SPONSORED PROGRAM SERVICES
CONTRACTING & POST AWARD

Kyle Wargo & Susan Corwin

November 08, 2022

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Sponsored Program Services

Contracting
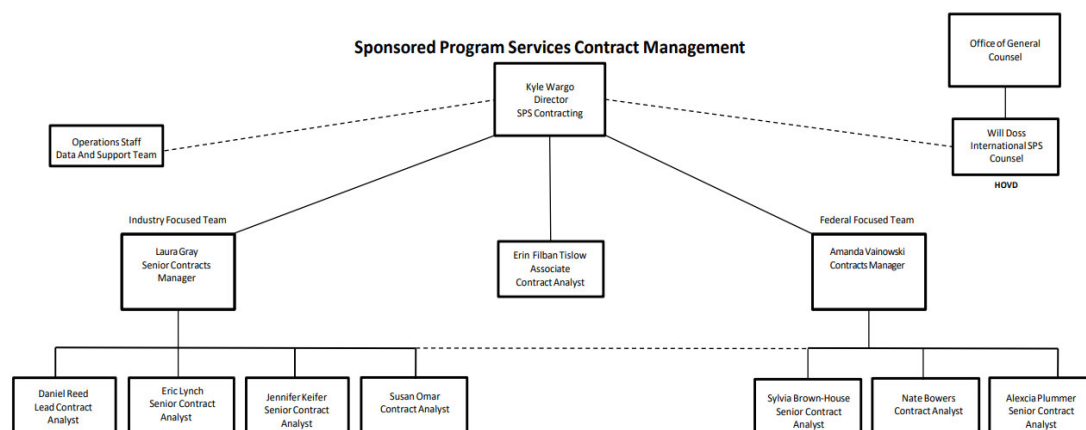
Proposal is Awarded

What happens next?

- Sponsoring Agency sends a Notice of Award or Agreement

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

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SPS Contracting

How SPS Contracting is organized

Sponsored Program Services Contract Management

Kyle Wargo
Director
SPS Contracting

Operations Staff
Data And Support Team

Office of General Counsel

Will Doss
International SPS Counsel

HOVD

Industry Focused Team

Laura Gray
Senior Contracts Manager

Erin Filban Tislow
Associate
Contract Analyst

Federal Focused Team

Amanda Vainowski
Contracts Manager

Daniel Reed
Lead Contract Analyst

Eric Lynch
Senior Contract Analyst

Jennifer Keifer
Senior Contract Analyst

Susan Omar
Contract Analyst

Sylvia Brown-House
Senior Contract Analyst

Nate Bowers
Contract Analyst

Alexcia Plummer
Senior Contract Analyst

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SPS Contracting

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

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

- Contract Analysts provide services which include, but are not limited to:

  - Answer questions on University contracts and contract negotiation issues

  - Draft Contract Agreements

  - Collaborate with other University staff as appropriate including:

    - Regulatory and Compliance, Export Control, Risk Analysis, Office of Legal Counsel, and others

  - Read and review all contract documents and prepare red-lines for sponsor review

  - Maintain up-to-date records in COEUS negotiation on all agreements initiated, in-process and completed

  - Negotiate the terms and conditions of an agreement to ensure compliance with all laws and University policies

  - Assure all regulatory requirements and export control issues are identified and necessary internal approvals are obtained

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SPS Contracting

Role of a Contract Analyst

- Obtain approvals as follows:
  - ✓ Regulatory/IRB
  - ✓ Export Control
  - ✓ Information Assurance
  - ✓ Private Business Use
  - ✓ Risk Management
  - ✓ Dean/Department Head

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SPS Contracting

Types of SPS contracts

- **NDA: Nondisclosure/Confidentiality/Proprietary Agreements**
  - Keep certain information confidential for a certain period of time
  - Can be unilateral or mutual
  - Typically for preliminary discussions before a research agreement
  - Often contain requirements that the confidential information be marked
  - **NDA Info Sheet found here:**
    https://www.purdue.edu/business/sps/contractmgmt/NDA/contractingNDA.html

- **MTA: Material Transfer Agreements**
  - Set terms under which proprietary materials are transferred to Purdue or from Purdue for use by another research institution
  - **MTA Info Sheets found here:**
    https://www.purdue.edu/business/sps/contractmgmt/agrtemplates.html

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SPS Contracting

Types of SPS contracts

- **Traditional Agreements**
  - Basic Research
  - Testing

- **Applied Research Agreements**
  - Up-Front Commercial Non-Exclusive License
  - Up-Front Exclusive License

- **Master/Strategic Alliance Agreements**

- **Subcontracts**

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

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Agreements not related to Sponsored Research

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

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

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SPS Contracting

Non-Core Agreements handled by the Office of Legal Counsel

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

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

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SPS Contracting

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

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SPS Contracting

Signature delegation

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

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Intellectual Property

What does the ownership of IP impact?

- Licensing Revenue or IP Fees for PI, Department and University

- Right to Publish

- Right to pursue related research

- Private Business Use

SPS Contracting

Additional Resources and Information

- SPS Contracting website:
  https://www.purdue.edu/business/sps/contractmgmt/index.html

- Best source of information for an active negotiation will be the **COEUS Negotiation Record** or the **assigned Contract Analyst**

- Best contact for new questions and agreements: **spscontr@purdue.edu**

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Sponsored Program Services

Post Award

Post Award

Award is fully executed – Now what happens?

- Reviews the file for Regulatory/Compliance approvals
  - Financial Conflict of Interest certification
  - Training & travel disclosures (if applicable)
  - Regulatory (Animals & Human Subjects)
  - Export Control
  - Foreign restrictions
- 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: Compliance to include Financial Conflict of Interest (FCOI) disclosures must typically be in order prior to start of research.

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Important information in Award

- Start/End Dates
- Award Amount – **What has been released for spending?**
- 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. Some reasons for more than one account:

- Multiple Investigators
- Unique categories & reporting needs (tasks, projects, sub-projects)
- Incremental funding
- Specific budgetary restrictions
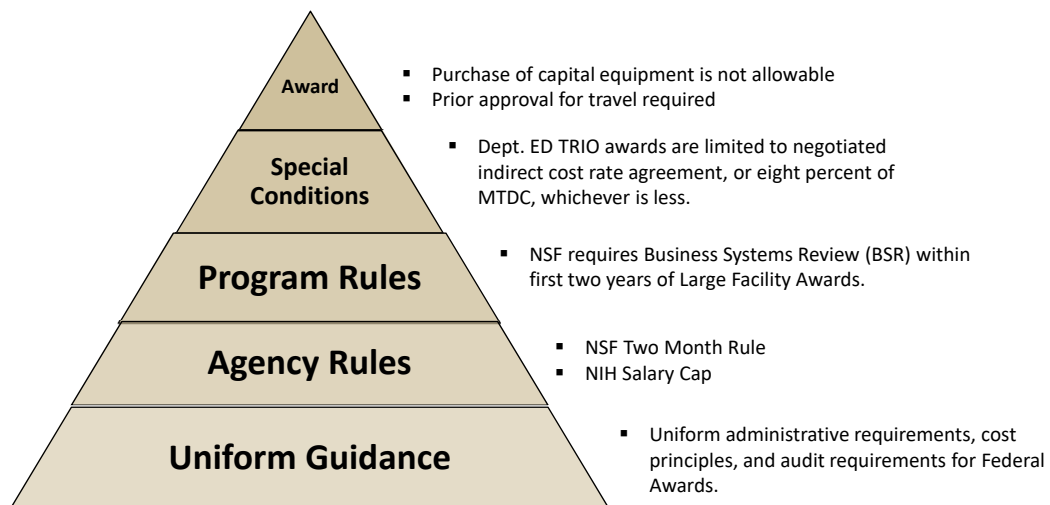 - Participant Support Costs
- Subrecipients
- Cost share

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Difference in Awarding documents

Spectrum of Sponsor Influence

No consideration

Gifts · MOU/MOA · Grant · Contract

Membership Agreements · Teaming Agreements · Cooperative Agreement

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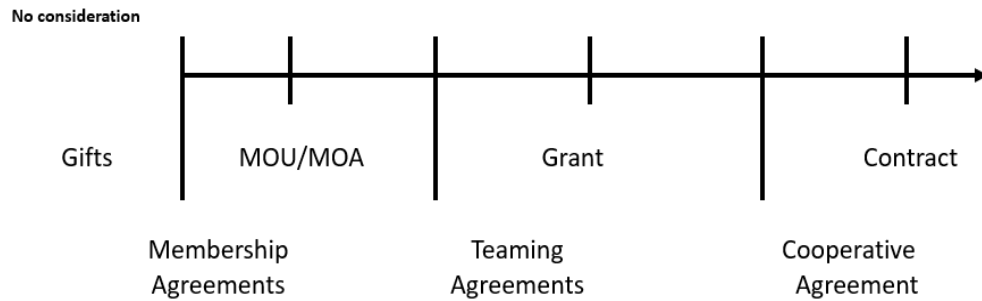
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Order of Precedence

- Award
- Special Conditions
- Program Rules
- Agency Rules
- Uniform Guidance

- Purchase of capital equipment is not allowable
- Prior approval for travel required

- Dept. ED TRIO awards are limited to negotiated indirect cost rate agreement, or eight percent of MTDC, whichever is less.

- NSF requires Business Systems Review (BSR) within first two years of Large Facility Awards.

- NSF Two Month Rule
- NIH Salary Cap

- Uniform administrative requirements, cost principles, and audit requirements for Federal Awards.

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Decision Process

Determining Chargeability of Costs to a Sponsored Program:

Reasonable
- Price
- Quantity
- Timeliness

Allocable
- Must benefit project
- Must be necessary

→

One project	Two or more projects

Proportions Determined with no undue effort

Allowable
- Uniform Guidelines
- Sponsor Guidelines
- University Guidelines

→

Consistent Treatment

Direct	Indirect

Allowable Direct Costs with Conditions
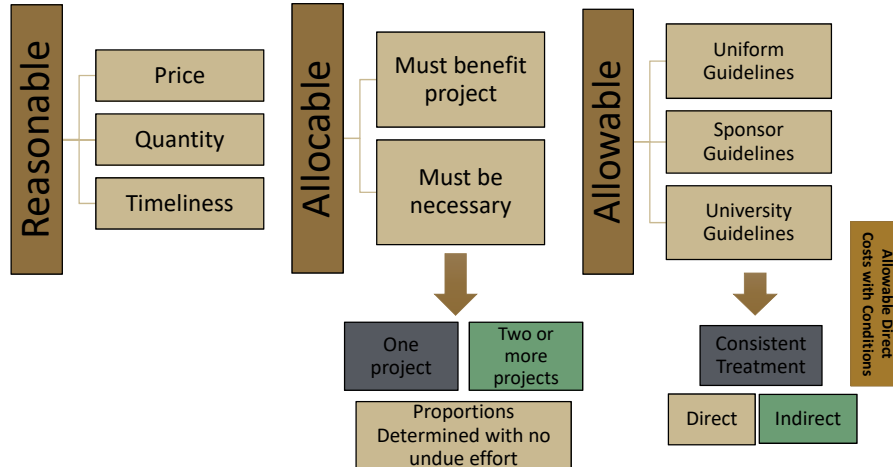
Managing the Award – Prior Approvals

Items that may require prior approval:

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

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

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Need an account before the award is fully executed?

Notice to Proceed (NTP)

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

  - NTP is a line of credit established to allow a project to begin prior to receipt of a fully executed award

  - Your Business Office will work with you and your department to approve the backing of the NTP.

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

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

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Role of the Principal Investigator (PI)

- Direct the work

  - Within project period

  - Within budget authorized by sponsor

  - Oversight of subrecipients work

- 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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https://www.purdue.edu/business/sps/preaward/menu/1.getti ngstarted/pi_role/pi_expectation.html

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Role of the PI - Audits/Monitoring Visits

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

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

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Role of the Principal Investigator (PI)

Subrecipients on a project

- Oversight of the Subrecipients work
    - Deliverables completed

- Approval of Subrecipients Invoices
    - Approval certifies that the subrecipient is meeting project deliverables/objectives
    - Invoice attached in the workflow for review
    - Option to reject invoice

    Note: Post Award will review expenses based on approved budget and sponsor spending restrictions

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Role of the Principal Investigator (PI)

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

Faculty website for Sponsored Research

Sponsored Program Services

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

PRF | https://www.purdue.edu/business/sps/postaward/faculty/index.html

Post Award / Faculty

Faculty Home
Meet SPS Post Award
PI Expectations
Contracting
Account Establishment
What is F&A?
What can I charge to my project?
Where can I find my account balance?
How can I approve a subcontract payment?
Regulatory Compliance
Closing my Grant
Faculty Resources - Executive Vice President for Research and Partnerships

Faculty

- Meet SPS Post Award
- PI Expectations
- Contracting
- Account Establishment
- What is F&A?
- What can I charge to my project?
- Where can I find my account balance?
- How can I approve a subcontract payment?
- Regulatory Compliance
- Faculty Offboarding
- Closing my Grant
- Faculty Resources - Executive Vice President for Research and Partnerships
- Internal Controls, Roles and Responsibilities, Direct Costs and F&A

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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
    - OneCampus page -https://one.purdue.edu/

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Faculty Reports
AIMS
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SPS Post Award Areas

SPS Teams based by Tasks/Functions

- Account Management
  - Main Point of Contact

- Award Setup & Subawards

- Finance (Billings & Closeout)

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

- Ag Field Office
  - International Funded Projects
  - USDA & USAID

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| Account Setup | Account Management | Cost Share | Audit & Compliance | Closeout |

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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Business Office – Post Award

Your Business Office will help you with:

- Management/Questions you have on your sponsored projects
  - Prior approvals
  - Budgets
- Payroll processing
- Purchases and travel
- Projections on your accounts (sponsored and non-sponsored funds)

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Areas within Post Award

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QUESTIONS?

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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, tell them about any changes;

- Train staff and keep records of training;

- Principal Investigators are responsible for the research study
  - design through implementation
  - 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.

- Examples- Company ownership, start-up companies, stock interest.

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 routinely 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 Lite system. Proper qualifications and training are required prior to authorization to conduct research with vertebrate animals.

- There are two types of review conducted by the IACUC based on risk (Designated (in office on a rolling basis by IACUC members) or Full Board (meets once per month).

- Approved protocols are routinely 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.

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?
- Sponsors may ask for these approvals during contracting
- 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

A FEW REAL EXAMPLES – SPONSOR EXPECTATIONS

5. Proposals Involving Human Subjects

a. Projects involving research with human subjects must ensure that subjects are protected from research risks in conformance with the relevant Federal policy known as the Common Rule (*Federal Policy for the Protection of Human Subjects*, 45 CFR § 690). All projects involving human subjects must either have: (1) approval from an Institutional Review Board (IRB) before issuance of an NSF award; or, (2) an IRB determination that the project is exempt from review, in accordance with the applicable subsection, as established in 45 CFR § 690.104(d) of the Common Rule. If certification of exemption is provided after submission of the proposal and before the award is issued, the exemption number corresponding to one or more of the exemption categories also must be included in the documentation provided to NSF.

Timing of IRB review

While a proposal can be reviewed without IRB approval, projects involving human subjects cannot be recommended for funding until this certification or its equivalent is filed in the proposal jacket.

- Researchers should file their proposal with their local IRB at the same time they submit it to NSF, so that the approval procedure will not delay the award processing.

20. Does the IACUC have to review proposed animal research activities at the time of grant award if the animal research activities will not be conducted until year 4 or 5 of a grant?

Yes, with rare exception.

The IACUC must review and approve the proposed use of animals described in the application or proposal prior to the conduct of any PHS-supported animal activity (PHS Policy V.B.). Approval is valid for a maximum of 3 years. A brief description of the animal activities planned for the 4th and 5th year of the award period should be provided in the animal protocol recognizing that the experimental details and procedures will be refined or amended at a later time or at the time of the 3-year renewal.

https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_2.jsp, accessed 11/4/22
https://www.nsf.gov/bfa/dias/policy/human.jsp, accessed 11/4/22
https://olaw.nih.gov/faqs#/guidance/faqs?anchor=question50346, accessed 11/4/22

TIPS TO HELP REGULATORY PROCESSING

- Assist students or those new to the process with their IRB, IACUC, and IBC applications.
- Review the terms of a contract or award. Outline protections and responsibilities with entities performing regulated research on Purdue's behalf.
  - Some sponsors require IRB and IACUC review locally and from the sponsor
- 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. Remember simple surveys may be human subjects research.
- 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 AND CONTACTS

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