What is Post-Approval Monitoring? - Lynne Kesel, DVM

Dr. Lynne Kesel joined RICRO to act as coordinator of Post-Approval Monitoring (PAM) for the IACUC the first of February on a six-month reassignment from Laboratory Animal Resources. Dr. Kesel brings to the position more than 30 years’ experience as a laboratory animal veterinarian and a principal investigator for both teaching and research protocols. She was involved with the IACUC in its very beginning at CSU when it was called the Animal Care and Use Committee (ACUC). She has also spent many years as a visitor or voting or non-voting member of the IACUC.

In the past, the main reason the IACUC reviewed animal protocols after approval was in response to concerns reported to the committee by individuals (who could remain anonymous). This reactive mode has been replaced by proactive visits to research studies using animals, which are consistent with federal guidelines instructing the IACUC to monitor animal welfare after a protocol is approved.

Prioritizing PAM Visits:

Because the IACUC has about 600 active studies at any one time, Lynne is prioritizing her PAM visits in the order listed below. Contacting investigators with single studies was found to be inefficient and non-productive because many studies, although listed as active, actually have no procedures ongoing with the animals, and “bunching” of protocols was begun. This is more of an economical use of the time of PAM personnel and investigators. Scheduling is done at the convenience of the investigators.

What Should I Expect During a PAM Visit?

When PAM staff visit a study, there are several aspects that are examined, including:

- Husbandry and condition of animals,
- Health records,
- Veterinary care,
- Drugs,
- Facility concerns,
- Training and other records,
- Personnel concerns

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Since animal welfare is the main charge of the IACUC, Lynne has tried to schedule observations of procedures with animals as well. All procedures should be conducted as described in the protocol.

Since February, Lynne, with the assistance of members of the IACUC, has reviewed several protocols for the IACUC, as well as concerns reported to the committee. The close “second look” has given the IACUC the confidence of knowing procedures will be done as approved and has allowed investigators to fix minor details which may have been overlooked in the original protocol.

Have more questions about the PAM program? Lynne Kesel can be reached at:
Lynne Kesel, DVM,
lynne.kesel@colostate.edu
(970) 491-5241

**RICRO Welcomes Karen Dobos as Associate Director**

Karen Dobos joined our office as the Associate Director of RICRO in April of this year. Her appointment will predominately serve to assist Dr. Partin with the day-to-day operations of RICRO, in addition to addressing special projects and short-term needs in line with the needs of the director, the mission of RICRO, and in continuing to support CSU as a premier research institute. Karen will maintain her position as an Associate Professor in the Department of Microbiology, Immunology, and Pathology, where she and her laboratory have a strong extramural research program primarily with funding from the American Type Culture Collection (BEI resources) and Bill and Melinda Gates Foundation, as well as active participation with UCSF in an NIAID Partnerships for Biodefense grant. Karen's goal is to strengthen partnerships between research administration and research faculty at CSU, as well as assist partnerships and relationships with sponsors and agencies governing regulated research. Dr. Dobos looks forward to learning about and the processes germane to maintaining and enhancing CSU’s regulated research environment to best serve CSU and welcomes any correspondence in this regard.

Karen can be reached at: Karen.Dobos@colostate.edu; or 491-2229.

**Elaine Kim - Now Senior IACUC Coordinator**

Here at RICRO, we are going through a lot of changes, a couple of which affect the IACUC staff. With Bill Moseley’s move to Sponsored Programs, we are pleased to announce that Elaine Kim has been promoted to Senior IACUC Coordinator. Elaine has been with RICRO since the summer of 2010, and brings a wealth of knowledge and expertise from her 4 years of dedication to the IACUC here at CSU, and her work as a Research Associate at Berkley, Genentech, and Exelixis. Congratulations Elaine! A search is currently being conducted to find a new Assistant IACUC Coordinator. In the meantime, the new RICRO Associate Director, Dr. Karen Dobos, is assisting with protocol and amendment review, and the RCR Coordinator, Dr. Carolyn Broccardo, is assisting with renewals, closures, and personnel amendments. As always, if you have any IACUC-related questions, please call RICRO and we will be happy to help you out.
Institutional Review Board (IRB) News

Staffing Update:

Janell Barker, Senior IRB Coordinator since 2003, has been on leave for the last few months, and has made the decision to leave her position to spend more time with her husband. Janell’s expertise and dedication to the IRB and CSU will be greatly missed by her co-workers, researchers, and the IRB. Janell has worked in the field of research administration for over 30 years, and her knowledge base has been an invaluable resource. We thank her for her service, and wish her all the best in her future endeavors.

Janell’s IRB partner in RICRO since 2007, Evelyn Swiss, is now the primary IRB contact, and can be reached at: Evelyn.Swiss@colostate.edu; 970-491-1381. In Janell’s absence, Evelyn has been fielding a heavy load of emails and protocol questions. She thanks you in advance for your patience as the IRB is in this transitional period. A search is underway to recruit a new full-time Assistant IRB Coordinator.

RICRO is hosting an informal Farewell Party for Janell Barker, and You Are Invited!

- Date: Wednesday, June 18, 2014
- Time: 11:00 a.m.—1:00 p.m.
- Location: RICRO, 321 General Services Building

RSVP not required. For more information, please contact Emily Bauer at: 491-1553

Thank you, Laurie Biela!

Those of you who have recently submitted a continuing review or a new protocol submission may have already received an email or phone call from Laurie Biela in her capacity as part-time IRB Coordinator. With the IRB being short staffed over the past few months and the stream of new-protocol activity remaining high, RICRO has been fortunate to have assistance from Laurie Biela.

Currently, Laurie splits her time between the Department of Health and Exercise Science (HES) and RICRO. At HES, Laurie is the lab manager of the Translational Research on Aging and Chronic Disease Lab and Clinical Trials Administrator for departmental regulated research. At RICRO, Laurie has been assigned to handle new-protocol intake review and processing the approvals of continuing reviews. She received her degree in Molecular Biology and Biochemistry from CU Boulder. She has a diverse background in the sciences ranging from care and enrichment of macaques, to working in quality control analytical chemistry laboratories, to performing electrophysiology on Drosophila larvae. Laurie’s varied background within the biomedical sciences has been a real asset to the IRB, and we are so grateful for her assistance in this busy, transitional time for the IRB.

When Laurie is not at the lab directing traffic, writing standard operation procedures or processing protocols, she enjoys gardening, camping, and hanging out with her awesome friends and family alongside her husband Vince.
External Review of IACUC Program & INSTAR: What’s developing at CSU

As you may have heard, one of the new Vice President for Research’s (VPR) initiatives is focused on “Infrastructure for Innovative and Agile Science and Technology Applications in Research,” aka “INSTAR.”

The goal of this initiative is to establish innovative and streamlined practices that enable research, foster collaborations, and encourage an adaptive approach to research administration. Two INSTAR activities have been undertaken. The first was an external review of the CSU animal care and use program, in which many of you participated (thank you). The result of that was a final report to Dr. Alan Rudolph. Alan will be working with constituencies of animal research on campus to study the recommendations and implement changes that will improve service to faculty researchers using animals.

A second INSTAR initiative is the external review of research administration, being performed in collaboration with Huron Consulting Group, to examine the life cycle of grant proposals at CSU with the idea of identifying areas for which service could be improved. Again, many of our faculty have met or will be meeting with the consultants who are gathering vital information about our current processes. We look forward to the completion of their work, as well as the final report they will provide to the VPR. Follow this story, as well as other exciting news from the VPR, with the Office of the Vice President for Research at CSU blog, http://vproffice.wordpress.com/.

IRB Website Updates

We hope that you have noticed several recent enhancements and updates to our IRB website. We will be adding more information and updates in the near future, but current updates include:

- A large group of consent and recruitment templates (e.g., layered consent template, verbal recruitment, online anonymous survey consent.)
- Recruitment Worksheet (What should be included on a recruitment flyer? Use this worksheet while you develop your files.)
- Tips on readability of documents and many helpful resources for creating your consent materials at the appropriate reading level
- Details for protocol submission: Exempt, Expedite and Full board
- eProtocol tips (e.g., How can I delete a form I created by mistake?)
- Guidance documents (Covering topics such as research that includes deception, research within the public schools, participant compensation, etc.)
- Quick access to the federal regulations, IRB blogs & resources, online ethical principals in research, etc.
- Up-to-date list of all researchers with current human subjects protection training. Do you wonder if your training is up-to-date, check it out here!
- Information for YOUR research participants in English AND in Spanish! (A huge Thank you to Noa Roman-Muniz for the Spanish translation of this information!)

The IRB site also includes a live Twitter feed from many research organizations that may be of interest to you. Be the first to know when HHS, FDA, PRIM&R, NIH, APA, NSF make an important announcement (these organizations have embraced Twitter, and Tweet throughout the day)! The live feed is on the bottom of the Twitter section (Research Organizations). The top section includes Tweets that may be of particular interest that I have re-Tweeted (RT).

We welcome your feedback, and please let me know if there are tip sheets or additional information that you would like us to include on the website. It’s a work in progress, and as we find the time, our goal is to provide you as much helpful guidance as possible.

Wishing you all a wonderful summer, and I hope to hear from you soon! Evelyn Swiss, CIP, Senior IRB Coordinator

Evelyn.Swiss@colostate.edu; 970-491-1381
Responsible Conduct of Research (RCR) SUMMER WORKSHOP:

Do you need face-to-face Responsible Conduct of Research (RCR) training, but don’t have time for a class this Fall or Spring? No worries! We are providing a one-day (8 hour) workshop that will meet all federal and CSU requirements for RCR instruction. The workshop is free and open to all graduate students and postdoctoral fellows; fellowships funded by NIH, NSF, and USDA who require face-to-face RCR/ethics training are particularly welcomed. Free breakfast and lunch will be provided.

Topics to be covered include: Data ownership, responsible authorship and publishing, research misconduct, collaborative science, COI, human and animal welfare protections, and mentor/trainee relationships.

⇒ **Date:** Friday, August 8, 2014
⇒ **Location:** Grey Rock Room, Lory Student Center
⇒ **Time:** 8:00 a.m.– 5:00 p.m.

[Click here for more information and to register.](#)

For inquiries, please contact Carolyn.Broccardo@colostate.edu

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**Schedule of Events**

**June—August 2014**

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<tr>
<th>June</th>
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<td>19 IRB Meeting (at Ram's Horn)</td>
<td>2 IBC Deadline</td>
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<tr>
<td>24 IACUC Meeting</td>
<td>4 <em>University CLOSED</em></td>
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<td>8 IACUC Deadline 12:00pm</td>
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<td></td>
<td>9 IBC Meeting</td>
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<td>9 UV-Basic Training Techniques w/ Mice</td>
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<td>9 UV-Rodent Anesthesia</td>
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<td>9 UV-Rodent Necropsy/Dissection</td>
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<td>10 IRB Deadline</td>
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<td>17 IRB Meeting</td>
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<td>22 IACUC Meeting</td>
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<th>August</th>
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<tr>
<td>6 IBC Deadline</td>
<td>8 RCR Summer Workshop</td>
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<tr>
<td>12 IACUC Deadline</td>
<td>13 IBC Meeting</td>
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<td>14 IRB Deadline</td>
<td>21 IRB Meeting</td>
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<tr>
<td>25 Fall Classes Begin</td>
<td>26 IACUC Meeting</td>
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National Science Foundation/National Science Board: “Reducing Investigators’ Administrative Workload for Federally Funded Research”

On March 10, 2014, NSF released the findings from a Task Force on Administrative Burdens that had been charged with “examining the administrative workload of investigators that receive Federal funding.” This is a topic that is a constant in the review & decision-making of the faculty and community members that make up our ethics review committees. There are numerous proposed changes to regulations in the near future that aim to address researchers’ workload.


Human Subjects Research and IRBs: Page 11

Animal Research and IACUCs: Page 13

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**Where to find RICRO**

**Physical Address:**
321 General Services Building
Colorado State University
Fort Collins, CO 80523-2011

**Mailing Address:**
Research Integrity & Compliance Review Office
Colorado State University
2011 Campus Delivery
Fort Collins, CO 80523-2011

**Phone:** (970) 491-1553
**Fax:** 491-2293
**Email:** RICRO@research.colostate.edu

**Summer Hours:**
Weekdays: 8:30 am - 4:30 pm
Responsible Conduct of Research (RCR)

SUMMER WORKSHOP

Friday, August 8, 2014

Grey Rock Room, Lory Student Center
8-5 pm

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or visit http://ricro.colostate.edu/events.htm