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FACILITATING RESEARCH, INNOVATION AND EDUCATION,
RESPONSIBLY FOR GLOBAL EXCELLENCE

OCTOBER 2018

HOT TOPICS

RESEARCH COMPLIANCE AND INTEGRITY

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>.

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CONFLICT OF INTEREST IN HUMAN SUBJECT RESEARCH

Researchers involved in human subjects research may have financial relationships related to or separate from particular research projects. Those financial relationships may include payments for services, equity interests or intellectual property rights. A financial interest related to a research study may be a conflicting financial interest. Special concerns arise when human subjects are involved, as the research subjects may be placed at additional risk because of a researcher's financial interests. Situations that warrant additional consideration include when a researcher has a financial interest in the sponsor or manufacturer of a product being tested in human subjects or in which the researcher is the inventor of the product.

The University is responsible for ensuring that human subjects are fully informed and not placed at additional risk because of financial interests on the part of the researcher(s). In addition to the conflict of interest (COI) disclosure requirements under the Federal regulations and State laws, researchers, including staff, who are responsible for the design, analysis, conduct, or reporting of the results of research performed under a human subjects protocol, must disclose whether or not they have a financial interest in or association with the sponsor or the company supplying the materials, drugs, or devices for

the project. This COI disclosure requirement applies to all individuals listed in the research plan as a research team member and is applicable for unfunded research projects (i.e., internal departmental or gift funds). For additional information regarding disclosure requirements for human subject research, please see the Human Research Protections SOPP 3.8, section, "[Financial Disclosure and Conflict of Interest for Investigators.](#)"

Disclosing a financial interest does not mean that the discloser cannot participate in the research project. The COI Independent Review Committee (IRC) may be required to review disclosures related to human subjects research. A common management strategy issued by the IRC to mitigate the financial interest includes disclosure in publications, presentations and in the study's informed consent form. By including the information in the informed consent form, this provides a potential subject with adequate information to allow for an informed decision about participation in the study.

More information on COI policies and the disclosure requirements, please see the [Conflict of Interest website](#). Submit COI disclosure forms to the COI Office at coiforms@ucsd.edu. Please keep in mind that the disclosure form must be received and review by the COI Office prior to the release of funds. If you have questions or need additional information, please contact the COI Office at (858) 534-6465 or info-coi@ucsd.edu.



If you suspect there may be an export control violation or are contacted by federal officials for inquiries related to national security or export controls, please contact the Export Control Office as soon as possible. It is the University policy to cooperate with outside investigating agencies to the fullest extent required by law, while fully protecting the rights and privacy of the students, faculty, staff and research subjects. The Office of Research Affairs recommends all researchers and research staff members be generally aware of the possibility of site visits or inquiries by oversight agencies and be prepared to respond appropriately.

Your Responsibilities:

In many cases, the most important action taken by the person who is the first point of contact (whether a principal investigator, a graduate student working in a laboratory or a staff member) is to promptly contact the [Office of Research Compliance and Integrity](#) so that someone who is familiar with state and federal laws and the University's obligations can provide assistance, and ensure the appropriate University offices are notified. If an outside investigating agency presents a subpoena, search warrant, court order, national security letter or other document compelling the University or an individual to produce documents or otherwise provide information immediately, notify the [Office of Research Compliance and Integrity](#) and campus counsel. Also see the [University PPM 470, Guidelines for Serving, Accepting and Responding to Subpoenas](#).

For national security inquiries or reports of potential non-compliance with export controls, the Export Control Office will review all facts to determine if there is actual non-compliance with federal export regulations or UC Export Control policy and, if so, escalate to the appropriate campus compliance leadership for review and disclose to the relevant U.S. government agency(s) in accordance with the federal export control regulations. International Traffic in Arms Regulation (ITAR) disclosures are done in conjunction with the UC Office of the President Empowered Official and Office of General Counsel.

What Information is Needed:

- What is the issue? What happened? When and where? Has activity ceased? Who was involved?
- What is the item, jurisdiction or classification?
- Is there an immediate threat to U.S. national security based on this suspected violation?
- Where is the specific item located right now?
- Is there a possibility to stop the transaction and secure the item before a potential violation occurs or to stop reoccurring violations?

The [Export Control Office](#) is here to assist the research community. If you have questions or concerns regarding export control compliance or national security issues, please contact the Export Control Office at exports@ucsd.edu or (858) 246-3300.



IT Services is pleased to announce the availability of two-step login procedures for faculty and staff access to key networks and applications. The two-step login increases account security by preventing anyone but you from accessing your account, even if they know the password. You may already be familiar with how it works. Any time you have to enter an additional code sent via text, phone call or email is an example of two-step login. For access at UC San Diego, you can complete the second step via a free smartphone app, phone call or passcode. It's optional for faculty and staff for now, and will be required in January 2019.

LastPass Enterprise is UC San Diego's password manager of choice. No more writing down passwords on a sticky note or keeping a spreadsheet on your desktop. Use it to securely manage your University accounts, like Business Systems, Office 365 and more.

IT Services has scheduled a series of informational sessions designed to help you better understand the two-step login and LastPass. For session dates and times, please visit the [Two-Step Login Session page](#). For additional information regarding the two-step login and LastPass, please visit the [Two-Step Login website](#) or contact the ITS Service Desk at servicedesk@ucsd.edu or (858) 246-4357.



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 [list of pre-approved custom antibody vendors](#). 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.

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