

Essential Compliance Topics in Research Administration

Presented by

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Agenda

- Welcome and introductions
- Purpose of the presentation
- Essential compliance topics
- Discussion



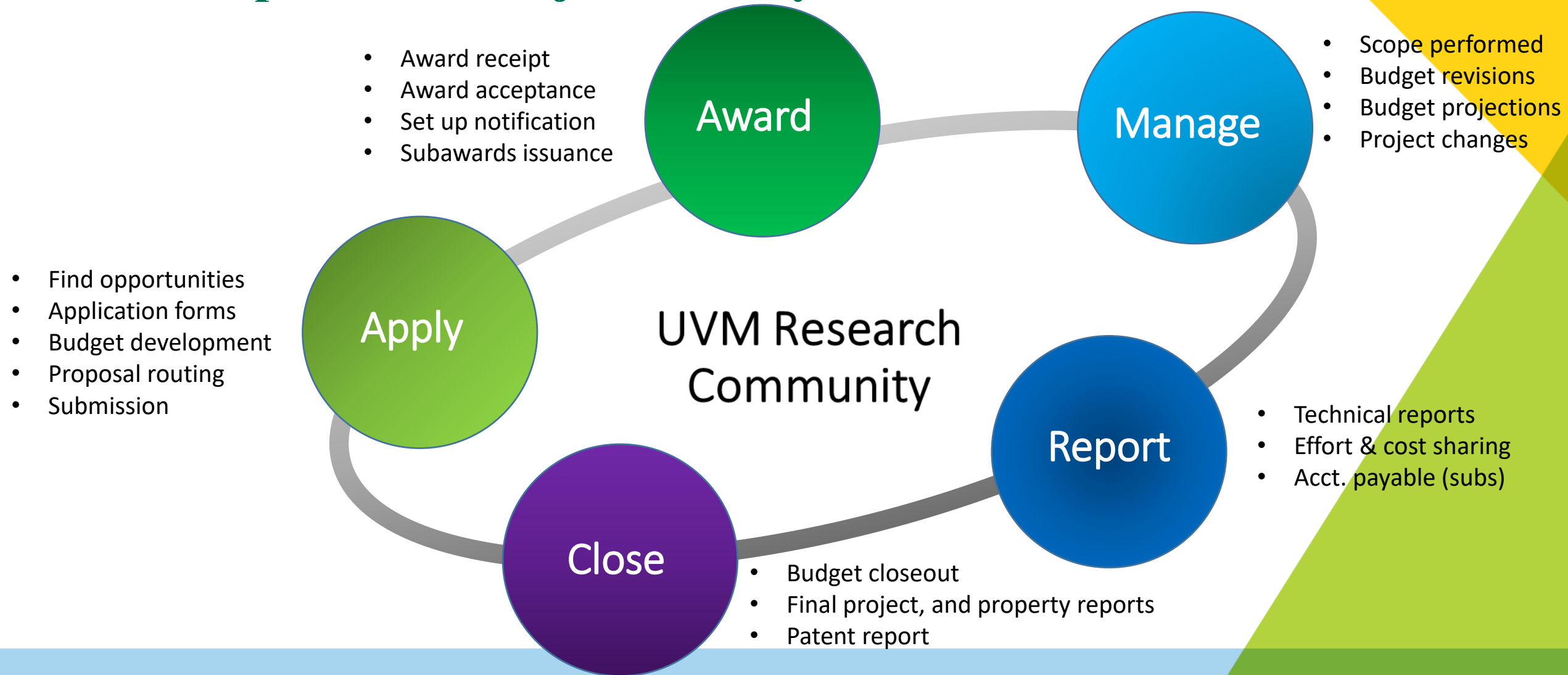
Purpose of the Presentation

- Research Compliance Essentials That Every Principal Investigator (PI) and Research Administrative Professional (RA) Should Know
- **Overall Objectives:** Provide participants with an overview of compliance requirements related to sponsored projects.
 - Learn about multiple areas of research compliance
 - Roles and responsibilities related to compliance

Essentials that Every Principal Investigator (PI) Should Know

- Research is integral to UVM's core mission
- PIs are central to the design, conduct and reporting of research
- PIs are responsible for all aspects of research conducted on behalf of the institution
 - Including compliance with institutional policies and terms/conditions of an award
- Scientific and administrative leaders are committed to assist PIs with this responsibility.
- Today we will discuss **common compliance areas surrounding research**

UVM Sponsored Project Life Cycle

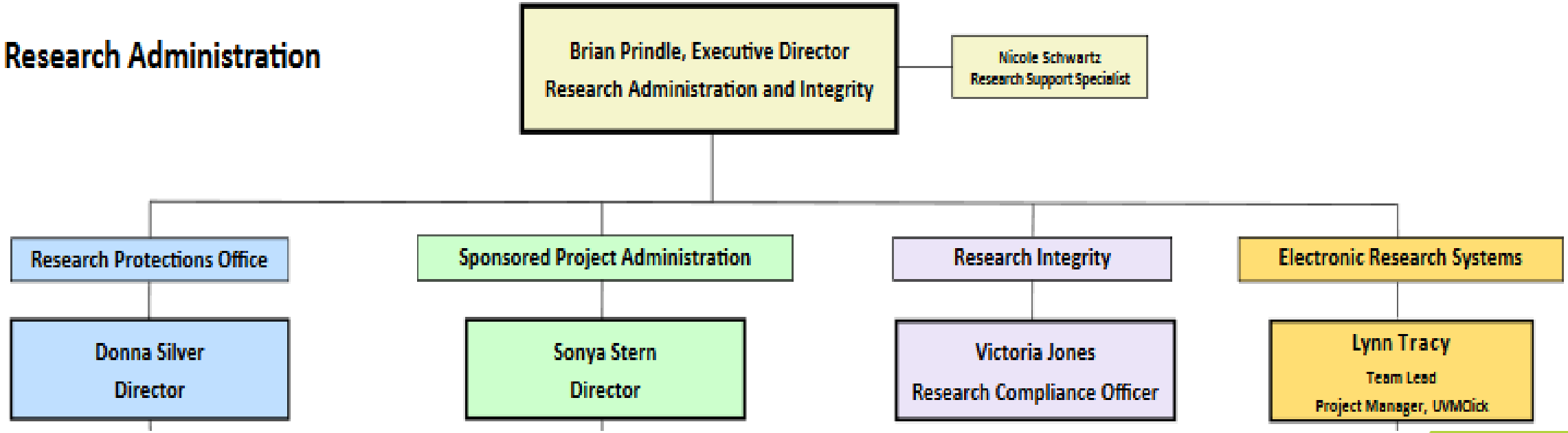


UVM Research Community

- **300+** Active Principal Investigators (PIs)
- **100+** Departments with Sponsored Projects from **300+** Sponsors
- **\$140M+** annual volume of awards on **700+/-** award actions
- **300+** subawards issued annually
- Office of Vice President for Research
- Many supporting departments

UVM Research Administration and Integrity Organization

Research Administration



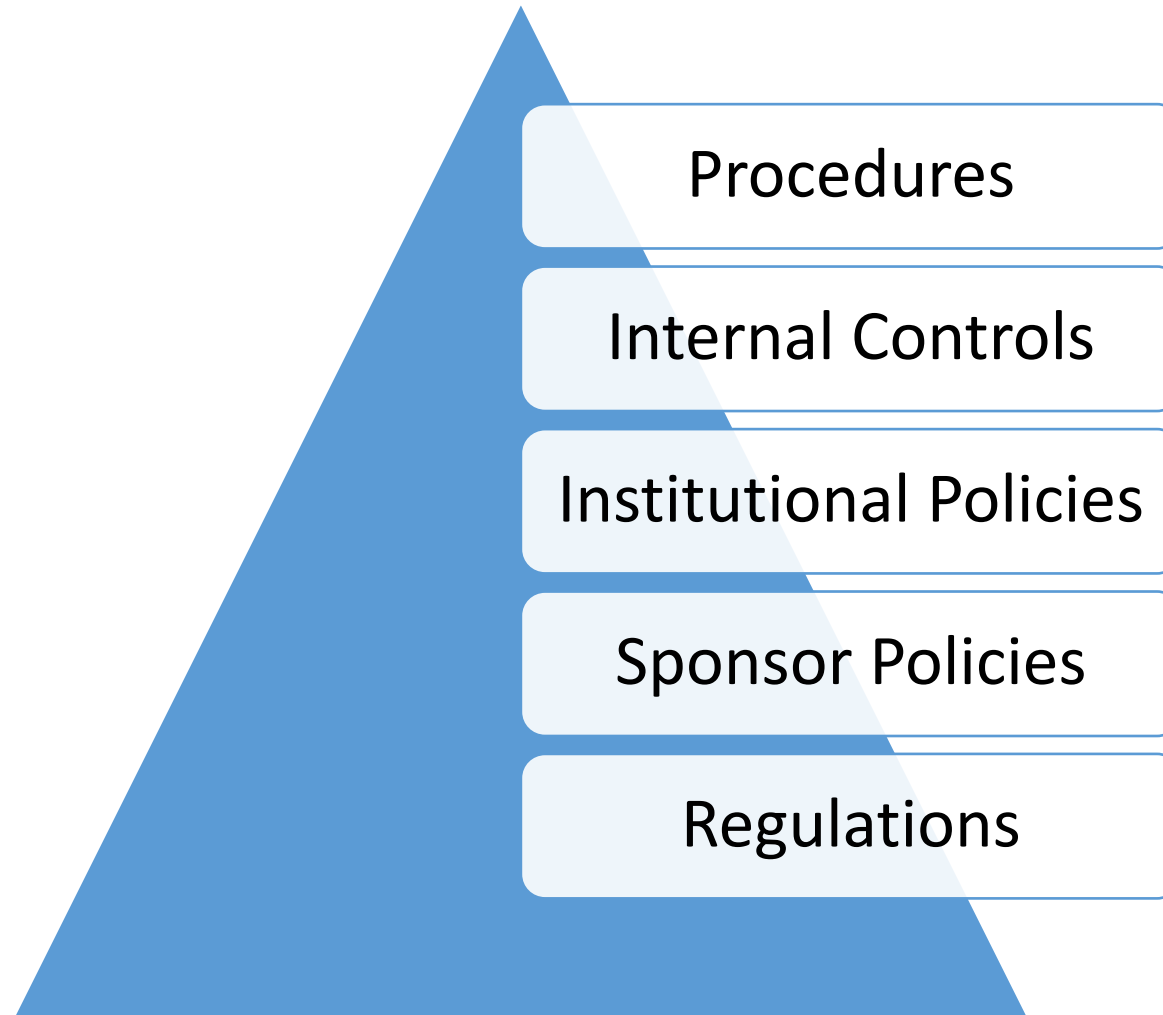


Fundamentals

- Whose grant is this?
 - Awards are made to the institution
- Who gets to call the shots?
 - PIs and administrators form a partnership
 - PIs direct the science
 - Administrators manage the business processes and compliance functions that support research
- Who answers to whom?
 - Science without administration would not receive grant funding
 - Administrators without science would not receive grant funding



Framework of “Rules” for Managing Sponsored Projects



Research Compliance

Research compliance refers to measures taken by scientists to ensure their **research** activities conform to federal and state laws and institutional regulations. They ensure organizations are committed to adhering to high standards of ethics, integrity and responsibility in their **research**.

External drivers: Rules, Guidelines, Laws, Policies, Regulations

Internal drivers: Institutional compliance program, designated officials, institutional risk management, written standards of conduct, written policies and procedures, process for reporting alleged violations of laws and policies, compliance education

Individual Financial Conflict of Interest

The UVM Financial conflict of interest in Sponsored Research, which implements federal rules purporting to protect the **objectivity of research**, requires:

- **Annual Disclosure of outside interests** related to the investigator's institutional responsibilities
 - Consulting income or other type of income (in excess of \$5,000)
 - Ownership in a company even with a low value
 - Intellectual Property Rights held outside of UVM

- **Training** : every 4 years, on CITI

In some instances (5-10%), if the interest is perceived as a conflict that could affect the **design, conduct or reporting** of a research project, a management plan is devised **to protect the public trust** in the research enterprise.

Conditions of the plan typically require disclosures of the interest to the research team and in publications.

Foreign Influence

The U.S. government has growing concerns about inappropriate influence by foreign governments over federally funded research.

A number of incidents have recently emerged revealing a violation of core principles and a threat to the integrity and academic competitiveness of U.S. research and innovation.

NIH and other agencies now require the disclosure **of all research support including foreign components, in-kind contributions, and other foreign resources.**

Such support has to be reported in a researcher's Biosketch / Application.

Your annual conflict of interest disclosure under CLICK now includes questions about foreign influence.



Institutional Review Board

- All research involving human subjects must be reviewed by the UVM IRB.
 - The CHRMS committee is tasked to review medical research and the CHRBSS committee reviews behavioral and social science research.
- The IRB is composed of an academically diverse set of faculty and community members from UVM and UVMMC.
- The IRB meets once a month so give yourself plenty of lead time

Institutional Animal Care and Use Committee

- At UVM, >97% of the animals used in research are rats and mice.
- IACUC must review and approve ALL animal use in teaching and research prior to any work with animals.
- The IACUC Committee at UVM consists of scientists, non-scientists, biosafety experts, statisticians, community members, and a veterinarian.

Institutional Biosafety Committee

- The IBC committee is the cornerstone of oversight for research involving recombinant and synthetic nucleic acid molecules here at UVM.
- The IBC Committee at UVM consists of scientists, non-scientists, biosafety experts, statisticians, community members.
- All UVM research involving the use of RNA, infectious agents, biotoxins, select agents and gene therapy must have an approved IBC protocol prior to work being done.



Cost Principles

- Compliance with Federal Cost Principles (Uniform Guidance)
 - Providing appropriate and compliant stewardship of sponsored funds
 - There are consequences for failing to comply
- Anyone authorizing the expenditures of federal funds must understand the cost principles
 - These principles govern costs that may be charged to the government directly or indirectly

Cost Principles, continued

- Any cost charged to a sponsor must satisfy the following:
 - The cost must be allowable as defined by federal regulations and/or by the terms of the particular award
 - The cost must be allocable; the project which paid the expense must benefit from it
 - The cost must be reasonable; the cost reflects what a prudent person might pay
 - The cost must be consistently treated; it treated as direct or indirect cost when incurred for the same purpose in like circumstances

Payroll Costs

- OMB Uniform Guidance requires that institutions have a system of internal controls which provide reasonable assurance that the payroll charges are accurate, allowable and properly allocated.
- Quarterly review of payroll distributions (perspective) and actual charges (retroactive) is an important internal control at the University
- The PI must ensure payroll charged to the award reflect actual work performed by the project staff



Payroll Costs

- PIs with multiple sponsored projects should carefully monitor payroll distributions
- Appropriate payroll distribution changes should be submitted in a timely manner
- Effort certification of payroll charges for each fiscal year is required by UVM employees whose payroll was directly charged or as cost share on a sponsored agreement

Travel Costs

- Benefit to the project
 - Direct connection to purpose and specific aims of project
 - Meets cost principles
- Conform with grant policy and award special conditions (Fly America, etc.). **Stricter of policies apply**
- Adherence to institutional policy
 - Reconciliation of expenses, itemized receipts, eliminate unallowable, and submission deadlines



Cost of Meals, Refreshments and Food-Related Items

In most cases, policy for this type of cost on sponsored project is **very** restrictive. UVM has three distinct types of food related charges:

- Travel meals, reimbursed through UVM's established [Travel Policy \(PDF\)](#).
- Sponsored provisions, food purchases on sponsored projects served during a UVM-hosted training, workshop, conference, etc. approved by the sponsor.
- Business meals, which are different from travel meals and sponsored provisions and must meet both [UVM's Business Meal, Hospitality and Amenity Policy \(PDF\)](#) and sponsor regulations.



Equipment Costs

- Purchases of capital equipment are subject to institutional policy and sponsor terms and conditions
- Equipment purchased using sponsored funds must be necessary for the performance of the project and consistent with policy, regulations and award terms and conditions
- Common equipment classes: scientific, computers and vehicles
- Unit acquisition value threshold: An acquisition unit cost value of \$5,000 or more is a common threshold to classify equipment

Cost Transfers

- Definition
 - Moves costs from one account to another to correct an error
- Charge correctly in the first place
 - Saves wasted effort and rework
 - Minimizes audit issues
- Transfers are allowed in special circumstances

Cost Sharing

- Definition
 - When a portion of the project costs are contributed by the institution
 - Types: mandatory and voluntary
 - Grant restrictions apply to institutional contribution
 - Becomes a binding commitment, if proposal is funded
- Specific criteria apply
- Post award administration
 - Companion account, funding amount, project period, spend at the same rate, report with grant account, maintain documentation



Export Controls in Sponsored Research

What are Export Control Regulations?

The U.S. Export Control regulations aim at protecting:

- the U.S. national security** interests, and
- the U.S. foreign policy** objectives.

They regulate the distribution of export controlled technology, equipment, software, information, or services to a foreign person or country.

Export Controls in Sponsored Research

Risk assessment: The Sponsored Project Administration Office runs a checklist for every sponsored research project to assess the risk of the project under Export Control regulations depending on the subject matter, the sponsor, the activities and participants involved.

Final determination: If there is a risk, the PI makes a final determination based on a comprehensive review of the list of export controlled items.

Licensing process: If an item is export controlled, a license may be required before allowing foreign access. The process may take a few months.

The Fundamental Research Exemption: basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly with the scientific community.

Other Important Topics?