Office of Research Affairs

Advancing Research and Innovation

September 2017

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/.

Recent Changes by NIH Regarding Clinical Trials Regulations and Definitions

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. These initiatives include:

- Change in definition of clinical trials (effective January 1, 2018)
- Good Clinical Practices training for clinical trials (effective January 2017)
- Clinical trial specific funding opportunities (due dates on or after January 25, 2018)
- New PHS Human Subjects and Clinical Trials Information form (due dates on or after January 25, 2018)
- Single IRB for multi-site research (effective January 2018)
- ClinicalTrials.gov registration and reporting requirements (effective January 2017)

For additional information, please see https://grants.nih.gov/policy/clinical-trials.htm.

Highlights of the Changes in the Definition of Clinical Trials:

It is important for UC San Diego investigators to understand NIH's new definition of a Clinical Trial. *The new definition includes as clinical trials any studies that involve human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.*

All NIH funded clinical trials will be subject to the additional application requirements, registration and oversight and reporting. While some aspects of the NIH requirements have been in place for some time, the change in the definition of clinical trials and the expanded pre-conditions requiring reporting and registration for all studies defined as clinical trials are more recent and are beginning to be communicated through many venues by NIH.

For additional information, please see the articles from Dr. Michael Lauer, NIH's Deputy Director of Extramural Research, titled "4 Questions for Researchers and Institutions involved in Human Subjects Research" and "Continuing to Clarify the NIH Definition of Clinical Trials." The first article explains the changes in the definition and provides an opportunity for researchers to post comments through the "Open Mike Blog." The second one responds to some of the feedback and provides further clarification.

Colleagues at University of California Office of the President, in coordination with the ten UC Clinical Trials offices and IRB Directors, are also evaluating the new definitions and will engage in dialogue with their counterparts and the NIH. As additional information becomes available, we will post information and guidance about how UC San Diego will be managing these new requirements. For questions, please contact Lisa Meredith, OCGA Associate Director, at lmmeredith@ucsd.edu.

Principal Investigator Eligibility and Research with Animals

Serving as a Principal Investigator (PI) on a research grant or contract carries enormous responsibilities. The PI is responsible for the direction of the research project, stewardship of resources, compliance with laws and regulations, supervision of staff and scholars, and meeting the obligations of the funding agency. When research involves human or animal subjects, the PI is also held ultimately responsible for ensuring that the requirements of the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) are met.

Not all employees of the University are eligible to serve as a PI on contracts and grants. PI eligibility is based on academic title. The list of PI eligible titles is available in PPM 150-10. Under certain circumstances, individuals who are not normally PI eligible may request a PI Exception, for example:

- Assistant Project Scientist
- Clinical Professors on Clinical Trials with appointment >50%
- Adjunct Professors with >50% appointment
- Postdoctoral Scholar-Employee for postdoc specific career development grants (for example an NIH K99)
- Director of undergraduate student for student outreach funding

For questions about PI exceptions, contact piexceptions@ucsd.edu or go to PI Eligibility in BLINK.

Please note for IACUC protocols:

- Eligibility to serve as a PI on an animal use protocol is the same as the University's requirements for eligibility to be a PI on a grant (even if the PI on the animal protocol is different from the PI on the grant)
- If a PI exception is required, the fully executed PI exception form must be provided to the IACUC Office before the IACUC will approve the animal protocol

For additional information regarding the IACUC processes, please contact the IACUC at iacuc@ucsd.edu or (858) 534-6069.

Conflict of Interest Considerations When Starting A Company

A key element for the University's Strategic Plan is to create a culture of innovation that benefits the University and the global community. The University encourages faculty to engage in outside activities that contribute to their respective professions and to the community. When new innovation is developed, the inventor(s) may want to form a new company. While under the Conflict of Commitment policies prior approval for starting a company is required for faculty, faculty and staff must also be aware of the conflict of interest implications.

A conflict of interest occurs when an employee has an interest in a company that is providing funding for the employee's research or other University activity or the research might directly and significantly affect the interest of an employee responsible for the conduct of the research. For any active or pending research activities, University employees will need to submit updated disclosures within 30 days of forming the company. The various COI disclosure requirements and forms can be found on the COI website.

When deciding to submit a proposal under an SBIR or STTR with a company, University employees must be aware of the UC policy that requires all University of California employees who receive any part of their salary through the University, or whose activities use any University resources or facilities, must submit their proposals for extramural support through the appropriate local contracts and grants office. Any exception to this policy must be approved by the Vice Chancellor for Research. Please keep in mind that while SBIR/STTR granting agencies may permit one Principal Investigator (for the small business entity and the research center), the University does not without an exception.

In addition, for graduate students and postdoctoral scholars, when starting a company it is recommended they consult with the Department Chair and the Graduate Division (for graduate students) or the Postdoctoral and Visiting Scholars Office (for postdoctoral scholars) to ensure the student's or scholar's educational interests are protected while maintaining an open environment free from undue influence of private outside interests.

When involved with a company or other outside activities, the following safeguards are recommended for University employees in order to avoid violations of University Policy or Federal and State Regulations governing conflict of interest:

1. No University time or resources should be utilized for the company
2. There should be no "appearance" of a potential conflict among staff or other employees, i.e. avoid distractions, phone calls, discussions, etc., during University time
3. University employees should recuse themselves from influencing or participating in future University business or purchase decisions with the company
4. University employee's association with the company should not imply a University endorsement of their products or a University affiliation with the company

For additional information or guidance, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

Postdoctoral Scholar's Contract

Since August 2010, postdoctoral scholars (postdocs) at the University of California have been exclusively represented by the international union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW). That contract expired on September 30, 2015, was extended for one year with minor changes, and on October 17, 2016, the four year successor contract was approved and implemented system-wide.

The new contract included the accretion of postdocs at Lawrence Berkeley National Labs (LBNL), which increased the total UC population to well over 6,200. We are approaching the one-year anniversary of the new contract and would like to recap some of the key articles.

1. Salary/Stipend Scale: The UC Salary/Stipend Scale level 0 starts at NIH NRSA rate for step 2 ($48,216 per year), and increases to the next level must be given every 12 months.

2. Appointments: Initial appointments are 12 months; however, the first reappointment must be 2 years, unless the Principal Investigator (PI) can justify a less than 2 year reappointment. Acceptable circumstances are:

- Less than 2 years of programmatic work
- Less than 2 years of funding
- Postdoc has exhausted eligibility as Postdoc (5 year limit)
- Work authorization limitations
- Change in PI

For Postdoctoral Scholar-Fellows and Paid Directs (title codes 3253 and 3254), the minimum duration of the appointment must be at least the duration of the fellowship funding. For example, if the fellowship provides funding for 18 months, the postdoctoral appointment would be for a minimum of 18 months. Please see http://ucnet.universityofcalifornia.edu/labor/bargaining-units/px/docs/PX_2016-2020_02_APPOINTMENTS.pdf.

3. Postdoc are eligible for 4 workweeks of paid parental leave: In addition to 24 days of Personal Time Off and 12 days of Sick Leave, Postdocs are eligible for 4 workweeks of paid parental leave. The

time can be used consecutively or intermittently, and is available to both the birth parent and spouse. However, the leave must be used within 12 months of the baby's birth or adoption. Information is available on page 8, Section 8b, of the Parental Leave article.

4. Annual Evaluations: The contract requires mentors to provide an annual review. The annual review is a "comprehensive assessment of the Postdoctoral Scholar's research progress and achievements, and her/his professional development during the previous year." Oral or written feedback should be provided to the postdoc on a regular basis; however, the written annual review is only required once a year and must be submitted to the Office of Postdoctoral and Visiting Scholar Affairs (OPVSA).

The Office of Postdoctoral and Visiting Scholar Affairs is responsible for overseeing campus compliance of this collective bargaining agreement. If you have any questions, please contact Jennifer Oh at jmoh@ucsd.edu, (858) 534-6632 or visit the OPVSA website.

Export Control Sanctions

Recent executive orders, sanction regulations and the licensing issuance for sanctioned country activities are changing. Please see the updates below:

North Korea Sanctions
Due to the serious and mounting risk of arrest and long-term detention of U.S. citizens, the Secretary of State restricted the use of U.S. passports to travel into, in, or through North Korea effective September 1, 2017. Per C.F.R. 51.63, persons who wish to travel to North Korea on a U.S. passport after that time must obtain a special passport validation under 22 C.F.R. 51.64, and such validations will be granted only under very limited circumstances. Additionally, the President has issued a new Executive Order on September 20, 2017, imposing additional sanctions with respect to North Korea. The Office of Foreign Asset Control (OFAC) is concurrently releasing new and updated FAQs along with a new General License 10 and an updated General License 3-A.

Iran OFAC Recent Actions
Travel to, collaborations with, payments, and imports and exports to certain sanctioned countries require export licenses from the U.S. Government. OFAC, which is in the Department of Treasury, is the agency that regulates sanctions on individuals, entities or countries. Ensure that your UC San Diego travel to sanctioned countries is pre-authorized by submitting your travel request in advance.

Regarding Iran sanctions, a UC campus was recently issued a letter from OFAC indicating that they had violated federal export control regulations after a member of their faculty traveled to Iran to attend a ceremony and accept a prize without prior approval from the U.S. Government. Under export control regulations, the campus disclosed the violation to OFAC once they learned of the activity. Each violation of the Iranian Transactions and Sanctions Regulations (ITSR) is subject to a civil monetary penalty of up to the greater of $289,238 or twice the value of each underlying transaction.

A number of professors from across the U.S. requested permission to present at an academic conference being held at a University in Iran and were denied permission to do so as OFAC indicated “upon interagency consultation, it would be contrary to current OFAC licensing policy to issue a specific license authorizing participation in the conference.”

Presentations at a conference (even of already published material) in sanctioned countries may require an OFAC license. It is not clear if these recent Iran license denials were specific to this particular conference or if this signals a change in licensing policy by OFAC. The Export Control Office is monitoring this and continues to file OFAC licenses to authorize activities with and in Iran and other sanctioned countries for researchers at UC San Diego.

Requirement for License Reviews with the Export Control Office

Contact the UC San Diego Export Control Office as soon as possible for sanction country license reviews for Cuba, Iran, North Korea, Syria and Sudan. Travel to a sanctioned country unrelated to UC San Diego business, but where UC San Diego equipment or material is exported, may still require an export license. The Export Control Office is responsible for assisting in the preparation of all export license applications and filing licenses with the U.S. Government. The Export Control Office will advise if a general license is permissible and if the general license may be used immediately. If your situation does not meet the terms and conditions of a general license, specific export licensing with OFAC can take a few months to a year to obtain as sanctioned country licensing has interagency license reviews. If equipment and technology exports are part of the transaction, other government agencies such as the Department of Commerce Bureau of Industry and Security (BIS) may also require an export license.

For export license reviews regarding sanctioned countries, contact export@ucsd.edu or Brittany Whiting at 858-534-4175, brwhiting@ucsd.edu. For additional information on OFAC comprehensive and other sanctioned countries as well as recent executive orders and regulation changes, see the OFAC website. A short video on OFAC requirements is also available on UC Learning. For information on immigration and visa issues associated with citizens of sanctioned countries, please contact the UC San Diego International Center.

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