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Contents

- Ribbon-cutting ceremony at the Regional Biocontainment Laboratory (RBL)
- Hot topics and frustrations for researchers using animal subjects
- Essay of the Month: “The Human Subjects Protection Program at CSU: Where we are going”
- Schedule for upcoming events, training sessions and submission deadlines
- Online protocol submissions for the IRB and DRC
- New faces and new roles at RICRO!
- What’s in a name? Why HRC=IRB and ACUC=IACUC

Ribbon-cutting ceremony at the Regional Biocontainment Laboratory (RBL)

The ribbon-cutting ceremony for the 38,000-square-foot Regional Biocontainment Laboratory (RBL) on the CSU Foothills Research Campus was held on October 2nd. This $30 million project, funded by the National Institutes of Health's National Institute for Allergy and Infectious Disease with matching funds from the university, began in 2003. Construction began in 2005 following the groundbreaking ceremony on a cold November morning. October 2nd 2007 was another chilly day, but you could feel the excitement in the air as the crowd listened to CSU dignitaries and anxiously waited for tours of this state-of-the-art facility.

The Rocky Mountain Regional Biocontainment Laboratory is among the most secure laboratories of its kind in the world, featuring level-three biocontainment security, and will house internationally recognized research already underway into infectious diseases at Colorado State. The university is an international research leader for West Nile virus, drug-resistant tuberculosis, yellow fever, dengue virus, hantavirus, plague, tularemia, chronic wasting disease, and many other infectious diseases. The new facility also provides the university with improved and safer equipment to research ways to protect the United States from bioterrorism and emerging diseases such as avian influenza. Within this state-of-the-art facility, researchers are better able to find ways to prevent the use of biological weapons and discover counters to their effects. The laboratory also will house the Regional Center of Excellence for Biodefense and Emerging Infectious Diseases. The Rocky Mountain RCE is a multi-disciplinary intellectual collaboration of researchers from Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming. The RCE focuses on zoonotic emerging diseases, which are animal diseases that are transmissible to humans. These diseases are the source of almost all emerging diseases throughout the world. The RCE works to develop new vaccines, drugs and diagnostics for these emerging diseases; train regional and national scientists, physicians, veterinarians and other public health personnel in emerging diseases and biosecurity, and help state and federal agencies respond to emerging diseases.

Though researchers at the facility will be primarily from Colorado State University, space also will be used by private industry and the federal government, including the Centers for Disease Control and Prevention (CDC) in collaboration with CSU. This new laboratory provides advanced research
capacity and facilities to bring university researchers together with government, academia, and industry scientists to develop new vaccines, therapies and diagnostics for many pathogens to help people across the globe. Congratulations to all who were involved in bringing this to fruition!

Hot topics (and frustrations) for researchers using animal subjects

Many recent and upcoming events may be of interest to a researcher with IACUC-approved protocols.

- The semi-annual inspections are complete! The IACUC members have reported back that PIs, students and staff are doing an excellent job of protecting animal welfare at the various campus sites. Very few deficiencies were noted, and these were almost all “Minor.” Since the campus can expect an AAALAC site visit next fall, it is important that we all continue to self-monitor our animal sites. By the way, did your inspector remind you to hang your mops on the wall with “MOP-HEADS UP”?? Many PIs have said that this practice does not make sense to them (germs drip down from the mop-head to the handle, where they are readily transmissible). The ultimate sourcebook, the Guide for the Care and Use of Laboratory Animals indicates that: “Cleaning utensils…should be stored in a neat, organized fashion that facilitates drying and minimizes contamination.” Well, that seems to indicate that they could be stored either way. So, we are sending out our sleuths to do some additional research on this topic. We will get back to you in the next Report!

- You may recently have been asked to send the University Veterinarian an accounting of all animals used in the past Federal fiscal year. Why is that necessary, since we all turn in A-101s that essentially count our animal usage in the past year? We can provide you with the technical reason¹, but the bottom line is that in order to stay in compliance with USDA regulations, someone has to certify that our animal-use records are “true, correct and complete.” Unfortunately, the A-101 reports are staggered across the calendar year, and thus the numbers do not allow a “real-time” estimate of current animal usage, even if we tabulate what gets reported on the A-101’s (which we do, through the animal-tracking module of our system software, Granite). So, CSU would not be in compliance with federal regulations if we depended solely on A-101s (bummer!), and therefore we need your help. The good news is that when the new SCIQUEST ordering system goes online, we think we will be better able to track animal acquisition in real time. So, if you can bear with us for ’07 and ’08, we think we can solve this problem in ’09! We know it is an issue and we are trying to solve the problem. Meanwhile, please contact James.Owiny@Research.Colostate.edu if you have any questions.

- By the way, the Office of the Vice President for Research is continuing to update its websites, through the talented Research Services staff. Check out the new Animal Care Program site – it has a wealth of good information for researchers! Logon to http://web.research.colostate.edu/ACP/default.aspx. The website is located in the RamPoint portal and will require your EID to access it. The data is located under the Research tab in the Laboratory Animal Resources channel.

- Looking for a place to party on Halloween? We know just the place! Laboratory Animal Resources (LAR) is hosting a shindig on Oct. 31 at 11 AM in 103 PATH, where “Everything you wanted to know about “the new” LAR but were too busy/bored/scared to ask” will be discussed. Throw on a costume and come gets some treats!

¹ The AWA and Animal Welfare Regulations require research facilities to submit an annual report (APHIS Forms 7023 and 7023-A) to the responsible AC regional office by 1 December of each year. The revised Policy #17 now requires each research facility to "certify that the animal usage information submitted is true, correct and complete." Further, it recommends "[t]hat every facility develop an animal accounting method sufficient to support this submission," asserting that "USDA inspectors will verify the accuracy of these numbers during their inspection." - USDA APHIS AC. Animal Care Policy #17. Annual Report (Revised). (25 August 2006). http://www.aphis.usda.gov/ac/publications/policy/policy17.pdf
Thanks to all who participated in the recent recruitment efforts for a new Associate Director of LAR. Four excellent candidates visited campus: Dr. Stephen Denny, Dr. Victor Lukas, Dr. Lonnie Kendall and Mr. Frank Ali. The charging party, Dr. Sue Vandewoude has been presented with all your evaluations, and is carefully considering these comments.

**Essay of the Month: “The Human Subjects Protection Program at CSU: Where we are going”**

The Human Subjects Protection Program has experienced a number of changes over the last several months. The name of our parent office has changed to Research Integrity & Compliance Review Office (RICRO) to better reflect the Office’s role in the CSU research enterprise. The name of the review committee has been changed to the Institutional Review Board (IRB) to be consistent with national trends. In addition, the protocol submission and review processes will go online in the next few months. All of this means changes for the entire human research community; changes that we believe you will find are all for the better. To improve our human subjects research protections program and to reflect the new name of our office, research ethics and responsible conduct of research modules will be added to our training courses. Training is currently only required for PI’s and is valid for three years. We currently have a monthly workshop taught by faculty, for faculty researchers who have not had initial CSU human research protection training. Coming soon will be an online refresher training course through RamCT for those PIs who have completed one of the initial training courses. It is highly recommended that Co-PI’s, or anyone on the research team who will be interacting with the participants or with the data, complete one of the training options.

Colorado State University is implementing eProtocol as its electronic online protocol submission to improve the application and review process for researchers seeking IRB approval for their human subjects research. This online system is similar in principle and use to the platforms used by NIH for grant submission and by a variety of journals in the process of peer-review. Thus, many PIs will be familiar with the basics of the system. The eProtocol platform has a number of benefits for all users. Listed below are a few examples.

**How will the online submission help the researcher? (Access to the online submission process is carefully controlled requiring a user name and password)**

- All approval notices and approved documents will be available for viewing at any time and from any computer using a standard web browser
- All activity by the Researcher will be available for viewing.
- Paper usage will be reduced!
- Training records will be available to view online and can be provided for sponsors.
- The online system will track the completeness of the protocol at the time of submission.
- Researchers will be able to “clone” old protocols, so common components will not have to be entered repeatedly.
- Reviews and approvals will occur with a faster turnaround time.
- Researchers will be able to readily access their current consent document.
- Sequential tracking of documents (i.e., history of the approval) will be available online.
- Special announcements for Researchers will be viewable at the initial login screen.

**How will the online submission help the IRB members?**

- Reviewers will get immediate access to new review material.
- Paper usage will be reduced!
- Protocols waiting for review will be available at any time from any computer using a standard browser.
- The history of each study will be recorded and will be retrievable.
- Reviewers will be able to see at-a-glance how the Researcher has revised a resubmitted protocol.
How will the online submission help the IRB Administrators?
- Researcher contact information will be entered once and will reference the university eID information, minimizing the potential for errors.
- Important documents will be easily accessible at all times.
- Approval letters will be “automatically” generated and emailed out.
- Paper usage will be reduced!
- The IRB Administrators will be able to access the system from any internet connection using a standard web browser – even Las Vegas!
- Announcements and action items for Researchers will appear at the initial login screen.
- The system will track the completeness of the protocol at the time of submission.

What we hope the future will bring.

Workshops will be provided at the college, department or class level on research ethics and the human subjects review process. Community outreach will provide researchers with additional guidance prior to their protocol submission and how to manage their protocol through completion.

Additionally, we would like to consider whether CSU should seek accreditation by AAHRPP (the Association for Accreditation of Human Research Protection Programs) to further develop and promote excellence in all aspects of our human research protection program. Seeking accreditation would assist us in establishing a balance between ethical principles and the required federal guidelines. This would be a joint effort involving numerous departments, led by the Institutional Official, William Farland, Vice President for Research, RICRO and the IRB. Please let us know your thoughts about adopting accreditation as a long-term goal.

We look forward to working with you with all of our upcoming changes and improvements and ask in advance for your patience and support. If you have any questions, please contact me at 491-1655 or janell.barker@research.colostate.edu

Janell Barker
Senior IRB Administrator

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

Upcoming Events

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<tr>
<th>November 1 – November 23:</th>
<th>Controlled Substances Approval – ANNUAL RENEWALS</th>
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<tbody>
<tr>
<td>*Thursday, November 8:</td>
<td>IRB Protocol-Submission Deadline <em>(Noon)</em></td>
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<tr>
<td>Friday, November 9:</td>
<td>IBC Submission Deadline <em>(Noon)</em></td>
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<td>Friday, November 9:</td>
<td>IRB Human Subjects Training Session (9:00-11:00 RICRO)</td>
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<td><strong>Tuesday, November 13:</strong></td>
<td>IACUC Protocol-Submission Deadline <em>(Noon)</em></td>
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<td>Wednesday, November 14:</td>
<td>IBC Bi-Monthly Meeting</td>
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<td>Thursday, November 15:</td>
<td>IRB Meeting</td>
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<tr>
<td>Tuesday, November 20:</td>
<td>IACUC Meeting</td>
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<tr>
<td>November 22-23:</td>
<td>Thanksgiving Vacation - RICRO Office Closed</td>
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*Remember: IRB submission deadline is always noon the second Thursday of the month.
**Remember: IACUC submission deadline is always noon the second Tuesday of the month.
Online protocol submissions for the IRB and DRC

IRB Online Protocol Submission. CSU has entered into a partnership with Key Solutions of Sunnyvale, CA (http://www.keyusa.com/eprotocol/inside/about.html) to implement “eProtocol” for all IRB protocol submissions. RICRO and Research Services will be working with the eProtocol team over the next few months to design, develop, implement and test the CSU online protocol management system, which will allow electronic submission, review and maintenance of IRB protocols. Look for more information coming soon on the RICRO website.

DRC Online Application Submission. The Drug Review Committee (DRC) has been working with Dr. Richard Bowen (Department of Biomedical Sciences) to develop an online data management system for the regulation of controlled substances at CSU. Dr. Bowen will be working with Research Services and the DRC coordinator, Ms. Evelyn Swiss, to get the new web-based system up and running for annual renewals this year! Look for announcements about using this system to appear in mid-November.

New faces and new roles at RICRO!

We are excited to welcome two new faces to the RICRO team! The recent resignation of Dr. Karen Sellins, Senior IACUC Coordinator, has led to some internal reorganization of the office, which we hope will allow us to better serve CSU researchers. Ms. Laura Martin will assume the role of Senior IACUC Coordinator when she returns from family leave in December. Laura has numerous years’ experience working with animal-care programs, including her experience at Pfizer, and she brings a wealth of new ideas about how we could improve our service to researchers. We look forward to having her work with the IACUC to streamline our processes. Meanwhile, Dr. Kathy Partin will be the IACUC Coordinator – please contact her with any of your IACUC needs.

Mr. Bill Moseley has been hired as a new Coordinator, and will step into Laura’s old job as IACUC Coordinator. Bill was born and raised in Fort Collins, and recently moved back after spending 20 years in the Midwest. He comes to RICRO after working in grant development and sponsored projects administration for a dozen years. Bill is married to Jami Smith-Moseley, and they have two children, William (8 yrs.) and Katie (4 yrs.). When the busy schedule of two children allows, he enjoys fly fishing and camping with the family. Bill says he is “excited to join the RICRO team.” Bill can be reached at Bill.Moseley@Research.colostate.edu or 491-8060.

The second new face in the office is that of Ms. Molly Gutilla, who is joining us as the new Assistant Administrator of RICRO. Molly will cover the front desk, provide critical support to the Coordinators, and work with the Director on Responsible Conduct of Research (RCR) activities and special projects. Molly graduated from Ohio State University and then worked at Williams College and the University of Michigan, prior to arriving at CSU. On the weekends she can be found out in the mountains climbing or hiking.
Dr. Sellins also served as the RICRO Assistant Director, and with her departure, **Ms. Evelyn Swiss** has stepped up to fill the roles of Senior Coordinator for DRC and Assistant Director – she will also continue to work with the Senior IRB Coordinator, Janell Barker. We are pleased to have her insight and energy in this position. As RICRO takes on more Responsible Conduct of Research activities, her talents will come in handy!

**What’s in a name? Why HRC=IRB and ACUC=IACUC.**

Some of you may be aware of the new acronyms flying around RICRO and the campus. The names of two of our largest review committees have changed. The Human Research Committee (HRC) will now be called the Institutional Review Board (IRB); and the Animal Use and Care Committee (ACUC) will now be referred to as the Institutional Animal Use and Care Committee (IACUC). The memberships, policies and duties of these committees will remain the same, so why were the names changed, you might wonder. The reason we wanted to change the names was so that we could “conform” with institutional practices across the nation and around the world. As CSU researchers reach out to new partners, we hope to standardize and streamline our interactions, facilitating better communication and more successful collaborations. “IRB” and “IACUC” are terms used widely, recognized by most researchers, and respected by all who know of their work. It may take a little bit of effort for researchers to learn the new acronyms, but we hope that the long-term benefit of conforming to widely accepted terms will far outweigh the inconvenience.