



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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RISING TO THE COVID-19 RESEARCH CHALLENGE

As the devastating effects of the COVID-19 pandemic continue to grip the world, health sciences research on the disease and the novel coronavirus (SARS-CoV-2) that causes it have been prioritized by the research community. In collaboration with national and international partners in academia, government and industry, UC San Diego researchers are working to develop better tests and treatments for the disease. If you are planning research with this virus that will involve international collaborators, please review the following information related to how Export Controls might affect you.

Export Restricted Biological Agents:

The U.S government controls the export of certain biological agents and toxins, regardless of quantity or attenuation, that could be exploited for the development of biological weapons. A full list of export-restricted biologicals can be found on the [Commerce Control List \(CCL\)](#) of the Export Administration Regulations (EAR) administered by the Department of Commerce.

Among other pathogens, the original Severe Acute Respiratory Syndrome (SARS) related coronavirus (SARS-CoV) is listed under export control classification number (ECCN) 1C351.a.46. While the SARS-CoV-2 virus is identified by the International Committee on Taxonomy of Viruses (ICTV) as distinct from the original SARS coronavirus, the Department of Commerce has indicated that this latest strain will likely be added to the CCL in time. Export Control regulations, which include the CCL, are updated on a regular basis. In order to stay compliant, researchers working with the SARS-CoV-2 virus should check the status of SARS-CoV-2 regularly and work with the UC San Diego Export Control Office whenever they plan to transfer material outside the U.S.

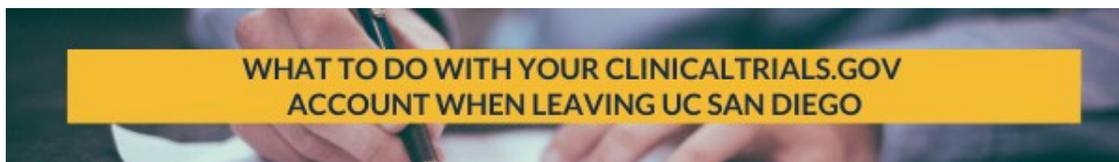
Export Controls Impact on COVID-19 Research:

All biological agents and toxins listed on the CCL, including SARS-CoV-2 when it is added, require an export license to any country outside the U.S. EAR export licenses typically take four to six weeks to receive from the U.S. government. License processing timing will likely be impacted by the current stay-at-home orders, so plan for exporting activities accordingly.

Regardless of how SARS-CoV-2 is listed on the CCL, the Department of Commerce still requires exporters to screen all export recipients in accordance with the “Know Your Customers and Red Flags” guidance outlined in [Supplement No. 3 to Part 732 of the Export Administration Regulations \(EAR\)](#), [the General Prohibitions in Part 736 of the EAR](#), [the Consolidated Screening List](#), [and the end-user and end-use-based controls in Part 744 of the EAR](#).

For screening recipients against the Consolidated Screening List and other export control related lists of denied parties, the University of California utilizes the Restricted Party Screening (RPS) tool at [VisualCompliance.com](#). Learn more about getting started with and using RPS [here](#).

You can learn more about export restricted biological agents and how export controls impact academia by watching several short videos on the [UC San Diego Export Control website](#).



When a Principal Investigator (PI) leaves UC San Diego, one of the things that is often overlooked is the ClinicalTrials.gov record. For studies where the PI is listed as the Responsible Party and is leaving UC San Diego, there are two options depending on whether the study will remain at UCSD or transfer with the PI:

- **Option 1:** If the research will stay at UC San Diego and continue under a new PI, the new PI must be assigned to the ClinicalTrials.gov study record and the study status must be updated within 30 days after the change has been made. To update the record, the PI will need to send an email with the following information to the Research Compliance and Integrity Office (RCI) at ctgov@ucsd.edu who will update the record(s) on ClinicalTrials.gov:
 - (1) The new PI name
 - (2) Study status (recruiting, active but not recruiting, completed, etc.)
 - (3) The new IRB number (if a new IRB number has been assigned)

- **Option 2:** If the research will continue at a new institution with the same PI, the ClinicalTrials.gov record can be transferred to the new institution. The PI must email RCI at ctgov@ucsd.edu and request the record transfer at least 30 days prior to transferring the study.

For additional information and resources, please see the RCI [ClinicalTrials.gov website](#) and the [ClinicalTrials.gov Frequently Asked Questions \(FAQs\)](#). For questions, please contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.



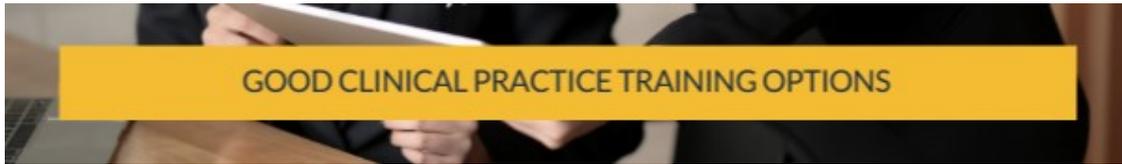
UC San Diego employees who work with animals for research purposes are required to be listed on an approved animal use protocol as well as fulfill other mandated requirements. The Principal Investigator (PI) or alternate contacts on a protocol are able to add personnel at any time through the Animal Use Protocol System (AUPS). Initial registration by personnel in AUPS is required prior to the PI or alternate contact being able to add personnel to their protocol. Detailed instructions on how to register in AUPS can be found on the [IACUC website](#), under the [New Employee Registration Guide](#). In addition, all personnel on protocols with animal handling responsibilities are required to submit a Personnel Qualifications (PQ) form, enroll in the Occupational Health Program and complete training modules related to their roles and responsibilities assigned on a protocol.

The PQ form contains the registrant's essential contact information, education and training. PQ forms are submitted through AUPS, and the IACUC office staff process and approve the PQ forms. It is the responsibility of personnel working with animals to update their PQ form any time they begin working with different species or are assigned different responsibilities.

Enrollment in the Occupational Health Program is required of all personnel who have direct contact with research animals, enter vivaria or animal housing rooms. Each person is required to complete and submit medical surveillance forms which are processed by the Environmental Health & Safety Occupational Health Nurse. Updated forms are required every three years, as well as when beginning to work with a new species. Additional information about the Occupational Health Program can be found on the [Occupational Health & Safety Program website](#).

In addition to completing a PQ form and enrolling in the Occupational Health Program, [focused animal training modules](#) through the Animal Care Program are required for those having specific animal care or handling responsibilities. Once added to an approved protocol, personnel may begin completing training modules or wait until they receive a PQ review email which details all requirements.

For any questions regarding the requirements of UC San Diego personnel on animal protocols, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.



The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials. The [National Institutes of Health \(NIH\) GCP training policy](#) requires GCP training for all NIH-funded investigators and staff who are involved in the design, conduct, oversight, or management of clinical trials. The NIH policy applies to all active grants and contracts regardless of what point they are in the life cycle of the trial.

Training in GCP can be completed through a class or course, academic training program, or certification from a recognized clinical research professional organization. There are a number of options to satisfy the GCP training requirement:

[CITI program:](#)

CITI Good Clinical Practice Course (ID: 30156)

GCP – Social and Behavioral Research Best Practice for Clinical Research (ID: 153898)

Please note that GCP training is separate from the protection of human subjects in research training on CITI Program required by the UC San Diego Institutional Review Boards (IRBs).

- [National Institute of Allergy and Infectious Diseases](#) (NIAID)
- [National Institute on Drug Abuse](#) (NIDA)
- [NIH Office of Behavioral and Social Sciences Research](#) (OBSSR)

GCP training should be completed prior to involvement in the clinical trial. The investigators and applicable staff are expected to retain their GCP training certificate of completion. The clinical trial Principal Investigator and his/her department are responsible for tracking the completion of training. Documentation of training is subject to review by the funding agency and the UC San Diego Research Compliance and Integrity (RCI) Office upon request.

Please see the RCI [Good Clinical Practice page](#) for general information on GCP training and the [Good Clinical Practice Frequently Asked Questions \(FAQs\) page](#). For questions or additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.



Kuali COI went live on January 21, 2020, and has integrated conflict of interest (COI) disclosure for proposals and awards for sponsored research in Kuali Research (KR) or manual projects in Kuali COI for the other related activities (i.e. gifts, Health Sciences service agreements, human subject research, material transfer agreements, etc.). The Conflict of Interest (COI) Office has been actively engaged with Kuali to design and develop enhancements for better usability to our research community.

The following Kuali COI enhancements have recently been deployed:

- ▶ Kuali COI clearly denotes a “needs attention” section with a pink bar advising Researcher which records require action in their portfolio (previously the records were outlined with red boxes). This enhancement is visible on the “700-U Projects” and the “Federal Project Declaration” screens and signifies that there are data elements missing that must be entered on that screen before moving to the next screen.

Projects

For assistance on your 700-U projects please review [700-U Instructions](#)

Click on all projects outlined in red to complete your new 700-U forms.

Search for something...

Needs Attention (1) + Expand all - Collapse all

- Usability of an Online COI system

All Projects (1)

- COI Functionality with online system

When researchers log into their disclosure, they will see the projects that require attention in red at the top under “Needs Attention”. Once the necessary actions are completed, projects will be marked as completed.

- ▶ 700-U Researchers who have interests with either a position, income or equity, the 700-U Supplement Questions will automatically appear on a separate screen. The Kuali COI system retains and re-displays the questions and answers for position, income or equity from the primary 700-U form in the 700-U supplemental screen. The 700-U supplemental questions are designed to use smart form technology to ensure the Researcher answers the least amount of questions based on their interest(s).

3. Filer Information

A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1?

Yes
 No

Title
Consultant

Supplemental Questions

Needs Attention (1)

- Usability of an Online COI system (FE36-GOOGLE INC.)

Project Title	Economic Interest
Usability of an Online COI system	FE36-GOOGLE INC.

Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1?
Yes

Do you, your spouse or registered domestic partner, or your dependent children have an investment of \$2,000 or more in the entity listed in Part 1 above?
No

Have you received income of \$500 or more from the entity listed in Part 1 during the reporting period?
No

Title of Office
Consultant

Non Federal Disclosure Questions

The system retains and re-displays the questions and answers for position, income or equity from the primary 700-U form onto the 700-U supplemental screen

- ▶ For sponsored research projects in KR Proposal Development, the PI and the proposal preparer can view the project COI “Disposition Status” for each researcher listed under the Key Personnel tab of the proposal.

Document was successfully saved.

Key Personnel
Search for and add key personnel

LILIAN CHANG (Principal Investigator) (Certification Incomplete)
Project Status: Up To Date Annual Disclosure Status: Approved Disposition Status: No Conflict

Kuali Research "Disposition Status" under Key Personnel for completed COI disclosures were inadvertently re-setting to blank when new projects were added to a Researcher's portfolio

The COI Office is testing the following latest Kuali COI enhancement:

- ▶ Allow the Researcher(s) and their delegate(s) to search projects on the "700-U Projects" and the "Federal Project Declaration" screens to easily locate their projects. This will be helpful for Researchers with newly acquired interests. The Researcher can search on project title, sponsor name, PI name and sponsor number. The Researcher must search for non-federal project on the "700-U Projects" screen and for federal projects on the "Federal Project Declaration" screen.

Projects

For assistance on your 700-U projects please review 700-U Instructions

Click on all projects outlined in red to complete your new 700-U forms.

Search for something...

Needs Attention (1) + Expand all - Collapse all

- Usability of an Online COI system

All Projects (1)

- COI Functionality with online system

High volume researchers will be able to use the search bar to search within their entire disclosure for specific projects. Search words include project title, sponsor name, PI name, role of researcher, project type (award, proposal, IP), and sponsor number

The COI Office welcomes feedback and recommendations about the Kuali COI system. To learn more, please review the tutorial content on the [Kuali COI Website](#). For questions, please contact the COI Office at info-coi@ucsd.edu or (858) 534-6465.

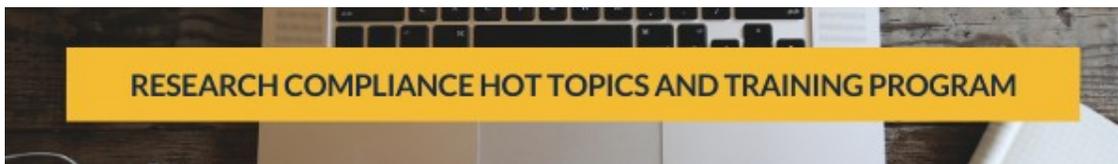


The U.S. government issued new regulations that will directly impact exports to China, Russia and Venezuela. On April 28, 2020, the Department of Commerce's Bureau of Industry and Security (BIS) published [new final rules](#) amending the Export Administration Regulations (EAR) significantly expanding the licensing requirements for exports, re-exports and transfers of certain goods, equipment, materials and software to Chinese, Russian

and/or Venezuelan military end users, and it broadens the definition of military end uses. While license requirements are expanded under this rule, BIS has indicated a presumption of denial, meaning that the license for export will not be issued for military end use for these countries and specific items. The rule also revises the regulations to require filing of Electronic Export Information for all exports of items to China, Russia, or Venezuela, regardless of the value of the shipment, that do not meet certain exemptions. The regulations come into force on June 29, 2020.

UC San Diego is determining the process changes needed in order to implement the regulations. More details will be provided on the requirements for shippers and those with collaborations in these countries to ensure compliance with the regulations.

For questions or additional information, please contact the UC San Diego Export Control Office at export@ucsd.edu or (858) 246-3300.



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:

► **May 27, 2020, 12:30 – 2:00 p.m., via Zoom**
Research and Privacy Considerations

This session will provide information about Research Compliance around data access, use, and storage with the Privacy Office and the Office of Compliance and Privacy. We will also provide considerations for conducting research during a crisis with a remote workforce. There will also be a question and answer period.

Please register by May 25, 2020, via this [UC Learning Center link](#). 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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