- ❑ Senator Charles Grassley (R-Iowa) launched a Congressional inquiry into conflict of interest from university researchers supported by grants from federal agencies (NIH, NSF, etc.).

Maintaining Public Trust in Research

Research Related Conflicts of Interest (COI) in the media

Dr. Charles B. Nemeroff – Chair of Psychiatry at Emory (at the time):

- ❑ Failed to disclose \$1.2 million in consulting arrangements with, and COI in clinical trials (sponsored by the National Institutes of Health) of drugs from, Merck, Eli Lilly and Johnson & Johnson.
- ❑ Failure to disclose led to NIH suspension of a \$9 million grant to Emory.
- ❑ Dr. Nemeroff stepped aside from all NIH grants on which he was a PI or Co-PI. He was banned from applying for NIH Grants for a three year period and is no longer at Emory.
- ❑ Others: using grad students to conduct faculty consulting work, buying overpriced equipment from faculty owned companies.

Why Do Researchers Need to Disclose and Manage FCOI?

- ❑ A requirement of the [University Policy on FCOI](#), federal and state regulations; promotes research objectivity, maintains public trust in research, good stewardship of University resources
- ❑ **Protects Investigators/Entrepreneurs from (unfounded) accusations of Conflict of Interest**
- ❑ [Preserves Investigator and University privileges](#) to apply for funding from sponsors
- ❑ [Disclosures](#) are subject to public record request laws
- ❑ [Academic journals have specific COI disclosure requirements](#); authors are able to indicate that financial interests have been disclosed and conflicts are managed by the university.

Definitions

- ❑ **Investigator** – a person responsible for the design, conduct, and/or reporting of research.

- ❑ **Financial Conflict of Interest (FCOI) in research** – a situation in which financial interests of Investigators (and/or their family members) may bias, or have the appearance of biasing, the design, conduct, or reporting of research.

- ❑ **Significant Financial Interest (SFI)**
 - Remuneration > \$5,000 (from consulting, board membership, etc.)
 - Ownership interest (> 0% in a non-publicly traded company; > 5% in a publicly traded company)
 - Intellectual property (IP) and royalty income from IP owned outside of Purdue/PRF.

- ❑ **Financial Interest Statement (FIS)** – Investigator statement of financial interest for each research project.

- ❑ **Research Related Significant Financial Interest Disclosure (RRSFID)** – a description of outside financial interests related to Purdue research.

Background – Research Framework



Investigators

- Comply with University policies and procedures

Award – SPS Post-Award



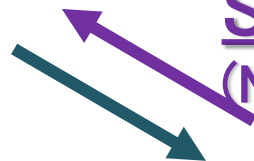
Proposal – SPS Pre-Award

Purdue/SPS/EVPRP

- Compliance with award provisions
- Compliance with federal regulations
- Assists and helps Investigators

Sponsors

(NIH/NSF/NASA/etc.)



Oversight



FCOI Management – Roles and Responsibilities

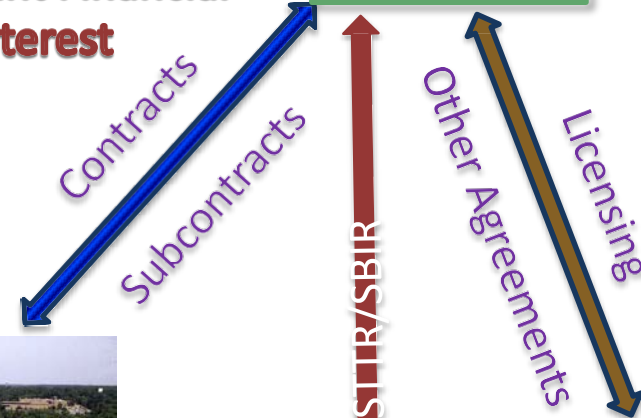


Investigators

- Disclose SFIs
- Comply with policies



Company



PRF/OTC

Purdue/SPS



Sponsors (NSF,NIH,NASA,etc.)



- Design FCOI policy
- Collect FIS
- Evaluate SFI
- Identify FCOI
- Manage FCOI
- Report FCOI to federal agencies
- Monitor compliance
- Assist and help Investigators

FCOI Policy - Roles and Responsibilities

Investigator

- Disclose any and all Significant Financial Interests that he, she or a Dependent has, as required by this policy.
- Update disclosures of Significant Financial Interests within 30 days of discovering or acquiring a new Significant Financial Interest (e.g., through purchase, marriage or inheritance) and, in the case of a project sponsored by a PHS agency, at least annually thereafter for the duration of the project.
- For Investigators participating in sponsored projects awarded by PHS agencies, complete training as required by the policy.
- Comply with the requirements of any management or mitigation plan approved by the Conflicts Committee.

Principal Investigator

- Notify SPS of all Investigators on a project, including additional Investigators and/or Senior/Key Personnel who may be added during the life of the funded project or identified in a report to a PHS sponsoring agency.



Practical Implementation of the Research Related Portion of the FCOI Policy

- ❑ Proposal Driven Disclosure (PDD) – an online tool for minimizing administrative burden for researchers and administrators
- ❑ Two track system:
 - Track 1: handles proposals submitted to DHHS/PHS/NIH and PHS-like agencies
 - Track 2: handles proposals submitted to non-PHS Sponsors
- ❑ Crucial Steps - SPS:
 - **SPS Pre-Award** works with PIs/Co-PIs to identify all “Investigators” on each project.
 - **SPS Technical Support** generates reports and uploads proposal information in the staging area of the PDD (twice a day).
 - **SPS Pre-Award** can directly add/remove projects and Investigators manually, as needed (e.g., if there is an urgent need).
- ❑ The system sends automatic notifications - customized by track - to all Investigators on each project.

Practical Implementation of the (RR) FCOI Policy – PDD Pre-Award Interactions

PDD calculates automatically Submission and Award Statuses for each project.

- ❑ PDD updates the proposal submission status to “**Ready**” when all Investigators have completed their FIS, and, for those with SFIs, RRSFIDs and Travel Disclosures have been completed (e.g., for proposals to NIH).
- ❑ When proposal Submission Status = “**Ready**” in the PDD, **Pre-Award** staff can proceed with proposal submission. If Submission Status = “Not Ready”, **STOP**; additional requirements need to be completed.

Practical Implementation of the FCOI Policy – PDD Post-Award Interactions

- ❑ PDD automatically updates the project Award Status to “**Award Ready**” when all FCOI requirements have been completed.
- ❑ For the PHS track, this means the FIS and FCOI Training have been completed by all Investigators; for Investigators with SFIs, the RRSFIDs are completed and “Up-to-Date”, a COI Management Plan is in place for the company and the Conflict Status has been updated to “Managed” or “Eliminated” by **EVPRP**.
- ❑ When Award Status = “**Award Ready**” in the PDD, **Post-Award** staff may proceed with account set-up.
- ❑ If Award Status = “**Pending**”, **STOP, do not set up an account**; additional FCOI requirements need to be completed.

Practical Implementation of the FCOI Policy – PDD Post-Award Interactions – continued

- ❑ When a Notice of Award is received and the Award Status for a project is still “Pending”, Post-Award staff update the Award Status to “**Notice of Award**”. PDD calculates the remaining FCOI requirements and sends notifications to Investigators and EVPRP.
- ❑ PDD recalculates Award Status after every Investigator/EVPRP interaction with the system.
- ❑ When the Award Status becomes “**Award Ready**”, PDD sends a notification to the specific Post-Award subgroup responsible for account set-up and award administration.

Research Related FCOI Management

A Case Study

Prof. Entrepreneur is a co-owner/founder of a start up company, Innovation Inc. Innovation has licensed Purdue technology from OTC which it plans to commercialize and further improve. The company was awarded several Small Business Innovation Research grants from NSF and is now sponsoring research in the E lab. Research support in the lab at Purdue also comes from NSF and several other federal agencies and industrial partners. In addition, Innovation has given an unrestricted gift to support research projects and provide financial support for a research assistant. Thesis projects of graduate students in the lab are related to both projects sponsored by the company and grants from NIH and NSF.

FCOI in the Life Cycle of a Research Project

- Step by Step -

Premise: Prof. E prepares a proposal for submission to NIH

- SPS Pre-Award and Prof. E:** Identify all Investigators on the project.
- SPS Technical Support** uploads proposal information to the PDD, including all identified Investigators to the PDD staging area.
- The PDD immediately generates and sends up to three notifications to Investigators and collects FISs before proposal submission (since this is a proposal to NIH).
- FCOI Requirements: All Investigators must submit their FIS (answers to YES/ NO questions) before proposal submission to NIH; if YES statements were submitted, Research Related Significant Financial Interest Disclosures (RRSFIDs) and Travel Disclosures must be completed by all Investigators (**Pre-Award + EVPRP**) before proposal submission.
- Before submission to NIH, **Pre-Award** makes sure that proposal submission status is **“Ready”** in the PDD.
- If not, STOP; the proposal can not be submitted to the Sponsor.** If this is an emergency, contact EVPRP (fcoi@purdue.edu).



FCOI in the Life Cycle of a Research Project – Investigator Interface

Each Investigator on a research proposal will receive a system generated email message:

Dear Investigator,

You are receiving this message because you are a PI/Co-PI, or an Investigator, on the following proposal(s):

Title: , **IP#:**, submitted to PHS-NIH NAT INSTITUTE OF HEALTH.

Federal regulations and the University policy on Individual Financial Conflicts of Interest (FCOI) require all Investigators participating in sponsored projects to disclose any Significant Financial Interests (SFI), including SFIs of their Dependents.

Please complete and sign electronically your Financial Interest Statement (FIS) online at:

https://webapps.ecn.purdue.edu/VPR/DevPDD/ptFinancialInterestForm?proposal_id=937474&puid=10025934

The above link will take you to a secure website (https) hosted on an internal Purdue server. To login and sign your form, please use your Purdue Career Account credentials.

Before completing your FIS and corresponding SFI disclosures, please review all relevant definitions (Significant Financial Interest, Institutional Responsibilities and Sponsored/Reimbursed Travel) provided at the website above.

Amanda Hamaker
Director, SPS Pre-Award

FCOI in the Life Cycle of a Research Project

SPS Pre-Award (Continued)

Premise 2: Prof. E submits a proposal to his own company

- Proposals submitted to Investigator owned companies require full costing review.
- SPS Pre-Award** personnel identifies the proposal to Prof. E's company and submits the SOW, budget, and budget justification to **EVPRP** (fcoi@purdue.edu) for full costing review.
- If the proposal is not fully costed or a determination can not be made, EVPRP negotiates with Investigator, etc.
- STOP**: If Investigator and EVPRP can not find common ground, the proposal can not be submitted.



FCOI in the Life Cycle of a Research Project

- EVPRP -

- If YES statements and RRSFIDs are submitted, **review and make a FCOI/relatedness to project determination.**
- If FCOI, **draft, negotiate with Investigator and execute Management Plan** (signatures required from Dept. Heads and Deans).
- STOP**: If FCOI was identified and no executed Management Plan is in place, an account for an award can not be set-up until the associated conflict is “Managed” or “Eliminated” (**Post-Award** and **EVPRP**).



FCOI in the Life Cycle of a Research Project

EVPRP (continued)

- ❑ When a PHS/NIH (or NIH-like) project with FCOI is Awarded, EVPRP makes a **“relatedness” determination** (upon notification from the PDD).
- ❑ If the project is related to the business scope and activities of Prof. E’s company, **EVPRP submits an FCOI Report to NIH** (within 60 days from the start date of a new award).
- ❑ **An annual report** of compliance is consequently submitted to PHS/NIH for the duration of the project/award.



FCOI in the Life Cycle of a Research Project

Post Award

Premise 3: Prof. E's proposal is funded by NIH (or highly ranked)

- Post-Award received an NOA/NTP/JIT; the manager in charge checks if all FCOI requirements are completed (i.e., the project is “**Award Ready**” in the PDD). If YES, proceed with account set-up.
- If NOT (i.e., the Award Status is still **Pending**), the Post-Award manager **updates the Award Status to “NOA/NTP/JIT”**; the PDD re-starts the notification process for completion of remaining FCOI requirements/training (the system calculates the missing requirements and assemblies and sends Investigator specific notifications).
- STOP:** An account will not be set up for an award until the project is “**Award Ready**”. (When the project is Award Ready, the PDD sends an automatic notification to the corresponding Post-Award group).



FCOI in the Life Cycle of a Research Project

- Contracting/Sub-Contracting -

Case 1. Prof. E's lab at Purdue is awarded a sub-contract from another university.

- Contracting and EVPRP (if needed) **review COI provisions** in the sub-contract; Pre-Award collects FIS from all Investigators; if FCOI and Prime Sponsor PHS/NIH, EVPRP **submits an FCOI Report and an Annual Report of Compliance** to Prime Awardee.
- STOP:** If an FCOI Management Plan (MP) is not in place, an account can be established for the sub-contract. **Wait until MP is executed.**



FCOI in the Life Cycle of a Research Project

- Contracting/Sub-Contracting -

- ❑ **Case 2.** A Sub-contract from Purdue to another institution/company.
- ❑ If from an award, **flow-down FCOI requirements.**
- ❑ The institution will inform Purdue of their Investigators' project related FCOI (if any) and EVPRP will submit a report to the Prime Sponsor (if PHS/DHHS).



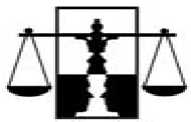
FCOI in the Life Cycle of a Research Project

- Contracting -

Special cases governed by the Indiana State statute on Conflict of Interest (applicable to procurement/purchasing and nepotism). Premise: Prof. E's lab at Purdue needs to purchase equipment from Innovation or to sub-contract to the company for a portion of the NIH sponsored project.

- ❑ **Subject to IN state statute:** subcontracts to, or purchases from, an Investigator owned company (i.e., money flows from Purdue to Investigator owned company). Approval from the Board of Trustees (BOT) required before completing the transaction.
- ❑ **Contracting contacts EVPRP/COI Officer** to verify that Prof. E has an approved **Conflict of Interest Disclosure Statement (COIDS)** from the Board of Trustees.
- ❑ **How to identify these instances:**
 - **Select contracting staff have access to the PDD** and can verify whether FCOI exists for the prime award.
 - EVPRP supplies lists of active FCOI Management Plans for Investigators/Companies to SPS (at least twice a year).

STOP: No purchase from or sub-contract to Prof. E's company will be completed before BOT approval of a COIDS.

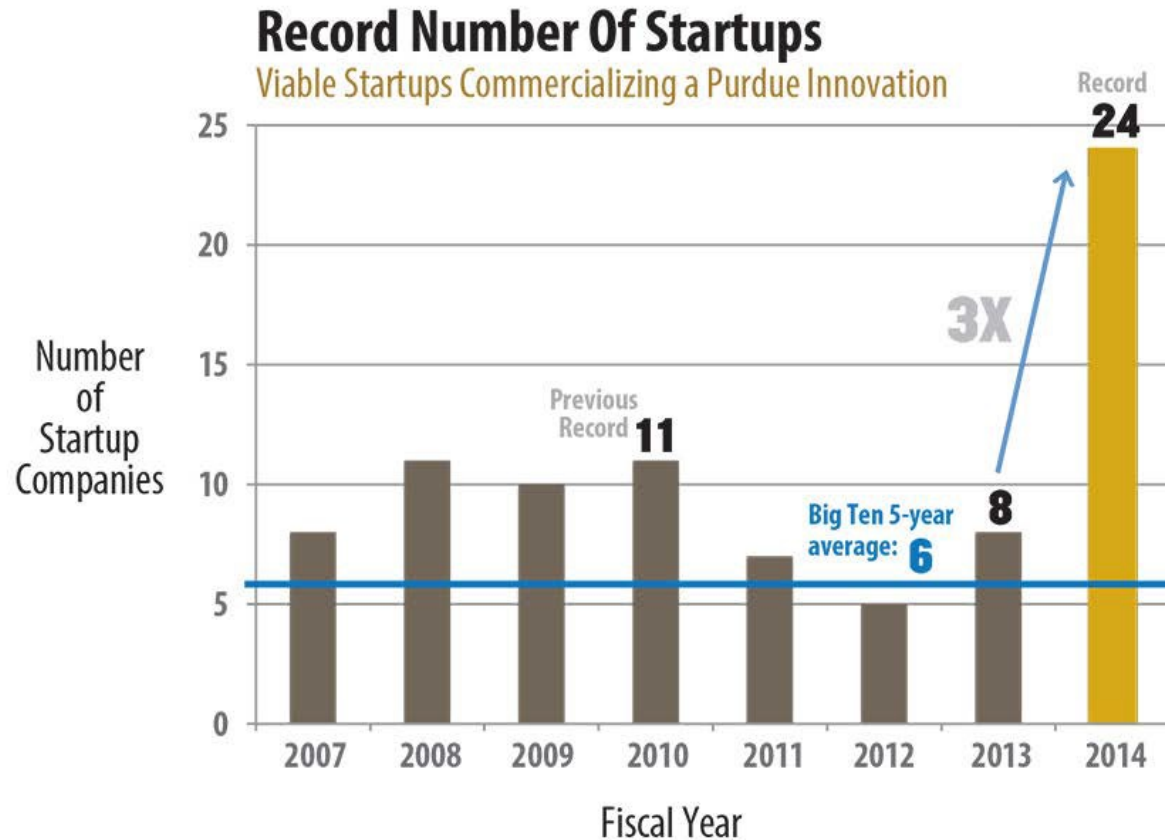


Implementation of FCOI Policy at Purdue

Some Statistics

- ❑ **Percentage of proposal-based Financial Interest Statements and corresponding Research Related SFI Disclosures reviewed by EVPRP for determination of FCOI: ~5% (1400 to date since July 1st, 2011).**
- ❑ **Number of active FCOI Management Plans: 150.**
- ❑ **Ranking of Colleges by the number of FCOI Management Plans:**
 - ❑ College of Engineering,
 - ❑ College of Science,
 - ❑ College of Agriculture.

Purdue \equiv “Entrepreneur U.”



- ❑ EVPRP: 36 new FCOI Management Plans were executed in 2014 (38% increase), ~same in 2015.
- ❑ Total number of active Management Plans: 150. Of these, 10% are for women entrepreneurs or women who engage in research related consulting.

Figure from President Daniels' January 2015 letter to Purdue Community.



FCOI Management – Promoting Research Objectivity and Maintaining Public Trust

References and Contacts

- ❑ FCOI Policy: **Individual Financial Conflicts of Interest (III.B.2)**
<http://www.purdue.edu/policies/ethics/iib2.html>

- ❑ [Table summarizing various COI related processes at Purdue Summary of Research Related Conflict of Interest Forms](#)

- ❑ The FCOI disclosure and management online application:
<https://webapps.ecn.purdue.edu/VPR/PDD>

- ❑ Additional information regarding Disclosure of Research Related Significant Financial Interests can be found on the Conflict of Interest website:
<http://www.purdue.edu/research/vpr/rschadmin/coi>

- ❑ For help with research related COI questions, please contact: Voichita Dadarlat voichi@purdue.edu and/or Howard Zelaznik, hnzelaz@purdue.edu, or fcoi@purdue.edu.

Managing Financial Conflicts of Interest in Research A Shared SPS/EVPRP Responsibility

Questions?

Comments?



Export Control Compliance

Intent of the Regulations

- 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



Export Control Compliance

Key Definitions

Term	Definition
U.S. Person	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Everyone else, including foreign students here are student visas (J and F) and foreign employees on H1-B visas.• 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

Export Control Compliance

Legal/Regulatory Basis for Controls

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

Export Control Compliance

Legal/Regulatory Basis for Controls - part 2

Jurisdiction	What's Controlled	License Requirements
<u>ITAR</u> 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
<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
<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)• Cuba, Iran, North Korea, Sudan and Syria

Export Control Compliance

Jurisdiction determination example

Scenario:

PI (U.S. Citizen) in Aeronautical Engineering Technology wants to receive a Proprietary Unmanned Aerial Vehicle (UAV) model and the related specifications and the Company requests an NDA be executed.

The project team includes a Co-PI who is a US Permanent Resident (citizenship is France), 1 US graduate student and 2 foreign graduate students from Canada and China. The PI indicates he wants the whole team to have the same access.

Step 1 – determine the Jurisdiction (EAR or ITAR) and applicable controls (ECCN number, if EAR)

Step 2 – determine the impact on the project team and what licensing may be required

Export Control Compliance

Jurisdiction determination example – From the CCL

9A012 Non-military “Unmanned Aerial Vehicles,” (“UAVs”), unmanned “airships”, related equipment and “components”, as follows (see List of Items Controlled).

License Requirements Reason for Control: NS, MT, AT

Control(s)	Country Chart (see sup No. 1 to part 738)
NS applies to entire entry	NS Column 1
MT applies to non-military Unmanned Air Vehicle (UAVs) and Remotely Piloted Vehicles (RPVs) that are capable of a maximum range of at least 300 kilometers (km), regardless of payload, and 9A012.b.5.	MT Column 1
AT applies to entire entry	AT Column 1

List of Items Controlled

Related Controls: See the U.S. Munitions List Category VIII (22 CFR Part 121). Also see ECCN 9A610 and § 744.3 of the EAR.

Items:

a. “UAVs” or unmanned “airships”, **designed to have controlled flight out of the direct ‘natural vision’** of the ‘operator’ **and** having any of the following:

1. Having all of the following:

a. A maximum ‘endurance’ **greater than or equal to 30 minutes but less than 1 hour**; and

b. Designed to take-off and have stable controlled flight in **wind gusts equal to or exceeding 46.3 km/h (25 knots)**; or

a.2. A **maximum ‘endurance’ of 1 hour or greater**;

Export Control Compliance

Jurisdiction determination example

Commerce Control List Overview and the Country Chart

Supplement No. 1 to Part 738 page 3

Commerce Country Chart

Reason for Control

Countries	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
	Bulgaria ³	X					X		X	X						
Burkina Faso	X	X		X		X	X	X	X	X		X		X		
Burma	X	X	X	X		X	X	X	X	X		X		X		
Burundi	X	X		X		X	X	X	X	X		X		X		
Cambodia	X	X		X		X	X	X	X	X		X	X			
Cameroon	X	X		X		X	X	X	X	X		X		X		
Canada	X										X					
Cape Verde	X	X		X		X	X	X	X	X		X		X		
Central African Republic	X	X		X		X	X	X	X	X		X		X		
Chad	X	X		X		X	X	X	X	X		X		X		
Chile	X	X		X		X	X	X	X	X	X	X		X		
China	X	X	X	X		X	X	X	X	X		X		X		
Colombia	X	X		X		X	X	X	X	X	X	X		X		

Export Control Compliance

Fundamental Research Exemption

Fundamental research is basic and applied research in science and engineering, where the resulting information **is ordinarily published and shared broadly within the scientific community**. The techniques used during the research are normally publically available or are part of the published information.

31 C.F.R. 734.8 (EAR definition)

Export Control Compliance

What is NOT Fundamental Research?

When we accept publication restrictions

- Sponsor requiring **approval** of publications
- DFAR 252-204-7000 Disclosure of Information - approval for the disclosure of any information related to the project. (*special case*)

When we accept participation restrictions based on citizenship (*fellowships are special cases*)

If these terms are NOT accepted, the project is **fundamental research** and the results are NOT subject to the Export Control Regulations

Controlled Inputs (e.g. proprietary information received with the obligation of confidentiality)

Export Control Compliance

Special Case of DFAR 252-204-7000 Disclosure of Information

The Contractor shall not release to anyone outside the Contractor's organization any unclassified information, regardless of medium (e.g. film, tape, document), pertaining to any part of this contract or any program

Unless...

The information results from or arises during the performance of a project that has been scoped and negotiated by the contracting activity with the contractor and research performer and **determined in writing by the *contracting officer* to be fundamental research...**

Export Control Compliance

Visual representation of the Deemed Export Issue

Proprietary Information and Results of Controlled Projects

Technical Information

EAR

Technology related to “Dual use” items on the Commerce Control List (CCL)

Country limitation depends on commodity and reason for control (e.g. NS – National Security, MT – Missile Technology etc.)

OFAC

For Technology not specifically identified on the CCL, (EAR 99) – restricted from the comprehensively sanctioned countries (Cuba, Iran...)

ITAR

Technical Data
related
Defense
Articles or
Services
On the USML

U.S. Persons

Export Control Compliance

Staff

Mike Reckowsky (full effort)	Steve Riedel (full effort)		
Review Contracts and determine if EC regulations apply			
Assist in the negotiations to achieve the appropriate scope and controls Works with the faculty to draft the Technology Control Plans (when appropriate)			
<i>Review flagged international shipments for MMDC</i>			
	<i>Review flagged International visitors</i>		
<i>Review new hires/students and visitors from OFAC sanctioned countries</i>			

Export Control Compliance

Method of verifying compliance

Risk Based – Factors

- Technology
- Lab
- PI

Mitigation options

- Email confirmation of the facts (saved in Coeus)
- Full Technology Control Plan

Export Control Compliance

Method of verifying compliance

Risk Based – Factors

- Technology
- Lab
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Mitigation options

- Email confirmation of the facts (saved in Coeus)
- Full Technology Control Plan

Export Control Compliance

Method of verifying compliance



Export Control Compliance

Caution, Hard Stops and Course Corrections

Pre-Award



- Note Publication, dissemination or participation controls in RFP
- Note any indication from the PI or sponsor that the project is proprietary or controlled
- Note significant foreign scope (e.g. work being completed in a foreign country or foreign sponsor)



On Special Review Tab – note Export Control Pending and in the comment sections, include why you flagged. Be as specific as possible (page number, contact information, if necessary, upload a information sheet. (Be as clear as possible)

Export Control Compliance

Caution, Hard Stops and Course Corrections

Contracting



- Flag all:
 - Contracts (regardless of type) with Foreign Sponsors
 - All project agreements with publication or dissemination restrictions (not delay – but approval by the sponsor) that can't be negotiated out.
 - All project agreements with a restriction participation by citizenship



Send to Export Control Team for review (exportcontrols@purdue.edu)

Include:

- **Why you are flagging it**
- **Information to identify the agreement (Coeus number and PI/Sponsor name)**
- **Pertinent information**
 - **What page or section the language is; The PI is already asking about the agreement, etc.**

Export Control Compliance

Caution, Hard Stops and Course Corrections



Contracting

- Proposal records that are flagged for Export control – review the comment and analyze if the understanding is confirmed with the contract or not.
- Non-Disclosure Agreements without Export Control labeling language – attempt to negotiate the labeling language in (truly is the in both parties best interest).
 - If you can't – flag and and send to Export Control Team for review

Export Control Compliance

Side note about activity types in Negotiations



Activity Type	Meaning
To Export Control Office	One of the mandatory review triggers exists and the contract can't be executed until the EC team has reviewed and approved moving forward
Export Control Comment <i>(new)</i>	Additional information related to the analysis of export control impact –e.g. Primary recipient (NDA) confirms he is the only one who will have access and he is a U.S. Person.
Export Control Response	EC team has reviewed the situation and has decided the contract can move forward. EC team will document what the decision was and provide enough detail to explain why the determination was made. Often this is a copy of an email (but information should be in the content section and not just an attachment)

Export Control Compliance

Caution, Hard Stops and Course Corrections

Contracting



- Amendments that have terms different from the original agreement
 - New restrictions
 - The removal of restrictions
- Controlled Projects that are extended or renewed



Send to Export Control Team for review – note why you are sending it (including identification of impacted project (grant and previous coeus number)

Export Control Compliance

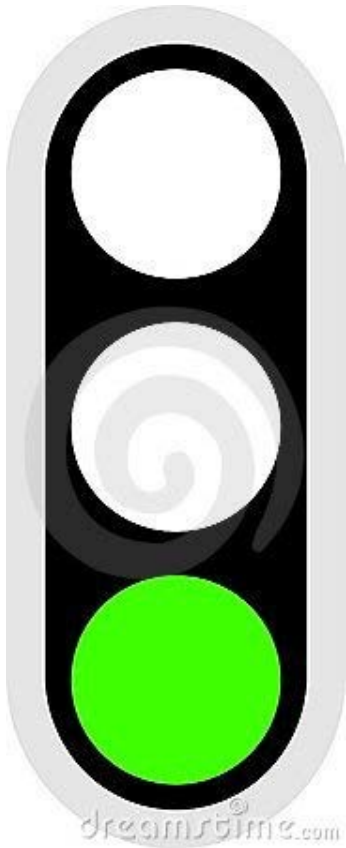
Caution, Hard Stops and Course Corrections

Contracting

- What doesn't need review –
 - Language that states the University will abide by the law.

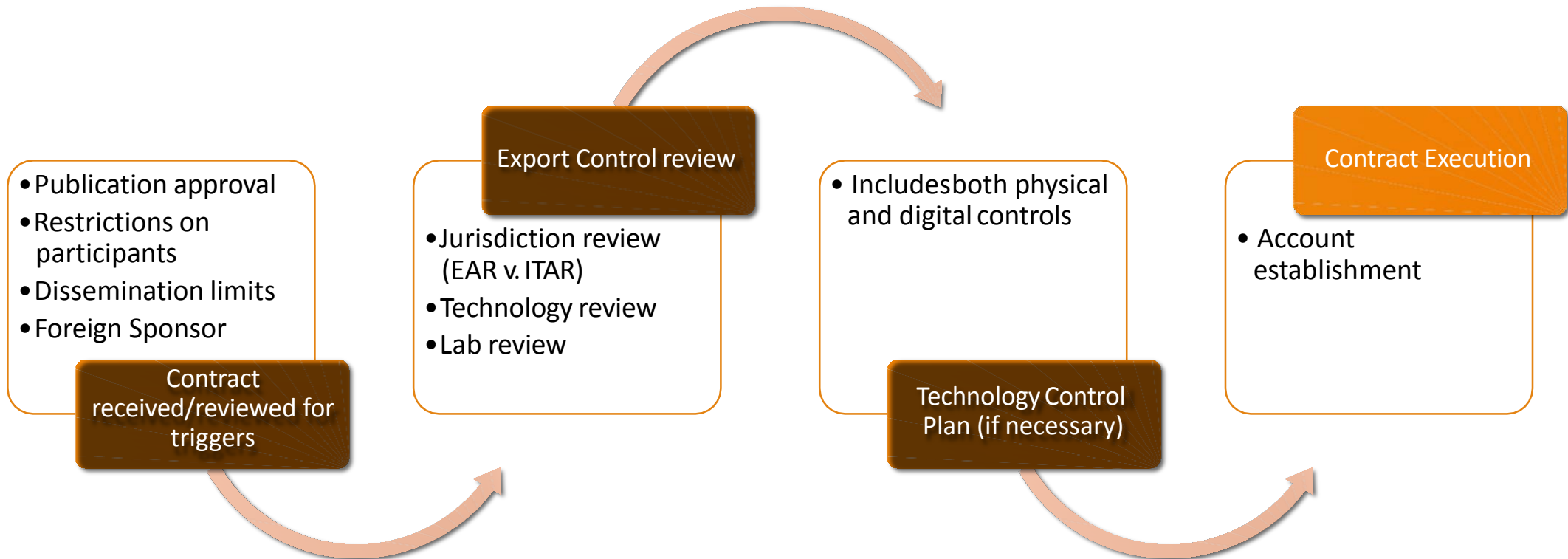
Example: The University hereby certifies that it will comply with the U.S. export and import controls laws and regulations, including by not limited to the International Traffic in Arms Regulations, 22 CFR 120 et seq.), the Export Administration Regulations (15 CFR Part 730-774), the regulations administered by the US Treasury Department's Office of Foreign Assets Control (31 CFR Part 500-598)...

When in doubt – ask



Export Control Compliance

The Contracting Process



Export Control Compliance

Caution, Hard Stops and Course Corrections

Post Award



- Coeus records with a Special Review marked Export Control Pending
- Foreign travel
 - ***On any project*** to OFAC Sanctioned Countries
 - Cuba, Iran, Syria, North Korea and Sudan
 - Charged to a controlled project (Export Control flag in SAP)



Send to Export Control Team for review – note why you are sending it (including identification of impacted project (grant and previous coeus number))

Export Control Compliance

Caution, Hard Stops and Course Corrections

Post Award



- When a Notice To Proceed is requested and the IP record or Negotiation is flagged for Export Control review.



Confirm with Export Control Team that the negotiation/analysis has progressed far enough to be confident it will be Executed

Export Control Compliance

Questions



**Does contracting get copies of the prime award to see what clauses are there?
What if the prime is not obtained on an Industrial flow-through and it is
discovered in year 2 that there is a clause such as the 7000 clause?**

Answer – It is the obligation of the sponsor to document any applicable terms. Only those Prime terms that are identified by the subcontract would apply to Purdue.

If the sponsor fails to flow down a term, Purdue is under no obligation to adhere to terms they are not aware of. In the event an amendment adds terms (like the DFAR 252.204-7000 (Disclosure of Information) Clause it should trigger, at the amendment negotiation stage, an Export Control review.

Export Control Compliance

Questions



How does Purdue handle Cyber security clauses like DFAR 252.204-7012 (Safeguarding Covered Defense Information and Cyber incidents)?

Although these clauses are NOT specifically Export Control clauses, the specific controls kick in if the information is controlled. (e.g. If the 252.204-7000 (Disclosure of Information) clause is also in the contract, and Contracting Officer has not issued a written determination that the scope of the project is controlled.)

The EC Team will work with ITSP to make sure the controls are documented and followed. If the -7012 controls are required, the project WILL have a TCP. Often times ITSP will have to work with the college level IT support to ensure compliance (e.g. ECN).

PreAward Note: if the -7012 clause is present, there WILL be specific direct costs for IT security that must be built into the budget. We are working on those rates now. If this clause is included in the RFP, you should be using an estimated amount in the budget.

Export Control Compliance

Take Away Messages

- Purdue **cannot** successfully comply with these complex regulations without the Principal Investigator, SPS and EC team all doing their part
- For Deemed Exports – it is the contract terms that drives the compliance requirements
 - Publication restrictions
 - Confidentiality obligation
 - Participation restrictions

Conclusion

When you see something that appears out of the ordinary or you have a question about the regulations or the processes that ensure compliance –

Ask the Subject Matter Experts!

Conclusion

Topics or questions that you would like to hear more about.