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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

Kuali COI is the new web-based conflict of interest disclosure process for UC San Diego. Kuali COI's implementation replaced the paper conflict of interest (COI) disclosure process. Kuali COI will launched concurrently with Kuali Research (replacing ePD) on January 21, 2020, and has integrated disclosure notifications for external proposals and awards.

There are **consulting sessions** to provide Researcher's with personal assistance for entering their interests in their federal COI portfolio. Administrative support staff can participate with Researchers as well. Please reserve your time online.

For approximately the first year, we want to clarify what transitioning from paper conflict of interest (COI) disclosures to Kuali COI means for Researchers. To reduce burden on the Researchers, we purposely did not trigger a COI disclosure for every research project into Kuali COI on the first day of go-live.

Therefore, there will be instances, where the COI Office collected a paper COI disclosure and Kuali COI is requesting another disclosure. We also want to clarify the following:

1. Researchers and their added Delegates will receive a Kuali COI email from "Kuali Notifications no-reply@kuali.co".
2. In order to be compliant with federal and state conflict of interest regulations, Researchers must work with their administrator who will create a proposal in Kuali Research and complete/save the "basic" information and "key personnel" screen listing the required senior/key personnel who are required to submit a conflict of interest disclosure by the sponsoring agency.
3. For Researchers that have submitted a **positive** disclosure (have interest(s)) for either a federal or non-federal sponsored research project and their COI portfolio (disclosure) is under review by the Conflict of Interest (COI) Office, the Researcher's entire COI portfolio (disclosure) is locked and cannot be edited/updated by the Researcher (or their Delegate). If the Researcher receives a notification to update their disclosure for a new proposal/award or if the Researcher needs to their update financial interests previously reported, the Researcher or their Delegate will need to contact the COI Office at info-coi@ucsd.edu and request their disclosure be returned in the Kuali COI system.
4. For non-federal (700-U) sponsored research (i.e. for-profit and non-profit sponsors), if anyone other than the Principal Investigator (PI) is listed as "Key Personnel" in Kuali Research, the Kuali COI system will send an email requesting disclosure and the 700-U form will not render as a 700-U form is not required. There is no action for the Co-Investigators. While Kuali re-programs the system, we recommend that only the Principal Investigator be listed on the "Key Personnel" tab in Kuali Research.

We thank you for your understanding during this transition. We welcome your feedback and recommendations about Kuali COI. To learn more, please watch Kuali COI Video and content on the Kuali COI Website. For questions, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

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 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.

The UC San Diego Visual Media Group can help you tell the story of your laboratory, make a video abstract, or a funding request video. To find out more about how your research can be better illustrated in video, email the UC San Diego Visual Media Group at vmg@ucsd.edu.

There are a number of export control related regulatory updates expected this year related to emerging technologies and geopolitical events that may impact UC San Diego researchers.

Controls for Military End Use/Users in China, Russia, or Venezuela:
The Department of Commerce will issue a new regulation on the “Expansion of Export, Reexport, and Transfer (In-Country) Controls for Military End Use or Military End Users in the People's Republic of China (China), Russia, or Venezuela” in 2020. This regulation will broaden the items for which the licensing requirements and review policy apply as well as expand the definition of “military end use.” It also creates a new reason for export control and associated review policy for regional stability for certain items to China, Russia, or Venezuela, moving existing text related to this policy. Finally, it adds Electronic Export Information filing requirements in the Automated Export System for exports to China, Russia, and Venezuela. For additional information, please see the Department of Commerce Fall 2019 Semiannual Agenda of Regulations.

National Defense Authorization Act (NDAA) FY20:
Under the most recent Defense Authorization signed into law in December 2019, the NDAA FY20 Section 1281 requires the Secretary of Defense to develop and continuously update a list, in consultation with multiple federal agencies of and Security of the Department of Commerce, the Director of National Intelligence, United States (U.S.) institutions of higher education that conduct significant Department research or engineering activities, and other appropriate individuals and organizations, of academic

institutions of the People's Republic of China, the Russian Federation and other countries that have a history of improper technology transfer, intellectual property theft, or cyber or human espionage; operate under the direction of the military forces or intelligence agency; are known to recruit foreign individuals for the purpose of transferring knowledge to advance military or intelligence efforts; or provide misleading information or otherwise attempt to conceal the connections of an individual or institution to a defense or an intelligence agency; or pose a serious risk of improper technology transfer of data, technology or research that is not published or publicly available.

China University Defense Tracker:
Not specifically related to the NDAA FY20 Section 1281, the U.S. Department of State funded the China University Defense Tracker, an online database released in November 2019, which details Chinese institutions engaged in military or security-related science and technology research. The Tracker is a tool to inform universities, governments and scholars as they engage with the entities from the People's Republic of China. It aims to build understanding of the expansion of military-civil fusion, the Chinese government's policy of integrating military and civilian efforts into the education sector.

Artificial Intelligence Software Export Control:
On January 6, 2020 the Department of Commerce Bureau of Industry and Security issued an interim final rule on Software Specially Designed to Automate the Analysis of Geospatial Imagery for training a Deep Convolutional Neural Network to automate the analysis of geospatial imagery and point clouds. Export licenses are required to all countries except Canada, including to foreign nationals in the U.S.

However, source code which is published or intended to be published, qualifying for the fundamental research exclusion, is not subject to this licensing requirement under Part 734 of the Export Administration Regulations. This is a first in a series of regulations that will be issued on emerging technologies from Department of Commerce.

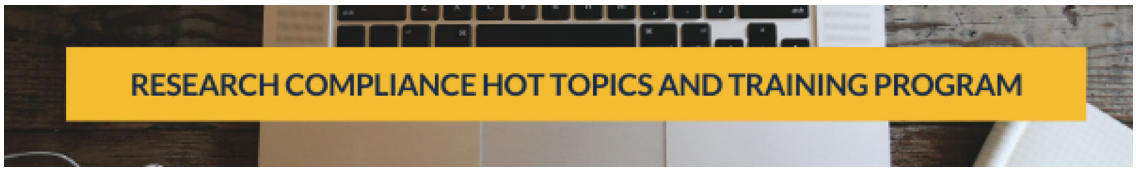
Iran and Venezuela Sanctions Updates:
Evolving geopolitical events have triggered a number sanctions changes on Iran and Venezuela. More information is listed on the Office of Foreign Asset Controls website. All interactions with Cuba, Iran, North Korea, Syria and Sudan require export license review to ensure that any research collaborations or travel to those countries does not require an export license.

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 the Export Control Office at export@ucsd.edu or (858) 246-3300.

After you submit your study record to ClinicalTrials.gov, it goes through a Quality Control (QC) review process by a ClincalTrials.gov staff member. The QC review identifies potential issues with the study record labeled as "comments." Comments are identified as either "Major Comments," which are comments that must be corrected or addressed or "Advisory Comments", which should be addressed to improve the clarity of the record, but are not required.

Recently, ClinicalTrials.gov has released the complete list of the ClinicalTrials.gov Major Comments (issues) that may be utilized during QC review. This list will be updated as Major Comments are added or retired from use. This list contains all of the QC review comments used to identify apparent errors, deficiencies, or inconsistencies in a submitted study record. As a reminder, the Responsible Party is required to address all Major Comments by the "Corrections Expected" date listed on the Record Summary Page.

For more information on the QC review process, see the ClinicalTrials.gov PRS User's Guide Section 6: PRS Review Process. If you have any questions regarding ClinicalTrials.gov, please contact the Research Compliance and Integrity Office at (858) 822-4939 or rci@ucsd.edu or visit the UC San Diego ClinicalTrials.gov page.



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:

- **February 27, 2020, 12:30 – 2:00 p.m., ACTRI Auditorium**
  Use of Good Clinical Practice (GCP) for a Compliant Study

This session will provide information on how Good Clinical Practice (GCP), a set of regulatory requirements, standards, and guidelines, applies to processes and roles in the conduct of clinical research. We will provide an overview and helpful tips to adhere to GCP on topics such as Informed Consent, Study Documentation, Delegation of Responsibility, and much more. We will also review available resources. There will also be a question and answer period.

Please register by February 25, 2020, 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.

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