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

In This Issue

During the course of your research or official activities at UC San Diego, you may need to ship or hand carry equipment or materials outside the United States. Moving goods internationally is highly regulated, depending on 1) **WHAT** the items are, 2) **WHERE** the items are going, and 3) **WHO** will be receiving the items. There are a number of regulations that apply to international trade that you must consider, even in cases where the goods are not being sold or permanently exported. Penalties for non-compliance may result in fines, delays, seizure of goods or potential imprisonment. The University of California's Export Control Policy affirms our commitment to compliance with these regulations. As the shipper, it is your responsibility to contact the UC San Diego Export Control Office before your items leave the U.S.

The Export Control Office and other cognizant offices at UC San Diego offer resources and support to faculty, staff and students to help ensure you understand the applicable laws and conduct your transaction legally, while still maintaining research timelines.

Depending on **WHAT** kind of equipment or material you are sending abroad, the government may have controls on the item if it is Export Controlled, depending on if the item has a potential use that may harm National Security, Foreign Policy or other areas of concern. We recommend requesting the "export classification" of your item(s) from the manufacturer or vendor up front. The classification number provides context on how and why the item is controlled and the destinations that would require an export license (i.e. government authorization) or license exception (regulatory carve out).

The government maintains sanctions and arms embargoes on a number of countries, so **WHERE** your item is headed must be evaluated in conjunction with how the item is controlled. **WHO** is receiving your items may also necessitate an export license or other approval. Individuals, organizations or businesses may also be sanctioned. A number of foreign research institutions and universities are listed as Restricted Parties. Just as with sanctioned countries, an export license or license exception is required to Restricted Parties. UC San Diego utilizes the VisualCompliance Restricted Party Screening (RPS) tool to screen recipients prior to exporting. It is the responsibility of the shipper to ensure a license review has been completed by the UC San Diego Export Control Office and Restricted Party Screening is done on both the receiving individual and entity.

In addition to Export Control regulations administered under the Departments of State, Commerce and Treasury, your shipment or hand carry may also require an import or export permit for controlled substances, infectious or toxic material, live animals, endangered animals and their tissue samples, or a number of other reasons related to health and safety, national security, or trade regulations.

For hazardous materials shipping, the UC San Diego Outbound Shipping team is certified to handle and package Dangerous Goods for transport. The EH&S Biosafety Officer can also advise on what may be required for infectious, toxic or other controlled substances that could affect public health and safety.

The value of your items is very important and must be declared to customs. Applicable tax, duty or fees may apply. Any export of a single commodity, as assessed by a Tariff Code that has a value of $2,500 or more and will not return to the U.S. within one year requires an Electronic Export Information (EEI) filing with the U.S. government. An invoice or other documentation is also required for shipments.

Lastly, if the items being exported were (1) solely developed at UC San Diego, (2) were transferred to UC San Diego for research purposes by a third-party and are now being sent out, or (3) were modified at UC San Diego to incorporate, rely on, use or were derived from third-party material, it is the responsibility of the Principal Investigator (PI) to ensure the appropriate agreement is in place to protect the material before transfer to a third party. Please note that this includes material modified or transferred that was purchased or obtained via a publically available source (i.e., Addgene, Jackson, ATCC, Wicell, MMRRC) or gifted/obtained from a third party. The Material Transfer Agreement (MTA) is the most common example of this type of agreement, but other examples include service, loan, and data-use agreements as well as procurement contracts. Additionally, some sponsored research agreements can also include intellectual property protection clauses. An MTA request may be sent through the online eMTA System. Please note that the PI must do the final review, certification, and submission and is responsible for ensuring that the information submitted through the eMTA system is correct.

The UC San Diego Export Control Office can advise on the requirements that apply to your specific situation. For additional information or assistance, please visit the UC San Diego Export Control website or contact us at export@ucsd.edu.

Responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Projects funded by the National Institutes of Health (NIH), National Science Foundation (NSF) and National Institute of Food and Agriculture (NIFA) have specific requirements regarding training in RCR. Who must obtain RCR training is dependent on the funding source, as outlined below.

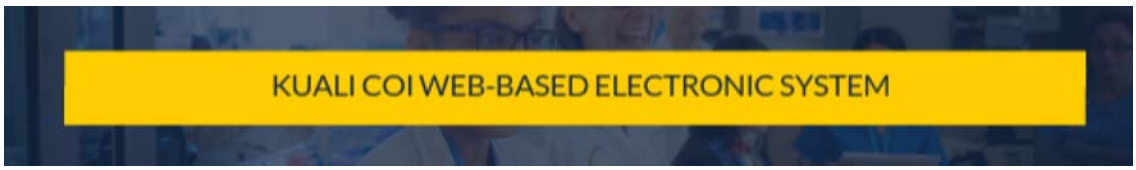
National Health Institute (NIH):
NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. This Notice applies to the following NIH programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R.

National Science Foundation (NSF):
NSF requires training and oversight in the ethical conduct of research for all undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.

National Institute of Food and Agriculture (NIFA):
NIFA requires RCR training for all Principal Investigators, Key Personnel, and Investigators participating in NIFA sponsored research. These designations may apply to faculty, staff, undergraduate students, graduate students, and postdoctoral fellows.

Recently, the UC San Diego Research Compliance and Integrity (RCI) Office webpage has been updated with Responsible Conduct of Research Frequency Asked Questions (FAQs). Please review these FAQs for answers to some of the most asked questions the RCI Office receives.

If you are unsure if you or any of your study team members may need to receive RCR training, please contact the RCI Office at (858) 822-4939 or rci@ucsd.edu. For general information on RCR training, including how to receive the training, please see the Responsible Conduct of Research training page.



The Enterprise System Renewal (ESR) procured Kuali for sponsored research with modules called Kuali Conflict of Interest (COI), Kuali Research and Kuali IRB. Kuali COI is a web-based platform that provides for an electronic conflict of interest disclosure process.

The Kuali COI system is designed to collect, process, store, and report information about the discloser's financial interests. With the implementation of Kuali COI system, we will be able to remove the archaic

paper/PDFs COI disclosure process; streamline the current COI disclosure and business processes; and improve compliance with Federal and State regulations and University policies for conflict of interest. The Kuali COI Module will integrate with Kuali Research to automate and facilitate the completion of conflict of interest disclosure forms for its employees and affiliates. In order for the Kuali COI system to be compliant with University of California's various conflict of interest policies, Kuali COI required significant enhancements, which have been underway since November of 2018.

Kuali Research and Kuali COI will launch on January 21, 2020. Some key Kuali COI features are:

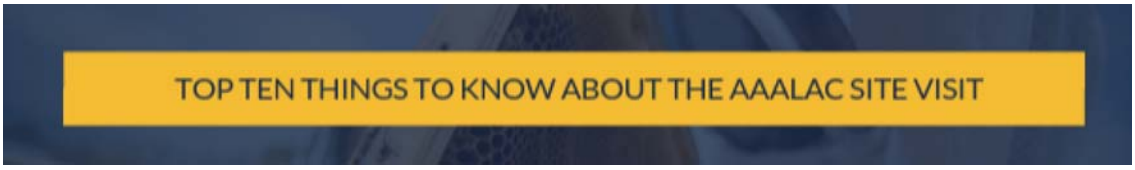
► For investigators with federal research (i.e., PHS and non-PHS) there will be "portfolio concept", which allows investigators to submit and update an annual research-related COI disclosure form and disclose any new financial interests. The Investigator will receive automated email reminders from Kuali COI 30 days prior to the disclosure expiration date, based on the last date of approval. This will replace the PHS and 9510 paper COI form.

► For investigators with non-federal funded research or other related activities (i.e. gifts, services, human subjects research, etc.) the system will require a COI disclosure for each project. The Kuali COI system will generate an automated email to inform the investigator to submit a COI disclosure. This will replace the 700U paper COI form.

► Investigators will be able to assign their support staff as delegates to receive automated emails, review and enter certain types of data elements in the Kuali COI system.

We will be engaging faculty and staff for training in November and December 2019 with learning labs and virtual instructor-led training. Information about the Kuali COI training strategy is available on the Kuali COI webpage.

For questions, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465 or Jennifer J. Ford, Conflict of Interest Office Director, jjford@ucsd.edu.



AAALAC will be conducting a site visit to UC San Diego soon! The Institutional Animal Care and Use Committee (IACUC) oversees the University's animal care and use program and is responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories, and overseeing training. AAALAC accreditation is considered the "gold" standard and is viewed very favorably by granting agencies.

1. **The site visit will occur from November 18-21, 2019:** The AAALAC site visit team will visit all UC San Diego animal use areas, including vivaria, laboratories, and satellite facilities. They will use the Guide for the Care and Use of Laboratory Animals as the basis for their assessment. They will also check that UC San Diego policies are followed.

2. **AAALAC accreditation is important to UC San Diego's research enterprise:** AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. AAALAC accreditation is similar to the Joint Commission accreditation for hospitals and covers organizations that use animals in research, teaching or testing. Accredited organizations include universities, hospitals, government agencies, pharmaceutical

and biotechnology companies and other types of research organizations.

3. AAALAC accreditation is important to your laboratory: University of California Office of the President (UCOP) Policy requires that all UC campuses be AAALAC accredited. UC San Diego must be re-evaluated at a site visit every three years to maintain its accredited status. AAALAC accreditation is viewed very favorably by granting agencies. Many institutions will not consider collaboration with other institutions or companies that are not AAALAC accredited.

4. AAALAC accreditation is for the entire animal care and use program: Site visitors are not only interested in the care of animals used in research at UC San Diego, they will also assess other aspects of the animal care and use program such as occupational health and safety for animal users, proper handling and disposal of hazardous agents, and the condition of vivarium and lab facilities.

5. Site visitors are skilled personnel from other accredited institutions: The site visit is meant to be a peer-review. Site visitors hold leadership positions in other AAALAC-accredited institutions and are often research scientists and/or veterinarians.

6. The site visitors have never assessed our animal care and use program before: AAALAC never sends the same team twice to an institution. Every site visit is a new set of eyes on our program and site visitors may focus on different areas of our program at each visit.

7. Site visitors may ask to speak with anyone: It is a good idea to have a designated person who will speak with site visitors. This person should be knowledgeable of the lab's animal work and is typically the lab manager. However, site visitors may ask to speak with someone else such as the newest member of the lab, a student, or anyone other than the lab manager. Everyone who works with animals must be knowledgeable of their own animal work and the UC San Diego policies that affect them. Knowing how to access the approved animal protocol is essential for all animal users.

8. It is ok if you do not know something, but you should know how to find out: If you do not know the answer to a question, just say so. It is always better to offer to find the correct information than to give incorrect information or make something up. Animal procedures are described on the protocol and the Animal Care Program can be contacted for animal health and vivarium concerns.

9. A clean lab appears to be a compliant lab: A well-organized and clean lab makes a good first impression. Site visitors will tend to assume that if the lab looks good, the lab is doing everything else right. If site visitors see a cluttered lab space with a floor that hasn't been cleaned in months, they may wonder what else is not being done in the lab and may ask more questions.

Check your vivarium space for clutter as well. Properly discard expired items as well as those that are no longer used. Clean supply boxes of debris. Remove records for animals that have been euthanized and file them in the lab. Site visitors may ask to see old records but there is no need to keep them in the vivarium.

10. You can (and should) continue your work as usual: There is no need to shut down the lab for the site visit. If your work cannot be interrupted, please let the site visit team know that. Site visitors will not want to negatively affect your work or do anything that is unsafe. Let them know if a procedure cannot be interrupted and how to be safe in your lab space. Site visitors may ask to return to your lab at a different time or ask to speak with another member of your lab.

We appreciate your efforts in helping to make the AAALAC site visit as successful as possible! If you have questions about preparing for the AAALAC site visit, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

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 provides 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. See the information below for the upcoming session:

- **October 23, 2019, 11:00 – 12:30 p.m., Leichtag Auditorium, Room 107**
  Compliance with Federal and State Permitting Requirements While Conducting Research

This session will provide information on the various federal and state entities (CDC, USDA/APHIS, FWS, etc.) which may levy permitting requirements regarding the importation, interstate transfer, or collection of biological materials. Topics covered will include investigator responsibilities, types of permits, where to submit permit requests, a generalized overview of what to expect during the permitting process and inspections, campus resources available to investigators to assist with obtaining permits, requirements for exempt materials, fulfilling permit conditions of approval, and permit transfer or closeout. There will also be a question and answer period.

Please register by October 21, 2019, at the UC Learning Center. Select Register in the dropdown menu. Select the radio button for the session and date, and click Submit in the lower right corner of the page. You will receive an email registration confirmation.

To listen to recordings of past sessions, please visit the Research Compliance and Integrity website. If you have any questions, please contact the RCI Office at (858) 822-4939 or rci@ucsd.edu.

UC San Diego, Research Compliance and Integrity
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