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RESEARCH COMPLIANCE AND INTEGRITY
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Equity, Diversity, and Inclusion: Whose Job Is It?

BY MARY DEVEREAUX

It is a well-understood tenet of research that the validity of results depends in significant part on the representativeness of the population studied. As the National Institutes of Health (NIH) Policy on the Use of Sex as a Biological Variable recognizes "overreliance on male animals and cells may obscure understanding of key sex influences" on biological processes and health. The historical failure to study women in cardiac research led to the false assumption, among both physicians and the lay public, that a heart attack typically presents with the same symptoms, e.g., crushing heart pain, in men and women. Until recently, cardiologists routinely treated women with coronary disease and heart failure, leading to disproportionately higher rates of death (Editorial, The Lancet, 2019). Similarly, studies focused narrowly on a particular socio-economic, racial, ethnic or educational demographic limit knowledge about excluded or under-represented groups. Given the real harm that conclusions based on non-representative data may cause, there are strong ethical as well as epistemic reasons for scientific research to include diverse populations.

A less familiar, perhaps more controversial, claim is that good research requires a diversified scientific workforce, one that adequately reflects the demographics of the population studied and served. As a matter of fairness, access to a career in science or medicine should be open to all. Excluding qualified individuals, intentionally or not, is discriminatory and as such unjust and unethical. As several studies suggest, a diverse workforce may also be important for increasing creativity and innovation. A variety of backgrounds and experiences contributes to research teams likely to ask new or previously ignored questions, overturning established methods and ways of thinking (MW Nielsen et. al, Nature Human Behavior 24 Sept. 2018). There are thus good pragmatic, as well as ethical, reasons for workforce diversity, the inclusion of previously absent groups in research.

The arguments in favor of a diverse workforce are even stronger in medicine. In 2003, the National Academies of Sciences, Engineering and Medicine published a report, Unequal Treatment, which documented now broadly recognized racial and ethnic disparities in the quality of healthcare received in the U.S. Nearly two decades later, The New England Journal of Medicine published a four-decade review of efforts to diversify admissions to U.S. medical schools. These efforts more than doubled the percentage of women attending medical school, achieving gender parity as far back as 2005 (Morris et al. NEJM 2021). However,

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the news is less positive, indeed far less positive, with respect to ethnic and racial equity among medical school admissions and the resulting physician workforce. The gains among women are largely among White and Asian women. The number of Black physicians, especially among men, has grown very little. Most of that gain has come from the graduates of historically black medical schools. Other underrepresented ethnic and racial groups, both male and female, have made only minimal progress relative to recent Census data. These negative outcomes are particularly discouraging as they come despite significant efforts to attract underrepresented groups not only to medicine, but also to health sciences and STEM fields generally. Despite an expanse of summer programs in pre-college and college research, mentorship and community partnerships, post-baccalaureate programs, and a more holistic approach to admissions, diversifying medical providers, particularly in underserved communities, remains an unrealized national goal.

The question of how best to achieve equity and inclusion is not limited to medicine, but also extends across the sciences and engineering. In April, the National Academies published the findings of a virtual workshop with a wide range of stakeholders in neuroscience training. This workshop took aim at addressing how to build a global workforce, how to support racial, gender, geographic, and institutional diversity, and how "the goals of inclusion intersect with the changing culture of science." The point of this workshop and many other efforts is fundamentally one of social justice. But it is also to ensure the future of a STEM workforce facing urgent needs to address climate change, global health issues, energy needs, international migration patterns, and unexpected, but life-altering biological developments such as the emergence of the recent Covid-19/SARS pandemic. (NASEM 2021).

UC San Diego, like most universities and medical schools, has made a firm commitment to admitting students and hiring a workforce that adequately reflects the diversity of the U.S. population, most particularly in terms of gender, racial, and ethnic parity. Equity, Diversity, and Inclusion (EDI) initiatives and the campus Principles of Community aim to create a climate of respect, fostering the talents and abilities of all. How are we doing? And whose job is it to see us do better?

Are EDI initiatives and goals rightly classified as part of Principal Investigator responsibilities? Of faculty and university staff generally? If so, how should the principles of equity, diversity, and inclusion be implemented in hiring, promotion, and tenure? Should trainee programs and graduate orientations include discussing the benefits of diversity in the workforce? Whose responsibility is it to ensure a fair, equitable, and inclusive lab culture? What exactly does fairness and equity require in this setting, particularly once students are admitted or faculty hired? What do we mean by "inclusiveness" and how do we create a receptive, non-discriminatory, and supportive research environment?

These and other issues now stand at the center of a range of campus and UC-wide initiatives. Further progress requires that all of us ask questions about how well our current practices in admissions, hiring, and mentoring reflect institutional commitments to EDI. It also requires recognizing that the sciences, like the social sciences and humanities, are increasingly global endeavors. As such, they require the talents of all of us.

AN OVERVIEW OF THE REGULATION OF ANIMAL RESEARCH

BY THE IACUC OFFICE

Taking good care of another living being should be a given. This is true for pets and livestock, but especially important when we use animals for research purposes. While the majority of researchers are aware of this responsibility and act accordingly, there have been instances across the United States (U.S.) of mistreatment and questionable ethics in the past, including the theft of pets for use in research laboratories. The latter was exposed in a Life magazine article in the 1960s and resulted in a massive public outcry. Congress, encouraged by activist groups like the Animal Welfare Institute, realized that laws were needed to codify the care and use of laboratory animals. In 1966, Congress passed the first such law, the "Laboratory Animal Welfare Act." This law covered the transport, sale, and handling of animals and provided for licensing of animal dealers to prevent pet theft and their sale to research facilities as well as set high standards of care for laboratory animals with regard to their housing, feeding, cleanliness, ventilation and medical needs. Since the law was passed, those standards have been refined and adapted to new types of research, but they still apply today. The law also made the use of anesthesia or analgesic drugs for potentially painful procedures and during post-operative care mandatory.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) enforces animal research laws by inspecting laboratories and monitoring for compliance with the applicable laws. The Laboratory Animal Welfare Act, now known as the Animal Welfare Act (AWA), has been amended four times (1970, 1976, 1985, and 1991), each time elevating the standard of animal care. The amendment of 1985 was the most extensive and had two very significant results. First, an Animal Welfare Information

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AN OVERVIEW OF THE REGULATION OF ANIMAL RESEARCH

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Center (www.nal.usda.gov/awic) was established to provide researchers with a database of alternatives to painful animal experiments. Second, each research facility in the U.S. using species covered by the AWA must register with the USDA and establish an Institutional Animal Care and Use Committee (IACUC) to review all experimental protocols involving live, warm-blooded animals (see below). Similar committees had already existed to monitor clinical trials, and the amendment now extended the same careful review to research on animals.

The definition of "animal" in the original AWA has been somewhat controversial because it only covered dogs, cats, nonhuman primates, guinea pigs, hamsters, and rabbits, but it excludes the most commonly used laboratory animals, mice and rats. While this has been repeatedly challenged by animal rights advocates, Congress recently passed an amendment to exclude permanently rats, mice and birds used in research from the AWA. However, these species are protected under another federal agency, the Public Health Service (PHS). PHS Policy requires that all institutions receiving research funds from the National Institutes of Health, the Food and Drug Administration or the Centers for Disease Control and Prevention, adhere to high standards of animal care. This covers most academic institutions that perform animal research. While PHS Policy applies only to PHS-funded research, it is broader than the AWA in that all vertebrate animals (including fish and reptiles) are covered.

The standard of care under the PHS Policy is "The Guide for the Care and Use of Laboratory Animals" (The Guide), which is published by the National Research Council and the Institute for Laboratory Animal Research. The Guide outlines rules and regulations for everything from the purchase, transport and housing of animals to experimental limitations and veterinary care. The Guide's recommendations are enforceable based on the Health Research Extension Act passed by Congress in 1985.

Both AWA and PHS Policy require the establishment of an IACUC which must include at a minimum one veterinarian and one member not affiliated with the institution as well as scientists and non-scientists. IACUCs require researchers to justify their need for animals, select the most appropriate species and use the fewest number of animals possible to answer a specific question, all of which is summarized in a document called an animal use protocol. IACUC approval of the animal use protocol is required before any animal work can be conducted. Protocols represent a contract between researchers and the IACUC to adhere to all rules and regulations laid out by PHS Policy and AWA.

In addition to federal requirements, there can also be state and local rules in place that govern animal research. In general, the IACUC is tasked with ensuring compliance with all applicable regulations at any given institution. It should be noted that the AWA and PHS Policy apply only to research institutions in the U.S., while regulatory oversight in other countries can be markedly different.

In 1965, the nonprofit AAALAC International (formerly known as the Association for the Assessment and Accreditation of Laboratory Animal Care) was founded with the goal to promote a uniform standard of animal care in the U.S. AAALAC International provides a service to accredit research institutions on a voluntary basis by evaluating animal care programs every three years to ensure scientists comply with the guidelines set forth in The Guide. With the ever-increasing degree of international scientific exchange and collaboration, AAALAC International has expanded since its inception and is now accrediting research and testing programs throughout the world, with over 1000 accredited institutions in 47 countries.

Even though AAALAC accreditation is voluntary, it provides a huge benefit to research institutions by assuring uniform standards of care. Many funding agencies now strongly encourage accreditation and University of California (UC) Policy requires all campuses to remain accredited, which makes it difficult to collaborate with non-accredited institutions if animal research is to be conducted there using UC funds. Therefore, while taking good care of laboratory animals is the right thing to do, it is also a crucial part of competing for research funding and establishing collaborations with other researchers.

For questions regarding animal research at UCSD, please contact the IACUC at iacuc@ucsd.edu or (858) 534-6069.

ATTORNEY CLIENT PRIVILEGE AND THE CALIFORNIA PUBLIC RECORDS ACT

BY STASI CHASE

How does a UC San Diego communication become Attorney Client (A/C) privileged?

In order to establish A/C privilege, a person must:

1. communicate with a lawyer[1]
2. to secure legal advice or services, or
3. to retain that lawyer.

This means that in general, communications by UC San Diego employees operating within the scope of their employment who are seeking legal advice[2] from In-House Counsel are A/C privileged communications.

That being said, not every communication between an employee and In-House Counsel is legal advice. Some communications are business advice, some are transitory or informational and some are personal. The only communications protected by A/C privilege are legal advice.

How does one determine that a communication with In-House Counsel is A/C privileged legal advice?

Determination of whether a communication is A/C privileged legal advice is made by In-House Counsel. An employee's belief that they were seeking legal advice is not determinative of whether a communication is A/C privileged.

Can communications with In-House Counsel be released pursuant to a California Public Records Act (CPRA) request?

Records created at UC San Diego in the course of business are deemed releasable under the CPRA unless the content of the records falls under an exemption. A/C privileged communications are exempt from production under the CPRA per Government Code §6254(k). Other non-A/C communications with In-House Counsel are deemed releasable under the CPRA (unless they fall under some other exemption).

To be clear, just because someone communicates with (or copies) In-House Counsel, does not mean that some or all of that communication is A/C privileged. For questions or assistance, please contact UC San Diego Policy and Records Administration at publicrecords@ucsd.edu.

[1] The attorneys in the Campus Counsel's office, the office of the Chief Counsel, UC San Diego Health, the UC Office of General Counsel and attorneys retained on their behalf are the only attorneys who are authorized to provide legal advice or services regarding UC San Diego matters. For convenience, we will refer to these authorized attorneys collectively as In-House Counsel.

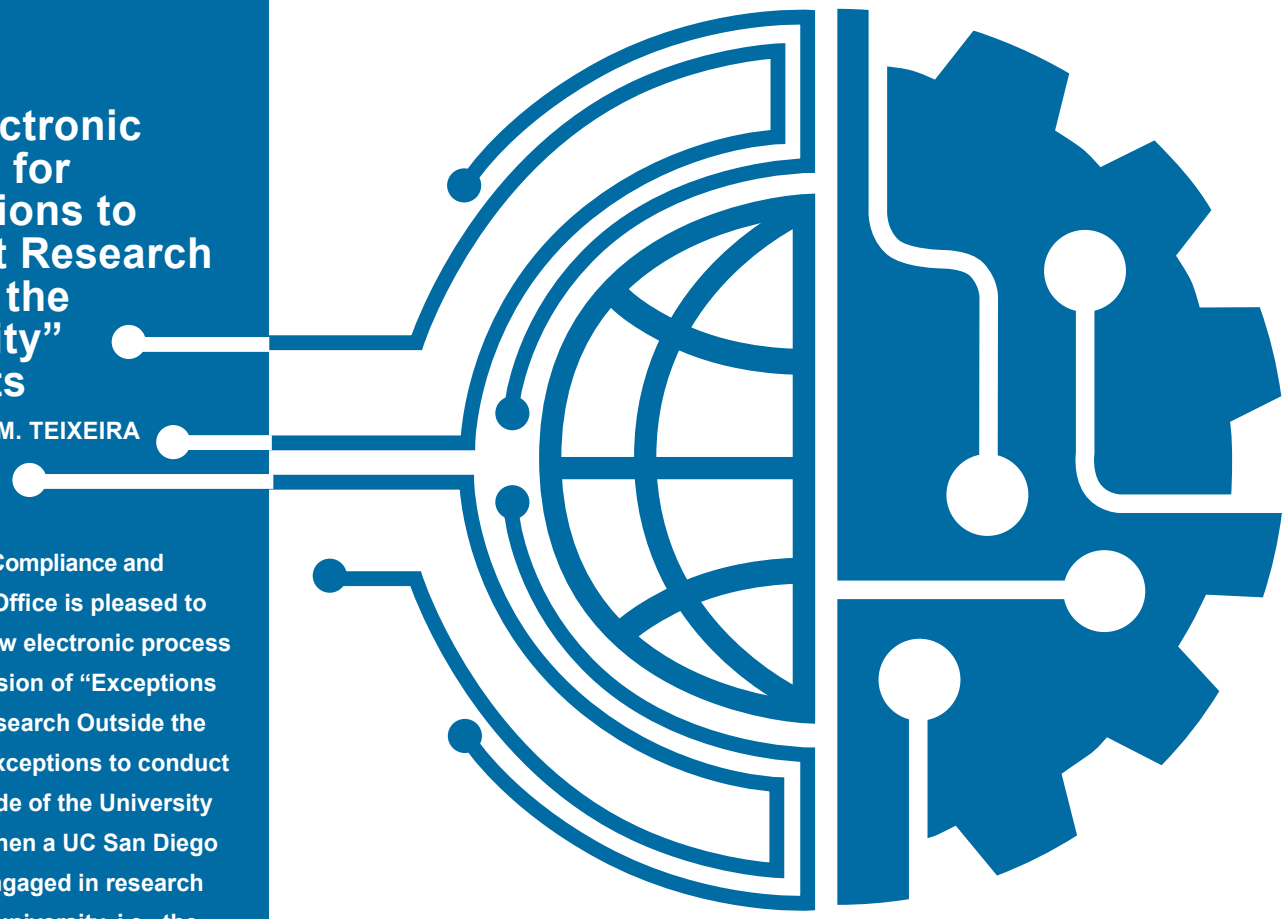
[2] For the purposes of establishing A/C privilege at UC San Diego, employees must be seeking legal advice regarding a matter related to UC San Diego. If an employee's interests are adverse to UC San Diego (even in a matter related to UC San Diego), A/C privilege may not apply. Ex: if an employee seeks legal advice from In-House Counsel regarding whether they should sue the University.

New Electronic Process for "Exceptions to Conduct Research Outside the University" Requests

BY MONIQUE M. TEIXEIRA

The Research Compliance and Integrity (RCI) Office is pleased to announce a new electronic process for the submission of "Exceptions to Conduct Research Outside the University." Exceptions to conduct research outside of the University are required when a UC San Diego employee is engaged in research outside of the university, i.e., the faculty or staff member is listed on a proposal, grant application and/or award and there is no agreement with UC San Diego. In order to streamline and simplify the review and approval processes, these requests will now be managed electronically through Kuali Build (the same electronic system that is being used to approve Research Ramp-up plans).

To access the electronic system, please visit the RCI Exceptions to Conduct Research Outside the University webpage (log into Kuali Build with your Active Directory (AD) account). If you have questions or need assistance, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.



FOOD AND DRUG ADMINISTRATION NOTICES OF NONCOMPLIANCE FOR CLINICALTRIALS.GOV

BY MONIQUE M. TEIXEIRA

It was previously reported the Food and Drug Administration (FDA) was beginning to issue preliminary notices of noncompliance for ClinicalTrials.gov. These "pre-notice" noncompliance letters describe the potential violation and requests that the Responsible Party (RP) take the necessary actions to address the potential violation within 30 calendar days from receipt of the notice. Potential sanctions include civil monetary penalties in excess of $12,000 per day, if the study is in noncompliance and loss of Health and Human Service (HHS) funding to the study and/or UC San Diego.

On April 27, 2021, the FDA issued its first notice of non-compliance to Acceleron Pharma, Inc. The FDA notice stated the Acceleron Pharma Inc. failed to submit results for the applicable clinical trial. The FDA provided Acceleron Pharma, Inc. with the opportunity to remedy its noncompliance by submitting the required clinical trial results information within 30 calendar days from the date the notice was received. The notice indicated that if the results are not submitted within 30 calendar days, the FDA may seek civil monetary penalties.

Please see the Research Compliance Corner: Word to the Wise section of this Newsletter (page 10) for additional information and a link to the FDA Acceleron Pharma, Inc. notice. The FDA noncompliance notices are sent the Responsible Party indicated on the ClinicalTrials.gov study record. If you receive a FDA Pre-Notice of Noncompliance or Notice of Noncompliance letter, please contact the Research Compliance Office and Integrity Office as soon as possible at ctgov@ucsd.edu or (858) 822-4939.

Restricted Party Lists

BY RYAN JORDAN

Knowing all parties to an export transaction is a critical component of any compliance program. The Federal government maintains lists of entities that pose a risk to National Security or Foreign Policy of the United States (U.S.). Export control laws and trade sanctions regulate how U.S. parties and individuals transact with these restricted parties or entities. Examples of restricted parties include terrorists, weapons proliferators, export control violators, drug traffickers, and others subject to government restrictions, debarments, or sanctions. With few exceptions, U.S. parties are generally prohibited from engaging with these restricted parties or entities without a license or other form of authorization.

Examples of restricted parties include terrorists, weapons proliferators, export control violators, drug traffickers, and others subject to government restrictions, debarments, or sanctions.

Within the University of California system, a consolidated list search tool provided by Visual Compliance is utilized to perform Restricted Party Screenings (RPS) to ensure that UC San Diego (UCSD) is not interacting with restricted parties or entities. RPS is the first step in protecting not only yourself but UCSD as a whole. At UCSD, faculty and staff across campus perform over 22,000 RPS a year before engaging in foreign activities, including shipments, payments, purchases, hosting visitors, collaborations, travel, and both funded and unfunded research agreements.

This RPS tool is similar to a Google search. The Visual Compliance tool will cross-reference all government lists subject to Export Controls, along with Law Enforcement and the Department of Health and Human Services debarred lists, among others. Anyone with an @ucsd.edu email address can sign up for a Visual Compliance account to run their screenings. For more information on running these screenings or how to escalate matches generated by these screenings, please contact the UCSD Export Control Office. If you are considering engaging with a restricted entity, the Export Control Office will review the activity and assist with any licensing requirements.

Regulatory Lists of Restricted, Denied, and Debarred Parties:

- The U.S. Department of State's Directorate of Defense Trade Controls (DDTC) maintains a list known as Debarred Parties that identifies violators of the Arms Export Control Act (AECA). These persons or entities are prohibited from directly or indirectly exporting defense articles (including technical data) and defense services.
- The U.S. Department of Commerce's Bureau of Industry Security (BIS) maintains three separate restricted party lists.
  - The first is the Denied Person list, consisting of entities and individuals denied export privileges. Any dealings with a party on this list that would violate the terms of its denial order are prohibited per Section 764.3(a)(2) of the Export Administration Regulations (EAR).
  - The second is the Entity List, which identifies foreign parties prohibited from receiving some or all items subject to the EAR without a license. These parties present a greater risk for diversion of weapons of mass destruction programs, terrorism, or other activities contrary to US national security or foreign policy interests.
  - The third is the Unverified List (UVL), which includes parties where BIS has not verified the entity's bona fides. There are various legal requirements for transactions with a UVL, and it is essential to contact the UCSD Export Control Office before any transaction.

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Restricted Party Lists

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- The Military End User (MEU) List includes foreign entities prohibited from receiving exports described under Supplement No. 2 to Part 744 in the EAR. In most cases, a license may be obtained to facilitate these transactions. There are also restrictions and a few named entities listed in 15 CFR 744.22 that restrict exports for particular military-intelligence end uses or end users in Burma, China, Cuba, Iran, North Korea, Russia, Syria, and Venezuela.
- The U.S. Department of Treasury's Office of Foreign Assets Control (OFAC) maintains several lists related to sanctions. The most prominent of the OFAC lists identifies Specially Designated Nationals (SDN) (includes both individuals and entities) whose property is blocked. The embargoed sanction countries include Cuba, Iran, North Korea, Syria, and the Crimean Peninsula of Ukraine. All transactions with parties on the SDN list or in an embargoed country require an OFAC license. If you anticipate any interactions with entities or persons located within an embargoed country, please contact the UCSD Export Control Office for assistance.

In addition to the regulatory lists noted above, some "red flag" lists can generate matches when running an RPS using Visual Compliance. The most common of these lists is the China Defense University Tracker, a project created by the Australian Strategic Policy Institute with funding from the US State Department. It may not be illegal to engage with universities and laboratories on this list, but many are deemed very high risk for their continued engagement with the People's Liberation Army.

The UC San Diego Export Control Office is here to facilitate your research and will review your proposed activity for licensing requirements and other risks. For additional information, guidance, or to initiate a review, please contact the UCSD Export Control Office at export@ucsd.edu.

Research Affairs: The Importance of Equity, Diversity and Inclusion

BY MADELEINE PALEY

Of the many challenges our country faced in 2020, systemic and structural racism has been front and center. The past year highlighted the nation's inequities that have been around for centuries and have disadvantaged the lives of many. Leadership at UC San Diego, particularly in Research Affairs, have maintained the deep understanding that diverse perspectives and experiences enhance research productivity. To uphold values and take part in active change in Research Affairs at UC San Diego, Vice Chancellor of Research Sandra Brown created the Research Affairs Equity, Diversity and Inclusion (EDI) Committee, made up of volunteer members from across Research Affairs. The Research Affairs EDI Committee is committed to giving a voice to the community, enhancing and celebrating diversity and fostering a culture of inclusive excellence.

The Office of Research Compliance and Integrity (RCI) reaffirms a commitment to bringing awareness and action when it comes to equitable communication and supporting EDI efforts in Research Affairs. Through the facilitation of responsible research, innovation and education, RCI practices thorough communication efforts with all individuals, upholds personal and institutional accountability and consistently demonstrates dedication to embracing change in the global research experience.

In March 2021, the National Institutes of Health (NIH) launched a new effort to end structural racism in research through the UNITE Initiative. UNITE is comprised of five committees with coordinated objectives on addressing racism and discrimination while promoting diversity and inclusion. The committees are:

- **U – Understanding stakeholder experiences through listening and learning**
- **N – New research on health disparities, minority health, and health equity**
- **I – Improving the NIH culture and structure for equity, inclusion and excellence**
- **T – Transparency, communication, and accountability with internal and external stakeholders**
- **E – Extramural research ecosystem: changing policy, culture and structure to promote workforce diversity**

The UNITE Initiative has representation from across NIH Institutes and Centers and hopes the efforts of UNITE will strengthen the NIH's commitment to diversity in science and racial equity both internally and externally. Researchers across the country and at UC San Diego can dismantle policies or practices that harm the members of this community and foster a diverse research enterprise.

If you have questions or would like to learn more about the Research Affairs EDI Committee, please contact vcr-edi@ucsd.edu. Join the Research Affairs EDI Committee at the June Pride Month Panel Discussion on June 25th from 12:00pm-1:00pm, with AVC Faith Hawkins and panelists Mel Medrano-Cordova, Frances Reed, Jayne Sommers, and Prizila Vidal. Please register here and submit any questions to the panelists at vcr-edi@ucsd.edu.

Conflict of Interest (COI) Office Guidance on Outside Personal Consulting Agreements

BY JENNIFER J. FORD

UC San Diego (UCSD) encourages its faculty to participate in activities that contribute to their profession and to the outside community. Personal consulting is a professional activity related to a person's field that is undertaken with an outside party, usually for a fee-for-service. Although outside consulting arrangements are personal, language in consulting agreements can create conflicts with the obligations of a faculty

member to UCSD. Faculty members and other researchers may engage in consulting with outside entities as long as UCSD facilities are not utilized and the consulting activities do not interfere with their teaching and research responsibilities to UCSD.

The UCSD Conflict of Interest (COI) Office developed a guide on outside personal consulting agreements to assist faculty, staff and students (who are employees at UCSD), with issues to consider when entering into personal outside consulting agreements. UCSD does not review or sign personal consulting agreements and this guide is not to be taken as legal advice (faculty may wish to seek personal legal advice prior to signing any such agreement). The COI Office, in consultation with other UCSD institutional offices, has developed sample contract language that can be included in a personal consulting agreement.

CONSIDERATIONS FOR OUTSIDE PERSONAL CONSULTING AGREEMENTS

- **Employee Obligations under UC Patent Agreement/ Acknowledgment:** All employees of the University sign a Patent Agreement/Acknowledgment as a condition of employment. Under the University Patent Policy, employees agree to disclose all inventions and patents to the University, and to assign them to the University, except those resulting from permissible personal consulting activities for faculty, staff and students.

  Often outside personal consulting agreements have language that requires assignment of patentable discoveries and/or other intellectual property to the company. Such a requirement might stand in direct conflict with obligations already made to the University and possibly with the obligations made by the University to sponsors of research. Faculty, staff or students (who are UCSD employees) who engage in consulting are advised to consider the terms of any proposed agreement with a company carefully to ensure that no conflict exists with existing obligations. It is also recommended that the company be informed of faculty, staff and students (who are UCSD employees) obligations to the University.

- **Compromising Future Research Funding:** Great care must be taken not to compromise future research funding. Although consulting agreements are personal, if such agreements are not properly formulated, they can jeopardize future University research programs and related funding. Companies employing consultants may desire commercial access to inventions made during the course of the consulting arrangement and often will seek rights to future yet-to-be-developed inventions made at the University related to the consulting activity. An agreement to provide such rights to future research results would preclude the University from providing comparable rights to other companies that sponsor University research. Most potential sponsors would refuse to fund research if their access to resulting inventions were denied because of prior obligations made through a consulting arrangement.

- **Acceptance of Confidential Information:** It is not uncommon that a company will disclose proprietary information to a consultant. In doing so, the company will want assurances that this information will be kept confidential. Confidentiality can be tricky for a faculty member, staff, and students (who are UCSD employees) involved in open, free exchanges of information in a public university setting. Disclosure of proprietary information, either intentionally or unintentionally, may be actionable

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Conflict of Interest (COI) Office Guidance on Outside Personal Consulting Agreements

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under criminal as well as civil law. Therefore, it is essential to limit the amount of confidential information received when consulting and to have the company agree to clearly identify such proprietary information by marking it as "confidential." Consulting agreements should always include a statement about the transmission of proprietary information and a no-fault statement regarding unintentional disclosure.

- **Disclosing Financial Conflict of Interest:** Under the California Political Reform Act of 1974, a Principal Investigator must disclose whether or not there has been any consulting activity with a company when accepting funding for research from that company. The National Science Foundation and the Public Health Service also require disclosure of consulting income under specified conditions. An existing or prior consulting arrangement might require that proposed funding be reviewed and approved by appropriate campus officials for possible financial conflicts. UC San Diego requires Conflict of Interest disclosures to be made in Kuali COI.
- **Reporting Personal Consulting Activities for Conflict of Commitment:** Under University policy (APM-025 / APM-671), certain faculty are required to submit annual reports on their outside professional activities, which includes personal consulting, in UC OATS.

If you have COI questions or need additional information about COI, please contact the COI Office at (858) 534-6465 or info-coi@ucsd.edu.

Acknowledging Federal Funding in Publications

BY DIANA D. KIM

The Department of Health and Human Services (HHS) "Stevens Amendment" requires recipients to acknowledge federal funding when publicly communicating projects or programs funded with HHS funds. Reporting the outcomes of projects and communicating the support of the funding agency not only ensures transparency and accountability, but also recognizes the achievements of the researchers' federally sponsored research.

It is important for researchers to know the terms of their awards for any requirement of acknowledgements or disclaimers. Note that non-federal sponsors may also have requirements for acknowledgements. Several federal agencies including the National Institutes of Health (NIH), provide guidance and specify formats of acknowledgement. The NIH directs researchers to acknowledge awards on publications when the activities that contributed to the publication are directly stemmed from the award and are within the scope of the award being acknowledged. In order to avoid citing awards not directly connected to the publication or failing to properly cite the funding on the publication, researchers are to cite the NIH support if:

- The personnel activity supported by the award contributed to the publication;
- The award supported the conduct of experiments or analysis of data that contributed to the publication or,
- There is a clear and apparent link between the work described in the publication with the aims and objectives of the grant.

Investigators must acknowledge support for all publications and presentations of work supported by the federal government with the name of the agency and the award number. Specifically, the NIH requires the following statements:

1. A specific acknowledgment of NIH grant support, such as "Research reported in this publication was supported by [name of the Institute(s), Center, or other NIH offices] of the National Institutes of Health under award number [specific NIH grant number(s) in this format: R01GM987654]."
2. An acknowledgement of the level of NIH funding that indicates:
   - The percentage and dollar amounts of the total program or project costs financed with Federal money, and
   - The percentage and dollar amount of the total costs financed by nongovernmental sources.
3. A disclaimer that states, "The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

For additional information and resources, please visit the NIH Policy and Compliance page. For information on acknowledgement of funding for National Science Foundation (NSF) and Department of Energy (DOE), please visit the NSF Proposal and Award Policies and Procedures Guide and DOE Office of Science page.

RESEARCH COMPLIANCE CORNER:

WORD TO THE WISE

HOSPITAL RESEARCHER SENTENCED TO PRISON FOR CONSPIRING TO STEAL TRADE SECRETS AND SELL TO CHINA

Yu Zhou, 51, pleaded guilty in December 2020 to stealing scientific trade secrets related to exosomes and exosome isolation from Nationwide Children's Hospital's Research Institute for his own personal financial gain. "Yu Zhou sought to exploit U.S. taxpayer dollars intended to fund critical, life-saving research at Nationwide Children's Hospital through the whole-sale theft of their trade secrets," said Assistant Attorney General John C. Demers for the Justice Department's National Security Division. "Zhou's greed was encouraged and enabled by a series of Chinese Government programs which incentivize thievery in an attempt to supplement China's own research and development goals on the back of American ingenuity and investment. This successful prosecution should serve as a warning to anyone who seeks to profit from pilfering hard-earned U.S. trade secrets."

"Yu Zhou willingly took part in the Chinese Government's long-term efforts to steal American intellectual property," said Acting U.S. Attorney Vipal J. Patel for the Southern District of Ohio. "Zhou and his wife executed a scheme over the course of several years to set up businesses in China, steal American research, and profit from doing so. The couple deserves the time it received in federal prison."

According to court documents, Zhou and his co-conspirator and wife, Li Chen, 48, worked in separate medical research labs at the Research Institute for 10 years each (Zhou from 2007 until 2017 and Chen from 2008 until 2018). They pleaded guilty to conspiring to steal at least five trade secrets related to exosome research from Nationwide Children's Hospital. Zhou was sentenced to 33 months in prison and Chen was sentenced in February to 30 months in prison for her role in the scheme.

As part of their convictions, the couple will forfeit approximately $1.45 million, 500,000 shares of common stock of Avalon GloboCare Corp. and 400 shares of common stock of GenExosome Technologies Inc. They were also ordered to pay $2.6 million in restitution.

For additional information, read the Department of Justice sentencing announcement.

STUDY COORDINATOR CHARGED IN SCHEME TO FALSIFY CLINICAL TRIAL DATA

A federal grand jury in Miami, Florida, returned an indictment today charging Jessica Palacio, 34, with conspiring to falsify clinical trial data regarding an asthma medication. According to court documents, Palacio worked as a study coordinator at a clinical trial firm called Unlimited Medical Research. Unlimited Medical Research was one of many companies hired to conduct a clinical trial designed to investigate the safety and efficacy of an asthma medication in children. The indictment alleges that Palacio participated in a scheme to falsify medical records to make it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research, received physical exams from a clinical investigator, and took study drugs as required, when in fact these things had not occurred. The indictment also alleges that when Palacio was confronted by a Food and Drug Administration (FDA) regulatory investigator about her conduct, she made a false statement to that investigator. If convicted, Palacio faces a maximum penalty of 20 years in prison for conspiracy to commit wire fraud, and five years in prison for making a false statement.

For additional information, read the Department of Justice announcement.

MATHEMATICS PROFESSOR AND UNIVERSITY RESEARCHER INDICTED FOR GRANT FRAUD

A federal grand jury returned an indictment charging a mathematics professor and researcher at Southern Illinois University, Carbondale (SIUC) with two counts of wire fraud and one count of making a false statement. According to court documents, Mingqing Xiao, 59, fraudulently obtained $151,099 in federal grant money from the National Science Foundation (NSF) by concealing support he was receiving from the Chinese government and a Chinese university.

"Again, an American professor stands accused of enabling the Chinese government's efforts to corruptly benefit from U.S. research funding by lying about his obligations to, and support from, an arm of the

RESEARCH COMPLIANCE CORNER:

WORD TO THE WISE

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Chinese government and a Chinese public university," said Assistant Attorney General John C. Demers for the Justice Department's National Security Division (NSD). "Honesty and transparency about funding sources lie at the heart of the scientific research enterprise. They enable U.S. agencies to distribute scarce grants for scientific research fairly and equitably. And they allow other researchers to evaluate potential conflicts of interest and conflicts of commitment. When researchers fall short of fulfilling these core academic values in ways that violate the law, the Department stand ready to investigate and prosecute."

According to the indictment, Xiao has worked in SIUC's mathematics department since 2000, focusing his research on partial differential equations, control theory, optimization theory, dynamical systems, and computational science. In that position, Xiao allegedly applied for and received NSF grant funds for a project set to run from 2019 to 2022 without informing NSF about another, overlapping grant he had already received from the Natural Science Foundation of Guangdong Province, China. Xiao also allegedly failed to inform NSF that he was on the payroll of Shenzhen University, a public university in Guangdong Province, and that he had already committed to teaching and conducting research at Shenzhen University from 2018 to 2023.

The indictment further alleges that in March 2019, while his NSF grant proposal was still pending, Xiao submitted another grant proposal to the Natural Science Foundation of China. According to the indictment, Xiao allegedly applied for the funds as an employee of Shenzhen University and did not disclose the new Chinese proposal to NSF. Xiao is charged with falsely certifying to SIUC that his NSF grant proposal was true, complete, and accurate.

If convicted, Xiao faces up to 20 years in prison on each count of wire fraud and up to five years in prison for making a false statement. All three charges are also punishable by a fine of up to $250,000.

For additional information, read the Department of Justice sentencing announcement.

UNIVERSITY RESEARCHER SENTENCED TO PRISON FOR LYING ON GRANT APPLICATIONS TO DEVELOP SCIENTIFIC EXPERTISE FOR CHINA

Song Guo Zheng, a former Oho State University rheumatology professor and researcher with strong ties to China, was sentenced to 37 months in prison for making false statements to federal authorities as part of an immunology research fraud scheme. As part of his sentence, Zheng was also ordered to pay more than $3.4 million in restitution to the National Institute of Health (NIH) and approximately $413,000 to Ohio State University.

Zheng was arrested after he arrived in Anchorage, Alaska, aboard a charter flight and as he prepared to board another charter flight in to China. He was carrying one small suitcase and a briefcase containing two laptops, three cell phones, several USB drives, several silver bars, expired Chinese passports for his family, deeds for property in China and other items. Zheng pleaded guilty and admitted he lied on applications in order to use approximately $4.1 million in grants from NIH to develop China's expertise in the areas of rheumatology and immunology.

Zhen was participating in the Chinese government's Thousand Talents program. The Assistant Attorney General indicated that, "Zheng will spend the next 37 months in a federal prison because he chose to lie and hide his involvement in this program from U.S. research funding agencies. "American research funding is provided by the American taxpayer for the benefit of American society, not as an illicit gift to the Chinese government."

For additional information, read the Department of Justice sentencing announcement.

FOOD AND DRUG ADMINISTRATION TAKES ACTION FOR FAILURE TO SUBMIT REQUIRED CLINICAL TRIALS RESULTS TO CLINICALTRIALS.GOV

The Food and Drug Administration (FDA) issued its first Notice of Noncompliance to Acceleron Pharma, Inc. (Acceleron) on April 29, 2021, for failing to submit required summary results information to ClinicalTrials.gov. The FDA determined that the responsible party who received a Pre-Notice of Noncompliance did not comply with its legal reporting obligations. The company's applicable clinical trial evaluated the safety and effectiveness of the drug dalantercept in combination with axitinib in patients with advanced renal cell carcinoma. The Notice of Noncompliance gives Acceleron 30 days to submit the required summary results information. The FDA is authorized to seek civil money penalties for Acceleron's violation, including additional civil money penalties if Acceleron fails to submit the required information within the 30-day period.

The Notice of Noncompliance has also been posted to the FDA's website and information about the noncompliance will be posted on the study record on ClinicalTrials.gov by the National Institutes of Health (NIH). The NIH will continue to update the ClinicalTrials.gov records for applicable clinical trials that are the subject of a Notice of Noncompliance with information regarding whether the noncompliance has been corrected and the amount of civil money penalties assessed, if any.

For additional information, read the U.S. Food and Drug Administration bulletin.

Correctly Using Official UC San Diego Logos, Names and Other Brand Elements

UC San Diego

What is a brand? Is it the name of a company? Is it a logo or a slogan? A feeling or mental image you get when you think of a certain product? Brand is all these things and more. In the case of UC San Diego, it's a reflection of campus essence and how our stakeholders feel about the institution, including students, staff, faculty, alumni, donors and community members.

A consistent brand for UC San Diego helps define and reinforce who we are. It supports the story of why we are different and why what we do matters. We communicate the brand by how we position the campus, create consistent messaging, and deploy brand elements across print and other media channels.

It is important to remember the University of California (UC) and UC San Diego have policies in place regarding use of its names, seals, logos and trademarked materials.

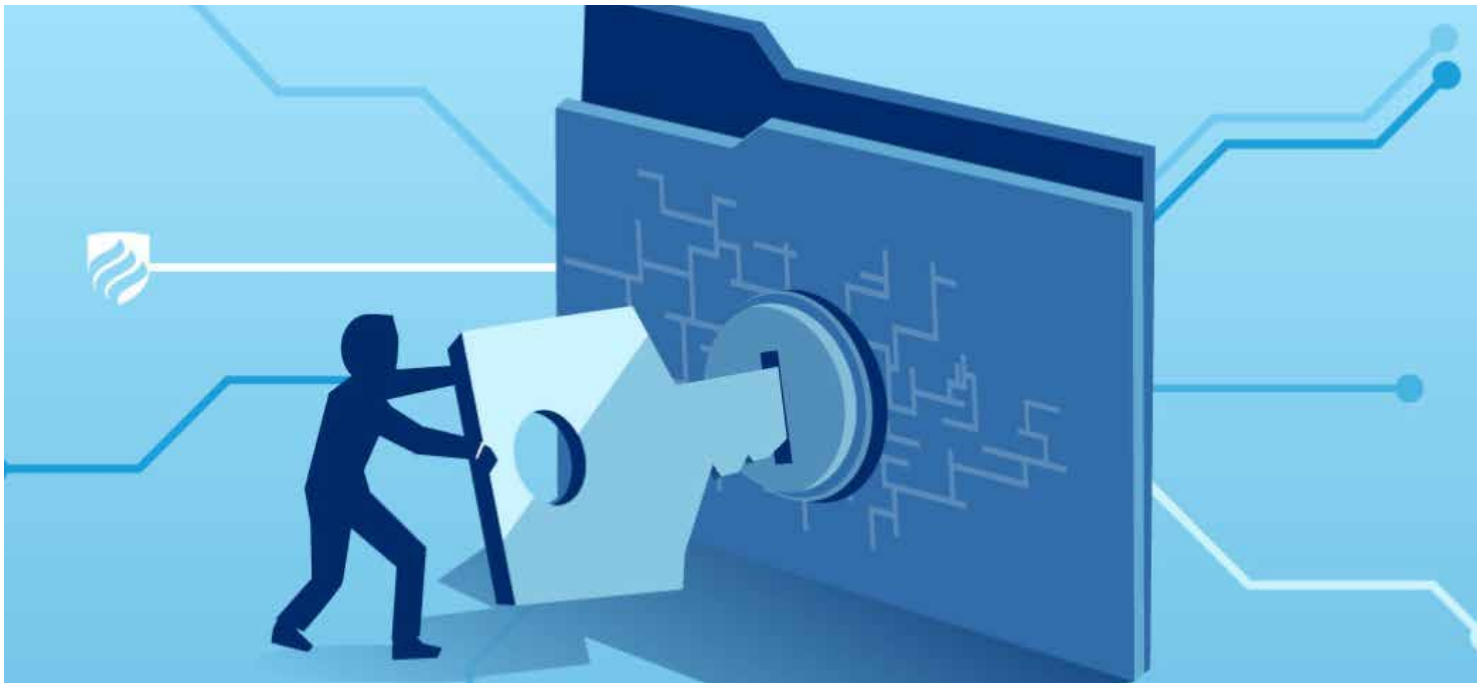
Researchers may be contacted by industry partners and sponsors, academic collaborators or other external organizations about issuing a joint press release, using the university logo on a website or on event materials, or endorsing a product or service. Things that may not seem overtly like endorsements may, nonetheless, run afoul of university policies.

Keep in mind:

- Employees may use the UC and/or campus name in making true and accurate statements of their relationship with, or employment by, the University of California.
- Employees may not use the UC and/or campus name or their affiliation with the university in any manner which suggests or implies university support or endorsement of any movement, activity or program.
- All commercial use of the UC and/or campus seal, name, logo and other trademarked material is prohibited unless express written permission is first obtained through a written license or prior authorization.
- Advertising that displays or lists the UC and/or campus as a user of any product or service or as the source of research information on which a commercial product, program, or publication is based is prohibited unless express written permission is first obtained from the Chancellor or the Assistant Chancellor Chief of Staff.

This policy has been created to protect the UC San Diego brand and ensure it is used in a way that enhances our reputation and prestige, rather than diminishing it. It is each individual employee's responsibility to follow the policy guidance. You can find this information on the Research Affairs Blink webpage. You may also review Brand Guidelines and download brand assets here.

If you have questions about a particular use case or have been approached about a joint press release, please contact your communications lead or send an email to brand@ucsd.edu.



New Cybersecurity Self-Certification Program Launched

BY MICHAEL CORN

As every member of the UC community is aware, the loss of our personal information due to a data breach is no longer a theoretical event, but something that has and continues to impact each of us and our families. While this is a terrible situation, the disruption to your research programs by ransomware and similar cyberattacks is also a growing and significant risk. As seen with our neighbors at UCSF, Scripps Health and the recent disruption of a gasoline pipeline, the loss of access to systems or the disruption of your scientific workflows will be devastating to a research program. Sponsoring organizations may also include language requiring their notification when research data is stolen or corrupted.

Recognizing the pace of modern research, and the time pressures faculty operate under, we have created a very lightweight program that begins to build cyber resilience into your research. The Cybersecurity Certification for Research (CCR) initiative was crafted to minimize the impact on researchers, while maximizing the security benefit to UC San Diego's research ecosystem. Cybersecurity risks are similar to those we've experienced throughout the COVID-19 pandemic, ransomware spreads over the network, thus your research data is only as secure as your weakest connection or system in your laboratory.

The CCR Program will request the following: (1) Provide information about your laboratory and information technology (IT) practices such as your backup strategy; (2) Install two programs (an anti-malware and a vulnerability identification agent); and (3) The Principal Investigator (PI) must attest to the accuracy of the information provided.

Upon completion, each PI will receive a statement of certification for inclusion with data management plans or any proposal where an attestation of security practices could be beneficial. Certifications are good for three years. Steps 1 and 2 can be delegated to whomever is best suited to perform the work. For a small or relatively small laboratory, the process can take less than an hour, while for larger projects or laboratories, the PI can include a projected completion date and receive the certification prior to completing the software installations.

A robust support system has been put into place to assist with the CCR program. All that is needed is an email to ccr-support@ucsd.edu and you will be connected to IT and security professionals who will consult on any aspect of your research IT and securing your systems as well as assisting with software installations. It should be noted that UC San Diego has a number of research domains that are exceptionally high value targets for hackers and are actively at risk. These specifically include researchers working on COVID-19, those with sponsored research by the Department of Defense and those who receive significant federal funding. Certifications submitted by those researchers will be reviewed by a team of professionals who will provide suggestions to enhance the laboratory's IT security.

Please visit the CCR program website for additional information and to access the Cybersecurity Certification for Research form. For laboratories that wish to address the security of students or visitors working in their environment, there is a separate Laboratory Worker Cybersecurity Attestation form.

For questions or assistance, please contact Mike Corn, Chief Information Security Officer, at mcorn@ucsd.edu.

EDUCATION

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

The UC San Diego Research Compliance and Integrity Office is pleased to offer the Research Compliance Hot Topics and Training Program (Program) to all UC San Diego faculty, staff and students. The Program will offer training through a variety of forums, including workshops, videos, newsletters and other activities, and is designed to serve as an educational resource to assist the UC San Diego research community with the complexities of conducting research. The following session has been scheduled:

- **Freedom of Information Act and the California Public Records Act Requests**
  June 16, 2021
  11:00 a.m. - 12:30 p.m.,
  via Zoom (to register, click on this link)

Information on additional sessions will be provided soon. For questions, please contact rci@ucsd.edu.

CLINICALTRIALS.GOV VIDEO SERIES

The Research Compliance and Integrity (RCI) team is excited to announce the addition of some new videos to the ClinicalTrials.gov Video series. The short videos will walk through tips and tricks on some common activities and issues related to the use of ClinicalTrials.gov. The following videos are available on the RCI website:

- **Requesting a User Account on the PRS System**
- **Updating Record: Overview of the Study Status Page**
- **Delay Results**
- **Copy Protocol and How to Change the Record Owner**
- **Grant Access**
- **Delete Record**
- **Addressing Major and Minor Comments**
- **Definitions**
- **Spell Check**
- **RP and PI Overview**
- **Review of PROCoM Emails**

To view these videos, visit the RCI ClinicalTrials.gov website and click on the **NEW ClinicalTrials.gov Video Series**. For additional information regarding ClinicalTrials.gov, please visit the RCI ClinicalTrials.gov Frequently Asked Questions (FAQ) page. If you have any questions or suggestions for videos you think would be helpful, please contact RCI at (858) 822-4939 or ctgov@ucsd.edu.

Q&A

"An investment in knowledge pays the best interest."

— Benjamin Franklin

Ask the Questions . . .

Does a National Institutes of Health (NIH) training grant or Center grant need to be acknowledged on publications?

Awards should be acknowledged only in publications that directly arise from research activities supported by the grant and fall within the scope of the grant. For a National Institutes of Health (NIH) training grant, it should be acknowledged if the training and career development activities that contributed to the publication were supported by the grant and within the scope of the grant. For an NIH Center grant, it should be acknowledged if the activities supported by the Center that contributed to the publication were supported by the grant and within the scope of the grant.

For more information, please visit the National Institutes of Health Frequently Asked Questions.

Who must apply for an animal use protocol with the UC San Diego (UCSD) Institutional Animal Care and Use Committee (IACUC)?

Anybody who wants to conduct a project involving research, teaching or testing on live vertebrate animals at UCSD must first submit an Animal Use Protocol and wait for approval by the UCSD IACUC before initiating any activity with the animals. Only UCSD faculty members or individuals otherwise eligible for research grants through UCSD may be the Principal Investigator (PI) on an Animal Use Protocol. All federal funding agencies also require an approved Animal Use Protocol for all vertebrate animal work listed on a grant proposal. The Animal Use Protocol represents a "contract" between the PI and the IACUC to conduct all animal work in compliance with all regulations, as reviewed and verified by the IACUC.

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

For conflict of interest, are there set rules or general guidelines as to what may or may not be an acceptable financial interests?

The Independent Review Committee (IRC) for Conflict of Interest (COI) reviews each financial disclosure in accordance with the University of California Policy on Disclosure of Financial Interests in Private Sponsors of Research, the University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects, and the University of California Policy on Disclosure of Financial Interests and Management of Conflict of Interest Related to Public Health Services Sponsored Awards for Research.

If the financial interest is presented to the IRC, the IRC will determine whether the financial interest represents a real or perceived conflict of interest, and if so, whether any action should be undertaken to eliminate, reduce, or manage the conflict of interest. The IRC applies standards that have evolved over time, based on their prior experience, the appearance of new types of conflicts, and input from the local and national research community.

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

RESEARCH COMPLIANCE AND INTEGRITY

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