**Research Tips**

**Vice Chancellor for Research: RJ Traystman, PhD**

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**DR. T’S CORNER**

**Single IRB Policy to Streamline Reviews of Multi-Site Research**

Accelerating clinical research studies benefits researchers, research participants, and all who stand to gain from research results. The time it takes to go from a sound research idea to the launch of a new, multi-site clinical research study is too long. One major contributor to the delay is that too many institutional review boards (IRBs) are reviewing the protocol and consent documents for the same study, often with no added benefit in terms of the protections for research participants. To address this bottleneck, NIH has issued a new policy to streamline the review process for NIH-funded, multi-site clinical research studies in the United States. The NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research sets the expectation that multi-site studies conducting the same protocol use a single IRB to carry out the ethical review of the proposed research. IRBs play a critical role in reviewing and approving studies involving human research participants. IRBs evaluate the potential benefits of research and risks to participants. In the past, most clinical research studies were carried out at single institutions. Now studies are increasingly conducted at multiple sites to help increase the number and diversity of the participants, improve operational efficiencies, and accelerate the generation of research results. However, for the majority of multi-site studies, the IRB at each participating site continues to conduct an independent review. This review adds time, but generally does not meaningfully enhance protections for the participants. This new NIH policy seeks to end duplicative reviews that slow down the start of the research.

NIH will support applicant and awardee institutions as they implement the new policy with guidance and resources, such as a model authorization agreement that lays out the roles and responsibilities of each signatory, and a model communication plan that identifies which documents are to be completed, and when.

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**COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD (COMIRB)**

We are very happy and excited to announce that, as of November 1, 2016, John Heldens is joining our human research protection program team as the new Director of Colorado Multiple Institutional Review Board (COMIRB).

John has more than 20 years of experience leading an institutional review board and serving as an integral part of the human research protection program at the University of California, San Francisco (UCSF). During that time, he helped that organization be successfully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and actively supported research not only at their large public academic medical center but also at the local Veterans Affairs Medical Center, community hospital and department of public health.

We believe that John Heldens' experience, enthusiasm and advocacy for research will help the University of Colorado Denver 1 Anschutz Medical Campus augment its current program to further integrate our human research protection program, while also improving the efficiency but maintaining the quality of COMIRB. He will also continue to support our important partnership with our affiliate hospitals.

Please join us in welcoming John to our institution as we continue to enhance our central research administration support for the important research conducted on both campuses.

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**NATIONAL INSTITUTES OF HEALTH (NIH)**

**Funding for Researchers who did not receive an NIH award**

NIH and Leidos combine to offer a portal to alternative funding sources for unfunded NIH-submitted proposals. It has a growing number of sponsors from a wide range of organizations. OnPAR, the Online Partnership to Accelerate Research, is free and abstracts may be submitted at any time.

Check it out. https://onpar.leidosweb.com/
Amanda Charlesworth, Ph.D., joined the Department of Integrative Biology in the College of Liberal Arts and Sciences at CU Denver in 2010 as an Assistant Professor. She earned her Ph.D. from the Imperial Cancer Research Fund and University College London in the UK in 1996. Amanda has been studying aspects of how cell signaling changes cell behavior throughout most of her scientific career. These changing cell behaviors have been in the fields of neurobiology, cancer biology, and developmental biology. Recently, she has been investigating how signals that tell eggs to prepare for fertilization, and signals that tell the embryo how to grow, act upon temporary genetic messages (messenger RNA, mRNA) that are loaded into the egg by the mother. After fertilization, the embryo's own DNA is not used immediately, and instead the early development of the embryo is determined by the time at which the mother’s mRNAs are used. This occurs until the mRNAs that activate the embryo’s DNA, are used and embryogenesis then continues under the control of the embryo. Amanda has discovered a new partnership between short sequences on some of the mother’s mRNAs and a novel family of proteins, called Zar. The Charlesworth Laboratory has found that Zar binds to mRNA and regulates when mRNA is used during egg development and during embryogenesis. As Zar is already implicated in growth of the embryo and activation of embryonic DNA, Charlesworth now wants to test if this is because Zar regulates the mRNAs that activate the embryo’s own DNA. Charlesworth is joined in her research activities by undergraduate and graduate students.

**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.

**CLINICAL RESEARCH ADMINISTRATION**

**New Material Transfer Agreement (MTA) Process**

Starting December 1, 2016, all MTAs should be sent to the Clinical Research Administration Office (CRAO) at the following email address: crao_contracts@ucdenver.edu. If UCD is receiving material, an MTA and a newly created form, the MTA Information Sheet, will be required for CRAO to begin work on the MTA. If UCD is providing material to another entity, only the MTA Information Sheet will be required. Websites will be updated in the upcoming weeks with this information.

The CRAO team will be doing outreach with departments over the next 3 weeks to discuss the new process. If you have any questions, please contact Amanda Peng at (303) 724-2865.

**ANIMAL CARE & USE COMMITTEE**

**USDA Covered Species and pre-review of proposed studies.**

Any IACUC protocol that requires the use of rabbits, guinea pigs, hamsters, cats, ground squirrels, sheep, goats, pigs, etc. must be submitted for veterinary pre-review by the pre-review due date that is posted on the IACUC webpage. This date is 14 days prior to the typical deadline for protocol submission. Protocols that require USDA covered species, not submitted by the veterinary pre-review deadline will be forwarded for veterinary pre-review and will be reviewed by the IACUC at the next convened meeting of the IACUC. Please make note of this in your protocol planning process.

The Animal Welfare Act specifies that, when utilizing USDA covered species in a research protocol, the attending veterinarian or his or her designee should be consulted in the planning of the study. Based on the USDA definition of animal, most warm-blooded animals are covered species with the exception of birds, rats (of the genus Rattus) and mice (of the genus Mus) which are bred for use in research.