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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>.

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NIH GOOD CLINICAL PRACTICES TRAINING REQUIREMENT: WHO QUALIFIES AS AN INVESTIGATOR OR STAFF INVOLVED IN THE DESIGN, CONDUCT, OVERSIGHT OR MANAGEMENT OF CLINICAL TRIALS?

Per NIH Policy NOT-OD-16-148, as of January 1, 2017, all NIH-funded investigators and staff who are involved in the design, conduct, oversight, or management of clinical trials, must receive Good Clinical Practices (GCP) training.

Study team members or staff are individuals who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management and to ensure integrity and compliance with regulatory and reporting requirements.

Examples of study related duties that require investigators and staff to receive training in GCP include, but are not limited to:

1. **Design:** Contributing to determining the study outcomes, study measures, or study procedures, and individuals that help write and execute the protocol. Examples would be sub-investigators.
2. **Conduct:** Identifying and/or recruiting participants, enrolling and consenting participants, or performing any study related activities and/or procedures. Examples would be research nurses or research/study coordinators.
3. **Oversight:** Serving in a role that is responsible for compliance and regulatory reporting requirements. An example would be regulatory coordinators.
4. **Management:** Accessing and managing participant data or recording any data from participants for study collection. Examples would be a sub-investigator, research associate or research/study coordinator.

Keep in mind that all investigators and key personnel listed on an NIH grant that funds a clinical trial must complete GCP training. Principal Investigators have the ultimate responsibility to determine the role of each member of their study team and ensure that the study team has the appropriate training. GCP training can be completed, without charge, through the [UCSD CITI Program](#).

For additional information or assistance, please contact the Research Compliance and Integrity Office at (858) 822-4939, rci@ucsd.edu.



On May 15th, 2019, an Executive Order was issued on [Securing the Information and Communications Technology and Services Supply Chain](#). Following this, the Department of Commerce updated the Entity List adding Huawei Technologies Co., Ltd. and its non-U.S. affiliates prohibiting exports without an export license. These actions follow the passage of the National Defense Authorization Act in August 2018, also known as the NDAA.

The NDAA prohibits the procurement of "covered telecommunications equipment or services" by executive departments which include agencies such as NIH, NSF and the Department of Energy. "Covered telecommunications equipment" includes telecommunications equipment produced by Huawei and ZTE as well as video surveillance and telecommunications equipment produced by other Chinese companies such as Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, Dahua Technology Company or any subsidiary or affiliates of these companies. This prohibition takes effect in August 2019 for federal agencies and in August 2020 agencies may not enter into a contract (or extend or renew a contract) with an entity that uses any equipment, system, or service that uses covered telecommunications, surveillance or other infrastructure equipment relating to the listed companies.

While further federal guidance is pending on these NDAA prohibitions, UC San Diego (UCSD) has been asked by the UC Office of the President (UCOP) to provide inventories of Huawei and ZTE devices attached to the UCSD network. As equipment manufactured by the listed entities is identified, Information Technology Services will reach out to the responsible unit for additional information and provide recommendations regarding the equipment.

When procuring information technology devices and other equipment, please keep the following in mind:

- ▶ Ask the vendor to certify that no NDAA listed entity equipment is used or included in the equipment or device. Often vendors re-brand networking components or equipment, so it is necessary to ask them explicitly. UCSD procurement is also developing controls to address this issue.

- ▶ Examine any internally maintained equipment inventories for items manufactured by the NDAA listed entities. If equipment manufactured by the NDAA listed entities is discovered, please contact Information Technology Services immediately. Also consider how the Department will approach replacing the equipment if necessary.

It's important to note that no NDAA federal implementing regulations or policies on covered telecommunications equipment have been issued yet, but equipment can be expensive and have a long life cycle. Planning for this possibility in advance is the best way to avoid disruption to your research.

For additional information or questions, please contact Mike Corn, Chief Information Security Officer at mcorn@ucsd.edu, or (858) 534-6495. For additional information from UCOP, see the [UC Office of the President's Guidance on Huawei and ZTE Inventory](#).

WHEN DO INVESTIGATORS HAVE TO DISCLOSE TRAVEL TO THE CONFLICT OF INTEREST OFFICE?

Investigators who have active and awarded sponsored research or other related activities (i.e. gifts, services, material transfer agreements, etc.) awarded to the University and have travel paid for by an outside entity (based on certain thresholds), must submit an **update of financial interest to the Conflict of Interest (COI) office within 30 days** for the applicable funded projects.

A financial interest is anything of monetary value, whether that value can be easily determined or not, that is held by the investigator, their spouse or registered domestic partner, and dependent children and meets reporting categories and thresholds for the applicable COI disclosure form as follows:

- ▶ For **PHS Funded Awards** (e.g., NIH, CDC, etc. and those that have adopted the PHS FCOI regulations): Investigators are required to disclose sponsored/reimbursed travel exceeding \$5,000 from the same entity over the last 12 months. Entities include for-profits (domestic and foreign), non-profits (domestic and foreign), foreign institutions and foreign governments. This includes travel paid directly for or reimbursed by the outside entity.

- Disclosure is not required if the entity sponsoring or reimbursing the travel is an U.S. institution of higher education, a U.S. academic medical center (or hospital affiliate with an institution of higher education, U.S. research institute or a federal, state or local government agency.

- ▶ For **Non-PHS Funded Awards** (e.g. NSF, CIRM, UC programs, etc.): Investigators are required to disclose other payments exceeding \$10,000 and the Investigator deems the interest and project awarded are related. Entities include for-profits (domestic and foreign), non-profits (domestic and foreign) and foreign institutions.

► For **Non-Federal Sponsored Awards** (e.g., for-profit and non-profit entities): Investigators are required to disclose any travel. Entities include for-profits (domestic and foreign), non-profits (domestic and foreign) and foreign institutions.

Travel does not need to be disclosed if the travel is reimbursed to the Investigator from their grant(s), gift (s) or service(s) held at the University or directly by other University funds.

Given the federal and state Conflict of Interest (COI) requirements, Investigators need to be mindful when accepting pre-paid travel expenses from outside entities. It is recommended that Investigators inquire with outside entities with written documentation to ensure proper compliance.

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

INFORMATION FOR NEW RESEARCHERS USING ANIMAL MODELS

Any work with live vertebrate animals is highly regulated and requires researchers to write an animal use protocol that will be reviewed by the UC San Diego (UCSD) Institutional Animal Care and Use Committee (IACUC). The 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 and educational programs. The IACUC is different from the Animal Care Program (ACP), which is responsible for animal housing, space allocations, animal acquisitions and veterinary care.

Principal Investigators and research staff are required to know a great deal of information concerning the animal work conducted as part of their research. The IACUC maintains a collection of informational material to assist UCSD researchers with understanding their responsibilities. The [Registration Guide for New Animal Researchers](#) contains the information necessary to initiate research with animal subjects at UCSD. The Registration Guide explains how to:

- Obtain access to the IACUC's online Animal Use Protocol System (AUPS)
- Complete the required Personnel Qualification (PQ) form
- Add personnel to a protocol
- Register for training classes
- Obtain access to the vivarium

Additional helpful information on the [IACUC website](#) includes:

- [Letter to New Investigators](#)
- [Top 10 Things You Must Know to Care for and Use Animals at UCSD](#)
- [Principal Investigator Responsibilities](#)

The IACUC Office staff is here to help! For questions or assistance, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.



EXPORT CONTROL: UPDATES TO THE ENTITY AND UNVERIFIED LIST

On May 16, 2019, the Department of Commerce updated the [entity list](#) adding Huawei Technologies Co., Ltd. and its non-U.S. affiliates of Huawei. Any exports subject to the Export Administration Regulations require export licenses to these listed entities. On April 11, 2019, the [Unverified List \(UVL\)](#) was updated and added a number of Chinese Universities and research institutions. A UVL status means:

1. The University is unable to use any license exceptions.
2. Any exports must include a UVL end user statement prior to the export.
3. The Electronic Export Information (EEI) must be filed for each export with U.S. Customs and Border Protection.

Below are examples of the Chinese Universities and research institutions added to the UVL (please note this list is not comprehensive and Visual Compliance screening should still be performed):

- Guangdong University of Technology
- Renmin University
- Tongji University
- Xi'an Jiaotong University
- Anhui Institute of Metrology
- Beijing Institute of Nanoenergy and Technology
- Changchun Institute of Applied Chemistry, Chinese Academy of Sciences
- Hefei Institutes of Physical Science, Chinese Academy of Sciences
- Shanghai Institute of Applied Physics, Chinese Academy of Sciences
- Shanghai Institute of Technical Physics, Chinese Academy of Sciences
- Yunnan Observatories, Chinese Academy of Sciences

When performing the Visual Compliance screening, [Restricted Party Screening](#) hits or alerts must be escalated to the Export Control Office at export@ucsd.edu for review.

Any physical, electronic or deemed foreign national exports affiliated with listed entities may require export licenses or additional paperwork to be filed prior to the export. Any unlicensed exports, failure to obtain end user statements, or failure to file an EEI could result in fines from the U.S. government for the individual and/or institution.

If you need assistance or have questions with Visual Compliance or exports, please contact the Export Control Office at export@ucsd.edu or (858) 246-3300.



RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

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:

► **June 18, 2019, 12:30 – 2:00 p.m., Leichtag, Room 107**
International Engagement Considerations, Existing and Evolving
Federal, UC and Campus Requirements

This session will provide information on the background on U.S. government foreign influence concerns, what steps need to be taken by investigators and administrators as it relates to international activities, export control, conflict of interest, conflict of commitment, postdoctoral and visiting scholars, agencies' existing and evolving policies on reporting foreign activities and what needs to be included on other support, grant applications and annual grant reporting. There will also be a question and answer period.

Please register by June 14, 2019, at the [UC Learning Center](#). In the search field (upper right corner), enter "RCI: Conflict of Interest (COI): Navigating COI, the Disclosure Forms and the Intersection with Conflict of Commitment." From the "Select" box, select Register in the dropdown menu. Select the radio button for the session and date, 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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