RICRO Welcomes Academic Year 2010-2011!

Temperatures lingering in the 90s, yellow school buses filled with Poudre School District children, packed school-supply isles at local stores. These are telltale signs that we have arrived at the dog days of summer, and are just about to embark on scholastic year 2010-2011 here at CSU. Whether you are new to campus or returning for another fantastic year, the staff at RICRO would like to send you a warm Welcome Back greeting. We hope that you have all enjoyed a lovely summer! RICRO staff has remained busy all through the summer, but we definitely have enjoyed the slightly slower pace than during the school year.

This issue marks a minor milestone for us: the 20th edition of the RICRO Report! Thank you for your positive feedback over the years, and remember that we welcome submissions and are always open to suggestions for topics to cover. In this issue, we will cover some late-breaking news concerning the Regional IBC group, RCR training, tips for eProtocol users, and much more! Please feel free to contact our office with any questions or suggestions on how we could improve this publication.

Best wishes for another tremendous school year!

Online RCR Training is Coming!!!

Undergraduate and graduate students, as well as post-doctoral fellows, who are engaged in research at CSU are now required by CSU to take an online Responsible Conduct of Research (RCR) training course. The online training is expected to be available by the end of September, and will be accessed through the CSU RCR website (http://rcr.colostate.edu). Additional ethics coursework is also a requirement for grant awards from some external agencies, such as the NIH and NSF. Information about ethics and responsible conduct training is available at the above website. If you have questions about ethics training, or grant requirements regarding RCR training, please contact Marty Welsch (RCR Coordinator; 491-4032).
RICRO Staffing Updates

A Fond Farewell to Molly Gutilla

As some of you may know, our IACUC Coordinator, Molly Gutilla, recently left CSU to begin a Ph.D. program in Public Health at the University of Colorado, Denver. Molly joined RICRO on Halloween 2007 as the front office Assistant Administrator, and recently moved into the IACUC Coordinator position. She brought forward-looking ideas and a contagiously positive attitude to the office. She is missed by one and all!

Molly holds a Master’s degree in Exercise Physiology, and moving forward to obtain her doctorate in Public Health (her area of focus will be epidemiology) is a fantastic path for her to follow.

Wishing you all the best, Molly, and don’t forget to stop by to visit your old friends at RICRO when you have a spare moment between homework, commuting, mountain climbing, or rowing!

Introducing…..

Renee Ikemire, Assistant Administrator

Renee comes to the Assistant Administrator position at RICRO with several years’ experience within school districts in the states of Colorado and Florida. Her most recent positions were with the Special Education Office Mountain BOCES in Carbondale, Colorado, and the Colorado Department of Education (Office of Special Education and Finance and Data) in Denver, CO. We are thrilled to have Renee’s computer-programming expertise and innovative ideas to help our office run at its best. In addition to her work at RICRO, Renee is pursuing an Associate Degree in Psychology at Front Range Community College, and is looking forward to taking classes at CSU in the near future. Welcome to CSU and RICRO, Renee!

Elaine Kim, IACUC Coordinator

Elaine Kim and her husband recently moved to Fort Collins from the San Francisco area. Elaine holds a BS degree in Bioresource Sciences with an Animal Science emphasis from the University of California, Berkeley. Elaine has had experience with IACUC issues from the researcher’s point-of-view, as she worked as a Research Associate at Berkeley, Genentech, and Exelxis, Inc. In addition to her Animal Science expertise, she has a wealth of knowledge about knitting and the fiber arts. Welcome aboard, Elaine!
The Ethical Care and Use of Animals Subjects: What You Need to Know about What the IACUC Wants to Know

During Fall 2010, the Research Integrity and Compliance Review Office is offering face-to-face training sessions related to the ethical care and use of animals. This interactive one-hour session will provide an overview of what you need to know about the ethical use of animals for research, teaching, or testing at CSU, and how to navigate the process of obtaining approval. The session is geared toward those individuals who are new to animal care and use at CSU, especially graduate students, postdoctoral scholars, and others who expect to need to complete protocol applications to the Institutional Animal Care and Use Committee (IACUC) for approval to conduct research, teaching, or testing involving animals.

The next session will be held:

2:00-3:00 p.m. Friday, September 10, 2010 in room 340, General Services Building

To register for this session please go to http://web.research.colostate.edu/ricro/acuc/training.aspx. If you would like to attend this session but are unable to make it, please check the above website later for additional dates when the training will be offered.

Documentation of Training of Laboratory Personnel

During the Spring 2010 Semi-Annual Inspections, the IACUC noticed that many laboratories and other groups that use animals for teaching and research did not appear to have a formal system for documenting the training of personnel working with animals in their employ. Documentation of the various training (e.g. animal handling, aseptic surgery, the ethical use of animals, occupational health, biosafety) that is required for all staff can be a daunting task, but ensuring that all individuals have received the required training is important. In an effort to assist investigators and laboratory managers with this task, the IACUC suggests that you consider using the training documentation document that is available on the RICRO website at http://web.research.colostate.edu/ricro/acuc/documents/TrainingRecordTemplate.doc.

IACUC Fall 2010 Semi-Annual Facility Inspection Approaching

The Fall 2010 Semi-Annual IACUC Inspection of the Animal Facilities will be held during the month of October. Look for more information as the time for the inspection comes around. We will be contacting PIs of protocols which indicate the use of animals outside of the central animal facilities as well as the directors/managers of central animal facilities to let you know the times that IACUC representatives will be inspecting the various facilities where animals are housed and/or used for research and teaching. The committee appreciates investigators and/or laboratory staff being available to show the inspection teams around the facilities and answer any questions they might have. The IACUC members also appreciate getting a chance to visit with laboratory personnel. As so much of the committee’s work is done without contact with the individuals carrying it out, the committee likes to be able to put faces and names together, and they hope that the opportunity for personal connection is likewise enjoyed by investigators and their staff. Thank you to all who assist with this important federally mandated function.
Updated Changes Regarding IACUC Annual Renewals

Our office is currently in the process of migrating IACUC approvals of protocols that were submitted and approved prior to the implementation of the online protocol system into eProtocol. Currently, we are accepting annual renewal forms for protocols that are NOT in eProtocol via submission of the old-fashioned A-101 form (http://web.research.colostate.edu/ricro/acuc/documents/A-101.Dec.29.2009.doc). Please just send the completed A-101 form to one of the IACUC Coordinators (Bill Moseley or Elaine Kim) via email or campus mail. Protocols that were initially reviewed and approved in eProtocol must be renewed using the online system (https://csu.keyusa.net).

A good rule of thumb you can use to determine if your protocol must be renewed in eProtocol or using the old-fashioned A-101 form is that if the protocol was submitted prior to October 2010, it is likely not in eProtocol, and so you would use the A-101 form. Any protocols submitted after October 1, 2010 were reviewed and approved in the online system, and therefore you will need to renew using the “Create Continuing Review” option in eProtocol.

A help document with basic instructions on creating and submitting a renewal in eProtocol is available on our IACUC eProtocol help page: http://web.research.colostate.edu/ricro/eprotocol.aspx?Area=IACUC.

Look for additional information from RICRO when we have migrated all of the pre-eProtocol protocols into the online system. At that point renewals and closures will all be handled through the single online system.

Changes to IACUC Policies and Guidelines

Please note that the IACUC has approved some new policies and revisions to existing ones and also created some guidelines in the past year or so. Some new/revised policies that you may not be aware of are:

- Purchasing Animals at CSU
- Use of Expired Materials in Research/Testing/Teaching Animals
- Policy on the Exercise of Dogs

Some guidelines that you may not be aware of are:

- Guidelines on Pain Categories
- Guideline on Environmental Enrichment
- Directions for CO2 Euthanasia of Rodents
- Use of Non-Steroidal Anti-Inflammatory Drugs in Immunological Research

Being aware of these policies and guidelines can be of tremendous assistance to investigators as they prepare protocols for IACUC review and approval. The CSU IACUC Policies and Guidelines are available online at http://web.research.colostate.edu/ricro/acuc/policies.aspx.

USDA Announces New Misconduct in Science Policy

The US Department of Agriculture (USDA) announced this month its Final Rule on Research Misconduct Regulations for Extramural Research, published in the Federal Register (75 FR 49357). Within this policy USDA defines research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.” This definition is very similar to the definitions used by the NSF, NIH and CSU, as are many other components of the policy. For example, there is a specific requirement for the protection of whistleblowers who bring good faith allegations against another party; and, there is a requirement that the USDA be notified at the time CSU initiates a misconduct in science Investigation. Questions about misconduct in science allegations at CSU should be directed to Hank Gardner, Associate VP for Research and Research Integrity Officer (RIO).
Regional Biosafety Group becomes Front Range Biological Safety Association (FRaBSA)

We are pleased to announce that at its August 13, 2010 meeting, the Regional Biosafety Group changed its name to the Front Range Biological Safety Association (FRaBSA) and elected its first board. FRaBSA was organized to allow collaboration and exchange of ideas among the biosafety programs of academic and private institutions along the Rocky Mountain Front Range, and aspires to become an Affiliate of the national American Biological Safety Association. FRaBSA held its meeting at the Research Innovation Center (RIC) on the foothills campus, allowing CSU to showcase to other members its new, state-of-the-art research facilities. Inaugural board members are:

♦ Christine Johnson (Colorado State University) – President
♦ Dean Calhoun (Affygility Solutions) – President-Elect
♦ Lolly Gardiner (Midwest Research Institute) – Secretary
♦ Charles Stith (University of Wyoming) – Treasurer
♦ Denise Donnelly (University of Colorado-Boulder) – Councilor
♦ Gabriel Garcia (Colorado State University) – Councilor

Other highlights from the meeting included interesting and informative research presentations from Drs. John Belisle, Herbert Schweizer, and Richard Bowen. The co-hosts of this month’s meeting, Christine Johnson and Jerry Tews, would like to thank all participants, particularly the guest speakers. Congratulations to all the new board members and thank you for your willingness to serve. For more information about FRaBSA or to find out how to become a member, please contact Christine Johnson at Christine.Johnson@colostate.edu.

Training Offered by the University Veterinarian’s Office…

Hands On Rodent Necropsy Workshop

LAR Veterinary Residents are the instructors for this workshop. The session will include necropsy of mice and rats.

When: Friday, September 3rd - 9:00 a.m. to 12:00 p.m.
Presented by: LAR Veterinary Residents
Where: Physiology, Room #121

Pre-registration is required, and the class is limited to 10 participants. For more information, contact the Animal Program Coordinator at:

TEL: 491-7184
EMAIL: denise.ostmeyer@colostate.edu; or
Navigate to: http://web.research.colostate.edu/ACP/VetTraining_HandsOn.aspx

Researchers with Mouse colonies: You may wish to check out JAX Colony Management System (JCMS): A free software application designed to help you manage your colony. For more information, link to: (http://colonymanagement.jax.org/).
IRB Basics - Consent Issues, Part II

As we discussed in our "IRB Basics - Consent" article this past May, informing your participants of what you are asking them to do and obtaining their permission (i.e., consent) to participate in your research project is a vitally important process for all studies involving human subjects.

The method of consenting your participants that the IRB expects researchers to use is documented or "signed" consent (i.e., it is considered the default form of consent). If you will be meeting with your participants in person (e.g., one-on-one interviews or focus groups), you are able to obtain signed consent and the IRB would expect that you would obtain signed consent. Please see the last RICRO Report IRB article for instances when not obtaining signed consent might be appropriate for a study.

Here are a few tips to help you create a well-written signed consent document:

To get started creating your documented consent form, we suggest that you use our Consent Form Template. You can locate our template at: http://web.research.colostate.edu/ricro/hrc/forms.aspx

- This template is a Word document. Simply “save as” and modify with your specific information. Please modify each section for your study. There are a few sections on the template that can be deleted if they are not applicable to your study (please see the consent template for these specific sections), but for the most part, please complete each section of the consent document.

- Remember that obtaining your participants’ consent is a process, not just a document. Use conversational language to bring the reader into the document. For example, instead of saying “The participant in this study will be asked to…” simply say “You will be asked to…” Refer to the participant as “you” throughout the document.

- Your participants are probably not experts in your field of research, be considerate to them and use lay language throughout the document.

- Pay special attention to the readability level on your consent form. The IRB asks that your consent documents be written at the 6th-8th grade reading level. You can determine what reading level your consent is written at by using the spelling/grammar check in Word (where you will be given the Flesch/Kincaid Readability Grade Level).

- The details count! Include each section in the model consent form. Be sure that the footers are placed correctly on each page, contact details are accurate, etc. It’s these little details that can take time when finalizing approval for your project. Taking time to get it right from the start helps the review process go smoothly and more quickly.

When submitting your protocol, you will be uploading your consent document in the consent section of your protocol (section #9 on the social behavioral form, or section #13 on the biomedical form). In addition to uploading your document, please be sure to answer all the consent process questions below the browse section of the screen.

Please feel free to contact the IRB Coordinators to discuss your project and what method of consent would be best: Janell (491-1655) or Evelyn (491-1381).
Congratulations all eProtocol users! The IRB has been using the live eProtocol system since December 2008, and the IACUC went live with eProtocol nearly a year ago. We know that change is never easy, but 1-2 years from its launch here at CSU, we are thrilled to report that researchers are routinely logging in and successfully submitting protocols, amendments, continuing reviews, etc. We thought we would share some tips for success with the system to help your online experience be an even more pleasant one:

Where is my Approval Letter? One of the most popular and convenient features of eProtocol is that anyone listed on a protocol (in the PI, co-PI, Admin. Contact, Dept. Head, or Other Submitter role) has access to the approval letter at all times. To access your approval letter: 1. Go to your approved protocols; 2. Select the protocol (mousing over the ID numbers will reveal the complete protocol title to help with protocol selection); 3. Click on the ID# and select to “Open in View Mode”; 4. Click on “Event History.” You will see a link to a .pdf of the approval letter(s) on the right-hand side of the Event History table.

But—I thought I had submitted my form? If you have tried to submit your IACUC or IRB protocol and the status of the protocol on your homepage still says “Yet to Submit to IACUC” or “Yet to Submit to IRB,” you will know that we have NOT received your protocol. The most common reasons that forms are not successfully submitted? Not clicking the small box on the “Obligations” page (your electronic signature) for human subject researchers and/or not clicking “Submit Form.” Note that if you clicked the “Submit Form” button and the system indicated that there were any questions that needed to be completed, you will need to complete the missing questions and then hit the “Submit Form” button again to submit the protocol.

Let’s get technical for a minute - Internet Explorer 8, Pop-up Blockers, and form navigation. For all web browsers, be sure that you have your pop-up blocker turned off when attempting to use eProtocol. Also, be sure to run eProtocol in “compatibility mode” if you are using Internet Explorer 8. For information on how to do both of these things, please visit our eProtocol help page http://web.research.colostate.edu/ricro/eprotocol.aspx.

Oops! I created this form by mistake!! Can I get it off my homepage? Yes! For both the IACUC and the IRB modules, you can delete any form that has not been submitted/reviewed. On your homepage, you will see three powerful buttons: Create Protocol, Clone Protocol, Delete Protocol. Click “Delete Protocol,” and you will see a list of created but not submitted forms. Select the form you would like to delete, and click “Delete.”

IRB/IACUC - Responding to the reviewers’ comments. 1. Respond to the comments in the response boxes (remember to Save your response); 2. Click “Get Protocol” to Update the Protocol (including uploading revised attachments, if applicable); 3. Close the protocol (you will now be back on the response screen); 4. Click the “Submit to IACUC” or “Submit to IRB” button; 5. Click “Yes” to confirm that you would like to submit your response. The status on your homepage will be “Responses Sent.”

Who is the best person to call if I’m having technical problems with the system? If you have technical problems with the system, please contact our eProtocol technical support help desk at RICRO_eProtocol_Help@mail.colostate.edu or (970) 689-0641. If you prefer a do-it-yourself approach, we have numerous help documents available on our eProtocol help page at http://web.research.colostate.edu/ricro/eprotocol.aspx. You can also submit a Help Ticket at this site.
## SCHEDULE OF UPCOMING EVENTS
### August-October, 2010

<table>
<thead>
<tr>
<th>DATE</th>
<th>EVENT</th>
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<tbody>
<tr>
<td>Tuesday, August 24</td>
<td>IACUC Meeting</td>
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<tr>
<td>Thursday, August 26</td>
<td>Human Subjects Protection Training (9:30 am – 12 pm) Room 340 General Services Bldg.</td>
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<tr>
<td>Wednesday, September 1</td>
<td>IBC Protocol Submission Deadline (Noon)</td>
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<tr>
<td>Friday, September 3</td>
<td>Rodent Necropsy Workshop, Physiology Room #121; 9:00 a.m. - noon</td>
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<tr>
<td>Monday, September 6</td>
<td>Office Closed – Labor Day</td>
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<tr>
<td>Wednesday, September 8</td>
<td>IBC Meeting</td>
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<tr>
<td>Thursday, September 9</td>
<td>IRB Protocol Submission Deadline (5:00 pm)</td>
</tr>
<tr>
<td>Friday, September 10</td>
<td>Human Subjects Protection Training (9:00 am – 12 pm) - Room 340 General Services Bldg.</td>
</tr>
<tr>
<td>Friday, September 10</td>
<td>IACUC Training (2 pm - 3 pm)</td>
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<tr>
<td>Tuesday, September 14</td>
<td>IACUC Protocol Submission Deadline (5:00 pm)</td>
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<tr>
<td>Thursday, September 16</td>
<td>IRB Meeting</td>
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<tr>
<td>Thursday, September 23rd</td>
<td>Grad 544 (RCR Core Competencies) begins</td>
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<tr>
<td>Tuesday, September 28</td>
<td>IACUC Meeting</td>
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<tr>
<td>Wednesday, October 6</td>
<td>IBC Protocol Submission Deadline (Noon)</td>
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<tr>
<td>Tuesday, October 12</td>
<td>IACUC Protocol Submission Deadline (5:00 pm)</td>
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<tr>
<td>Wednesday, October 13</td>
<td>IBC Meeting</td>
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<tr>
<td>Thursday, October 14</td>
<td>IRB Protocol Submission Deadline (5:00 pm)</td>
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<tr>
<td>Thursday, October 21</td>
<td>IRB Meeting</td>
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<tr>
<td>Thursday, October 21</td>
<td>Communication Symposium Workshop at the Hilton (2 pm – 5 pm)</td>
</tr>
<tr>
<td>Tuesday, October 26</td>
<td>IACUC Meeting</td>
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### Who Do I Contact with Questions Regarding Controlled Substances?
With Molly Gutilla’s resignation from RICRO, Evelyn Swiss has resumed her duties as the DRC Coordinator. If you have any questions or concerns regarding approval to purchase/use Controlled Substances in your research projects, please feel free to contact Evelyn at: 970-491-1381 or the Chair of the DRC, Rick Allen, at 970-297-1291. REMINDER to PIs with current DRC approvals: Please remember to submit your renewal to use controlled substances by December 30, 2010.