

SPONSORED PROJECTS LEGAL ISSUES IN RESEARCH ADMINISTRATION



LEGAL ISSUES IN RESEARCH ADMINISTRATION

RECAP OF THE RULES &
WHY THE RULES ARE IMPORTANT

TYPES OF LAWS IN RESEARCH ADMINISTRATION

- FED AND STATE CRIMINAL CODES
- FED AND STATE CIVIL CODES
- IRS AND STATE TAX CODES
- EXECUTIVE ORDERS
- FEDERAL AND STATE REGULATIONS
- OMB CIRCULARS
- FED AND STATE ADMINISTRATIVE RULES

LAWS-CONTINUED

- FEDERAL AND STATE AGENCY GUIDELINES
- INDIVIDUAL CONTRACT AND GRANT REQUIREMENTS
- UNIVERSITY POLICY AND PROCEDURE
- DEPARTMENTAL AND COLLEGE REQUIREMENTS

FED & STATE CRIMINAL CODES - EXAMPLES



- FED FALSE CLAIMS ACT
- ANTI- KICK BACK LAWS
- STATE CONFLICT OF INTEREST LAWS
- MISAPPROPRIATION OF GOVERNMENTAL FUNDS (THEFT)

FEDERAL AND STATE CIVIL STATUTES

- FOIA
- GRAMA
- BUY AMERICAN ACT
- GOVERNMENTAL IMMUNITY LAWS
- PATENT AND COPYRIGHT
- FAIR LABOR STANDARDS ACT



IRS AND STATE TAX LAWS

- IRS CODE - 501C3 NON PROFIT STATUS
- NEVADA SALES TAX LAWS
- WORKERS COMPENSATION AND SOCIAL SECURITY TAXES
- EXPORT AND TRADE TAXES & FEES

REGULATIONS



- PROTECTION OF HUMAN SUBJECTS
- ANIMAL CARE
- OCCUPATIONAL SAFETY
- ENVIRONMENTAL PROTECTION
- EAR AND ITAR (Export & Foreign Nationals)

GOVERNMENTAL REGULATIONS

- OMB CIRCULAR [A-21](#) (FINANCIAL)
- OMB CIRCULAR [A-110](#) (ADMIN)
- OMB CIRCULAR [A-133](#) (AUDITS)



SPONSOR SPECIFIC GUIDELINES

- NIH GUIDE
- NSF GUIDE
- NASA HANDBOOK
- DOE TERMS AND CONDITIONS
- GRANTS GUIDELINES
- FOUNDATION REQUIREMENTS
- ETC.

CONTRACT TERMS AND CONDITIONS

- FEDERAL ACQUISITION REGULATIONS
- CONFIDENTIALITY
- PUBLICATION
- INTELLECTUAL PROPERTY
- LIABILITY



POLICIES AND PROCEDURES



- UNR ADMINISTRATION MANUAL
- SIGNATURE AUTHORITY
- TRAVEL POLICY
- RESEARCH HANDBOOK
- ACCOUNTING PROCEDURES

SCENARIO #1



- A PI prepares a budget for DRUGS R US, a research company where her husband serves as CEO. The budget does not include funds for her time on the project. Instead, it states that she already has NIH and NSF funds paying for her time on the project. She e-mails her proposal to the company and they send her a nondisclosure agreement to sign before work begins. She signs it. The company then sends a check made out in PI's name with a cover letter stating that acceptance of the money implies an agreement that all project IP belongs to the company. PI deposits the check in her bank account and then gifts the money back to her lab. 6 months into the project, one of her grad students develops a new compound and posts his discovery on his really cool website.

POTENTIAL LEGAL CONSEQUENCES

- *NO SIGNATURE AUTHORITY (outside scope of employment – loss of governmental immunity for individual)
- *MISALLOCATION OF GOVERNMENT FUNDS & Property
- *PERSONAL LIABILITY FOR RELEASE OF CONFIDENTIAL INFORMATION
- *IRS CODE TAX ISSUES
- *POTENTIAL LAWSUIT BY COMPANY FOR VIOLATING PATENT RIGHTS
- *LOSS OF WORLDWIDE PATENT RIGHTS BY UNIVERSITY
- *VIOLATION OF CONFLICT OF INTEREST DISCLOSURE

APPLICABLE LAW OR RULE

- VIOLATION OF CONFLICT OF INTEREST LAWS
- dismissal from employment or removed from office and
 - (a) as a felony of the second degree if the total value of the compensation, conflict of interest, or assistance exceeds \$1,000;
 - (b) as a felony of the third degree if: the total value of the compensation, conflict of interest, or assistance is more than \$250 but not more than \$1,000; or
 - (c) as a class A misdemeanor if the value of the compensation or assistance was more than \$100 but does not exceed \$250; or
 - (d) as a class B misdemeanor if the value of the compensation or assistance was \$100 or less.
- (e) Right to rescind or void contract. If any transaction is entered into in violation of law

EXAMPLES – YOUR TAX DOLLARS AT WORK



- Stanford University 1990: charging depreciation of yacht to the feds, hiding research funds in gift accounts to increase F&A rate, etc. – Feds Claimed 55 Million in Penalties & Fines.
- In addition to 3.5 Million settlement, led to changes in and heavier enforcement of OMB Circular requirements.

EXAMPLES - Continued

- University of Michigan: A Physician who was found to be in violation of the conflict of interest laws was fined \$100,000.00 and put on one year probation.
- Medical College of Georgia: two investigators charged with theft of research funds related to clinical trials. Settlement of 10 Million and both investigators served jail time.
- University of Washington: Investigation and hearing concluded there were grounds for prosecution for fraud and theft and termination of employment when a PI used University office computer and supplies during office hours to prepare airplane designs for a private company without proper University approvals and without any reimbursement to the University for institutional resources used.

SCENARIO #2



- A PI submits a proposal to NIH to study how mental stress affects children's immune systems. The proposal lists three companies who will provide in-kind support for the project. PI hopes to get the companies' support if NIH funds come through. He asks for 50% of his salary – including money from the University's practice plan. The proposal was a success. In year 2 of the project, he tells his project coordinator to bill his anniversary trip to the Bahamas to the grant. He tells the administrator to sign his ERS for him delegating 50% effort while he is away. Luckily, because the project is only billed for his contract salary amount (not including the practice plan funds), he can rebudget some of his salary into travel.

SCENARIO #2 CONTINUED

- During the research, a gene was discovered that controlled the immune system. The PI developed a stress reliever compound using a virulent (but weakened) form of the flu virus as a vector. The drug was so effective, he began selling samples to parents whose children were study participants. Shortly thereafter, one of the children fell ill and the PI suddenly decided to take a job at the University of the Bahamas. He found a company that would fund the start up of his new lab if he agreed to issue them a subcontract out of his NIH money and an exclusive license to his intellectual property. This was too sweet a deal to say no to, so, he told his lab tech to box up his lab notebooks, computer and drug samples and ship them to his new employer in the Bahamas.

POTENTIAL LEGAL ISSUES

- MISAPPROPRIATION OF GOVERNMENTAL PROPERTY/FUNDS
- MISCONDUCT IN SCIENCE
- VIOLATION OF ANTI-KICK BACK
- FALSE CLAIMS ACT (FRAUD)
- VIOLATIONS OF THE FEDERAL FOOD AND DRUG COSMETIC ACT
- VIOLATIONS OF THE PUBLIC HEALTH SERVICE ACT
- UNRELATED BUSINESS INCOME TAX AND STATE SALES TAX VIOLATIONS
- IRB & HUMAN SUBJECTS ISSUES
- FAILURE TO REPORT PROGRAM INCOME
- VIOLATION OF EXPORT TRADE LAWS
- BIOTERRORISM PREPAREDNESS ACT & PATRIOT ACT

APPLICABLE LAWS

- VIOLATION OF THE FALSE CLAIMS ACT
 - Civil Penalties: only requires reckless disregard and not actual knowledge of fraudulent act. Results in actual damages plus treble (3X) the actual damages and interest, penalties of up to 10,000.00 per occurrence and legal costs.
 - Criminal Sanctions: requires knowledge of fraudulent act, resulting in Federal Prison time for perpetrator, time spent dependent on seriousness of allegations.
- VIOLATION OF ANTI-KICK BACK Two times the amount of the kickback, plus, \$30,000 for each kickback and up to ten years imprisonment
- VIOLATION OF EXPORT/TRADE LAWS. \$11,000 per occurrence plus jail time.

APPLICABLE LAWS EXPORT/TRADE LAWS

- **Criminal: for "Willful violations:"**
- **Corporation** - A fine of up to the greater of \$1,000,000 or five times the value of the exports for each violation;
- **Individual** - A fine of up to \$250,000 or imprisonment for up to ten years, or both, for each violation.
- **"Knowing violations:"**
- **Corporation** - A fine of up to the greater of \$50,000 or five times the value of the exports for each violation;
- **Individual** - A fine of up to the greater of \$50,000 or five times the value of the exports or imprisonment for up to five years, or both, for each violation.

APPLICABLE LAWS EXPORT/TRADE LAWS

- **Administrative:**
- For each violation of the EAR any or all of the following may be imposed:
 - The denial of Export Trade privileges
 - The exclusion from practice; and/or
 - The imposition of a fine of up to \$11,000 for each violation, except that the fine for violations involving items controlled for national security reasons is up to \$120,000 for each violation.

EXAMPLES

- Northwestern University 2003, A whistleblower claimed that PIs were sending NIH budget proposals that included practice plan income in their base salaries but when expending the award funds, they were only charging their base salaries and then moved excess salary funds into supply or other budget categories. PIs were also overstating the actual % of effort they would be spending on the proposed projects in order to inflate their budgets. University settled with Dept of Justice for 5.5 Million. Whistleblower kept 1 million.



EXAMPLES

- University of Wisconsin, Madison, A Principal Investigator overstated the financial support and number of industrial sponsors on a federal grant application. At the time of the application, the PI did not actually have external support, but hoped to get the support later on. The government prosecuted the PI for fraud on his application. The PI paid a \$10,000.00 fine and spent 3 months in jail.



EXAMPLES-CONTINUED

- Beth Israel Deaconess Settlement, November 2001. A researcher at the institution applied for and received a \$368,000.00 grant from NIH. The PI was expected to devote 50% FTE to the project. During the project, the PI left the institution on a leave of absence but occasionally returned to Boston to oversee some of the work on the project. The PI continued to charge 50% of his salary to the project. Some of the grant funds were diverted to pay for activities on other hospital projects. The Medical Center agreed to pay \$920,000.00 to settle federal fraud claims that it misused grant money targeted for genetic research.



EXAMPLES-CONTINUED

- University of Minnesota November 1998. A researcher with NIH funds began selling a drug developed at the institution with the NIH funds. The funds from the drug sales were not reported to NIH as program income. There were also allegations of improper effort reporting on the grant, failure to obtain informed consent from clinical trial participants, scientific misconduct and charging the grant for supplies not directly related to the grant. 32 million dollar settlement and loss of expanded authorities.



EXAMPLES-CONTINUED

- US v. Zhu and Kimbara, D. Mass 02-M-0421-ALL. June 19, 2002. Two former Harvard Medical School researchers left Harvard for other employment, and took more than \$300,000.00 worth of books, lab notebooks, biological materials and intellectual property with them to their new employer, University of Texas. The researchers allegedly had discussed selling commercial licensing rights to the intellectual property to a Japanese pharmaceutical company. Prosecuted criminally for theft across state lines. Plead guilty April 2006. Sentencing pending.



Examples- Continued

- July 2006 University of Alabama wins \$25 Million lawsuit against former chemistry professor, Milton Harris, for patent-infringement. Professor used University facilities and resources to create intellectual property & failed to disclose it to the University. He then used it in his start-up company without licensing rights from the University.



EXAMPLES-CONTINUED

- Johns Hopkins: deaths related to experimental gene therapy, IRB irregularities, conflict of interest.
- Thomas Jefferson University. Thomas Jefferson applied for NIH funding promising that the PI would devote 75% of his time on the project. The PI left for Italy to care for an ill wife, but still had his time charged to the grant. 2.9 Million settlement and signed a three year oversight plan with the federal government.

EXAMPLES - CONTINUED

- University of Connecticut – January 2006: 2.5 Million Settlement with DOJ for “poor management” of 500 sponsored project awards including inaccuracy in contract salary base amounts, claiming additional compensation (overload) salaries in violation of OMB A-21 and failure to appropriately and accurately document cost share (UCONN’s total awards did not exceed \$40 Million for audited periods).
- University of Vermont – January 12, 2006: criminal case against PI for falsifying research data. Result: PI to serve 5 years prison & pay \$250,000 fine

Examples – Research Misconduct

- June 28, 2006: Professor Eric Poehlman, University of Vermont sentenced to 1 year in federal prison and paid \$180,000 in penalties for falsifying data in an NIH grant application. Was also debarred from receipt of federal grant funds for life.

EXAMPLES-CONTINUED

- April 2006 – Clark Atlanta University pays 5 Million Settlement to settle Dept. of Energy misuse of funds whistleblower suit. University admitted “the system of grants management then in place proved insufficient to the task of effectively administering the contract.” They could not account for use of funds between 1990 and 2002. DA stated that the funds were used to “run the school” rather than support the project. “Accounting records were incomplete.” Chronicle of Higher Ed 4/28/06

Examples - Continued

- January 12, 2006 RGJ Article: **UNR Ordered to Repay Grant Funds**, By Lenita Powers
- “The University of Nevada, Reno has been ordered to repay more than \$21,000 in grant money spent on questionable expenses while conducting a study for the U.S. Environmental Protection Agency. In a report issued two weeks ago the EPA inspector general said the [University] must repay \$21,260 spent during a 1997 study . . .”
- Article stated that it was “common practice” at UNR to charge salaries to projects when the individuals whose salary was charged to the project never worked on the project.

HOW DO YOU GET CAUGHT?



- AUDITS
- WHISTLEBLOWERS
- SITE VISITS
- MEDIA
- JUSTICE DEPARTMENT
- SPONSOR ENFORCEMENT
- YOU

DIAGNOSTIC PROFILE



- Large sums of funds
- Excessive cost transfers
- Attitude that “the rules don’t apply to me”, or, “they’ll never find out”
- Organizational loyalties
- Suspicious placement of departmental administrators
- PIs with large #s of active projects

WHAT CAN I DO? TOP WAYS TO AVOID PROBLEMS

If you are concerned about something happening in your area you can:

1. Talk with the individual about your concerns.
2. Alert the OSP office, internal audit, and/or dept. chair, dean, or director as appropriate.
3. Do not deposit funds in a foundation account if it is not a gift.
4. Advise PIs about marking their proposals confidential.
5. Follow University Procedures -they are there for a reason.
6. If you see an external agreement, advise the PI/Dept. Chair, etc. to have someone with signature authority sign the document.
7. Get reports in ON TIME.

WHAT CAN I DO? TOP WAYS TO AVOID PROBLEMS

6. Do not sign off on another individual's ERS forms certifying as to their percent of effort on a given project unless you know how they actually spent their time.
8. Do cost transfers and/or assign costs to projects only when those costs provided a benefit to the project charged, not because it is "convenient" or because there are more funds available in one project than another or because you need to "spend out" an award before it ends.
9. If a PI starts boxing up his/her lab before a move, make sure the proper university approvals have been obtained first.
10. Assist in obtaining IRB, IACUC, Biosafety, Rad Safety, and/or Select Agent approvals are obtained before work begins. File amended protocols if the work changes.

Module 5B Complete

Thank you



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