Conflicts of Interest

Epiphanie Gillette
Conflict of Interest Officer
October 21, 2016
Individual Conflict of Interest in Research Policy

What does the Conflict of Interest Program do?

What are the regulations?
INDIVIDUAL CONFLICT OF INTEREST IN RESEARCH POLICY
Who is an “investigator”?  

Dr. Wildcat is a full professor in the College of Agriculture and Life Sciences. She was recently awarded a grant from the National Institutes of Health and will serve as the principal investigator for the grant. Other members of the study team will include:

- Dr. Wilbur, an Assistant Professor who will serve as a co-investigator on the grant;
- William, a graduate student who will be graduating at the end of the academic year; and
- Wilma, an undergraduate student.
Who is an “investigator”? Any person who is responsible for the design, conduct, or reporting of research.
Requirements

Training
• Complete conflict of interest training every four years

Disclosure
• On an annual basis between June 1 and June 30 of every year
• Within 30 days of a change to the existing disclosure (ex. acquiring a new SFI)
• If the Investigator has one or more disclosed outside interests, then prior to proposal submission for any federally funded proposal
Dr. Wildcat owns and operates a restaurant in town.
Outside Interests

• Significant Personal Interest

• Significant Financial Interests
Example: Dr. Wildcat serves on the scientific advisory board for Old Agriculture Company, Inc.
Outside Interests

• Significant Personal Interest

• Significant Financial Interests
What do investigators need to disclose?

- Dr. Wildcat owns and operates a restaurant in town.

- Further, Dr. Wildcat provides consulting services for Old Agriculture Company, Inc., a public company. She received $4,000 in compensation in the past 12 months for her consulting services.
What do investigators need to disclose?

- Dr. Wildcat owns and operates a restaurant in town.

- Further, Dr. Wildcat provides consulting services for Old Agriculture Company, Inc., a public company. She received $4,000 in compensation in the past 12 months for her consulting services. She owns stock options in the company worth $4,000.
What do investigators need to disclose?

- Dr. Wildcat owns and operates a restaurant in town.

- Further, Dr. Wildcat provides consulting services for Old Agriculture Company, Inc., a public company. She received $4,000 in compensation in the past 12 months for her consulting services. She owns stock options in the company worth $4,000.

- Dr. Wildcat owns equity in a non-public company called Small Agriculture Company, LLC and provides consulting services to this company. She received $2,000 in compensation in the past 12 months for her consulting services.
What do investigators need to disclose?

- Dr. Wildcat owns and operates a restaurant in town.

- Further, Dr. Wildcat provides consulting services for Old Agriculture Company, Inc., a public company. She received $4,000 in compensation in the past 12 months for her consulting services. She owns stock options in the company worth $4,000.

- Dr. Wildcat owns equity in a non-public company called Small Agriculture Company, LLC and provides consulting services to this company. She received $2,000 in compensation in the past 12 months for her consulting services.

- Lastly, Dr. Wildcat also recently started her own start-up company called Wynona Agriculture, LLC. This is a non-public entity, and she is the only owner of the company. She has not received any income from the company.
What do investigators need to disclose?

- Dr. Wildcat owns and operates a restaurant in town.

- Further, Dr. Wildcat provides consulting services for Old Agriculture Company, Inc., a public company. She received $4,000 in compensation in the past 12 months for her consulting services. She owns stock options in the company worth $4,000.

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Other Applicable University Policies

• Conflict of Commitment Policy

- Conflict of Commitment relates to an individual’s distribution of time and effort between his/her full-time duties as a University Employee, and his/her responsibilities resulting from Outside Employment and Outside Professional Commitments.
Intellectual Property Interests: Income related to intellectual property rights or interests (e.g., as owner of a patent or copyright or as a licensee of such rights)
Significant Financial Interests

Investigators funded by a PHS Agency

• Any reimbursed or sponsored travel
Excluded Interests

• Salary, royalties, or other payments by the University to a current University employee or appointee;

• Income from investment vehicles such as mutual funds and retirement accounts; and

• Certain other payments from U.S. government agencies or U.S. institutions of higher education.
How does the process work?

Investigator submits initial training and disclosure

Discloses a Financial Interest

No further action required until annual disclosure update or gaining of a financial interest

Investigator is asked to complete project specific questionnaire

Investigator action

Conflict of Interest Program/Institutional Review Committee

COIP completes initial review of submitted disclosure

Submitted for Full Committee Review

Conflict Identified?

Yes

No

Expedited Approval?

No

Yes

Administrative Approval?

COIP updates disclosure and investigator is notified

COIP contacts investigator to gather any additional information necessary for review

COIP arranges to meet with investigator to go over management and elimination options
Institutional Conflict of Interest Policy

- “Institutional conflicts of interest arise when an institution’s own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution’s primary interests.”

Source: Conflict of Interest in Medical Research, Education, and Practice (http://www.ncbi.nlm.nih.gov/books/NBK22934/)
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To confidentially report suspected unethical or illegal conduct:
866-364-19008
Research Laboratory & Safety Services (RLSS)

Research Laboratory Compliance at the University of Arizona

Richard Wagner

10/21/2016

THE UNIVERSITY OF ARIZONA
Research
Office for Research & Discovery
RLSS Nuclear, Biological, Chemical & Quality Control Programs

- All programs
  - Training, On-site Lab Inspections, Regulated Material Inventory, Hazard Assessment, Incident Investigation, IACUC Review, Inventory Management, Emergency Response, Emergency Drills, Hazard Communication, HAZMAT shipping, Maintenance of Required Plans & SOP’s, Reports to University, Federal, State, County & Municipal entities
  - Currently available to research, clinical, academic labs and support facilities

- **Radiation Safety Program** – Radioactive materials, radiation generating machines, radiation dosimetry, non-ionizing radiations, nuclear waste, detection instrument calibration, increased controls program
- **Biological Safety Program** – BSL & PSL 1-3, Select Agent & Toxin (SA&T) program
- **Chemical Safety Program** – ATF explosives, DEA controlled substances, DHS vulnerability information, Legacy waste services, Anesthetic device leak checking
- **Quality Control Program** – Medical device quality, Good Laboratory Practices (GLP)
Introduction to RLSS, CHESTER & Online User Dashboard

• UA Research Laboratory & Safety Services (RLSS)
  - Reports to the Senior Vice President for Research (SVPR)
  - Assists, monitors and provides oversight to ensure that federal, state, local, and University regulations and policies are implemented in a safe and secure manner

• RLSS Approval Process
Laboratory Chemical Safety Program

Objectives

• Developed to satisfy the requirements of Occupational Safety and Health Administration (OSHA) regulations
  - “Occupational Exposure to Hazardous Chemicals in Laboratories” 29 CFR 1910.1450

• Assist UA faculty, staff, students, and volunteers with obtaining and maintaining compliance with laboratory chemical safety requirements

• Provide environmental and occupational health services to the UA laboratory community
  - Laboratory cleanout/legacy chemical assistance
  - Chemical hazard assessments
  - Electronic database for hazard communication (e.g. training records, chemical inventories, Safety Data Sheet libraries, etc.)
Notify RLSS for assistance with the redistribution or collection of hazardous chemical wastes, items/rooms labelled for nuclear or biological hazards.
Office of Research & Discovery (ORD) Research Gateway

- Access to all laboratory compliance entities
  - RLSS compliance programs
- RLSS User Dashboard
  - Available to all registered researchers
- RLSS online training
Secure User Dashboard Access for University Researchers & University Research Partners

• User Dashboard Access
  - Only for University researchers or University Research Partners registered in RLSS compliance programs

• Secure Login by:
  - U of AZ NetID
  - Banner ID
    – Other Clinical Partner ID’s assigned by RLSS
User Dashboard – User Main Page

• Provides User:
  - Alerts for:
    – Due & overdue training
    – Due & overdue hygiene plan affirmations
  - Training certificates
  - History of chemical hygiene Plan affirmations
  - Radiation exposure history
  - Status of their application to other research groups
  - Chemical inventory records

• Provides PI’s & Lab Managers access to Management Tools
User Dashboard – PI & Lab Manager Tools

- Provides PI’s & Managers:
  - Alerts for:
    - Due & overdue training
    - Due & overdue hygiene plan affirmations
  - List of registered researchers & RLSS training certificates
  - Summary of Research Committee authorization
  - Chemical inventory records
User Dashboard – Chemical Inventory

- Chemical Hazards Classified & Categorized
- Access to MSDS’s
- Access GHS Label Generator
- All columns may be sorted and exported to excel
- Lab inventory tailors inspection checklist & room postings
User Dashboard Chemical Inventory Utilization (As of September 21, 2016)

204 Lab Groups

26,411 Inventoried Chemicals
Chemical Inventory – Compound Database

- Over 80,000 normalized compounds
- Ability to add unique hazard codes and prevention codes
- DEA, NFPA, ITAR, EAR & ATF material tracking
Chemical Inventory – GHS Label Generator

- Provides labels in 4 sizes
Chemical Inventory – Room Postings

• Tailored to communicate Radiation, Biological and Chemical hazards
  - Can provide by room, building or campus
• Lab Data
  - Tracks safety features & equipment
  - Tracks users
  - Provides map
Chemical Hygiene Plans (CHP’s)

- CHP’s are required by OSHA
  - Workers must read & understand
  - Approval Holders must review and reauthorize annually

- RLSS User Dashboard maintains all CHP’s and documents worker affirmation to reading & understanding them
User Dashboard Published Hygiene Plans & Researcher Affirmations (as of September 21, 2016)

**Published Laboratory Chemical Hygiene Plans**

- 55 LCHP’s
- 1173 UCHP Affirmations

**Affirmations to Current LCHP’s**

- 288 LCHP Affirmations

**Affirmations to Current UCHP**

- 1173 UCHP Affirmations
Key Idea:
RLSS Online Services & Tools Enhance Compliance Services & Improve Communication & Cooperation
**Biohazardous Material Management Services**

- Training & Biosafety SOP development and documentation
- Inspections, agent registration/procurement, transport, online inventory & site visits
- Support for Select Agent & Toxin and APHIS regulated plant biohazard users
- Assistance with establishing protocols & obtaining committee approval
- Contact Heather Matthies

**Hazardous Chemical Management Services**

- Training & Chemical Hygiene Plan development and documentation
- Inspections, hazard assessments, lab cleanouts, exposure measurements & site visits
- Online chemical inventory, Safety Data Sheet & hazard communication system
- Assistance for "Extremely Hazardous Activities," DoD grant environmental certifications, Controlled Substance Registrants & Explosive Material Licensees
- Contact Richard Wagner

**Radiation Generating Devices & Material Services**

- Training
- Inspections, device licensing, online inventory, radiation measurements & site visits
- Radioactive material procurement, delivery, transport, waste collection & disposal
- Radiation exposure records, monitoring badges & clinical administration support
- Assistance with establishing protocols & obtaining committee approval
- Contact Keith Carsten

**Research Validation Services**

- Training
- Good Laboratory Practice and Good Medical Practice compliance visits
- Assistance with establishing FDA required procedures, protocols & documentation
- Contact Langley Silvain

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The University Export Control Program

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Export Control Analyst
University Export Control Program
Presentation Overview

- “Export” – what it means and how it affects “U”
- The export control regulations and government agencies that affect UA research
- “Fundamental Research” – how it can be nullified
- “Red Flags” – what to look for
- UECP Review
- Resources for “U”
“Export” what it means and how it affects “U”

- **An Export can occur in many ways:**
  - Shipping / Mail
  - Electronic Transmission (*i.e.*, email, text, video chat, online storage)
  - Meetings / Conferences and other Conversations or Presentations
  - Travel outside the U.S. with items and/or technical information contained on electronic devices or hard copies (*e.g.*, drawings, formulae, schematics).
  - Visual or other inspection

- **The “Deemed Export” rule:**
  The release or transfer of export controlled information, technical data, technology, commodities or software to a non-U.S. person located in the U.S.
“Export” what it means and how it affects “U”

- **Affects UA Research conducted both on campus and outside the U.S.**
  - An export could occur if a non-U.S. person is given access to certain data, software, or equipment related to research projects on campus.
  - An export could occur if the PI has a collaborator located outside the U.S.
  - An export could occur if the PI conducts research abroad, including taking / shipping equipment or technology.

- **Affects UA activities:**
  - Traveling to restricted/embargoed countries
  - Hiring non-U.S. persons for certain projects (e.g., agriculture vs. space-related)
  - Engaging with non-U.S. sponsors / vendors
  - Publishing

21-Oct-2016
Export Control Regulations

- **Export Administration Regulations (EAR)**
  - U.S. Department of Commerce – Bureau of Industry & Security (BIS)
  - Commercial / Dual-Use Items listed on the Commerce Control List
  - “May” require a license

- **International Traffic in Arms Regulations (ITAR)**
  - U.S. Department of State – Directorate of Defense Trade Controls (DDTC)
  - Military Inherent Articles listed on the U.S. Munitions List
  - A license *is* required

- **Office of Foreign Assets Control (OFAC)**
  - U.S. Department of Treasury
  - Economic and Trade Sanctions
  - A license *may* be required
What is *not* Controlled?

- **Publically Available Information**
  - Basic marketing descriptions
  - Educational information (textbooks, etc.)
  - Artistic or non-technical publications
  - Unclassified technology or software available to public without restrictions
  - Information excluded under the Fundamental Research Exclusion (FRE)

21-Oct-2016
**Fundamental Research**

- **Defined**
  “Fundamental research means research in science, engineering, or mathematics, the **results** of which ordinarily are **published** and shared broadly within the scientific community, and for which the researchers have **not accepted restrictions** for proprietary or national security reasons.”

- **The FRE can be lost if:**
  - Sponsor **approval** required prior to publication.
  - Publication of project **results** are restricted.
  - Other access and dissemination restrictions are in the agreement.
Fundamental Research

- **Limits to the FRE:**
  - Only applies to the *results* of the research.
  - Export controlled hardware, software, technology, and other activities still subject to EAR/ITAR.
  - Engagement with Prohibited Parties or Entities still subject to sanctions.
  - Transactions involving sanctioned countries or prohibited parties still restricted.

- **Identifying issues starts at the proposal stage**
  - Look for “red flags”
Red Flags

- **Topic / Project is:**
  - Specially designed for military
  - Related to space technology
  - ITAR controlled
  - Proprietary in nature

- **If the sponsor will provide technical data or equipment**
  - Need to know ECCN or USML Category

- **If the funding agency, sponsor, collaborator, subcontractor or consultant is:**
  - Military or space-related (*i.e.*, Army, ONR, AFRL, DARPA, NASA)
  - A non-U.S. entity
  - Related to an SBIR or STTR project
  - An industry defense contractor (*e.g.*, Raytheon)
Agreement / Solicitation includes language of:

- Foreign Person restrictions / notifications
- Sanctioned country participation restrictions
- The DFARs 7000 clause
- The DFARs 7012 clause
- Overly restrictive export control language
  - Export control language can be found in multiple areas of the agreement:
    - Compliance
    - Export / Import Controls
    - Miscellaneous
    - Confidentiality
TEAMWORK

- Sponsored Projects Services
- Contracts & Research Support Program
- Human Resources
- Payroll
- Procurement
- University Information Technology Services
- Tech Launch Arizona
- Department Administration (Liaisons)
- Global Initiatives
- Shipping

and, YOU!
Resources

University Export Control Program

Website:  http://rgw.arizona.edu/compliance/export-control-program

Email:  export@email.arizona.edu

Kay Ellis
UECP Director
(520) 626-2437

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Export Control Analyst
(520) 626-5865

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