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RICRO Open House

The Research Integrity & Compliance Review Office has a lot to celebrate, and we want you to be there! We are hosting an *Open House* for the campus, Friday September 14th from 2 – 4 pm. Please stop in!! We are still in Suite 321 of the General Services Building, conveniently located near your favorite railroad track.

You will have an opportunity to share ideas with staff from RICRO and the OVPR, as well as the wonderful PIs who serve on our protocol review committees. We will have computers set up to demo software, review the website, or help you in any way we can. And … let us treat you to some delicious refreshments and beverages.

Update on human subjects protocol electronic submissions

We have been working hard reviewing software for electronic protocol submission and management for our Human Research Committee (HRC). A special thanks to Drs. Hickey and Davies for helping us try out a couple of the RICRO favorites. A potential vendor has been identified! Pending contract negotiations, we hope to be able to make a final announcement at the Open House. Janell (Human Research Committee) will have a computer set up at the Open House that will allow a brief demo of the intended vendor, if you would like to preview the software. We are still working towards the goal of fully implementing electronic protocol submission, review, renewal and management before winter hits. Stay tuned for details about when and how to get training to use the new software. Our goal is to make human protocols faster and easier to submit, and to allow the review process to be the least burden on faculty members as is possible. PIs may be pleased to learn that the new software will allow them to “clone” or copy old protocols when they start working on a new protocol.
**Essay of the Month: “What Can CSU Learn From Texas A&M”**

**Bad press for Texas A&M**
On July 1, 2007 the Dallas newspaper, Dallas Morning News, reported that “The Centers for Disease Control and Prevention has indefinitely suspended all of Texas A&M University's federally sanctioned research on the most dangerous infectious diseases after the university's failure to report two 2006 cases of human exposure to biological agents.” The first accidental exposure occurred in February 2006 when a researcher, using what Texas A&M admits were inappropriate protocols, cleaned an aerosol exposure apparatus ‘by climbing partially into the chamber to disinfect it.’ A&M officials later concluded that the exposure likely occurred via her eyes as a result of this improper procedure1. The individual subsequently became ill and had “been home sick for several weeks” before the disease was diagnosed in April 2006. The second incident occurred in March 2006 when three laboratory workers were found to have increased antibody levels against *Coxiella burnetii*, the causative agent of Q Fever, following annual blood testing performed as a routine precaution2. None of the researchers became ill nor has it been reported how the exposures may have occurred. After the second incident and a subsequent inspection, the CDC halted Select Agent research at Texas A&M. Federal regulations on select agents require researchers to immediately inform the CDC of “theft, loss or release,” which includes human exposure, and to file a formal report within seven days of the occurrence. In the Brucella case, university officials acknowledge that they did not follow proper protocols for reporting such incidents to the CDC, but they dispute allegations that they broke the rules with the Q fever exposure2,3. Both incidents are under investigation by the CDC and the U.S. Health and Human Services Department’s inspector general. Penalties could include steep fines and/or loss of federal funding.

**The Biosafety Program at CSU**
The Biosafety Team at Colorado State University has a number of programs in place to ensure that this type of thing does not happen at CSU. First and foremost are the SOPs and training. It is required standard procedure at CSU for a researcher to use a PAPR in addition to wearing an N95 mask whenever they are operating or cleaning an aerosol exposure apparatus, especially when Select Agents are involved. Strict adherence to this protocol has proven successful in the TB research program which has been using aerosol exposure apparatuses for over 20 years with no incidents of aerosol exposure of investigators. Investigators are trained in the proper donning and doffing of personal protective clothing and equipment; what to do in case of a spill; what to do in case of an exposure or suspected exposure; and to whom spills and exposures are to be reported. In addition to the SOPs and training, the Biosafety Team has instituted an Occupational Health Program. This program instructs all researchers working with BSL-3 pathogens that come down with a fever of 100.4°F or higher to immediately go to the Emergency Room. Furthermore, the program requires all individuals working in the BSL-3 facilities to carry a “wallet card” that can be given to the health care provider with information about where the individual works and the potential pathogens they may have been exposed to.

The Select Agent Program at CSU is directed by Dr. Robert Ellis, University Director of Biosafety and CSU Select Agent Responsible Official (RO). Colorado State University has been registered with the CDC for Select Agent possession since 1999. Dr. Ellis, along with Dr. Claudia Gentry-Weeks (CSU Alternate RO) and Heather Blair (CSU Alternate RO) conduct regular training exercises and audits regarding Select Agent use at CSU. Importantly, they are in constant communication with CDC officials to ensure that CSU is in compliance with all Select Agents regulations. Our institution’s willingness to work with federal regulatory agencies, openly and with integrity, has served the research community well.
What can we learn from the Texas A&M story?
Even with the best training programs mistakes will happen, after all we are all human. What’s important is how those incidents are handled. Had Texas A&M properly reported the incidents when they occurred they would not be facing possible termination of all Select Agent research, hundreds of thousands of dollars in federal fines, and a tarnished reputation. The new Regional Biocontainment Laboratory (RBL) at CSU is scheduled to open this fall. With the opening of this facility come many new opportunities in research, and, since many more researchers will be active in the new laboratories, there is an increased possibility of mishaps, making this the perfect time for those of us at CSU to reevaluate not only our protocols and procedures but also our research culture.

The integrity of our research program is a reflection of the integrity of each individual involved with it. Even with strong protocols and procedures, it is the researcher who takes responsibility for his/her own actions, following through to “do the right thing” because it is the right thing to do, who protects the individual, our institution, and our community. CSU is committed to promoting a culture that values high ethical standards in all areas of research. This starts with the modeling of responsible conduct of research by our talented principal investigators; in this way we transmit our institutional values to the next generation of researchers. I am proud to work at an institution that is committed to excellence not only in research, but also in research ethics. However, we must remember not to become complacent with the job we doing. The incidents at Texas A&M and elsewhere should serve as reminders that SOPs must be continually reviewed, updated, and adhered to strictly, training is essential, no one is above the regulations, and that we must always hold true to our principles and do the right thing.

- Christine M. Johnson, MS, IBC Senior Coordinator, Research Integrity & Compliance Review Office

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1 The Sunshine Project, New Release, 12 April 2007
3 The Dallas Morning News, 1 July 2007

*** Have something to say to the CSU research community? We welcome contributions to the RICRO Report!  

Upcoming Events

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ACUC Annual Retreat

The ACUC typically reviews between 25 and 40 protocols monthly. CSU’s ACUC periodically holds retreats that do not involve protocol review but instead focus on member training and/or big-picture business items. For example, at the ACUC’s retreat held last January, Dr. Temple Grandin gave a presentation on pain and distress in animals. The committee also heard presentations on best IACUC practices and on the Scientists Center for Animal Welfare.

The next ACUC retreat will be held September 7, 2007 to discuss a wide variety of business issues and policies. The ACUC will hold its regularly scheduled meeting the third Tuesday, September 18, 2007.

If you have something you would like the ACUC consider at this retreat, please contact the ACUC Chair, Dr. Terry Engle, or the ACUC Senior Coordinator, Dr. Karen Sellins, and let them know about it.

“Did Laura have her baby yet?!” & other RICRO personnel news

If you have visited the RICRO office lately, you may have noticed that Laura Martin (ACUC Coordinator) and her husband, Steve, are anxiously awaiting the birth of their first son, Baby Boy Martin. As of this writing there is no news to report. However, when the happy event occurs Laura will take a well-deserved hiatus (but not a rest!). Her able colleague, Evelyn Swiss, will assist Dr. Karen Sellins (ACUC Senior Coordinator) to meet all your ACUC needs.

In other RICRO news, we are pleased to have Ms. Marilee Rowe’s expertise at our ever-busy front desk. Stop by and introduce yourself to her! Marilee is being kind enough to help us out temporarily as we proceed with the search process for a new Administrative Assistant for RICRO (props out to the RICRO AA Search Committee!!). You might be missing the smiling face (and voice) of Hillary Swiss, who departed the office in August to head off to her freshman year at Oberlin College. We sure are! We send our gratitude to Hillary for helping us out this summer, with warm wishes for a spectacularly fun year!

Update on Responsible Conduct of Research (RCR) activities at CSU

This summer Drs. Bill Farland and Kathy Partin were out and about at venues such as the new Chair, new graduate student and new faculty orientations, talking about the responsible conduct of research
at CSU. As an institution CSU promotes for outstanding research and scholarly activity, performed in a manner that models ethical professional behavior. You can expect to see more RCR training activities come out of the Office of the Vice President for Research. Did you know that CSU already has a number of course listings that focus on RCR, and meet federal standards for providing trainees with formal ethics training? Check out:

- **PHIL 666** - Science and Ethics. Spring (odd years). Ethical issues of research on humans and animals; biosafety; fraud and deception in science; genetic engineering. 3 Credit Hours.
- **BC 601** - Responsible Conduct in Biochemistry Fall (even years). Design of experiments; error and fraud, publishing/grant application submission, scientific misconduct, classic examples of fraud, case studies. 1 Credit Hour.
- **BMS 610** - Managing a Career in Science. (Fall.) • A: Survival skills for coursework (M.S.). • B: Survival skills for research (M.S. and Ph.D.). 1 Credit Hour.
- **MIP 654** - Research Policies and Regulations. Fall. Reviews CSU and federal policies, rules, and regulations on integrity, use of humans and animals, authorship, data, genetics, etc., using case studies. 1 Credit Hour.
- **MIP 540** – Biosafety in Research Laboratories. Spring. Discussions of guidelines, regulations, and procedures for conducting research at Biosafety Level (BSL)-1, -2, and -3; design of BSL-1 and -2 laboratories. 2 Credit Hours.
- **CHEM 580** - Responsible Conduct in Chemistry Research - Spring. Scientific misconduct, fraud, publishing and intellectual property, ethics of job hunting and negotiating, case studies, social responsibility of scientists. 1 Credit Hour.

If we missed a course, please let us know (ricro@research.colostate.edu). On the other hand, if your department needs assistance in developing an RCR course, we may be able help you. Grab the phone and call 1-1563.

**Conference on “Research for Native Health” in Denver**

Janell Barker (Human Research Committee Senior Coordinator), Evelyn Swiss (HRC Coordinator) and two members of the HRC (Drs. Matt Hickey and Roe Bubar) headed down to Denver on Aug. 22-23 to participate in “Research for Native Health: Strengthening Partnerships, Promoting Trust, and Increasing Communication”, a conference sponsored by HHS’s Office of Public Health and Science (OPHS) in collaboration with OHRP, Indian Health Service, the Office of Minority Health and others. The overall outcome of this meeting was to remind investigators initiating a research project with Native Americans to view them as people, not data. It is important to show respect at all levels, and to communicate continually and thoroughly with tribal authorities and participants. If you would like more information about using Native Americans as subjects in your research, please contact Janell at 1-1655.