Office of Research Affairs

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The Office of Research Affairs provides timely notices to the research community on important information, policies updates and regulatory initiatives and changes. See the Office of Research Affairs website at http://blink.ucsd.edu/sponsor/ora/.

Dual Use Research of Concern Requirements

Research with one or more of the fifteen (15) Dual Use Research Concern (DURC) agents and/or toxins currently listed in the U.S. Government DURC Policy and which produces, aims to produce or can be reasonably anticipated to produce one or more of the seven (7) experimental effects of concern listed in the Policy must be evaluated by the UC San Diego Institutional Review Entity (IRE) for its DURC potential. Principal Investigators (PIs) must notify the Institutional Contact for Dual Use Research that they are using DURC agents through the Biohazard Use Authorization Program.

DURC agents and toxins include: Avian influenza virus (highly pathogenic), Bacillus anthracis, Botulinum neurotoxin, Burkholderia mallei, Burkholderia pseudomallei, Ebola virus, Foot-and-mouth disease virus, Francisella tularensis, Marburg virus, Reconstructed 1918 Influenza virus, Rinderpest virus, Toxin-producing strains of Clostridium botulinum, Variola major virus, Variola minor virus and Yersinia pestis.

Export licenses are required for any exports of DURC agents and in certain cases, export licenses may be required for foreign person access to confidential, proprietary or information restricted from publication. Licensing takes a minimum of six (6) weeks and must be in place prior to export.

For questions on the DURC requirements, please contact Brittany Whiting, Export Control Officer and Institutional Contact for Dual Use Research of Concern, at 858-534-4175 or brwhiting@ucsd.edu.

New NIH Requirement for Training in Good Clinical Practice

An NIH policy with an effective date of January 1, 2017, establishes that NIH-funded investigators and staff who are responsible for the conduct, management or oversight of NIH funded clinical trials, have training in Good Clinical Practice (GCP) consistent with the International Council on Harmonisation (ICH).

The FDA is the primary source of regulations related to therapeutic trials in the United States; however, the International Conference on Harmonisation was organized in 1990 to provide a global perspective for clinical trials and eliminate the need to repeat trials in individual countries prior to introducing new therapies. Although the ICH was created specifically for drug trials, its principles are applied to a range of research GCP. FDA regulations are closely aligned with those of the ICH, recently renamed as the International Council on Harmonisation.

Countries participating in the ICH include members of the European Union, Japan, the United States, Canada and Switzerland. These countries represent 15% of the world's population and encompass 90% of all drug products. Familiarity with the ICH is an essential element for investigators to conduct research in a responsible and safe manner. The ICH is anticipated to formally accept revisions to their guidelines in December 2016 and the FDA is expected to adopt these revisions in early 2017. UC San Diego is developing educational tools related to ICH guidance for its research community. For additional information, please see the FDA draft guidance with the revised ICH Good Clinical Practice and general information regarding the International Council on Harmonisation.

Good Clinical Practice (GCP) training is available through the CITI training program at no cost to UC San Diego faculty and staff. To access the CITI training program, please see the UC San Diego Health Sciences Research Compliance Program INTRAnet. For questions regarding GCP training requirement, please contact the UC San Diego Human Research Protections Program at (858) 246-4777 or hrpp@ucsd.edu.

Effect of a Last Minute Grant Submission on the Success Rate for NIH Proposals

According to Dr. Michael Lauer, NIH's Deputy Director for Extramural Research and principal scientific leader and advisor to the NIH Director on the NIH extramural research program, many applications fail to be considered for funding because they miss the due date deadline altogether. In fact proposals submitted minutes, hours or on the same day as the deadline are less likely to be favored by the NIH review committee.

Following are a few highlights of his findings:

- Submit applications up to a full week prior to the due date, to allow ample time to address application errors or issues that need to be completed to satisfy successful and timely submission.
- Use ASSIST as this method incurs far fewer submission errors than those using downloadable form submissions.
- Avoid application errors by coordinating with the institution's grant submission offices (OCGA, HSSPPO and SIO OCGA for UC San Diego) to ensure that instructions in both the application guide and the funding opportunity announcement are carefully followed.
- Check the eRA Commons to ensure all errors are corrected and verify that the application image is displaying prior to the submission deadline.

To review Dr. Lauer's full article, click here. For additional information on data associated with RO1 and SBIR applications received during 2015, click here.

Sponsors aren't the only ones impacted by last minute submissions. The central Sponsored Projects Offices (OCGA, HSSPPO and SIO OCGA), responsible for ensuring that proposed applications submitted to all sponsors incorporate all essential data, forms, and information, and that they comply with both University and sponsor requirements are also impacted by last minute proposal submissions for all sponsors. Approximately 60% of all proposals received for review, consultation, finalization and submission by the central Sponsored Projects Offices are received the same day as the due date. That does not leave much time for the valuable and necessary due diligence to occur.

Given the growing complexity and rigor of the proposal submission process associated with almost 2000 different sponsors and the extensive volume of proposal activity (5000 proposals were submitted in 2016), it is ideal to submit all the elements of a proposal package, including a draft of the science, three to five business days prior to the deadline in order for OCGA, HSSPPO or SIO OCGA to fulfill their responsibilities effectively and to ensure that the requirements of the sponsors and the University are fully met. The most significant section of the proposal, the final version of the scientific abstract, can be submitted no later than 8:00 am the day the proposal is due, allowing the Principal Investigator as much time as possible.

As proposal submission guidelines vary for each Sponsored Projects Office, please refer to these web sites:

- Office of Contract & Grant Administration (OCGA)
- Health Sciences Sponsored Projects Pre-Award Office (HSSPPO)
- Scripps Institute of Oceanography (SIO OCGA)

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