Inside this issue:

- Featured Essay: RCR Training, Kathy Partin 1-2
- RICRO On the Road 3
- IRB Update: When can I Close my Protocol? 3
- Training Requirements Have Changed for Human Subjects Researchers 4
- Congratulations to IRB Members 4
- University Veterinarian Presents: Upcoming Workshops 4
- IACUC News: Alternatives Search Seminar 5
- Schedule of Upcoming Events and Deadlines 5
- Safety First! New OHSP Risk Assessment Requirements for LA- 6
- DRC News: Biennial Controlled Substances Inspection 6

Have you heard...?

Have you heard that more positive changes for PIs are in the works at RICRO? Here is just a sampling of a few of the main projects that are on our plates: Training requirements from federal agencies are changing, and RICRO is working hard to keep abreast of these changing requirements by bringing you new training opportunities to fulfill these requirements. One of these training opportunities is the upcoming Responsible Conduct of Research Workshop (June 9th, see pages 1-2 & 6). The IBC and DRC have been paperless for some time, and the IRB has recently gone paperless with the launch of the new online protocol submission-and-review system, eProtocol. The IACUC group at RICRO is next to go paperless, and is now working intensely to implement the IACUC module of eProtocol within the next few months. If you are interested in learning more about eProtocol for IACUC, please feel free to contact Laura (1-0236), Kathy (1-1563) or Bill (1-8060). If you have any questions about what is new at RICRO, please don’t hesitate to give our office a call (1-1553).

Wishing you all a lovely spring!
RICRO staff

RCR Training: What is it and do we need it?

There is much talk around RICRO and the campus about Responsible Conduct of Research, also known as “RCR,” training initiatives. RCR training is a broad term that can mean different things to different people, but essentially, the goal of RCR training is to impart upon trainees the professional ethical values we share as scientists and scholars. Some believe that the term should be “research integrity” or “academic integrity and scholarship,” because a diverse campus such as CSU has many types of research and scholarly activity for which such training is vital.

According to the PHS Office of Research Integrity (ORI), there are nine “core” competencies that encompass RCR training (http://ori.dhhs.gov/education/):

- Data Acquisition, Management, Sharing and Ownership
- Conflict of Interest and Commitment
- Human Subjects
- Animal Welfare
- Research Misconduct
- Publication Practices and Responsible Authorship
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science

You may also see mention of a “10th” core area, which, depending on the institution could be institutional biosafety, the ethical use of computers, social responsibility, or other relevant topics.

A determination of what needs to be taught to a trainee, and how it needs to be taught, can vary widely depending on the institution. Is the trainee an undergraduate doing laboratory research, a master or doctoral student, or a postdoctoral fellow? Clearly,
these trainees need different types of RCR training. Or, consider the training that a graduate student in biomedical sciences might need compared to that of an anthropology, chemistry, or electrical engineering student. Do they all need training on animal welfare or human subjects research? Another issue that can be hotly debated is how we most effectively train on ethics: what is the best teaching method? Many would argue that this is something best accomplished by direct, mentor-trainee tutelage.

This mode can be extremely effective; it can also be uneven and in the worst cases, incorrect. At CSU there are several RCR training course offered by individual departments. These, too, can be very effective because they can be tailored to specific disciplines, and are typically taught by researchers who are known and respected by the trainees. There are also online/distance venues for RCR training, including the very thorough Collaborative Institutional Training Initiative (CTII), which contains some 15 modules taking 8-9 hours to complete, with RCR training tailored to each of several disciplines: Biomedical Sciences, Social and Behavioral Sciences, Physical Sciences and Engineering, and Humanities (http://www.citiprogram.org). An institution can get good coverage with this type of delivery, but many would argue that these “out of the box” courses are not the most effective teaching tool.

These issues are being discussed urgently across the USA since the National Science Foundation (NSF) recently announced its implementation plan for Sections 7008 and 7009 of the America COMPETES Act, which deal with mandated RCR training for undergraduates, graduate students, and postdoctoral fellows. Section 7008 will require that a 1-page “Mentoring Plan” be included for all postdoctoral trainees listed on an NSF grant. This information had previously been included within the body of a grant, but will now be required as a 1-page supplement. It is hoped that this method of presentation of the mentoring information will allow reviewers to better assess the quality of the mentoring plan. Section 7009 would mandate that every institution (including CSU) develop a single, coherent “Institutional RCR Plan” for the training of all undergraduate and graduate students, as well as postdoctoral fellows. It is expected that Sections 7008 and 7009 will have to be implemented by October 1, 2009. And note, these mandates are for trainees, not the investigators themselves. Link for more information: http://edocket.access.gpo.gov/2009/E9-4100.htm

How should CSU respond to these new training regulations? Last month, Bill Farland, Senior Vice President for Research and Engagement, posed that question to a working group of NSF investigators, RCR educators, and research administrators. They responded with a letter that was sent back to NSF, supporting RCR training and raising some of the very issues discussed above. It is expected that there will be a great deal of latitude by NSF to allow an institution to tailor a plan that is appropriate for their activities. On the other hand, at CSU there are certainly many non-NSF-funded activities; will we require RCR training for all trainees?

The time seems right for CSU to take a serious look at these issues and start making some plans. On June 9th, 2009, there will be a workshop, hosted by the Office of the Vice President for Research and The Institute for Learning and Teaching (TILT), entitled “Building a Research Environment at CSU that Promotes Best Practices.” All are welcome to attend; to register, go to http://vpr.colostate.edu/rsvp.aspx or call Molly Gutilla (491-1553). The workshop will be led off by a keynote talk from an internationally acclaimed RCR instructor, Dr. Kenneth Pimple of the Poynter Center for the Study of Ethics and American Institutions. There will then be several work sessions focused on the who, what, where and why of RCR training at CSU in an “ideal” scenario. Can we find a shared vision and a consensus for a path to it? Certainly, this goal is more likely to be met if the right voices are heard at the workshop. We urge all undergraduate and graduate students, as well as postdoctoral trainees, faculty, and staff who are interested in this topic to join us.

What should RCR training at CSU consist of, and how do we deliver it to best empower our trainees to be successful and productive throughout their career? You are welcomed to join in this discussion!

Kathy Partin, Ph.D., RICRO Director
RICRO – On the Road!

This winter has been busy with travel for the RICRO staff. In November, Janell Barker and Evelyn Swiss attended the 2008 Advanced Research Ethics PRIM&R conference in Orlando, FL, and presented a poster concerning the transition from paper to an online system for protocol submission and review. The poster was co-authored by Evelyn, Janell, and Sylk Sotto (Compliance Director, DU). Bill Moseley attended the 2008 AALAS National Conference in Indianapolis, IN. Bill presented a poster co-authored by himself, Laura Martin, Denise Ostmeyer, and James Owiny, on the positive effect of business process changes on time to approval of IACUC protocols.

Also in November, Bill represented RICRO at Kuali Days VII, in Newport Beach, CA. The conference attracts institutions interested in the Kuali Foundation’s overarching effort to develop community-source enterprise software applications for colleges and universities. RICRO is involved in this effort because CSU is a partner institution and will be implementing an already-developed Kuali Financial Systems module later this year. Kuali is currently developing online compliance modules for human subjects and animal research, which CSU may use in the future. In an effort to ensure CSU has a voice in the process, Bill is helping with the development of the functional specifications for the IRB and IACUC modules.

In early March, Laura Martin and Kathy Partin visited the computer software development team at Key Solution, Inc., the developer of our new IRB online protocol submission and review system, eProtocol. Their visit was helpful in planning a smooth transition to paperless IACUC. As human subjects researchers already know, RICRO has just gone live with eProtocol IRB. Look for more from RICRO in the coming weeks about the process of going to eProtocol for the IACUC.

Laura Martin represented CSU at the PRIM&R 2009 Annual IACUC Conference in San Diego, CA, March 30-31, 2009. Laura presented a poster, co-authored by herself, Kathy Partin, and Bill Moseley, entitled “IACUC Oversight of Collaborative Work with the Private Sector and Federal Agencies.”

IBC Chair, June Medford, represented CSU at the “IBC Basics” session in San Diego, CA on March 12. Thanks for attending this session, June!

Kathy Partin and a crew from Sponsored Programs traveled to Santa Fe, NM for the NCURA Regional Conference on April 6-8, 2009. Along with Carmen Morales from Sponsored Programs, Kathy presented a workshop focusing on “Integrating the Activities of the Investigator, Sponsored Programs, and Compliance Review Offices to Facilitate Proposal Submission.”

IRB UPDATE

When Can I Close My IRB Protocol?

By Federal regulations, an approved IRB protocol must be reviewed by the IRB on an annual basis. Are you getting ready to renew an IRB protocol, but you are wondering if you could just close it? You may be able to close your protocol if you are no longer recruiting or interacting with participants, and will be continuing to analyze data already collected. Read on for the details! If you will be analyzing data that can be linked back to individuals (i.e., your data still has identifiers), the answer is that you must renew your protocol; this is still considered human subjects research. If, however, you are analyzing data with no identifiers, you can submit a Final Report on eProtocol to close out your protocol. To close your approved protocol: 1.) Navigate to approved protocols; 2.) Click on the protocol ID# that you would like to close; 3.) Select “Start Final Report;” 4.) You must be able to answer Yes to the first series of Yes/No questions; 5.) Click “Next” and complete questions 2-8; 6.) Click Submit Form. If your protocol is not yet uploaded into eProtocol, you can find the Final Report form on our website at: http://web.research.colostate.edu/ricro/hrc/forms.aspx (email the completed Final Report Form to: Evelyn.Swiss@Colostate.edu). Need more information? Contact Janell (1-1655) or Evelyn (1-1381).
Training Requirements Have Changed for Human Subjects Researchers

Until recently, only PIs were required to complete human subjects projection training at CSU; however, this has changed. The IRB feels it is important that the people who interact with the participants and/or the data have this training as well. The IRB training policy at CSU is now that in addition to Principal Investigators (PI), Co-Principal Investigators (Co-PI), and “key personnel,” on NIH-funded grants are required to complete one of our two methods of training. Although Co-PIs and NIH-funded key personnel are now required to complete training, we will have a grace period during which individuals can obtain human subjects training. Training must be updated every three years.

All researchers have two methods to obtain this training: On-campus and via CITI, a web-based training offered from the University of Miami: [http://www.citiprogram.org/default.asp?language=english](http://www.citiprogram.org/default.asp?language=english). CSU’s on-campus training currently consists of the history, ethics, federal regulations, and CSU procedures about protecting human subjects in research. To register for a campus session, please link to: [http://www.vivo.colostate.edu/hrc/hrctraining.php](http://www.vivo.colostate.edu/hrc/hrctraining.php). If you have taken the training in the past, but are not sure when your training will expire, don’t hesitate to contact Molly (1-1553) or Evelyn (1-1381), and we will let you know when you need to renew your training.

Congratulations to IRB Members!

Congratulations Toni Zimmerman on being named a University Distinguished Teaching Scholar!!!

Congratulations also to Steven Matthews on being selected as a "Distinguished Administrative Professional."

We have always known that Toni and Steve are extraordinary individuals! Way to go!!!

The University Veterinarian Presents:

Mouse Breeding 101
April 21st, 8-9 am in the Microbiology building, room A-101
This is a beginner/intermediate level class which will address mating schemes, colony planning and management and dealing with common problems that occur. Please RSVP to denise.ostmeyer@colostate.edu or 491-7184.

Sign up for the animal program listserv to get important announcements
There is a new listserv titled Animal Program which will be used to disseminate important news and announcements related to CSU’s animal care and use program. Every attempt was made to ensure that all animal research personnel were added to the list, however it is possible that some were inadvertently missed. If you have not received any communication from animalprogram@colostate.edu then you are not on the listserv. Please sign up! Just go to [http://www.acns.colostate.edu?page=frame&src= http%3a%2f%2fwww.colostate.edu%2fServices%2fACNS%2flistserv%2flsubother.html](http://www.acns.colostate.edu?page=frame&src=http%3a%2f%2fwww.colostate.edu%2fServices%2fACNS%2flistserv%2flsubother.html) and select ANIMALPROGRAM from the drop down menu, then fill out and submit the form.
IACUC News

Alternatives Searches Seminar

Mary W. Wood will present three seminars sessions on conducting adequate and efficient literature searches for animal use alternatives. The sessions are as follows:

May 21:
9:00AM-10:00AM, Painter A107A  Open session directed at research protocols
10:30AM-11:30AM, Painter A107A  Open session directed at research protocols
2:00PM-3:00PM, VMC A221  Open session directed at teaching protocols

Mary W. Wood is a veterinary and medical librarian at UC Davis, specializing in animal alternatives and animal welfare information. She has a BS from UC Davis in Entomology and an MS from UC Berkeley in Library Science. Mary collaborates nationally with USDA AWIC and Johns Hopkins CAAT, and internationally with NC3Rs (UK), ZEBET (Germany), NCA and Norina (Netherlands), and others.

SCHEDULE OF UPCOMING EVENTS: APRIL-JUNE, 2009

<table>
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<tr>
<th>DATE</th>
<th>EVENT</th>
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<tr>
<td>Tuesday, April 21</td>
<td>IACUC Meeting</td>
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<tr>
<td>Tuesday, April 21</td>
<td>Mouse Breeding 101 (8:00-9:00 a.m.) Microbiology, Room A-101</td>
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<tr>
<td>Friday, May 1</td>
<td>eProtocol Basics Training (9:00-10:30 a.m.) Room #340 General Services Building</td>
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| Tuesday, May 5     | IRB Human Subjects Protection Training Session + eProtocol Basics (9:00-Noon)
                     Room #340 General Services Building |
| Wednesday, May 6   | IBC Deadline (Noon)                                                 |
| Tuesday, May 12    | IACUC Protocol Submission Deadline (Noon)                            |
| Wednesday, May 13  | IBC Meeting                                                          |
| Thursday, May 14   | IRB Protocol Submission Deadline (New time: 5:00 p.m.)               |
| Tuesday, May 19    | IACUC Meeting                                                        |
| Thursday, May 21   | Mary Woods - Alternative Searches Seminar (see article above for times/locations) |
| Thursday, May 21   | IRB Meeting                                                          |
| Monday, May 25     | RICRO Office Closed                                                  |
| Wednesday, June 3  | IBC deadline (noon)                                                  |
| Tuesday, June 9    | Mark the date!! RCR Workshop (8:00-3:00) Fort Collins Hilton—Lunch is provided |
| Tuesday, June 9    | IACUC Protocol Submission Deadline (Noon)                            |
| Wednesday, June 10 | IBC Meeting                                                          |
| Thursday, June 11  | IRB Protocol Submission Deadline (New Time: 5:00 p.m.)               |
| Tuesday, June 16   | IACUC Meeting                                                        |
| Thursday, June 18  | IRB Meeting                                                          |
Safety First!

**New OHSP Risk Assessment Required for IACUC and IBC Protocols**

If you have been a part of a protocol submitted to the IACUC in the past month, you may have noticed a new requirement for protocol approval, namely the completion and submission of the Occupational Health and Safety Enrollment Program (OHSP) Risk Assessment Form. Federal regulations and Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) require CSU to provide occupational health and safety risk assessment for all protocol personnel working with animals or biohazards in research, testing or teaching. In order to fulfill that requirement, all individuals participating on IACUC protocols and IBC protocols involving rDNA at Biosafety Level 3 must fill out and submit the Risk Assessment Form to the OHSP.

Anyone who will be working with animals and/or biological pathogens (i.e. on an IACUC protocol or IBC protocol at Biosafety Level 3) should complete the Risk Assessment Form. This includes all students (both paid by CSU and not-paid by CSU), post-doctoral fellows, veterinary residents, CSU employees, individuals that work at other locations (e.g. CDOW, CDC, NWRC) and are not paid by CSU, volunteers, and contractors.

Additional information and guidelines for participation are forthcoming from Environmental Health Services. However, in order to speed the ability of the IACUC and IBC to approve protocols, PIs should be aware of this new requirement, and ensure that all personnel who will be working on the protocol are named in the personnel section, and that they have all completed the Risk Assessment Form and submitted it per the instructions on the form to the Assistant Biosafety Officer, Amanda Toot (Environmental Health Services, campus mail code 6021). If you are interested in finding out more about occupational health and safety concerns, including links to the CSU OHSP forms, information on hazards of working with animals, the use of Personal Protective Equipment, and Material Safety Data Sheet information, can be found on the University Veterinarian’s website at [http://web.research.colostate.edu/ACP/Default.aspx](http://web.research.colostate.edu/ACP/Default.aspx).

DRC News

**Biennial Controlled Substances Inspection**

The DRC will be holding biennial inspections during the week of April 27- May 1. A member of the DRC will be contacting all PIs with approval to store/use controlled substances in order to schedule a time to visit labs. If you will not be available to meet with the DRC member, please be sure to let the DRC member know the name of a person in your lab who has a key to your controlled substances, has access to the log-books, and who would be available to meet with the DRC member for the inspection. Please contact Molly Gutilla, DRC Coordinator, with any questions regarding this upcoming inspection. Molly can be reached at: 491-1553.