OFFICE OF REGULATORY COMPLIANCE - CONFLICT OF INTEREST

ANNOUNCING.....

UCD 2015 Conflict Of Interest Disclosure Collection

The 2015 Conflict of Interest Disclosure collection period will commence on Monday, August 17, 2015. You can access the disclosure form at https://era.cu.edu. Detailed instructions for completion of your disclosure can be found on the COI website. For more information on these regulations, please see the Office of Regulatory Compliance-Conflict of Interest website at: http://ucdenver.edu/academics/research/AboutUs/regcomp/conflictofinterest/Pages/default.aspx

Please complete your 2015 COI disclosure as soon as possible. If you have a current COI disclosure on file, it will need to be updated on or after August 17, 2015 until you have updated your COI Disclosure for 2015, you will not be able to:

- Submit a PHS or NSF grant or receive approval of a PHS or NSF human subjects protocol
- Obtain approval for a new protocol or continuing review, when receiving minor modifications to renew your COI Disclosure.

Questions? Please contact the Office of Regulatory Compliance at COI@ucdenver.edu, (303) 724-0034.

REMINDER: Annual COI Disclosures must be submitted by October 31, 2015.

DR. T'S CORNER

AAMC joins health, science, research, academic organizations in support of 21st Century Cures Act

The Association of American Medical Colleges (AAMC) has joined more than 100 patient and voluntary health groups, medical and scientific societies, and academic and research institutions and organizations in signing a letter of support for the 21st Century Cures Act (H.R.6). Provisions in the measure would reauthorize the National Institutes of Health (NIH) for three years at funding levels that represent an increase of $1.5B per year, and provide $10B over the next five years in mandatory funding through an NIH-Innovation Fund. This is a most welcome infusion of funding that will help revitalize and rebuild our nation’s biomedical research capacity, which has eroded because of NIH losing almost one-fourth of its budget after inflation in the past decade. An important aspect of the Innovation Fund is that it supplements, not replaces, the regular appropriations for NIH. The architects of the 21st Century Cures initiative are House Energy & Commerce Chair Fred Upton (R-Mich) and Representative Diana DeGette (D-Colo), who both want to maintain funding for medical research as a national priority. The AAMC is a not-for-profit association representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these individuals and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. Additional information about the AAMC and U.S. medical schools and teaching hospitals is available at https://www.aamc.org/newsroom/.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Recruitment of Technical Members

We are currently recruiting additional members for the Institutional Biosafety Committee (IBC). The IBC provides review of all recombinant DNA research conducted at UCDenver. We are particularly recruiting Technical Members to assist with the review and approval of research involving recombinant DNA. Technical members consist of Lab Managers and PRAs that are knowledgeable in rDNA research. The time commitment for members is a monthly 2 hour meeting and review of approximately 3-4 protocols/month. Approval from your PI for this time commitment is required. The IBC meets once per month; treats are provided! If you are interested in this opportunity for University community service, please contact Mark Douse at 303-724-1057.
**RESEARCH CORNER**

Rachael Van Pelt, Ph.D. is an Associate Professor of Medicine in the Division of Geriatric Medicine and Center on Aging. She obtained her B.S. in Zoology from the University of Washington, Seattle (1993 and her Ph.D. in Anesthesiology and Applied Physiology from the University of Colorado, Boulder (1998). Dr. Van Pelt began her postdoctoral training at Washington University School of Medicine, St Louis and completed her fellowship at the University of Colorado in 2001. Dr. Van Pelt has been continuously funded by NIH for 16 years to pursue her passion in Aging Physiology, following two major lines of research. First, to determine what makes some adipose tissue beneficial to cardiometabolic health. Although early research focused on the harmful effects of abdominal visceral adiposity on cardiometabolic risk, Dr. Van Pelt was among the first to recognize the independent and apparently beneficial effect of gluteal-femoral adiposity. Based on these observations her laboratory conducted a prospective study to determine whether removal of this favorable fat depot is harmful. These studies were the first to demonstrate an increase in fasting and postprandial triglycerides 1 year following femoral lipectomy. Her second major line of research is focused on the physiologic actions of estradiol. Dr. Van Pelt has completed a series of studies designed to isolate the independent action of estradiol on: 1) insulin-stimulated glucose uptake, 2) insulin suppression of lipolysis, 3) insulin secretion and clearance, and 4) postprandial triglycerides. Current studies are testing whether the timing of estradiol in the context of prolonged estrogen deficiency (i.e., late in menopause) alters its action. Estradiol appears to improve insulin-mediated glucose uptake early (≤6 years) in menopause, but has a detrimental effect late (≥10 years) in menopause. New studies will test whether changes in estrogen receptors with prolonged estrogen deficiency explain, at least in part, these adverse changes in the physiologic action of estradiol.

**OFFICE OF RESEARCH DEVELOPMENT AND EDUCATION (ORDE)**

**Deciding to Resubmit**

At many agencies, resubmitted grants have a higher success rate than first-time grant submissions. Yet many researchers are deterred from resubmitting when reviewer comments and critique are difficult to swallow. The most successfully funded researchers have usually received as many no's as they have yes's and often more. However, when you receive a "no," you have a decision to make. If you decide to resubmit, you want to move as quickly as you can to revise and resubmit.

As you consider resubmitting and what you might do in your resubmission to enhance your chances of success, consider the following suggestions:

**Identify the level of suggested revisions**

Getting comments from reviewers that suggest you clarify a section of your grant or make minor changes to your methods are very different from comments that suggest a flawed hypothesis or a poor fit between your research goals with the agency's funding priorities. Determining if reviewers are excited about your project and whether changes you make can move you from a not funded to funded in the next iteration is key to deciding if you should resubmit to the same agency.

**Consider other agencies**

Sometimes in reading reviewer comments, you may get a sense that there is a fundamental disconnect between your project and the agency's mission or goals. If this is the case, you may want to begin to search for agencies whose mission might better align with your work.

**Talk with your Program Officer (PO)**

It’s always a good idea to talk with your PO about your review. But, with resubmissions, make sure that you’re not angry or trying to defend yourself before you pick up the phone. Once you're ready to have the conversation, do call/email your PO. Oftentimes, your PO was in the room during the review of your grant and they can offer you some clarification, advise you on changes you're considering making, and even help you make the decision as to whether you should resubmit.

For more information, see ORDE’s blog on resubmissions here: http://orde-cu.blogspot.com/2015/03/deciding-to-resubmit.html

**ENVIRONMENTAL HEALTH & SAFETY (EHS)**

**Things to Know About Marijuana Research**

With some State grant funding now available to researchers interested in performing marijuana research, it is important to understand what the Drug Enforcement Administration (DEA) expectations are of you before you start your marijuana-based research.

Despite the fact that marijuana is now legalized for recreational use in Colorado, marijuana is still a federally-regulated, DEA Schedule 1 controlled substance. Before any research can be done with marijuana a DEA license must be obtained. Applying for a DEA marijuana registration is different from the regular application process in that applications for work with schedule 1 controlled substances require the submittal of the corresponding IACUC or IRB protocol for review by the Food and Drug Administration (FDA) along with the standard application form 225. Once the FDA protocol review is approved and the DEA successfully completes their background checks and site security visit a DEA registration is issued for work with marijuana.

After obtaining your DEA registration, please note that the only legal source for marijuana used in human research is the National Institute of Drug Abuse (NIDA). Obtaining marijuana for human research studies from a source other than NIDA is illegal and will cause you to lose your DEA registration as well as adversely affect the validity of your research. Marijuana for use in animal research or for analytical studies may be obtained from another DEA Schedule 1 license holder (i.e., a Schedule 1-to-Schedule 1 transfer). However, currently none of the recreational marijuana businesses in Colorado are DEA Schedule 1 license holders. In other words, it is forbidden to locally purchase recreational marijuana for any research purposes at the University.

The Department of Environmental Health and Safety maintains a registry of all DEA licenses on campus. Please contact EHS if you plan to apply for any level of DEA license or if you have questions. Visit our website here www.ucdenver.edu/DEA for additional information.