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. You may have to cut and paste the url into your browser address window.

RETRACTION WATCH

New tool found on Retraction Watch:
http://explorer.opentrials.net/
"All the data, on all the trials." OpenTrials is a new tool to link all available information on every trial conducted, and you can contribute.

VIVARIUM SECOND QUARTER SENTINEL TESTING

I am happy to announce that we have completed the Second Quarter Sentinel Testing for the RC1, R2, Downtown and Denver Health vivariums. The results show that, there are no known excluded pathogens present in our facilities.

As has been reported in previous quarters, we do have norovirus and helicobacter positive colonies throughout the facility. At this point we are continuing to monitor these agents and currently have no immediate plans to exclude these two agents. We are also continuing our efforts to exclude Corynebacterium bовis from our nude colonies. If you have questions about this effort, please contact Chris Manuel (Chris.Manuel@ucdenver.edu).

I want to thank everyone involved in the animal program from research staff to OLAR staff for their continued diligence. It is also important to thank all the users of the vivariums. It is difficult to maintain a "CLEAN" animal facility. Please continue to be diligent in your work so that our facility can continue to be a "model" facility. Thank you.

Please let me know if you have any questions or concerns regarding OLAR operations.
RESEARCH CORNER

Sharon Poisson, MD MAS is an Associate Professor of Neurology at CU Denver. She earned her MD at Indiana University, completed a neurology residency at the University of Michigan, and a clinical stroke fellowship and Masters in Clinical Research at UCSF, where she remained as an Assistant Professor until 2012 before coming to CU Denver.

Dr. Poisson’s early research interests included gender differences in the workup and treatment of ischemic stroke and TIA, imaging findings in TIA and the prevention of medical complications following ischemic stroke. Both clinical experiences and mentoring by successful and dynamic pediatric stroke researchers built an interest in young adult stroke, which remains the main focus of her research today. Along with a group of researchers at Kaiser Permanente Northern California and UCSF, Dr. Poisson has spent the last several years further investigating the recent findings that while ischemic stroke hospitalizations overall have been declining over the last several decades, the rate has been increasing in young adults over the same time period, and most significantly among African American young adults. Dr. Poisson found a rising mortality from ischemic stroke among young adults over 2 decades, again in contrast to a sharp decline in ischemic stroke mortality among older adults over that time period. At CU Denver, she has been able to continue her research program in young adult stroke with the Kaiser Northern California-UCSF group through a Stroke Disparities Program Grant through NINDS as the co-PI of a large retrospective cohort and case-control study of stroke in the young. The focus of this study is to clearly define the trend in incidence of ischemic stroke among both children and young adults, emphasizing the role of atherosclerotic risk factors and racial disparities in this changing incidence.

After arriving at CU Denver, Dr. Poisson built a clinical Young Adult Stroke Program, and has joined with other basic and clinical researchers with a focus on stroke in the young. As the fellowship director of the AHA/Bugher Foundation Pediatric Stroke Program at CU Denver, she has been involved in recruiting fellows to expand and continue work in investigating the causes, current treatment strategies and recovery from ischemic stroke in young people.

OFFICE OF RESEARCH DEVELOPMENT AND EDUCATION (ORDE)

Do you have a research project you’ve been contemplating? A great idea, but no preliminary data? Many agencies offer pilot project or seed grant funding for just these purposes. ORDE has updated the Pilot Project Funding e-Book, providing information about funding agencies across the many disciplines represented at the University of Colorado Denver | Anschutz Medical Campuses. Details for each sponsor include eligibility, funding levels, award duration and a link to the sponsor’s website. To download your own copy, go to http://www.ucdenver.edu/research/ORDE/Pages/PilotProject.aspx

NEW NIH TRAINING REQUIREMENTS

Effective January 1, 2017, the NIH will require ICH/GCP training. The policy applies to all NIH-funded investigators and staff “who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6 (R2).”

NIH Clinical Trial Definition. A research study 1) in which one or more human subjects 2) are prospectively assigned 3) to one or more interventions 4) (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

In order to address this new requirement, the UC Denver office of Regulatory Compliance will use the CITI training on ICH/GCP. This module is now available through CITI.

It will be the responsibility of the Principal Investigator to ensure that all members of the study team who are working on NIH funded clinical trials have this required training and may be asked by the NIH to provide proof of completion.

Please note that study team is broadly defined by NIH to include all individuals involved in the project including:

- Principal Investigator
- Co-investigators
- Study coordination,
- Individuals conducting data collection and
- Individuals doing data management

Once the course is completed, we recommend that the study team member download a copy of their ICH/GCP certificate from the citiprogram.org and maintain it in a study file to provide upon request to NIH.

NIH Request for Information (RFI)

Strategies for NIH Data Management, Sharing, and Citation National Institutes of Health (NOT-OD-17-015).

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.