Ask almost anyone engaged in business or industry what field of endeavor is the most highly regulated today, and you are likely to get an earful about government interference in whatever line of work that person happens to be in. Healthcare, nuclear energy, oil & gas, banking/finance, air travel, construction, and even casino gambling giants all see themselves as over-regulated, and it would be difficult to argue that any of them are wrong. You would be hard pressed, however, to find any among them who are expected to comply with all of the regulations governing all of these industries at the same time. That unenviable position belongs to higher education alone.

Institutions of higher education are, of course, engaged in all of these industries, directly or indirectly, for themselves or on behalf of others, some or all of the time. Our own institution - modest in size by comparison to behemoths like the University of Phoenix (532,000 students), University of California System (235,000), and peers like Arizona State (75,000), Ohio State (62,000), or Michigan State (46,000) - carries on activities that are subject to most of the laws and regulations listed above, if only on a small scale. We generate our own electrical power (no, not from a nuclear reactor, but we would by no means be the first university to do so, should we ever go that way); we operate a health clinic; we create toxic, bio-hazardous and nuclear waste every day; we carry out medical research; we’ve even owned an airplane or two, at one time or another. We make automobiles—and fire engines. We help design (and even build) new buildings. We grow crops that end up on people’s dinner tables and we engineer many of the foods raised by others. We raise livestock, and make hay while the sun shines. We study diseases like tuberculosis and leprosy, and we treat cancer patients—albeit non-human ones—every day in our Animal Cancer Center.

According to a recent national survey of faculty, a considerable percentage of faculty time related to federally-funded research is spent on administrative issues. Is it any wonder that regulatory burden is a hot topic among research administrators and researchers? Many thanks to Bob Schur for this thought-provoking article that paints an overview of the multitude of regulatory compliance areas to which institutions of higher education are subject to. You may be surprised to discover just what a jungle of regulations we all follow as part of the CSU community!
And, of course, we do something else that is one of the most highly regulated activities in the world, that none of those other giants of industry do directly: we teach students.

Every one of our teaching, research, and outreach programs is carried out subject to a myriad of governmental restrictions, requirements and rules. We can no more admit a student than we could fly a rocket to the moon without government scrutiny, and government money. (Did I mention, we’re also in aerospace)? On top of that, we are just as strictly governed by non-governmental regulators—think of the Higher Learning Commission, without whose accreditation we could not grant degrees, or the NCAA, without whose approval we could not field a single varsity athlete. No aspect of life at Colorado State is free from compliance issues and responsibilities, and no single administrator or department can possibly know, understand, and assure compliance with so many rules in so many areas. As a faculty member and principal investigator, you may be aware of many of these regulatory requirements, but knowing where to turn for guidance in maintaining compliance with the ones you know about—not to mention those you never heard of—can be a challenge. Let’s review just a sampling of the areas in which compliance programs are required and the resources on campus for obtaining compliance information and assistance.

**Do I own all I create?** Regulatory areas include: copyright, patent, trademark and trade secrets laws, and laws designed to prevent internet piracy. The intellectual property rights provisions of the *CSU Academic Faculty and Administrative Professional Manual* are also governed and/or impacted by regulations relating specifically to federally-funded research (such as the Bayh-Dole Act), as well as the specific terms of a grant or contract under which research funding is provided.

**Who handles it?** Both the Vice President for Research and the Office of the Executive Vice President/Provost are involved in administering rights to intellectual property. The University also collaborates with the CSU Research Foundation (CSURF) and its Technology Transfer Office, as well as private firms, to handle, protect, develop and market great ideas.

**Do I risk owing taxes on income I didn’t realize I got?** Federal tax laws are complex. If the University’s benefits plans were improperly designed or administered, for example, you could end up owing taxes on the value of benefits you received under plans like Deferred Compensation or Flexible Spending Accounts. You can also incur tax liability on travel reimbursements, prizes and awards, use of University-owned property, and any perquisite or benefit you receive. The University has to be extremely careful when designing and administering programs to avoid unwanted tax consequences to both the institution and its employees.

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**Who handles it?** The Department of Business & Financial Services, under the Division of University Operations, has a Tax Services Unit that works closely with Human Resource Services and other departments to keep a handle on these complex laws.

**Is the University a financial institution?** Of course you don’t think of it that way, but CSU is subject to a number of laws that were designed to regulate banks and other financial entities. For example, the University could be subject to provisions of the Gramm-Leech-Bliley Act that regulates the handling of private financial information of consumers, and can lead to fines of up to $100,000 per violation if not followed. CSU also must comply with numerous obligations under the Payment Card Industry Data Security Standards (PCI DSS) or face potential penalties for non-compliance. Using your PCARD depends upon a cadre of knowledgeable staff who run and monitor the program behind the scenes. And that doesn’t even begin to cover what’s involved in opening a bank account overseas.

**Who handles it?** Business & Financial Services, including the Bursar, Cashier’s Office, and Controller, the Purchasing Department, units within the Student Affairs Division, and of course the Vice President for Information Technology are all involved in maintaining compliance.

**I’d love to own the company that sells THAT kind of thing to CSU!** Numerous state and federal laws govern (and, of course, can prohibit) conflicts of interest between the personal and public activities of University employees. Are you in a position to both supply something to CSU, and help make the decision to buy it? **Conflict.** Can you use your position or influence to benefit one vendor over another? **Conflict.** Do your University-funded activities result in income to you from an outside business concern of your own, or someone else’s? **Conflict.** In addition, the University itself can have conflicts—known as Organizational Conflicts of Interest—that prevent it from acting in dual roles with respect to a federally-funded activity. All of these conflicts, whether real or apparent, must be disclosed, managed and (when necessary) eliminated in order to avoid civil and criminal penalties (not to mention violations of the University’s own policies and codes).

**Who handles it?** The Office of the Executive Vice President/Provost is the starting place for conflicts of interest inquiries; also involved are the offices of the Vice President for Research, General Counsel, and of course your department head and responsible Dean or VP.

**Can I go to jail for taking my laptop on vacation?** Well, yes, you certainly could. Federal export control regulations are numerous, complex, pervasive and downright scary. It’s not just about technology hardware being shipped overseas. Just carrying a laptop with installed programs and data you may use everyday can constitute a violation. Higher ed gets a pass only when the information involved is strictly related to “fundamental research,” doesn’t have dual uses that could relate to military applications, and involves only countries that aren’t on a government watchlist.

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**Who handles it?** The Vice President for Research, Office of Sponsored Programs, and Office of General Counsel, among others, all play important roles.

**What if my published paper isn’t quite up to snuff?** Quality is one thing, but irresponsibility in the conduct of research is quite another, involving numerous regulatory requirements and concerns. Among these are rules relating to financial disclosures by investigators in clinical trials; laws prohibiting fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results; requirements for policies to be promulgated and communicated by the University relating to misconduct in research or science; codes of conduct applicable to activities financed under federal grants and contracts; fraud and false claims liability; and reporting on instances in which integrity and ethical performance of grantees is questioned. If human or animal research subjects are involved, more protections for their safety and well-being are also applicable. The University also has to prove that it trains its researchers in the responsible conduct of research. Even in the absence of any hint of wrongdoing, the University must make full disclosure to the public of all grants and contracts involving federal funds, and the expenditures made under those grants (both as an awardee and sub-awardee), via a searchable website accessible to the public at no cost.

**Who handles it?** The University’s Research Integrity and Compliance Review Office (RICRO) handles issues like protection of human and animal subjects in research. The Provost and Executive Vice President has overall responsibility, along with the Faculty Council, for overseeing issues of academic and research integrity, while the Vice President for Student Affairs (also under the Provost) is primarily responsible for programs relating to misconduct of students.

**What do you mean, I can’t hire/fire her?** Everyone knows that CSU is a public employer, subject to certain laws and regulations regarding employees and their rights in the workplace. The extent of these laws, and the areas they cover, is astounding. Do you know the requirements for securing, retaining, and disposing of records related to an employee? Are you sure you know what constitutes age discrimination, as you think about how to deal with budget cuts and demands for more productivity from fewer staff? When reducing your workforce, does it matter whether a position is state-classified or admin pro? What about accommodating an employee who is called to active military duty, or to respond to a forest fire? What if an employee under your supervision needs to breastfeed her infant during work-time? Do all employees have to undergo background checks? What if you do, and that thing you thought everyone forgot about from your college days turns up? Dozens of separate laws, and tens of thousands of pages of regulations, govern how CSU hires, promotes, demotes, transfers, and terminates workers, from the moment that a job position is first conceived of, and from then on. At least 11 separate laws govern what posters must be displayed in the workplace alone.

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Who handles it? The Department of Human Resource Services, together with the Office of Equal Opportunity, Vice President for Diversity, Office of General Counsel, Office of Policy & Compliance, Ombuds/Employee Assistance Program, Commission on Women and Gender Equity, Office of Resources for Disabled Students, and many others play key roles in assuring that all our employees (and students) are treated fairly by helping to create sound policies, identify and correct discriminatory practices, and improve the work and academic environments for everyone. The Purchasing Department, Office of Contracting Services, and the Office of Sponsored Programs also help watch out for fairness and non-discrimination in bidding out contracts for supplies and services, and making sure that minority-owned, women-owned, veteran-owned, and other disadvantaged small businesses get a fair shot at University business.

I don’t have any clients coming in this afternoon, and it was only a glass of wine or two at lunch, so, what’s the problem? State and federal laws, along with the University’s own drug and alcohol policies, apply to everyone—faculty, staff, students, contractors, and visitors to campus. Among these laws and policies: the federal Drug Free Workplace Act of 1988; Drug Free Schools and Communities Act Amendments of 1989; Drug & Alcohol Testing of Transportation Employees Act; University Policies Regarding Controlled Substances, Illicit Drugs and Alcohol (Academic Faculty/Administrative Professional Manual, sec.I.19); Guidelines for Serving Alcoholic Beverages at a University Function; Lory Student Center Food and Alcohol Policies; Greek Life—Information about Alcohol Concerns; Student Conduct Code; Residence Hall Drugs and Alcohol Policy Statement; Hughes Stadium Alcohol Policy; Worker’s Compensation Act; Alcohol Beverages Act; and many others.

Who handles it? Many campus offices and officials are involved in drug and alcohol enforcement, awareness, and prevention programs, as well as regulating the possession, use, sale and advertising of alcoholic beverages on the CSU campus, including (for example) the CSU Police Department, Department of Housing and Dining Services, CSU Health Network, and Facilities Events Support offices, among others.

Whoa-Who’s keeping track of all this stuff? Many of the administrative and academic offices mentioned above collaborate to understand, apply and monitor compliance with these regulatory requirements, but, ultimately it is the responsibility of every employee, whether faculty or staff, and every student, to know and understand the requirements that apply to his or her conduct. Faculty in mathematics may not be expected to be conversant with the same laws as their colleagues in biosafety, but all have compliance responsibilities. The Office of Policy and Compliance is one resource for finding compliance requirements, along with the Research Integrity and Compliance Review Office (RICRO), Office of General Counsel, and Office of Sponsored Programs. Check the Policy and Compliance website as a starting place. Remember, we’re always here to help you wend your way through the compliance jungle.

Robert Schur
491-1059
IACUC Policy Changes: Increasing or Decreasing Regulatory Burden?

In recent months, the IACUC has revised a number of the institution’s policies regarding the care and use of animals. Related to the issue of training, the committee implemented a new “Policy on Animal Care and Use Program Training.” Clearly a new policy which, as previously discussed, requires individuals to take a training and document that they have done so does on decrease regulatory burden. However, the committee has also recently revised one of the central animal care and use policies for the institution in a way that should work the opposite.

The committee recently streamlined some policies to attempt to clarify them. They also revised the “Policy on the Use of Live Vertebrate Animals” to clarify what animal use requires IACUC review and approval. The policy also allows researchers conducting live animal work at other institutions to avoid the previously required duplicative review by CSU’s IACUC and the other institution’s IACUC and now allows for the use of a simple Inter-institutional Agreement form when another institution’s IACUC is overseeing the work. Thereby avoiding the time and energy needed to create and have a CSU protocol reviewed and approved for such work as custom antibody production or even subcontracted animal studies when a CSU investigator is the awardee of a federal grant.

IACUC Training Requirements

Colorado State University’s laboratory animal care and use program is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). This accreditation is voluntary, but because it is recognized as the gold-standard in a quality animal care and use program by federal funding agencies, having this accreditation facilitates CSU’s ability to receive federal grants for research which involve the use of live vertebrate animals.

Last fall, a team from AAALAC conducted an accreditation Site Visit. One of the findings of that site visit was that CSU’s animal care and use program should have consistent and documented training for all individuals involved in the care and use of live vertebrate animals in order to be compliant with the provisions of the new, 8th edition of the Guide for the Care and Use of Laboratory Animals. They asked the institution to provide a training program that would provide all animal users with information on the federal and local regulations regarding the use of animals, and to document that individuals have received that training.

As a result, as of January 1, 2012, the IACUC has implemented a mandatory online training module. All individuals listed on all new protocols are required to complete the online training and certify that they have done so at the CSU Animal Care and Use Training webpage. Mindful of the regulatory burden, the committee kept this training brief, and made it accessible 24/7. Please take a few minutes and do the training, and ask others in your laboratory to do so as well.
An ANPRM—Proposed changes to the Code of Federal Regulations for Human Subjects Researchers: Aimed to improve protection of human subjects participants & to reduce burden for researchers

The federal regulations that human subject researchers who are engaged in HHS-supported or HHS-conducted research must follow were first published in 1974, and have remained essentially unchanged since 1991 when 14 Federal departments and agencies agreed to adopt a uniform set of rules and regulations that are frequently referred to as the “Common Rule.” This past July, the U.S. Department of Health and Human Services announced that they were seeking comments regarding their proposed changes to the regulations. *Advance Notice of Proposed Rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.* The ANPRM asked for comments to 70 questions (the announcement was over 20 pages in length), covering such topics as revisions to the exempt and expedited criteria and review processes; updates to the consent process, requirements and the possible addition of standardized consent templates; standardized data security measures to protect participants’ virtual identities, etc. RICRO staff, the IRB, and OVPR personnel collaborated to create and submit a response to the ANPRM announcement. If you would like to see the announcement and the responses from multiple institutions, agencies and individuals, please link to: [http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html](http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html). Of course, it will most likely be at least 3 or more years before changes to the regulations are finalized, but we believe that this is a step in the right direction. Along with HHS, RICRO IRB staff and committee members are striving to expand our educational outreach to human subjects researchers in an ongoing effort to reduce regulatory burden. Do you have IRB-related questions? Please don’t hesitate to ask the IRB Coordinators: Janell and Evelyn.
RICRO Staff Updates and Announcements

Welcome Jenny Thompson, RICRO Assistant Administrator

We are pleased to announce that the RICRO Assistant Administrator position has been filled by Jenny Thompson. Jenny holds a BS in Health Education from Mankato State University and a Business Manager Certificate from CSU’s School of Business. Jenny has most recently been working in the private sector, but before that, Jenny worked for 8 years as a Research Associate in the CSU Marketing Department. Jenny’s expertise and enthusiastic outlook are wonderful additions to our team. Welcome back to CSU, Jenny, and a big welcome to RICRO!

IACUC Assistant Coordinator

RICRO would like to congratulate our IACUC Assistant Coordinator, Elaine Kim, and her husband on the arrival of their baby daughter. We wish the family all the best with the new bundle of joy.

In Elaine’s absence, we are grateful that Denise Ostmeyer will be assisting Bill Moseley with some of Elaine’s key duties. Denise will be assisting in the continuing-review process, so don’t be surprised if you are an animal researcher, and Denise calls or emails you about an upcoming protocol renewal. Thank you, Denise!

Schedule of Events
March 2012– May 2012

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<td>FBI Biosecurity Wksp (12:30pm-5:00pm)</td>
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<td>27</td>
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<td>28-29</td>
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To access the full RICRO calendar, go to:
http://web.research.colostate.edu/ricro/calendar.html

Congratulations to Bill Moseley and Denise Ostmeyer – 2012 AP Star Winners! Thank you for your many contributions to our division!
Many individuals and groups have expressed the intent to attack the United States with biological weapons. In order to further their plans, these individuals have targeted laboratories, biotechnology companies, scientists, and students.

**The FBI Biosecurity Workshop will:**

- Increase awareness of potential biosecurity risks.
- Identify methods used by individuals to acquire the information and skills they need for a successful attack.
- Explain warning signs that may indicate targeting procedures.
- Enable detection of institutional issues impacting biosecurity.
- Promote the early reporting of suspicious activities.
- Establish and solidify mutually beneficial relationships between law enforcement, research institutions, community stakeholders, and academia.

The event is free however requires advance registration, to register please go to: [www.academicbiosecurityworkshop.org](http://www.academicbiosecurityworkshop.org)

For more details: [http://web.research.colostate.edu/ricro/events.aspx](http://web.research.colostate.edu/ricro/events.aspx)