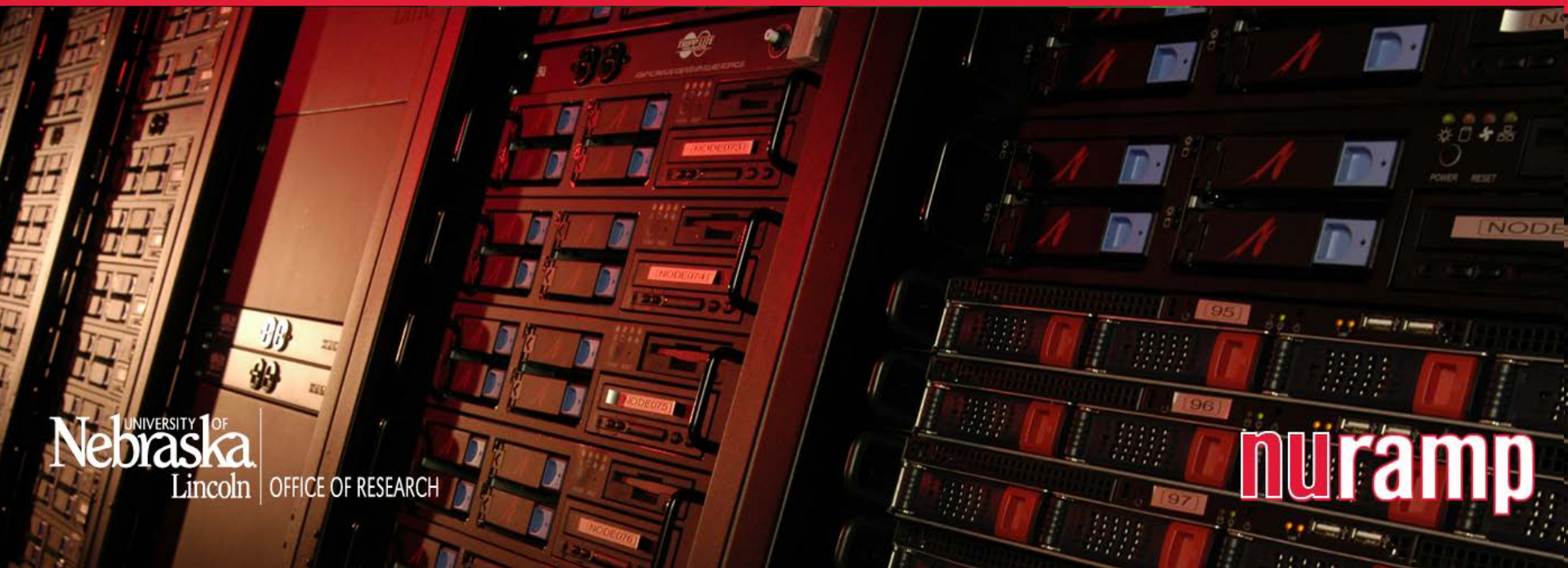
# Research Compliance Services

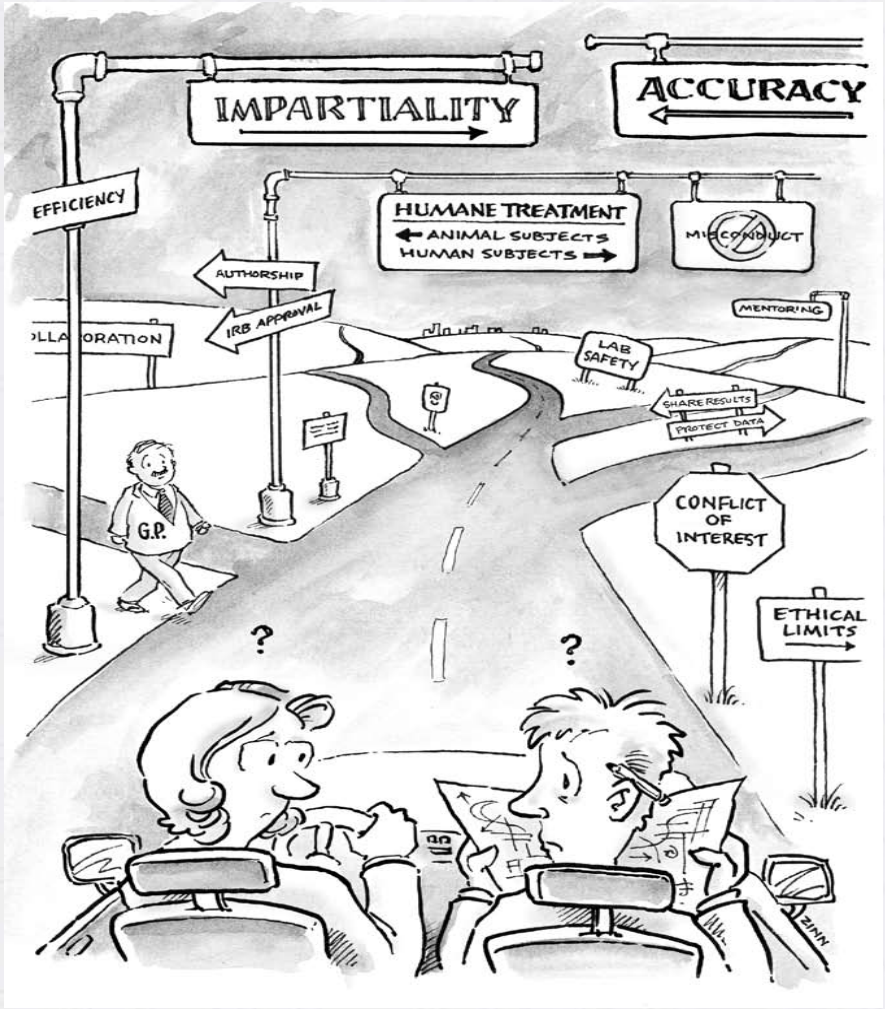
## NUramp Fall 2016



# Topics

- Responsible Conduct of Research
- Conflict of Interest
- Institutional Review Board/Human Research Protections Program
- Research Misconduct
- Export Control

# Responsible Conduct of Research



# Responsible Conduct of Research

The Responsible Conduct of Research (RCR) is a training initiative to educate undergraduates and graduate students, postdoctoral researchers, research staff and faculty. RCR is required when receiving funding from the National Science Foundation (NSF), the U.S. Department of Agriculture-National Institute of Food and Agriculture (USDA-NIFA), and the National Institutes of Health (NIH).

At UNL, RCR training is primarily completed via online CITI RCR training modules (citiprogram.org). Topics covered include:

- Overview of Responsible Conduct of Research
- Data management
- Authorship
- Mentoring
- Peer review
- Collaborative science
- Conflict of interest
- Data acquisition and monitoring
- Ethics and regulations of research with humans and animals
- The scientist as a responsible member of society
- Export controls

# Responsible Conduct of Research

| Funding Source | NIH | NSF | USDA/NIFA |
|---|---|---|---|
| Who Must Complete Training? | Undergraduate students, graduate students, and postdoctoral researchers (Trainees, fellows, participants, and scholars). Faculty highly encouraged. | Undergraduate students, graduate students and postdoctoral researchers. Faculty highly encouraged. | Program directors, faculty, undergraduate students, graduate students, postdoctoral researchers and any staff participating in research and research-related activities. |
| Training Frequency | No Less Than Once every 4 Years | One time requirement | One time requirement |
| CITI Training Required? | Yes | Yes | Yes |
| 8 Hour In-Person Training Required? | Yes *See specific NIH funding programs below | No | No |
| Blackboard RCR Training Can Be Utilized? | No | Undergraduate students per Dept discretion (UCARE) | Undergraduate students per Dept discretion (UCARE) |

**NIH 8 Hour In-Person Training: Please note that the NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. This policy will take effect with all new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2011. This Notice applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R. This policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant funding opportunity announcements.**

**All other awards with RCR training requirements can be satisfied via completion of the online CITI RCR training course.**

**UNL RCR website: http://research.unl.edu/researchresponsibility/responsible-conduct-of-research/**

# Responsible Conduct of Research

Why Do We Care?

- The protection of human and animal subjects
- Sound scientific process
- Reinforces public support of science and medicine
- UNL public image in supporting, promoting and teaching ethical research
- No room for misconduct

# Responsible Conduct of Research

**Scott Reuben, Anesthesiology Professor**

- 2009: One of the most prolific researchers in anesthesiology admits to fabrication of data
- Longest-running and widest ranging case of academic fraud ever
- 21 journal articles since 1999

Paul White, another editor at the journal, estimates that Reuben's studies led to the sale of billions of dollars worth of the potentially dangerous drugs known as COX2 inhibitors, Pfizer's Celebrex (celecoxib) and Merck's Vioxx (rofecoxib), for applications whose therapeutic benefits are now in question. Reuben was a member of Pfizer's speaker's bureau and received five independent research grants from the company. The editors do not believe patients were significantly harmed by the short-term use of these COX2 inhibitors for pain management but they say it's possible the therapy may have prolonged recovery periods.

http://www.scientificamerican.com/article/a-medical-madoff-anesthestesiologist-faked-data/

# Conflict of Interest

Conflicts of Interest are situations where a Covered Person's direct or indirect personal financial interests may compromise, or have the appearance of compromising, the Covered Person's professional judgment or behavior in carrying out his or her obligations to the University of Nebraska-Lincoln. This includes indirect personal financial interests of a Covered Person that may be obtained through third parties such as a Covered Person's Immediate Family, business relationships, fiduciary relationships, or investments.

Covered Person means:

1) University administrative officers and employees, specifically including any University employees with delegated signature, purchasing or contracting authority on behalf of the University;

2) University employees and faculty engaged in outside employment or other activities specified in this policy (technology transfer/use of University facilities or equipment) that may create a Conflict of Interest; and

3) Sponsored Research investigators, including University employees, faculty, staff and support personnel (managerial/professional and office/service positions), volunteers, trainees, students, contractors and other persons under the direct control of the University of Nebraska, whether paid by the University of Nebraska or not, who participate in Sponsored Research as defined in Section 6 of the Board of Regents policy 3.2.8.

# Conflict of Interest

- Bias may be real, perceived, or potential.
- It is important to understand that it is a condition not a behavior. Many fail to declare a conflict of interest because they are confident that the conflict has not caused them to behave in a different way.
- When in doubt, disclose!

# Conflict of Interest

In the sponsored research setting, a potential conflict exists when there is a possibility that an individual's outside financial interest could directly and significantly affect the design, conduct, or reporting of the research.

"a set of conditions in which professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest (such as financial gain)"

# Conflict of Interest

- Why do we care?
  - Public trust in the University
  - Public confidence is central to our mission

# Conflict of Interest

At UNL:

1) Annual Disclosures are processed through completion of the Interest and Outside Activities Reporting Form (IOARF), routing and administrative review.

2) If there is a conflict, the disclosure is reviewed by the Conflict of Interest in Research Committee.

   a) Written and signed Management Plans are put in to place.

# Conflict of Interest

Public Health Service (NIH, CDC, FDA, & more)

- Extra requirements include training and disclosure of sponsored and reimbursed travel. Training for PHS funded at UNL is completed through the required online CITI COI modules (citiprogram.org)
- Disclosure must be made PRIOR to submitting a grant application.
- Training must be completed by the time of PHS award.

# Conflict of Interest

Current events discussion:

- A university professor testified at an environmental impact hearing that the proposed construction of a chemical production facility will have no negative impact on the surrounding community even though the plan will be dealing with highly toxic materials, some of which are in gaseous form. The company claimed that the dangers to the community are very slight because of the safety measures they propose to take, and they quoted the results of a detailed engineering analysis carried out by the professor.

- The research was supported by a grant from a federal agency, but the professor had financial ties to the company because he received a salary for sitting on its board of directors. At no time during the testimony, however, did the professor or the company reveal that the researcher had financial ties to the company.

# Conflict of Interest

Case Study

- In 2009, the University of Michigan announced that its three campuses – Ann Arbor, Flint and Dearborn – would be smoke-free on July 1, 2011.

- University President Coleman also earned a $230,000 salary in 2009 for sitting on the board of Johnson & Johnson. Alza Corporation, a subsidiary of Johnson & Johnson, markets Nicorette and Nicoderm, smoking cessation products.

- Institutional COI

# IRB/HRPP

In research involving human subjects, the review helps to assure there is:

- Respect for persons
- Beneficence
- Justice

# IRB/HRPP

- What qualifies as human subjects research?
  - Data is collected about a living individual
  - Data or information is obtained about those individuals through intervention or interaction or receiving identifiable private information
  - Examples: Surveys, interviews, focus groups, obtaining biological specimens, medical testing, etc.

# IRB/HRPP

- Levels of Review
  - Exempt
  - Expedited
  - Full Board

# IRB/HRPP

Project 1:

- An investigator wants to test the soil of 100 farms to determine the chemicals present in the soil. Samples will remain anonymous. The farmers will not be asked any questions.

# IRB/HRPP

- Project 2:

An investigator wants to test the soil from 100 farms. He also wants to discuss farming techniques and opinions of best practices.

# IRB/HRPP

- Project 3:

An investigator wants to test the soil from 100 farms. He also wants to discuss techniques and best practices with the famers and any teenage children living on the farm.

# IRB/HRPP

- Project 4:

An investigator wants to test the soil from 100 farms. She will also interview the adults and all children living on the farm about techniques, best practices, feelings of isolation, depression, and serious accidents that have occurred. Blood pressure readings will be taken from all family members pre-, during, and post-harvest season. Investigators will also collect protected health information (PHI) from each participant's medical provider.

# IRB/HRPP

Case study

A professor in the engineering department has developed a new device for cell phones which can track if the person is texting while driving. She needs people to test the device and has decided to make it a class requirement for students in her class. The students are asked to plug the device into their phone and test it while they are driving around town.

# IRB/HRPP

Social media review

- Recruitment
  - Posting messages as Facebook Status Update
  - Sending a PM to a person
  - Tweet sent via Twitter
- Researching what is on Social Media
  - Looking at publicly available information.
  - Asking questions about the participants Facebook page, twitter post, etc.

* The use of social media in a human research project would depend on the specific study.

# IRB/HRPP

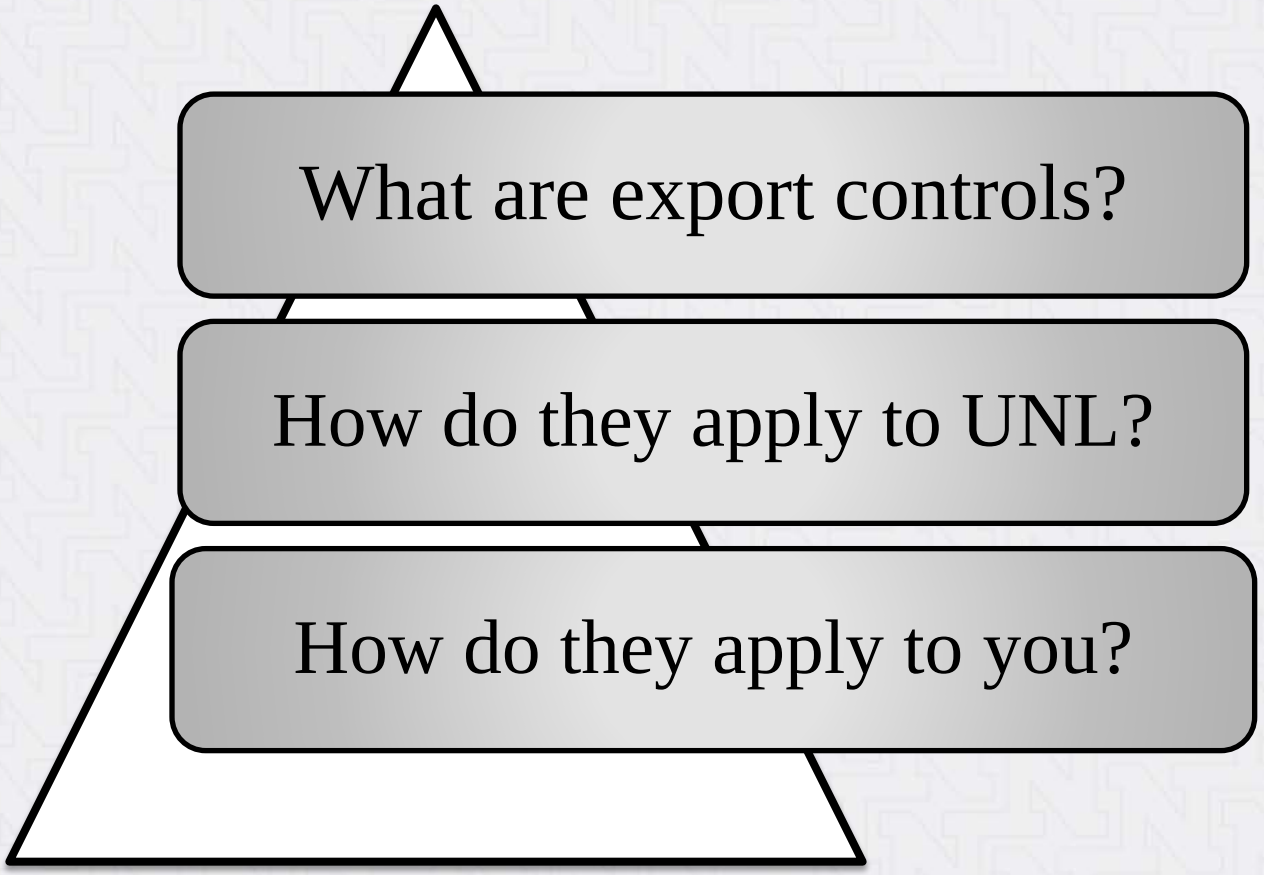
- Harvard Facebook Study
  - 2006 study funded by NSF; was IRB approved
  - “Anonymous” study on how friendships & interests evolve
  - 1700 profiles – student’s gender, home state, major, political views, network of friends, romantic partnerships, and cultural tastes in books, music, and movies
  - Students were not aware of the study

# IRB/HRPP

- Harvard Facebook Study
  - Research assistants were used because they had access to profiles that the researcher may not have.
    - Some may have been set to ‘private’
  - 2008 – public release of the data
  - Someone proved that the code to protect the data could be cracked
  - Public release of data has ceased.

# Export Control Compliance Program

# Export Controls Awareness Training



# What is an Export?

Physical Export: Any Shipment, Transfer or Transmission of any Controlled Commodity, Technology, or Software Code outside of the US

Deemed Export: disclosing “controlled” technical data either Oral, Written, Electronic or Visual Disclosure in the US to a foreign person

A foreign person is anyone who is NOT a:

* US citizen * Permanent Resident (“green card-holder”) * Refugee/Asylee * Other protected status under INA.

* Companies are people too!

# Who Regulates Export Control?

| Federal Agencies | | |
|---|---|---|
| U.S. Dept. of State International Traffic in Arms Regulations (**ITAR**) | U.S. Dept. of Commerce BIS Agency Export Administration Regulations (**EAR**) | U.S. Dept. of Treasury Office of Foreign Assets Control (**OFAC**) |
| ITAR governs all military, weapons, and space related items, technical data on defense articles and defense services | EAR governs the export of most items including those with military and non-military applications such as Dual Use, Deemed Export and EAR99 in the U.S. | OFAC enforces U.S. foreign fiscal policy, including all trade sanctions, embargoes and financial activities w/prohibited or blocked individuals or entities. |

# National Policy Fundamental Research

## "**Fundamental Research**"

Basic and applied research in science and engineering performed by universities is exempt from export controls so long as:

- It is carried out openly
- Without restrictions on publication, foreign national access, or dissemination

# Limits to FRE – Subject to Export

Fundamental Research does **NOT** cover --

- **Tangible Exports** of Hardware, Software, Technology
- Export controlled **technology** or **technical data** received from a sponsor
- **Export Controlled activities –** "defense services"
- Research involving the creation or use of certain encryption source code

**Transactions involving embargoed or sanctioned countries, individuals & entities & restricted end uses must be reviewed independent from Fundamental Research for license requirements.**

# Most Common Activities at UNL that may Involve Export Controls?

# EC Office Responsibilities:

- Review grants and other agreements that have been flagged – based on funding source, sensitive material, publication restrictions or foreign national restrictions
- Implement and enforce **Technology Control Plans** (TCP) – when the research is subject to Export Control regulations
- Advise and coordinate export compliance activities campus wide – Export Control Assessments for H1-B and J1 visas, IBC protocols, Int'l shipments, Int'l travel, etc.
- Apply for export licenses on the University's behalf
- Disclose violations to federal agencies

# Awareness for IP & Trade Secrets Protection

Knowledge and information are valuable assets and are an integral part of university activities, but not all campus information is for public consumption. Individuals and organizations that want to obtain innovative or restricted information may have ulterior motives and may misrepresent themselves and their intentions in order to gain access to restricted information, or they may outright steal it. Intellectual Property (IP) theft can be an invisible crime.

**The Open Environment of Universities May be Misused in Order to**:

- Steal technical information or products
- Bypass expensive research and development
- Recruit individuals for espionage
- Exploit the student visa program for improper purposes
- Spread false information for political or other reasons

**Common Tactics or Methods Used**:

Conduct computer intrusions, collect sensitive information, utilize students or visiting professors to collect information, send unsolicited emails,  surveillance, etc.

# How Do Export Controls Apply to You?

## Contact ECCP Staff If:

- You think your research might be controlled or there are troublesome clauses with restrictions
- You are shipping material to a foreign country or collaborating with a foreign entity
- Payment to vendors on a denied or restricted list
- Someone from outside UNL wants to visit your lab
- You are purchasing ITAR controlled equipment
- There's a security breach in your lab, unauthorized access or items have been stolen
- You're planning international travel to a country with sanctions, restrictions or risk alerts
- If you notice any suspicious behavior or activity either in you lab or during Int'l travel, report it as soon as possible.

## General Guidance:

- Do not travel with any unnecessary information or current research on a laptop. Avoid placing internet addresses ("favorites") on any laptop you take. Take only that info which you will present or discuss at the conference. Make sure your laptop is password protected. Do not continue to use a laptop that begins to run slowly, or acts strangely after taking it overseas.
- Do not allow personal software or hardware (thumb drives) to be installed or attached to your laptop
- Lock computer workstations when unattended and do not leave electronic storage devices unattended.

# Penalties Vary by Agency

- **Criminal: up to $1,000,000 per violation and/or up to 20 years in prison**
- **Civil: seizure and forfeiture of articles, revocation of exporting privileges, fines of up to $500,000**
- **Debarment from future federal funding**

## University of Tennessee Professor Found Guilty on 18 Counts of Export Violation

On January 18, 2012, John Reece Roth, a former professor of Electrical Engineering at the University of Tennessee (UT) in Knoxville, began serving a four-year prison sentence for his September 2008 convictions. Roth received this sentence for illegally exporting military technology, in large part due to his work with graduate students from Iran and China. Although, Roth claimed he was ignorant of the regulations, the prosecution pointed out that he was warned on a number of occasions, including by university counsel, that the technology may have been controlled. Professor Roth's conviction and prison sentence forcefully remind the research community, as well as academia, of the potentially severe consequences that may arise from ignoring technology export controls.

# Other Export Violation in Universities

**In March 2013, University of Massachusetts in Lowell** (UML) has been sanctioned for two past violations of the Export Administrations Regulations: in 2006 and 2007 UML exported an antennae and an atmospheric testing device as EAR99 to SUPARCO, an organization listed on the Entity List (one of the Restricted Parties Lists).

**In New York City 1995-2000, Sergei Tretyakov** was the head of political intelligence for Russia's foreign intelligence service, the SVR [one component of the old Soviet KGB service]. In other words, he was a Russian spy who later defected to the US. He described how a man in California traveled to New York, met with an SVR agent, and handed over years of US government funded medical research. The research studies had not been released to the public because many of them contained proprietary information based on medical patents held by US companies. The man who provided the data to the SVR agent was a Russian immigrant who wanted to help Russia and refused to be paid for the information; however, he did agree to be reimbursed for his air travel. Tretyakov observed: "The reports were extremely technical, and I noticed each had a dollar amount in the index that described exactly how much the US government had spent to pay for this research. This scientific research that cost the US government forty million dollars for the price of eight hundred dollars in airplane ticket!"

**In 2004, Dr. Thomas Campbell Butler**, M.D., a professor of Texas Tech University received a 2 year prison sentence for illegally exported the Yersinia pestis (human plague), which is a controlled item under the EAR and cannot be exported without the required export licenses. Dr. T. C. Butler had to resign from Texas Tech and accepted a denial of his export privileges for a period of ten years.

# Possible Scenarios

1. An Asian student gets accepted into a graduate program at a US university. The student has connections with a research group at a university back in Asia and is allowed to establish a formal collaboration between the two research labs. The Asian student invites personnel from the Asian university lab to visit the US university. Without permission, the visitors take photographs of all the equipment in the lab including the make and model of the equipment in order to reproduce the US university's lab at the Asian university. About a year into the collaboration, the graduate advisor becomes concerned that too much information is going out to the Asian research lab and not enough is coming back to the US university. Although the research is unrestricted, the graduate advisor recognizes that applications of the research could have national security implications. The Asian lab has more resources and is able to follow-up on ideas more quickly but the sharing of data and results is unbalanced, so the graduate advisor decides to end the collaboration.
2. A researcher receives an unsolicited invitation to submit a paper for an international conference. She submits a paper and it is accepted. At the conference, the hosts ask for a copy of her presentation. The hosts hooks a thumb drive to her laptop, and unbeknownst to her, download every file and data source from her computer.
3. A researcher at a US university receives an email asking to collaborate. He does not recognize the sender, but would like to collaborate and decides to respond. The sender asks for data on how to conduct a particular experiment, and the US researcher responds hoping to get the results of the experiment. The sender of the email provides a draft paper and asks for input; the US professor notes errors in the paper and corrects them. In the meantime, the sender asks for more data or research clarifications. Several months later, the US researcher realizes that for all the "collaboration" the two have been doing, he has no idea of the true identity or location of the sender, has received no information of value in return, and it now appears the sender was essentially milking the US researcher for unpublished and sensitive information.

# Research Misconduct

- Fabrication – making up data
- Falsification – changing data
- Plagiarism – taking someone else's words or ideas and passing them off as your own
- Research Misconduct does NOT include honest errors, differences in opinion, or authorship disputes.

# Research Misconduct

"Fuzzy Areas"

- Image manipulation, data selection, failure to correct the scientific record

# Research Misconduct

Research Misconduct Process:

- Inquiry
- Investigation
- Consequences

# Research Misconduct

Case Study

* This case was adapted from Schrag B, “Research Ethics: Cases and Commentaries,” Vol. 3. Prepared under NSF Grant No. SBR 9241897.

- John and Sam – 4th year grad students.
  - Both have yet to publish.
  - Both worry they will not be able to write a thesis and graduate without publishing.

# Research Misconduct

Case Study, cont.

- John has made an important discovery! He has synthesized a compound to degrade plastic in landfills. But he only has a little bit left.

- Sam will repeat the initial experiments with the remaining compound while John synthesizes more compound.
  - Sam will become the second author on the resulting publications.

# Research Misconduct

Case Study, cont.

- Sam's first experiment verifies John's results. But, Sam's follow-up experiment does not.
- She asks John about it and he says that she should save the rest of the compound and he will repeat the experiment.
- Instead, Sam says that she repeated the experiment again and got the original results.

# Research Misconduct

Case Study, cont.

- The group proceeds with publication.

- Months later a group contacts them indicating that they cannot reproduce the results.

- John repeats the experiments and cannot reproduce Sam's results. He cannot find Sam's original data.

# Research Misconduct

Case Study, cont.

- The group proceeds with publication.
- Months later a group contacts them indicating that they cannot reproduce the results.
- John repeats the experiments and cannot reproduce Sam's results. He cannot find Sam's original data.

# Research Misconduct

Case Study, cont.

- At this point, it remains unclear whether Sam has done anything wrong, even through she did not follow John's instructions to let him do the second experiment. What action should John take?

# Research Misconduct

Case Study, cont.

- What is misconduct? If it is found that Sam engaged in misconduct, is John also guilty because he did not report his concerns earlier?

- If science is self-correcting, as it is in this case study, why are there federal laws and regulations against misconduct?

# Contact Information

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