Office of Research Affairs

Advancing Research and Innovation

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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/.

Revisions to the Federal Policy for the Protection of Human Rights

The Federal Policy guiding human subjects research for fifteen Federal agencies put into effect in 1991 and last amended in 2005, is referred to as the Common Rule (subpart A of 45 Code of Federal Regulations [CFR] part 46). A recently released update to the Common Rule, the Final Rule, is intended to enhance the protection of human research subjects while promoting research and simplifying oversight. An Advanced Notice of Proposed Rulemaking was released by the Department of Health and Human Services in 2011 and a Notice of Proposed Rulemaking (NPRM) involving numerous proposed changes to the Common Rule released in 2015, received more than 2100 comments from a diverse group of researchers and the general public.

Topics addressed by the Final rule include improving the consent process, using single institutional review board (IRB) for multi-site research studies, use of stored bio-specimens, new exempt categories for research, continuing review for low risk studies and public posting of consent documents. Below are some highlights:

- Consent documents associated with human subject research have become increasingly complex with a trend to providing protection for institutions rather than as a means to inform and protect research subjects. The Final Rule requires consent forms to better present the elements of a research study with a summary of risks and benefits presented early in the document. The Final Rule requires that consent documents related to federally funded clinical trials are posted on a public website.

- Using a single IRB for multi-site studies is intended to reduce redundant IRB reviews, reduce the time initiating studies at multiple research sites and maintaining uniformity in conducting trials at multiple locations. The requirement for single IRB review included in the Final Rule is more flexible than initially presented in the NPRM and allows groups of studies to be excluded from the requirement of using a single IRB. The change does not affect the NIH requirement for single IRB review for multi-site studies, which goes into effect in September 2017.

- The NPRM included a controversial provision for a broad consent to be required for the use of non-identified data or specimens in research; however, the Final Rule includes provisions for a broad consent while maintaining the ability for an IRB to waive consent for the use of non-identified data or specimens.

- Elements of the Final Rule designed to reduce the burden of research oversight include the introduction of new exempt categories, including the use of identifiable private information for secondary research if HIPAA rules protect subjects. Removing the requirement for ongoing continuing review for select low risk research is intended to eliminate unnecessary efforts by researchers and administration without compromising the protection of research subjects.

The Final Rule is effective on January 19, 2018, with the exception of regulations related to cooperative research being January 20, 2020. Click here to review the complete Final Rule. A summary of the Final Rule is located on the OHRP website.

The UC San Diego Human Research Protections Program (HRPP) will be providing additional information and guidance regarding the Final Rule's impact to the HRPP processes in the near future. Please visit the HRPP website.

Export Control: Sanctioned Country Licensing Requirements

Travel to, collaborations with, payments, imports and exports to certain sanctioned countries require export licenses from the U.S. Government. The Office of Foreign Assets Control (OFAC) within the Department of Treasury, is the agency that regulates sanctions on individuals, entities or countries. OFAC comprehensively sanctioned countries are Cuba, Iran, North Korea, Syria and Sudan. While there have been some changes to sanctions on Cuba and Sudan in the past year, general licenses are still required. Sanctions are generally issued by an executive order and are constantly changing.

Travel

Ensure that your UC San Diego travel to sanctioned countries is pre-authorized by submitting your travel request in advance. Presentations at a conference (even of already published material) in sanctioned countries may require an OFAC license. In addition, 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.

Requirement for License Reviews with Export Control

Contact the UC San Diego Export Control Office as soon as possible for sanction country license reviews. 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 sanction 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.

Penalties

Penalties for not obtaining the required export license can include monetary penalties, debarment, loss of export privileges or imprisonment for criminal violations. Monetary penalties for OFAC violations are based on the transaction value, for example, for BIS, penalties are $284,000 or twice the shipment value, or based on the value of the transactions. In March 2017, OFAC and Commerce fined ZTE Corporation $1.19 billion for failure to obtain export licenses to Iran, obstructing justice and making a material false statement.

For additional information on OFAC comprehensive and other sanctioned countries, see the OFAC website. A short video on OFAC requirements is also available on UC Learning. For questions, please contact Brittany Whiting, Export Control Officer at 858-534-4175 or brwhiting@ucsd.edu. For information on immigration and visa issues associated with citizens of sanctioned countries, please contact the UC San Diego International Center.

Compliance and Conflict of Interest Briefing

On January 27, 2017, the University of California launched an online Compliance and Conflict of Interest Briefing for all researchers who were paid with any extramural grant or contract funds (regardless of the source) in one or more months of FY 15 - 16. The Compliance Briefing satisfies two mandatory training requirements, the UC training requirement that all researchers be trained periodically to recognize and deal with ethical issues and conflict of interest situations that may arise during their work, as well as the Conflict of Interest training requirement by the National Institutes of Health.

Only identified researchers are required to complete the online Compliance Briefing. The UC Office of Ethics, Compliance and Audit Services identified job titles that they believed would likely be involved with externally funded research. From that population of individuals, they screened those who had received a portion of their salary from extramural funding sources.

The Compliance Briefing takes approximately 20 - 30 minutes to complete, can be taken on any computer with internet access and does not need to be completed in one sitting. However, it must be completed within 90 days from the email notification. If you are required to complete the course, the UC Learning Center will send you an email on how to access the course. For those required to complete the course, you can also access the course by going to Blink, selecting “Personal Tools”, then the UC Learning Center. The course will be in your “to do” list. After completion of the Compliance Briefing, an email from the UC Learning Center will be sent to the researcher and the completion will be automatically recorded.

Additional information can be found on the Office of Research Affairs website or contact the Conflict of Interest Office at (858) 534-6465, info-coi@ucsd.edu.

New Video Case Studies on Responsible Conduct of Research Topics

The Office of Research Integrity (ORI) has recently released a new series of video case studies to address integrity issues faced by those involved in research. The videos touch on topics that affect researchers at all levels of their careers, such as mentoring, authorship and publication practices, data integrity and research misconduct. The videos and their scenarios encourage viewers to consider how to make responsible choices at every turn.

The following video case studies are now available:

- Choosing the Right Lab
- Reproducibility or Luck? The Struggle to Get Results
- Data Cherry Picking
- The Misuse of Placeholders
- To Proceed or Not to Proceed Without Raw Data?
- Crossing the Line into Misconduct
- I Wrote It, Why Re-Write It?
- When Authorship Gets Personal
- How Impact Factors Impact You
- Biased Peer Review or Flawed Methodology?
- You Suspect Research Misconduct. Now What?

The video case studies can be viewed and downloaded from the ORI website.

Reference: The Office of Research Integrity

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