

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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Due to the COVID-19 Pandemic, there are a number of students and employees that have not been able to return to the United States and UC San Diego and are studying and working remotely abroad. There may be a need to ship items abroad for class projects or research. Even if items are for educational or fundamental research purposes, export license reviews are required for all export shipments that are not published documents. As the shipper, it is your responsibility to contact the UC San Diego Export Control Office prior to international shipments for an export license determination.

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. Depending on **WHAT** kind of equipment or material you are sending abroad, the government may have controls on the item it if 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 <u>VisualCompliance Restricted Party Screening (RPS)</u> 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.

The value of your items must be declared accurately to customs. Applicable tax, duty or fees may apply. Any export of a single commodity, as assessed by a Harmonized System Tariff Code (HS code), 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) filling with the U.S. government. Recently the export regulations changed for shipments to China, Russia and Venezuela that there are new EEI filling requirements depending on the export classification of the items. Outbound Shipping, Export Control or UC's freight forwarder, American Cargo Service, are the groups authorized to file EEI for UC San Diego.

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.

In addition to shipment delays or possible seizure of items that do not have the required paperwork or export clearance, there are penalties for non-compliance which may result in fines, delays, seizure of goods or potential imprisonment. The <u>University of California's Export Control Policy</u> affirms our commitment to compliance with export control regulations and outlines responsibilities for individuals with regards to international shipping.

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



The National Institutes of Health (NIH) grant applicants are required to include a biographical sketch (or Biosketch) document with their applications. NIH does not have strict reference requirements and does not require a specific style. This allows the Principal Investigator to use whichever style they prefer, with consistency and accuracy being key. When providing a bibliography of any references citied in the research plan, NIH expects applications to cite papers exactly as they appeared in print, including the order of authors.

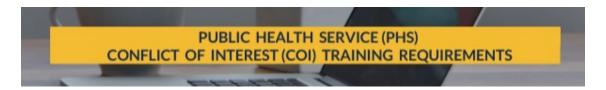
Each reference must include the names of all authors (in the same sequence in which they appear in the publication, the use of "et al." is not an acceptable in place of listing all of the authors), the article and journal title,

book title, volume number, page numbers, and year of publication. Be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

It is also important to remember to comply with NIH's <u>public access policy</u> by <u>including the PubMed Central®</u> (PMC) reference <u>number</u> (PMCID) when citing <u>applicable papers</u> that you author or that arise from your NIH-funded research.

One tool to help with citations is <u>SciENcv</u>. SciENcv is a tool to prepare biosketches for NIH and other agencies, which uses a standard format used by the National Library of Medicine. The UC San Diego Library has <u>online guides</u>, <u>classes</u> or <u>consults</u> for these and other citation tools. For more information on NIH application guidelines visit NIH website.

For questions or additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.



Every four years, UC San Diego Researchers with Public Health Services (PHS) funded research must complete their PHS training through <u>UC San Diego's LMS system</u>. PHS Researchers are those who regardless of their title or role on the project (Investigators and senior/key personnel), receive funding from PHS agencies. In order to release PHS-funded research projects, all Researchers must have completed the PHS training in the past four years as well as their conflict of interest disclosure in Kuali COI.

In addition, the UC Office of the President requires University employees who received any portion of their salary from extramural funding sources to complete the UC Compliance and Conflict of Interest for Researchers (COIR) Briefing. This COIR briefing also satisfies the PHS training requirement.

PHS training will take approximately 15 to 20 minutes and provide guidance on:

- ➤ The overall FCOI regulation and its purpose, i.e. to safeguard the public's trust and to ensure that the research is free from the bias of researcher's financial interest(s).
- Specific information regarding travel disclosure requirements, disclosure thresholds, how the University manages disclosures, and more.
- A Researcher must report his or her Significant Financial Interests (SFIs) and those of their spouse and dependent children that may be related to the Researcher's institutional responsibilities. These disclosures are expected to be completed:
 - > At the time of PHS application
 - Within 30 days of a new SFI
 - Annually

It is the shared goal of the University and Researchers to maintain the public's trust in their work by jointly taking all the necessary steps to maintain the Researcher's compliance with federal and institutional regulations. If you have questions or need additional information, please contact the Conflict of Interest Office at (858) 534-6465 or info-coi@ucsd.edu.



Accepting the National Institutes of Health (NIH) awards comes with the responsibility of protecting sensitive and confidential data. The <u>NIH cybersecurity policies</u> are designed to protect sensitive information and keep data safe in the world of evolving and emerging cybersecurity threats. As part of proper stewardship of federally funded research, researchers should:

- Take all reasonable efforts to prevent sensitive personal information from being inadvertently disclosed, released, or lost.
- Not house sensitive and confidential information about NIH-supported research on portable electronic devices.
- Encrypt the data.
- Use proper controls to limit access to personally identifiable information.
- Transmit data only when the security of the recipient's systems is known and satisfactory.

Researchers who collect, store, process, transmit, or use federal data, must make sure that all information systems, electronic or hard copy, are protected from unauthorized access per <u>federal policies</u>. In addition to ensuring the security of the data, researchers are responsible for maintaining the original federal data and intellectual property.

To get started building a solid foundation of cybersecurity for your research project, please see the campus' cybersecurity certification for research initiative at https://assure.ucsd.edu. Please visit the Department of Homeland Security page for helpful protection and reporting tips. For UCSD IT Services Security, please contact security@ucsd.edu. For questions or additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.



Custom antibodies are used in research in various immunoassays. Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf). Custom antibodies may be generated as part of an investigator's Institutional Animal Care and Use Committee (IACUC) approved protocol or may be purchased from an off-site vendor.

There are specific regulatory requirements governing the acquisition of custom antibodies. As the generation of custom antibodies is an activity involving vertebrate animals, it is covered by the Public Health Service (PHS)
Policy. Per the Office of Laboratory Animal Welfare (OLAW), which oversees the care and use of research animals in PHS-funded research, "an organization producing custom antibodies for an awardee must have or obtain a PHS Assurance, or be included as a component of the awardee's Assurance." Additionally, AAALAC International, the organization that accredits UC San Diego's Animal Care and Use program, expects accredited institutions to assume responsibility for overseeing the animals involved in the production of the custom antibodies. Finally, if species covered by the Animal Welfare Act are utilized, the custom antibody producer must be registered as a Research Facility with the United States Department of Agriculture (USDA).

To comply with all of these requirements, UC San Diego's IACUC requires that custom antibodies only be purchased from vendors which are PHS-assured, AAALAC-accredited, and USDA-registered (if rabbits or other USDA-covered species are used). For your convenience, the IACUC Office has prepared a <u>list of pre-approved custom antibody vendors</u>. If you are interested in purchasing custom antibodies from a company or vendor that is not on this list, please consult with the IACUC Office first to determine if the company meets all of these requirements.

Please note that standard antibodies that are catalog stock items from vendors, or are manufactured without the use of live animals, are not considered custom antibodies and are therefore not subject to these specific requirements.

For additional information regarding purchasing custom antibodies, 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 sessions:

➤ November 18, 2020, 11:00 – 12:30 p.m., via Zoom ClinicalTrials.gov - Registration

This session will provide information on how to register studies and make updates as required by the federal regulations as well as provide tips and tricks on how to best navigate ClinicalTrials.gov and the Protocol Results and Registration System (PRS) review process.

Please register by November 16, 2020, via this <u>UC Learning Center link</u>. 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 from UC Learning.

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.

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UC San Diego, Research Compliance and Integrity 9500 Gilman Drive, MC 0992 La Jolla, CA 92093-0992

Website: http://blink.ucsd.edu/sponsor/rci/index.html

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