



Research Tips

University of Colorado Denver

Vice Chancellor for Research: RJ Traystman

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Stimulus Funding Update (ARRA)

As of February 17, 2010, UC Denver has submitted 590 ARRA proposals and received ARRA funding for a total of 134 ARRA awards funded at \$54,672,298.

Colorado Multiple Institutional Review Board (COMIRB)

Investigators are reminded that Office for Human Research Protection (OHRP) considers the institution and the investigator are engaged in research if UC Denver is the primary recipient of the grant award even if no other activity is occurring at this site. The PI is still required to obtain IRB approval for the protocol from COMIRB or work with COMIRB so that we can cede to another IRB that will be primarily responsible for the research under the sub-contract. For more information please see the DHHS "Guidance on engagement of institutions in human subject research" available at <http://www.hhs.gov/ohrp/policy/index.html#engagement>.

Biosafety

Shipping of Hazardous Materials & Compliance

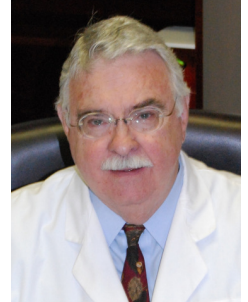
There are specific federal standards for meeting packaging, labeling, documentation and training requirements if you or anyone in your laboratory is shipping hazardous biological, chemical or radioactive materials.

The Federal Aviation Administration and US Department of Transportation can make unannounced inspections of laboratories that ship materials from UC Denver. They typically review the documents of carriers (e.g. FEDEX, DHL, etc) and then pick which labs to visit. They review for compliance with federal and international shipping regulations (DOT, IATA) and documentation that personnel are correctly trained.

Specific training is offered for those laboratories who ship biological materials, through the University Employee Learning & Development (Skillport) on-line training. To access Skillport, you must log in to My.CU.edu and click on the "MY.Training" tab.

If you have shipping questions, please contact the Department of Environmental Health and Safety at (303) 724-0345.

Dr. T's Corner



Colorado Multiple Institutional Review Board (COMIRB) Update

As discussed in the September 15th Research Tips newsletter, we are working to improve timelines for review of research protocols by COMIRB. I would like to give you an update as to what we have done since that newsletter item appeared. As you may remember, there were 5 broad initiatives: 1) to increase membership on the review panels with members who have appropriate expertise so that protocols can be reviewed more efficiently. In this regard, I would like to thank the department chairs from Cardiology and Infectious Disease for facilitating new membership in these fields. However, we still have an urgent need for expertise in the areas of endocrinology, psychiatry, maternal health, and neonatology. The Colorado Clinical Translational Science Institute (CCTSI) has provided a list of faculty who have expressed an interest in joining COMIRB, and we are in the process of following up with these individuals to begin training. 2) to expand the pediatric review capacity to include an additional panel and to distribute the volume across the panels. We are taking a step up approach by first increasing the membership of the existing pediatric panel. We will then work to increase the administrative support to this panel. Finally, after processes are in place and training of new members has occurred, we will structure the pediatric panels to function as parallel panels similar to the structure we have for the adult panels. We are exploring several ways to achieve increased capacity with the reality of limited financial resources. 3) the need to have resources outside of COMIRB to help and assist investigators within the regulatory knowledge and support core of the CCTSI. We are adding a staff person to act as such a resource for pre-review and assistance with protocol submissions. For the pediatric protocols, KC Clevenger at the Children's Hospital (Clevenger.kc@tchden.org) is currently available on a part-time basis for review assistance. The volume of expedited and exempt protocols has increased 35% over the last calendar year. This increased volume has led to delays in protocol review timelines and has lengthened the timeline for approval. 4) to add an additional full-time individual to this team and restructure administratively to produce maximum efficiency. We have increased the staff and are currently working to restructure efficiently. Currently exempt review is at 2-3 weeks, and expedited review is at 5-6 weeks. We anticipate the cycle times to continue to improve as electronic submission is brought online. 5) to improve efficiency by the use of an electronic submission system (InfoEd). Training sessions have been held bi-weekly since October to enable faculty and study staff to access the system. Dates for these training sessions are on the COMIRB website at the new address <http://comirbweb.uchsc.edu/portal/infoed.cfm>. Electronic submission of protocols will begin in January for requests for exemption only. Once the system has been tested for this process, then submission for new, initial, expedited and full board reviews will follow this spring. If you have any questions regarding COMIRB, please contact Alison Lakin at Alison.Lakin@UCDenver.edu.

Research Corner

Dr. Barbara J. Walkosz is Associate Chair and Associate Professor in the Department of Communication at the University of Colorado Denver (UCDenver). She received her BS in Political Science from the University of Minnesota and her MA in Communication



Barbara J. Walkosz, PhD

from UCDenver. She received her PhD in 1996 in Communication from the University of Arizona. She was appointed Assistant Professor in the Department of Communication at UCDenver in 1997. In 2004, she was appointed Associate Professor, and in 2007 became Director of Graduate Studies in the same department at UCDenver. Barbara and her colleagues Drs. David Butler and Allan Wallace have been awarded \$2.8M from the National Cancer Institute to study "Sun Safe Work Places: A Campaign on Sun Protection Policies for Outdoor Workers". Skin cancer is a national priority because it is the most common cancer in the United States with over one million cases of skin cancer diagnosed annually. Unprotected and excessive exposure to ultraviolet radiation is a primary risk factor for skin cancer so skin cancer incidents could be decreased with some safety practices. A work place risk that has received limited attention is sun protection, despite the fact that 8% of the United States workforce work outdoors. In previous studies without outdoor workers funded by the National Institutes of Health and the Colorado Cancer, Cardiovascular and Pulmonary Disease Program, Barbara's research team has demonstrated that sun safety education can promote sun protection at work. In this new project, she and her team will systematically study a more comprehensive approach to workplace sun safety that goes beyond employee education to promote institutional change. A proactive campaign to change workplace sun protection policies and promote sun safety to managers rather than individual employees will be implemented and evaluated. This research group will be working with public employers in the city, county, and special districts throughout Colorado to develop workplace policies that address sun protection.

RC1 Animal Facility to Close for Decon on March 31, 2010

OLAR will close the RC1 animal facility on March 31, 2010. Please be sure that you have timed your experiments to finish your experiments and all animals (rodents and non-rodents) are removed by this date. Please note that mice that have been in RC1 will NOT be permitted to enter R2. If you work with mice and are planning on transferring your studies to R2, please note that all mice must be rederived into the R2 facility, brought in from a non-routine source and quarantined, or purchased from a standard vendor. Rats, gerbils and fish are the only other species permitted in R2. Researchers that use other species will need to plan a shut down of studies for the few weeks that the RC1 facility is closed for decontamination. [OLAR has the following guidelines for completing studies in RC1 by the March 31, 2010 deadline:](#)

- All non-rodent animal orders will be scrutinized for project finish date starting immediately.
- All rodent orders set for arrival into RC1 will be scrutinized for project finish date starting March 1, 2010
- Breeding for colony maintenance (not experimental procedures), should end by March 1, 2010
- All euthanasia requests should be submitted to OLAR by March 15, 2010 for a guarantee that the animals will be taken care of by the date requested. Otherwise, please expect delays.
- Please communicate early with the R2 facility if you plan to bring equipment from RC1 to R2. All equipment must be decontaminated, and due to demand the schedule may be 2 weeks out.
- Only bring down disposables that you will use between now and when you vacate the facility.
- Please clear out all cabinets, unless you are leaving hard equipment for decontamination. All disposable items, including paper, will be disposed of in the decontamination process.
- All keys issued to RC-1 (both animal rooms and cabinet keys) must be returned. We can accept them at the front office of CCM (RC-1) or, they can be returned to the lock shop.

Please let me (303-724-3987), Michelle Wallace, RC1 Facility Manger (303-724-3002), or Jamie Tackett, R2 Facility Manager (303-724-3168) know if you have any questions. Please contact Lorraine Bell (303-724-2317) for access to R2.

Colorado Multiple Institutional Review Board (COMIRB)

New process changes designed to improve efficiency and compliance:

As of March 1, 2010

1. There will be only one Change Form instead of the Amendment Form and the Update Form.
2. There will no longer be a Safety Form instead:

Medwatch reports from other sites should either be submitted as Unanticipated Problems within 5 days if it meets the COMIRB definition of a reportable event or at continuing review;

- Changes to Investigational Brochures or Package Inserts will be submitted with a Change Form;
- Monitor reports, DSMB reports, Audit reports etc. should be submitted as Unanticipated Problems within 5 days or at continuing review depending on the findings.

As of April 1, 2010

3. There will no longer be a separate HIPAA B Authorization Form instead the HIPAA Authorization language will be incorporated into the consent form document (except at the VA).

If you have questions about these changes or if you would like to understand how to complete the new forms please come to one of the Brown bag sessions on the 3rd Thursday of each month from 12:00 to 1:00 in the COMIRB Conference Room, Building 500, 3rd floor, Room N3214.