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The Office of Research Compliance and Integrity (RCI) provides timely notices to the research community on important information, policy updates and regulatory initiatives and changes. See the RCI website at <http://blink.ucsd.edu/sponsor/rci/index.html>.

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A professor and researcher at Massachusetts Institute of Technology (MIT) was recently charged and arrested in connection with failing to disclose relationships and activities with foreign entities. The MIT professor held various appointments and advisory roles in China, offering technological and scientific expertise in return for compensation. During this time, the MIT professor obtained a U.S. Department of Energy (DOE) grant for his research at MIT, but he allegedly failed to disclose his ongoing affiliation with China as required by the DOE. U.S. authorities assert that the MIT professor was a member of at least two Chinese government sponsored "Talent Programs" (see the full article from the [Department of Justice Press Release](#)). The issue of federally-funded researchers at U.S. institutions failing to disclose their ties to foreign institutions and funding agencies is at the forefront of the enforcement actions by U.S. authorities. Ensuring transparent and accurate disclosure of relationships and activities with any foreign entities is important.

UC San Diego believes that scientific research and academic scholarship work best with open collaborations. Our campus is committed to having an open environment, respecting the rights of faculty, students and staff, and abiding by its Principles of Community. As a global research University, UC San Diego proudly has hundreds of faculty and educators from around the world teaching in our classrooms. UC San Diego however must also protect research integrity, address the federal government's increasing concerns about foreign entities unduly influencing United States (U.S.) research and adhere to the guidelines and policies the U.S. government puts in place. There is a heightened concern that certain foreign governments may seek to influence U.S. research through recruitment of U.S. researchers which includes providing appointments and resources at foreign Universities.

Foreign Government Sponsored Talent Recruitment Program

Foreign government sponsored talent recruitment programs, typically referred to as “Foreign talent programs,” includes any foreign government-run or funded programs that target individuals including but not limited to scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working or educated in the U.S. in an attempt to acquire U.S. scientific funded research and/or technology in exchange for financial and other types of support.

Ways to Recognize Foreign Talent Programs

Foreign talent programs have varying names depending on the country initiating the program. Features of foreign talent programs may include¹:

- Compensation in exchange for knowledge, expertise, or other intellectual asset transfer to the foreign state. The compensation can take several forms such as cash, research facilities or other in-kind support, honorific titles, career advancement opportunities, promised future compensation, or other types of remuneration or consideration.
- The foreign-state-sponsor’s active engagement in attracting the targeted individual to join the foreign sponsored program and transfer their knowledge and expertise to the foreign state. Recruitment would not necessarily include an invitation to attend or present work at an international conference.
- Incentives to physically relocate to the foreign state. Of particular concern are some foreign talent programs that allow for continued employment at U.S. institutions and/or receipt of U.S. federal research funds while receiving compensation from the foreign state at the same time.

Concerns about Foreign Government Sponsored Talent Programs

Foreign talent programs often create a one-way transfer of technology and expertise. The [FBI Public Service Announcement](#) summarizes the government’s concerns related to the foreign talent programs. Such programs often seek to obtain proprietary technology or software, unpublished data and methods, and intellectual property from abroad. By agreeing to participate in a program, researchers may agree to be subject to the laws of the foreign country, which may prohibit the researchers from advancing their research with their U.S. employer or funding agency without special authorization from the foreign government, undermining reciprocity of research.

Disclosure

While participation in a foreign government sponsored talent programs is not in itself prohibited, provisions in such programs may conflict with the federal agencies and/or the University’s policies, especially if the individual does not appropriately disclose the foreign government sponsored talent plan affiliation. Specifically, the U.S. Department of Energy prohibits participation in foreign government sponsored talent programs in addition to requiring a full disclosure. Be transparent in disclosing foreign relationships and activities as it protects the interests of everyone involved, e.g. the individual researcher, their international collaborators, UC San Diego and the U.S. government. Disclosures may need to occur for conflict of interest, conflict of commitment as well as in the researchers Other Support and Biosketch.

Resources

The Office of Research Affairs [International Research and Engagement page](#) includes the best practices, [contacts at UC San Diego](#), and links to guidance, regulations, policies, and procedures. The UC Office of the President also has a [comprehensive resource on Foreign Influence](#) with more background information and links to the relevant UC system policies. There may be additional guidance in the future as foreign talent programs evolve. For questions or additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

¹ Information from the U.S. Department of Energy Order 486.1.



What is a Public Health Service (PHS) Funded Project? The Public Health Service (PHS) regulations require all research sponsored by PHS, including the National Institutes of Health (NIH) and [other non-federal sponsors who have adopted the PHS FCOI regulations](#), require disclosure of significant financial interests by Investigators who participate in PHS funded research either directly or through a subaward.

In addition, all Investigators are required to complete PHS training prior to engaging in PHS funded research and at least every four years while engaging in PHS funded research.

What is a Federal Non-PHS Funded Project? Federal regulations as well as University of California policy, require Investigators to disclose certain significant financial interests. Federal Non-PHS Funded projects are funded by the National Science Foundation (NSF) and other Federal Non-PHS agencies with financial conflict of interest disclosure requirements as well as the California Institute for Regenerative Medicine and certain University of California Programs, either directly or through a subaward.

What is a Non-Federal Funded Project? The State of California requires that University Investigators disclose their position (whether compensated or uncompensated) or financial interest(s) when their research project is being funded or supported in whole or in part by a non-federal funded project, such as a non-profit foundation or for-profit company, either directly or through a subaward. Investigators must disclose their 700-U form per project in Kuali COI. Human Subjects projects whether funded or unfunded, an Investigator with a position or financial interest(s) with the company's product or the Investigator is the inventor of technology must self-report their conflict of interest to the COI Office in Kuali COI.

Do I need to certify annually for my federal PHS and Non-PHS awards? When University Investigators are awarded PHS (i.e., NIH, CDC, or non-profits that follow PHS FCOI policies) or Non-PHS (i.e., NSF, CIRM and UC programs) sponsored research, Investigators must review, update and certify on an annual basis in Kuali COI. Under a recently deployed enhancement, Kuali COI will send an email to the Investigator if their federal PHS or non-PHS COI portfolio before their portfolio has expired in Kuali COI. Investigators must log in and certify before expiration to be in compliance with their active federal awards.

If my financial interests change, when do I have to update my federal and non-federal awards? When University Investigators are awarded sponsored research or other related activities (i.e., gifts, services, material transfer agreements, etc.) and have new financial interest(s) the University Investigator must submit an update of financial interest within 30 days for Public Health Service (PHS) funded projects to the Conflict of Interest (COI) Office. A financial interest is anything of monetary value, whether that value can be easily determined or not, that is held by the investigator, their spouse or registered domestic partner, and dependent children and meets reporting categories and thresholds for the applicable COI disclosure in Kuali COI. As a reminder, Investigators must disclose financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

Besides new federal or non-federal awards, when do I need to update my interest(s) in Kuali COI? Depending on your active research awards, you may need to provide an annual certification and/or an update of financial interest to the Conflict of Interest (COI) Office through Kuali COI.

What happens if I do not disclose my interest(s) in a timely manner? Under Public Health Services (PHS) regulations when there is a financial conflict of interest (FCOI) and an Investigator has not disclosed in a timely manner, the Institution is required to perform a "retrospective review" to determine whether any PHS funded research conducted during the time period where the FCOI was not reported, was the research biased in the design, conduct or reporting. If bias is determined by the Institution, the funding agency must be informed and mitigation plan must be proposed by the Institution.

For questions or additional information, please contact the Conflict of Interest Office at info-coi@ucsd.edu, (858) 534-6465 or visit the [Conflict of Interest website](#).



The [Food and Drug Administration \(FDA\) Amendments Act of 2007 \(FDAAA\)](#), Title VIII, expands the National Library of Medicine (NLM) clinical trials registry and results database known as [ClinicalTrials.gov](#) and requires that a "Responsible Party" (RP) submit clinical trial registration and results information to the ClinicalTrials.gov data bank for certain "applicable clinical trials (ACTs)." The regulation became effective on January 18, 2017, and RPs have been required to be in compliance starting April 18, 2017. ACTs generally include:

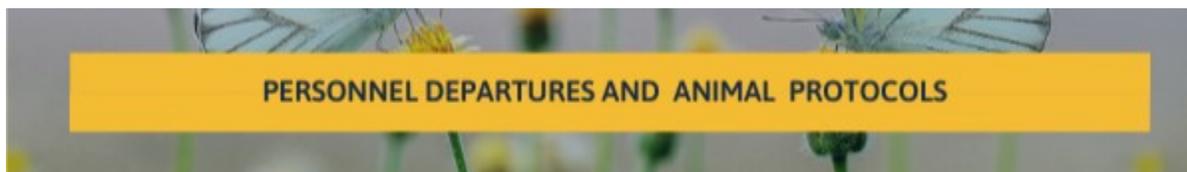
1. Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and
2. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post market surveillance.

The consequences of noncompliance may include public notices of noncompliance and violations, withholding of federal funds, FDA sanctions and civil monetary penalties (in excess of \$12,000 per day). Civil monetary penalties may be assessed for:

1. Failing to submit required clinical trial registration and/or results information to the ClinicalTrials.gov data bank,
2. Submitting false or misleading information to the ClinicalTrials.gov data bank,
3. Failing to submit the required certification to FDA, or
4. Knowingly submitting a false certification to FDA.

The FDA has begun issuing Preliminary Notices of Noncompliance (Pre-Notice) Letters. These Pre-Notice Letters describe the potential violation and requests that the RP take the necessary actions to address the potential violation within 30 calendar days from receipt of the letter. After 30 calendar days from receipt of a Pre-Notice Letter, the FDA will conduct a further review and assessment of the clinical trial information submitted to ClinicalTrials.gov (and other relevant information available to FDA) to determine if regulatory action is required, inclusive of the issuance of a Notice of Noncompliance, civil money penalties, an injunction, and/or criminal prosecution.

For additional information, please visit the [RCI FDA Pre-Notice and Notices of Noncompliance website](#). If you receive an FDA Pre-Notice letter, please contact the Research Compliance Office and Integrity Office as soon as possible at ctgov@ucsd.edu or (858) 822-4939.



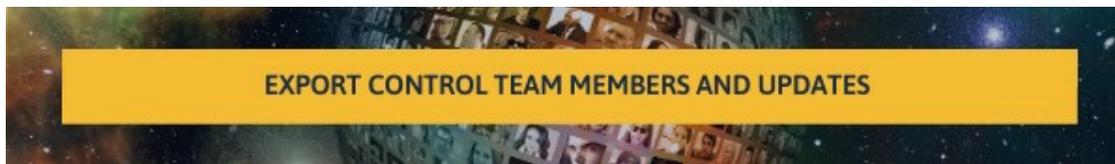
Those who work with animals in research are required to be listed on an animal use protocol, complete training, and fulfill other requirements. Likewise, there are requirements when personnel leave the laboratory or are no longer involved in animal research. It is important to remove them from the protocol, notify the relevant departments, and in the case of a Principal Investigator (PI) leaving UC San Diego, to ensure the animal protocol is managed appropriately.

The PI or alternate contact can remove a person from a protocol at any time through the animal use protocol system (AUPS). Adding and removing personnel from a protocol can be done independent of the amendment process so these changes are immediate. If the person is listed on multiple protocols, they will need to be removed from each protocol.

In addition to removing personnel from the protocol, it is important to notify the Institutional Animal Care and Use Committee (IACUC) Office and Animal Care Program (ACP) of the person's departure. Notify the IACUC office at iacuc@ucsd.edu. This is particularly important if the person was the point of contact for the laboratory for animal related matters. Notify the Animal Care Program at acp-access@ucsd.edu so the person's vivarium access can be terminated.

When a PI plans to leave UC San Diego or if they will no longer use animals in their research, it is best to notify the IACUC Office and ACP as soon as possible. Animal use protocols can be transferred to another PI or inactivated. Transferring a protocol to another PI requires that a protocol amendment be submitted by the originating PI and approved at a convened IACUC meeting, so it is important to plan accordingly.

If no animals are currently in census on the protocol, the PI or alternate contact can simply send a request for inactivation to iacuc@ucsd.edu. If there are animals assigned to the protocol, contact ACP at acp-ops@mail.ucsd.edu to make arrangements for the animals in addition to contacting the IACUC Office. For any questions regarding personnel departures and animal protocols, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.



Learn about the New Export Control Team Members and Updates

There have been some exciting changes in the Export Control team at UC San Diego. We would like to take this opportunity to introduce our new export control team members and provide some updates.

➤ Ryan Jordan, Senior Export Control Analyst/Facility Security Officer

As a Senior Export Control Analyst, Ryan Jordan provides UC San Diego with an extended knowledge base in export compliance, international trade, and global logistics. As the Facility Security Officer (FSO), he manages the industrial security apparatus surrounding various research programs to ensure compliance with the National Industrial Security Program. Ryan “cut his teeth” on international trade, global logistics, supply chain management, and overseas manufacturing when he co-founded Happy Owl Studio, a design and manufacturing firm specializing in technology accessories. Besides his international experience, Ryan also has a long and diverse history with the Marine Physical Laboratory at Scripps Institution of Oceanography where he was an engineering intern with a research group, worked for the R&D Machine Shop, and supported the business office by coordinating complex international shipments for many of the department’s seagoing research groups. Ryan received his BA from California State University Northridge and is a Lean Six Sigma Green Belt.

➤ Tamara Hemingway, Senior Export Control Analyst

Tamara (Tami) Hemingway is a Senior Export Control Analyst for UC San Diego. Tami has worked in academia for more than 20 years. She formerly worked as a Research Associate in the Human Cancer Genetics Lab at Ohio State University while attending law school. After graduation she accepted a position as a Licensing Associate with Michigan State University (MSU) where she was responsible for assisting faculty with patenting and licensing novel developments in human and animal medicines. While at MSU she was appointed Export Control Officer to assist with growing the export control program. Prior to joining UCSD, Tami was the Director of Export Compliance and Research Security acting as the Empowered Official, Facility Security Officer, and Insider Threat Program Senior Official at Clemson University. Tami holds a BA in English from Ohio State University, a BA and an MS in Biology from Eastern Michigan University, and a JD from Ohio State University with a license to practice in the state of New York.

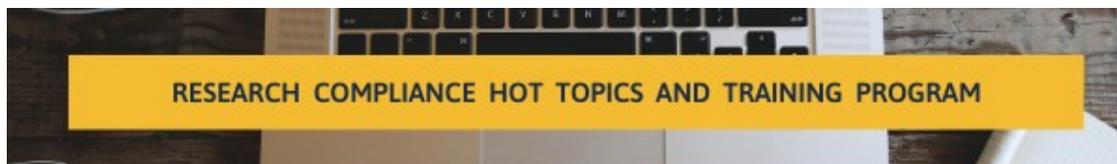
➤ Ashley Rubio, Senior Export Control Analyst/Assistant Facility Security Officer

Ashley Rubio is the Export Analyst and Assistant Facility Security Officer for UC San Diego. Ashley graduated with her BA in English from San Diego State University (SDSU). While studying for her undergraduate degree, she worked for a biology laboratory and on grants which supported first generation and underrepresented students. Her interest in research compliance for higher universities brought her to work for SDSU’s Research Affairs Office for over six years focusing on Financial Conflict of Interest and Responsible Conduct of Research. Ashley also led programs and events that promoted and helped advance student research.

➤ Brittany Whiting, Export Control Officer

Since 2013, Brittany has been UC San Diego’s Export Control Officer and served as the campus leader and resource for designing, developing, and implementing an export control education, licensing, and compliance program. She will be moving on to lead Amazon’s Project Kuiper Export Controls on March 1, 2021. Recruitment is underway for a new Export Control Officer.

For assistance or additional information, please contact the Export Control team at export@ucsd.edu.



The UC San Diego Research Compliance and Integrity Office (RCI) 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. Below is the information for the next session.

➤ **February 17, 2021**
All About Innovation and Commercialization

Dr. Paul Roben, Associate Vice Chancellor for Innovation and Commercialization, will provide information on the roles and responsibilities of the Office of Innovation and Commercialization (OIC) and where it fits in the university structure. Additionally, the process of commercializing inventions and how OIC supports that process will be discussed. Guidance on resources available to inventors and entrepreneurs across the campus will be provided as well.

To register, please click on this [UC Learning Center link](#) to directly register for the session. Select Register in the dropdown menu. Select Add and click Register in the lower right corner of the page. You will receive an email registration confirmation.

If you have any questions, please contact the RCI Office at (858) 822-4939 or rci@ucsd.edu.

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