Office of Research Compliance

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Director

The Constant Pursuit of Discovery

Office of Research Compliance

Responsible for providing programs to address:

- Responsible conduct of research training (RCR)
- Export control compliance
- Financial conflict of interest (FCOI)
- Research Integrity / Misconduct

Office of Research Compliance Cont’d

Coordinate with the following:

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Radiation Safety Committee
- Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)
- Research Safety Committee
- Office of Environmental Health and Safety (EHS)

Responsible Conduct of Research (RCR)

Responsible Conduct of Research Training is required by:

- National Science Foundation (NSF)
- National Institutes of Health (NIH)
- USDA National Institute of Food and Agriculture (NIFA)

National Science Foundation Requirement

- RCR training required for undergraduate, graduate students and post-doctoral scholars.
- Collaborative Institutional Training Initiative (CITI) online training is required in one of the following areas:
  - Biomedical
  - Social and Behavioral
  - Physical Science
  - Humanities
  - RCR for Engineers
  - RCR for Administrators

National Institutes of Health Requirement

- Trainees, fellows, participants, and scholars receiving support
- Important to look at what type of grant - exceptions
- Eight hours of face to face training required - “online instruction is not considered adequate.”
- “at least once during each career stage, and at a frequency of no less than once every four years.”
USDA National Institute of Food and Agriculture Requirement

- Required for program directors, faculty, undergraduate students, graduate students, postdoctoral researchers and any staff participating in the research project.
- CITI online training required

Export Control Compliance

Export controls are United States laws and regulations that regulate and restrict the release of critical technologies, software, equipment, chemical and biological materials, and services to foreign nationals and foreign countries.

Activities that involve export controls

Export controls may apply to:
1. Shipment (or hand carrying) of items to locations outside of the U.S.
2. Travel to sanctioned or embargoed countries
3. Transfer of export controlled technical data to persons located outside of the U.S.
4. Sharing of export controlled scientific or technical information with foreign nationals within the U.S.
5. Foreign person access to most defense articles

Export Control Regulations

1. ITAR – International Traffic in Arms Regulations
   - State Department → military items
2. EAR – Export Administration Regulations
   - Commerce Department → Dual use items (items with both military and commercial application) or strictly commercial applications
3. OFAC – Office of Foreign Assets Control
   - Treasury Department → embargoes and sanctions of specific countries.
4. DOE – Department of Energy
   - Nuclear Regulatory Commission

Fundamental Research Exclusion (FRE)

Applies to any basic or applied research in science or engineering where the resulting information is ordinarily published and broadly shared in the scientific community. All of the following must be true:

- No restrictions on publications
- No access or dissemination restrictions
- Research must take place at an accredited institution in the U.S.

Export Control

- Is anything military related? Most likely controlled under ITAR.
- Is it a government contract, especially Department of Defense? DFARS!
- Does contract involve travel to, collaboration with or other relationship with embargoed or sanctioned counties?
- Comprehensive sanctions – Cuba, Iran, North Korea, Sudan, Syria
- Limited sanctions – Balkans, Iraq, Ivory Coast, Liberia, Myanmar (Burma), Zimbabwe
- Subject to change
Financial Conflict of Interest (FCOI)

- Federal regulations:
  - Public Health Service (PHS) of the US Department of Health and Human Services
  - National Science Foundation (NSF)
- PS-98
  - LSU policy that governs disclosures of Significant Financial Interests and management of individual Financial Conflicts of Interest in research performed at LSU

PS-98: LSU Financial Conflicts of Interest in Research

- Promotes objectivity in PHS, NSF and other applicable agencies funded research by establishing standards to identify and address potential, actual, and apparent Financial Conflict of Interests.
- When an individual has an outside economic interest that can affect the conduct of their LSU institutional duties, a Financial Conflict of Interest exists that may threaten the objectivity and integrity of research.

Financial Conflict of Interest

- PHS and NSF definitions of FCOI are similar but not the same.
- PHS funded researchers must complete FCOI training every four years. LSU requires completion of online CITI training.

Process to Disclose

- Answer Yes/No to PS-98 question in SPS at the time of proposal routing
- If yes, complete SFI Disclosure form and load in SPS as an attachment
- OSP will forward the disclosure form to ORED for determination of FCOI
- Proposal can go forward with a submitted disclosure form

Process to Disclose (cont’d)

- At the time of the award, each investigator must complete the SFI disclosure form
- Positive disclosure form will be forwarded to ORED for determination of FCOI before award funds can be expended
- SFI disclosure must be made annually thereafter
- Within 30 days of acquiring or discovering new SFI

Research Integrity and Misconduct

- PM-76: Detection, Reporting and Investigation of Incidents of Financial Irregularity
- PS-69: Policy on Research Misconduct
- LSU Ethics and Integrity Hotline
Policy on Research Misconduct

• LSU provides this policy and administrative procedure to review reports of alleged research misconduct conducted under University auspices.
• Definition of research misconduct - fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
• All covered individuals associated with LSU should report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO) who is the Vice Chancellor for Research and Economic Development.

LSU Ethics & Integrity Hotline

• provides a secure and confidential means to report activities that may involve fraudulent, unethical, or otherwise inappropriate behavior in violation of LSU by-laws, or policies.
• LSU assures that hotline reports will be handled promptly and judiciously. No retaliatory action will be taken against anyone for reporting or inquiring in good faith about potential ethical misconduct or breaches of laws, rules, regulations, or university policies, or for seeking guidance on how to handle suspected misconduct or breaches.

Institutional Review Board (IRB)

• ensure the safety and welfare of human subjects in research and scholarly projects.
• facilitate research
• comply with research regulations

Does my survey require IRB approval?

If it is designed to produce generalizable knowledge (e.g. get published) then it needs IRB approval:
- Exempt from approval
- Expedited review
- Regular approval

Institutional Animal Care and Use Committee (IACUC)

• The use of vertebrate animals in research requires registration, review and approval by the IACUC. Review and approval is required to ensure compliance with all regulations, policies and standards that protect animal welfare.
• Must have an approved animal use protocol before animals can be obtained or used for teaching or research purposes, regardless of funding source.
Institutional Biological and Recombinant DNA Safety Committee

• follows federal guidelines with respect to the review and approval of protocols involving biological materials.
• all teaching, diagnostic, research and extension activities which involve recombinant DNA or potentially hazardous biological materials and performed by LSU faculty, students, and visitors must be reviewed and approved by the IBRDSC.
• comprised of faculty from many academic disciplines at LSU, non-scientific members, and community representatives not affiliated with the University.

Radiation Safety Committee

• PM-30 Radiation Protection Program
• To develop and implement a program to assure the proper and safe usage of radioisotopes and other sources of radiation and radioactive materials within the LSU System in University research, instructional, and service programs.

Research Safety Committee

• charged with providing oversight and coordination for all safety programs and committees affecting LSU and LSU AgCenter research
• provides strategic direction to ensure regulatory compliance for scientific research,
• promotes a strong safety culture and
• encourages best safety practices consistent with the university’s safety policy

Research Safety Committee Focus

• Focus for the current year – A Guide to Implementing a Safety Culture in our Universities by Association of Public and Land-Grant Universities (APLU) Council on Research. The RSC will work to:
  • analyze the 20 recommendation in the report
  • raising awareness of and promote the safety culture at LSU
  • identify improvements to the safety culture at LSU

Contact Information

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