ON-SITE RESEARCH ACTIVITY MOVES INTO THE ORANGE PHASE

BY FAITH HAWKINS AND MICHELLE FRANKLIN

During the COVID-19 pandemic, UC San Diego's first priority has always been to protect the health and safety of our faculty, students, staff and community. We have tried to balance this priority with our university's essential mission as a research-focused public university. This led to the decision to ramp down on-site research activity in March, while allowing critical research activity to continue on-site (at a rate of approximately 15% of normal operations). Guided by state and county public health metrics and plans, UC San Diego is now able to begin ramping up research, scholarly and creative activity, in a way that still prioritizes the safety of our community.

Given the continued threat of community spread of COVID-19, activity will resume and expand in phases. This allows for flexibility in responding to what are likely to be variable circumstances, as all available scientific evidence indicates we must expect. In the months ahead, while we can hope for continued improvement in public health metrics, we must be prepared to ramp activity up and down if the threat of COVID-19 transmission requires. Researchers, faculty and staff returning to on-site activity must remain prepared to discontinue that activity, should circumstances and public health concerns dictate.

Our phased approach was designed in consultation with our own infectious disease experts and epidemiologists as well as the World Health Organization, the Center for Disease Control, and regional public health experts. The guidelines were prepared by our Continuity of Research Task Force, comprised of faculty and staff from across campus, with additional input from students and postdoctoral scholars. Throughout, we have worked to recognize the many different types of activity our faculty and researchers engage in, developing specific health and safety requirements aimed at mitigating the risk of COVID-19 transmission in various settings.

On June 1, 2020, we moved into the Orange Phase of on-site activity, the first of three phases allowing for a gradual, measured return to on-site research activity. This does not mean a return to research activity at the levels we knew before March. In the Orange Phase for research, all work that can be done remotely must be done remotely. In order to limit the risk of transmission, there are restrictions on how many people can be in one laboratory or workspace at one time (density at no more than 25% of pre-COVID levels) and how close those people can be to one another (social distancing). All those working on campus must use face coverings and, in some settings, other

personal protective equipment (PPE). Everyone must sanitize work areas and commonly-touched surfaces regularly. In compliance with County of San Diego Public Health orders, all those working on campus must also conduct mandatory daily symptom screening.

In order to return to on-site research, whether that work is on-campus or at field sites, researchers must submit a "Research & On-site Activity" plan (log-in required) which is reviewed by their academic leaders (Department Chairs and Deans), and as necessary, Environmental Health & Safety or other UC San Diego offices. No one can return to on-site work before their plans are approved, and personnel and workspaces are adequately prepared. Some research activity will not be able to meet the minimum safety requirements and therefore will not be able to resume in the Orange Phase. You can read more about these requirements on our UC San Diego Research Ramp Up website.

As on-site research, scholarly and creative activity resume, it is important to remember that all compliance requirements that existed before the pandemic still exist and must be followed. This includes guidelines and regulations from IACUC, IRB, BioSafety, Conflict of Interest, Export Control and other areas. If additional compliance requirements exist specific to the pandemic, you can find them on our Research Ramp Up website.

We share your excitement in bringing more research activity on-site and ask for your patience and flexibility as circumstances may quickly change. If you have any questions about the research ramp up and cannot find the answer on our Research Ramp Up website, please contact research@ucsd.edu.

For additional information, please see the Office of Research Affairs International Research and Engagements website or contact the Research Compliance and Integrity Office at rci@ucsd.edu, (858) 822-4939.

The Importance of Kuali Research Proposal Certifications by Principal Investigators

BY ROSS DAMMANN

Research at an accredited academic institution is complex and highly regulated. With a recent uptick in sponsor, the U.S. government and public scrutiny, it has become critical to emphasize full adherence to upholding institutional commitments to support proposed research applications. One of these commitments is in ensuring Principal Investigators (PI) respond to the Kuali Research proposal development Research Questionnaire and complete the PI Certification.

The Research Questionnaire is an important element when preparing each research application because it collects essential project information for which the PI is uniquely qualified to ensure the answers are factually accurate. Incomplete or incorrect answers to the Research Questionnaire poses significant risk for compliance with institutional and sponsor requirements for conflict of interest, export control, foreign influence, human research, health and safety and PI eligibility. The answers to the questions trigger systematically designed institutional actions that ensure a) flow of information to appropriate compliance offices, b) conforms with federal, state and UC requirements and c) accurately classifies the project for transparency and institutional reporting.

The PI Certification provides the assurances necessary to acknowledge federal, state and UC required institutional obligations to our sponsors on behalf of the PI. These assurances include:

◻ True, complete and accurate information is being submitted

◻ Acknowledgement that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties

◻ The PI accepts responsibility for the scientific conduct of the project and to provide the required progress reports if an award is issued as a result of the application

◻ Confirmation that neither the PI nor anyone on the research team is currently Debarred, Suspended, or proposed for debarment or Suspension and they will notify the University immediately if this status changes

◻ No federal funds were used for lobbying activities related to the proposal

For these reasons, it is important that the PI and not an administrator complete the Research Questionnaire. While many PIs are already adhering to this expectation, some still allow administrators to complete these sections of the Kuali Research Proposal Development record on their behalf. While this practice may be logistically required under unique and unusual circumstances, the expectations of both the sponsor and UC San Diego is that it is imperative for the PI to complete the Research Questionnaire and certification prior to proposal submission.

Please visit the UCSD Kuali Research Information for Faculty Blink page for step-by-step instructions, or contact researchadmin@ucsd.edu for additional assistance.

HUMAN SUBJECT COMPENSATION: SCRIP ELIMINATION

BY SHANTAL FLORES

Nearly three decades ago, UC San Diego created Scrip, a payment product offered by Wells Fargo, exclusively to compensate research participants. While UC San Diego's Office of Integrated Procure-to-Pay Solutions (IPPS) has tried its best to maintain this offering and manage the associated risks, Scrip continues to present challenges in terms of cost and risk exposure to the university.

UC San Diego policy requires departments to order only the amount of Scrip necessary for each study and to return unused Scrip in a timely matter. However, today, we have more than 34,000 outstanding Scrip items dating back to 2000, totaling over $700,000. Large amounts of outstanding cash equivalents expose the university to undue risk in an economic climate where the university continues to be the target of sophisticated fraud schemes. In addition, Wells Fargo has expressed the strong desire to sunset the program due to their administrative challenges associated with Scrip.

In support of campus-wide initiatives to become more virtual, paperless and cashless, IPPS will discontinue the issuance of new Scrip as of June 19, 2020. In order to support the UC San Diego research community, IPPS has several other convenient options for research participant compensation.

HUMAN SUBJECT EXPRESS CARD

► Purchase merchant gift cards on a Procurement Card at your convenience directly from merchant websites as needed (online or plastic formats)

VANILLA VISA GIFT CARD

► Card can be used anywhere VISA is accepted
► Significantly reduced per card fee of $1.15 (comparable to $5.95 when purchased at retail locations)
► Cards available for pick up within three business days from department approval

DIRECT PAYMENT

► Direct deposit or check mailed directly to participant's home address. ***Note:*** *Participant must provide a completed form W-9 for tax reporting purposes (the participant will receive a W-9 for $600 or more of payments).*

CASH ADVANCE

► Available in very limited circumstances when other payment methods are not viable based on conditions of the study

What does this mean for the Scrip that a Principal Investigator has now?
- ◆ The last day to order new Scrip will be June 19, 2020.
- ◆ Scrip issued prior to July 1, 2018 will be canceled, written off and no longer be negotiable as of July 1, 2020.
- ◆ If you have Scrip dated July 1, 2018 or prior, please return to Disbursements at MC 0955 by June 19 to credit your index (see here for information about returning Scrip).

In most cases, PIs who have specified the use of Scrip in their Institutional Review Board (IRB) applications do not need to submit an amendment. An amendment is only needed if the payment amount or schedule will change or if Direct Deposit/Check will be used and Social Security Numbers will be collected. The IRB will be posting information regarding the elimination of Scrip on their website in the near future.

As always, IPPS is here to support the very important work that your departments perform and continuously strives to provide solutions that meet your needs while upholding our duty to manage risk to the university.

Virtual Q&A sessions will be hosted on June 18 at 9:00 and June 25 at 9:00. If you would like to join, please complete this form and we will send you an invite. You may also reach out to us directly at Services & Support - Finance.

What Documents are Required to be Submitted on ClinicalTrials.gov?

BY MONIQUE TEIXEIRA

When results are due for a study posted on ClinicalTrials.gov, there are also documents that must be submitted with the results. For any studies with a Primary Completion Date on or after January 18, 2017, a Study Protocol and Statistical Analysis Plan are required to be submitted. Additionally, all studies initiated on or after January 21, 2019, that are conducted or supported by a Common Rule (45 CFR 46) department or agency, must upload an IRB approved informed consent form after the study is closed to recruitment and no later than 60 days after the last study visit by any subject.

STUDY PROTOCOL:
ClinicalTrials.gov regulations define a protocol as, "the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations." The protocol must clearly delineate the primary and secondary outcome measures.

STATISTICAL ANALYSIS PLAN:
The ClinicalTrials.gov regulations do not define what is a Statistical Analysis Plan (SAP), however the Food and Drug Administration (FDA) defines SAP as, "a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data." The SAP either may be a standalone document or can be a section of the protocol.

INFORMED CONSENT DOCUMENTS:
The New Common Rule requires that clinical trials which receive IRB approval after January 21, 2019, and are supported by federal funding, must publish, "The informed consent form on the federal website after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol." ClinicalTrials.gov is one of the federal websites approved to upload the Consent Form. Please note, to protect study participant privacy, an unsigned copy must be uploaded.

TIPS AND TRICKS FOR UPLOADING DOCUMENTS:
1. UC San Diego researchers have uploaded the IRB Research Plan as the protocol and Statistical Analysis Plan and this has been accepted by ClinicalTrials.gov.
2. The documents that are submitted will be posted publicly on the ClinicalTrials.gov website after Protocol Registration and Review System (PRS) Review. For this reason, be sure that there is no proprietary or study participant identifying information on the documents uploaded. There are instructions on when and how to redact documents on the Research Compliance and Integrity Office ClinicalTrials.gov webpage.
3. All documents uploaded must be in PDF/A format.
4. All documents must be in English.
5. A cover page with the official title, National Clinical Trial (NCT) number and document date (date document last updated) must be included in each document.

For additional information, please visit the Research Compliance and Integrity (RCI) Office's ClinicalTrials.gov webpage or contact RCI at (858) 822-4939, ctgov@ucsd.edu.

CONSIDERATIONS WHEN STARTING A COMPANY

BY JENNIFER J. FORD

A key element for the University's Strategic Plan is to create a culture of innovation that benefits the University and the global community. The University encourages faculty to engage in outside activities that contribute to their respective professions and to the community. When new innovation is developed, the inventor(s) may want to form a new company. While under the Conflict of Commitment policies, prior approval for starting a company is required for faculty (submit requests through UC OATS), faculty and staff must also be aware of the conflict of interest implications.

A conflict of interest (COI) refers to situations in which financial or other personal considerations may compromise or have the appearance of compromising an employee's professional judgment in administration, management, teaching, research and other professional activities. If the employee has an interest in a company that is providing funding for the employee's research or other University activity or the research might directly and significantly affect the interest of an employee responsible for the conduct of the research, a COI may exist. For any active or pending research activities, University employees will need to submit an updated disclosure within 30 days of forming the company in Kuali COI. For instance, PHS funded research (i.e., NIH and those agencies and

sponsors that have adopted the PHS COI regulations) require COI disclosure of start-up companies regardless of their value. There are various COI Disclosure Requirements that need to be reviewed to determine the conflict of interest disclosure thresholds.

If the company decides to submit a proposal for an SBIR or STTR and a University employee will be included on the company proposal and/or award, University employees must be aware of the UC policy that requires all University of California employees who receive any part of their salary through the University, or whose activities use any University resources or facilities, must submit their proposals for extramural support through the appropriate local contracts and grants office. Any exception to this UC Policy must be approved by the Vice Chancellor of Research based on a request from the Department Chair. Please keep in mind that while SBIR/STTR granting agencies may permit one Principal Investigator (for the small business entity and the research center), the University does not without an exception. It is recommended that all University employees participate solely on the University's portion of work of an SBIR or STTR, and company personnel (not affiliated with the University) participate on the company's award.

In addition, for graduate students and postdoctoral scholars, when starting a company, it is recommended that the scholar

or student consult with the Department Chair and the Graduate Division (for graduate students) or the Postdoctoral and Visiting Scholars Office (for postdoctoral scholars) to ensure the student's or scholar's educational interests are protected while maintaining an open environment free from undue influence of private outside interests.

When involved with a company or other outside activities, the following safeguards are recommended for University employees in order to avoid violations of University Policies or Federal and State Regulations governing conflict of interest:

1. No University time or resources should be utilized for the company including facilities, equipment, supplies or materials.
2. There should be no "appearance" of a potential conflict among staff or other employees, i.e. avoid distractions, phone calls, referrals, discussions, etc. during University time.
3. University employees should recuse themselves from influencing or participating in future University business or purchase decisions with the company.
4. University employee's association with the company should not imply a University endorsement of their products or a University affiliation with the company.

All University employees are subject to the disqualification rule of the Political Reform Act ("Act"). The disqualification rule states "University employees are required to disqualify themselves from making, participating in making or influencing University decisions in which they have a disqualifying conflict of interest." Those that plan to start companies should read further about the Disqualification Rule and further review the UC compendium for COI and Integrity.

University employees have certain obligations with respect to disclosure of intellectual property and its ownership. University employees have to disclose inventions/copyrights to the Office of Innovation and Commercialization (OIC). University employees with outside interests must be mindful to not inadvertently disclose non-publically disseminated information to their outside interest prior to protection by the University through OIC.

It is also important to keep in mind that no person or organization may use the University name in conjunction with advertising or to list the University as a user of any product or service or as the source of research information on which a commercial program or publication is based.

For additional information or guidance on conflict of interest, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

IS RESPECT FOR SCIENCE AT RISK?

BY MICHAEL KALICHMAN

It is now clear that the COVID-19 pandemic is a largely unprecedented public health crisis. It would be reasonable to expect that the response to this crisis would have been a simple matter of applying what we know from science and medicine. However, the lack of uniformity of response just in the US is a sign that decisions are being made based on bias and preference rather than evidence. There are likely many reasons for this outcome, but one factor may be a diminishing respect and trust for scientists. A recent global study (3M, 2019) found that about one-third of respondents are skeptical of science, a quarter were suspicious of the role science will play in the next 20 years, and nearly half trusted the science only when it aligned with personal beliefs. For those who chose science as a career, and spend their lives working closely with other scientists, it can be difficult to fathom how it is that so many people would choose anecdote or opinion over data and evidence. However, both data and evidence from the social sciences tell us that this is to be expected (e.g., Kolbert, 2017). In short, the problem is not that those distrustful of science lack essential knowledge (even though that may be the case at times). The challenge is to address attitudes that are resistant to evidence.

So what, if anything, can and should be done about the disconnect between evidence and attitudes? A compelling argument can be made that this challenge will be best met by more scientists willing to engage in outreach. However, to be effective, this "outreach" cannot be seen as a one-way street. Instead, meaningful outreach is an opportunity to engage in dialogue, to humanize both the scientists and the non-scientists (e.g., Varner, 2014). This message is particularly timely as many scientists find themselves unable to conduct their research. In the meantime and in these uncertain times, one way to regain some agency and sense of control could be to design and implement new approaches to engaging in dialogue with others about why you love science, how science works, and what you are hoping to learn. As many homes are finding a need to resort to home schooling, perhaps there will be many opportunities for creative approaches to meeting this goal. Doing so might just help shift the balance toward increased respect for science.

For additional information, please visit the Research Ethics Program website or contact the Research Ethics Program at (858) 822-2647, ethics@ucsd.edu.

Collaborative Institutional Training Institute (CITI) Program Courses

BY DIANA D. KIM

UC San Diego offers a variety of training opportunities at no cost for the research community through the Collaborative Institutional Training Institute (CITI) program. CITI is comprised of various learning modules. CITI is designed to educate and provide a resource to researchers and staff.

Please note that Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) trainings are separate from human subjects training required for Institutional Review Board (IRB) submissions. For instance, researchers who conduct a clinical trial funded by the National Institute of Health (NIH) must complete a CITI module for GCP training as well as Human Subjects Research training. Below is the information regarding the three main training resources UC San Diego utilizes on CITI; however, there are additional CITI training topics available at no cost to the UC San Diego research community.

While some trainings are required for a specific entity, some sponsors and departments may require additional training. Researchers may also be directed to modules for other training topics on CITI by the appropriate University offices.

The certificate of completion report remains on the CITI database if the training is completed through affiliation with UCSD. Researchers can add UCSD affiliation to their CITI profile if they have already completed a particular course at another institution to account for the course completion. Documentation of training is subject to review by appropriate offices, including the Office of Research Compliance and Integrity (RCI).

TRAINING TOPIC	CITI MODULES	APPLICABILITY
Good Clinical Practices (GCP)	1. CITI Good Clinical Practice* 2. GCP – Social and Behavioral Research Best Practice for Clinical Research* 3. Buenas Practicas Clínicas (Módulos en Español)	All investigators and staff involved in the conduct, oversight, or management of NIH funded clinical trials
Human Subjects Research	1. Biomedical Research* 2. Social & Behavioral Research*	Principal Investigators and Key Personnel conducting human subjects research
Responsible Conduct of Research (RCR)	1. Physical Science RCR 2. Biomedical RCR 3. Humanities RCR 4. RCR for Administrators 5. RCR for Engineers 6. Social and Behavioral RCR	Varying requirements for specific funding agencies: National Institute of Health (NIH), National Science Foundation (NSF), National Institute of Food and Agriculture (NIFA)

* Refresher options are available for GCP training and Human Subjects Protections training.

Please see the UC San Diego RCI Research Compliance Training page that includes links to required and recommended training for researchers and research support staff. For questions or additional information, please contact the RCI Office at rci@ucsd.edu, (858) 822-4939.

INTERNATIONAL RESEARCH

Expansion of Export License and Export Filing Requirements for China, Russia and Venezuela

BY BRITTANY WHITING

Effective June 29, 2020, export license and export filing requirements will expand for certain exports to China, Russia and Venezuela. Recently the U.S. government issued new export control regulations regarding China, Russia and Venezuela regarding military end use and electronic export information filings (EEI) for exports certain technologies and items to those countries. This expands the export licensing requirements for these countries as well as export documents that previously were not required. The expanded regulation triggers export license requirements for specific items in these categories:

- ➤ **Materials, Chemicals, Microorganisms, and Toxins**
- ➤ **Materials Processing**
- ➤ **Electronics Design, Development and Production**
- ➤ **Computers**
- ➤ **Telecommunications Information Security**
- ➤ **Sensors and Lasers**
- ➤ **Navigation and Avionics**
- ➤ **Marine**
- ➤ **Propulsion Systems, Space Vehicles and Related Equipment**

In addition, items on the Department of Commerce, Commerce Control List of dual-use items that are being physically exported or hand-carried to China, Russia and Venezuela, will now require EEI filing in the Census Bureau's Automated Export System (AES), regardless of the shipment's value or whether an export license is required. The UC San Diego Export Control Office can assist you with a determination if an export license is required from the federal government for any export as well as determine and file any EEI.

Please be aware that export licenses can take 6-8 weeks or longer for processing by the federal government and may be denied. Contact the Export Control Office early for assistance to avoid delays.

ENTITY LIST UPDATES

Additionally, there are continuous updates to the government's restricted parties lists that identifies persons or organizations reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the U.S. The U.S. government imposes additional license requirements on, and limits the availability of most license exceptions for, exports, re-exports, and transfers (in-country) to listed entities.

Effective June 5, 2020, a number of companies and research institutions in China, Hong Kong, and the Cayman Islands, that were added to the Entity List, represent a significant risk of supporting procurement of items for military end-use in China. In the regulation update to the Entity List, it indicates that Harbin Engineering University is listed for acquiring and attempting to acquire U.S.-origin items in support of programs for the People's Liberation Army and Harbin Institute of Technology has sought to use U.S. technology for Chinese missile programs. Additionally, added to the Entity List is another group of Chinese government entities and companies that are complicit in human rights violations and abuses committed in China's campaign of repression, mass arbitrary detention, forced labor and high-technology surveillance against Uighurs, ethnic Kazakhs, and other members of Muslim minority groups in the Xinjiang Uighur Autonomous Region. UC San Diego conducts restricted party screening on international transactions as part of the export license review. There have also been updates to many other entities in other countries such as Russia and Venezuela in recent months.

All international shipments, that involve non-published documents, are subject to Export Control Regulations and are required to be reviewed by the Export Control Office prior to shipping. This is a requirement under the UC Export Control Policy to ensure that there are no unlicensed exports. If you are working with UC San Diego Outbound Shipping for the shipment, they work with Export Control Office for the license review. **If you or your lab is conducting the shipment yourself, you are responsible for contacting the Export Control in advance of the shipment for an export license review.** Email the Export Control Office at export@ucsd.edu.

Export Controls is a dynamic area directly impacted by changes to U.S. foreign policy. The Export Control Office provides service to UC San Diego by reviewing international interactions and determining licensing requirements to comply with federal requirements. You are an important part of ensuring that UC San Diego international engagements have the required export documentation. Please contact the Export Control Office for reviews at export@ucsd.edu.

For additional information, please visit the Export Control website.

CYBERSECURITY AND EMERGING RISKS RELATED TO CORONAVIRUS RESEARCH

BY MICHAEL CORN

With UC San Diego's highly visible presence in the news for the Return to Learn and Return to Research initiatives, UC San Diego's researchers have become highly desirable targets for operatives looking to obtain COVID-19 related intellectual property. This is not a theoretical concern for the campus, UC San Diego has long been directly targeted by foreign governments for our extensive cutting edge research and these same hacking groups have shifted towards our medical research programs. For more information, see the May 13, 2020, Federal Bureau of Investigation and the Cybersecurity and Infrastructure Security Agency's public service announcement.

You may believe that you and your research are not at risk, however that is incorrect. UC San Diego's IT Security experience is that these highly skilled hacking groups target any vulnerable research project to obtain a toehold into the campus computing environment and then use this access to attack other systems from within the campus. While the UC San Diego's Office of Information Assurance does have some sensors within the network to detect attacks, they are far smaller in scope than those protecting the campus from off-campus attacks.

A common misconception by researchers is that securing their research project will disrupt the science workflow. Nothing could be further from the truth! If your laboratory systems are attacked or compromised, that could lead to days if not weeks of disruption. The technology UC San Diego Office of Information Assurance has available is in most cases completely transparent and can be provided at no cost to UC San Diego laboratories. While nothing can guarantee that your

research or laboratory will not be targeted, the goal of IT Security is to increase our ability to detect malicious activity and minimize successful attempts by hackers.

IT SECURITY RECOMMENDATIONS

- **Departmental or Divisional IT Support:** Talk to your department or divisional IT support team. Ask if your laboratory network is protected by the campus firewalls. These are configured to allow any activity your laboratory engages in while blocking millions of attacks per day originating from the Internet. They also provide some level of protection from attacks from other campus computers.
- **Laboratory Data Backup Strategy:** Review your laboratory data backup strategy. How many days of backup do you have? How long would it take to restore? Is anyone testing the integrity of the backup?
- **Active Directory Credentials:** Use whenever possible campus Activity Directory credentials in place of local system accounts. These are generally protected by multi-factor authentication and are monitored for malicious use.

Remember you have many avenues for support and the UC San Diego Office of Information Assurance is here to support your custom research needs.

If you need general IT assistance for your research, contact the IT Research Support team at research-it@ucsd.edu. If you have specific questions about securing your research, contact the Office of Information Assurance at security@ucsd.edu or Michael Corn, UCSD's Chief Information Security Officer, mcorn@ucsd.edu.

DEFINITION OF AN "ANIMAL" FOR IACUC OVERSIGHT

BY THE IACUC OFFICE

Scientific research uses a wide range of animal models, from nematode worms, insects and aquatic species, all the way to nonhuman primates. Researchers may be confused as to what models require the submission of an animal use protocol and oversight by the Institutional Animal Care and Use Committee (IACUC). This is largely dependent on whether the research institution receives federal funding and is subject to the Public Health Service (PHS) Policy (is PHS-assured), and if the institution is registered with the United States Department of Agriculture (USDA) and is subject to the Animal Welfare Act (AWA) and its regulations. Each of these regulatory bodies have slightly different definitions of the term "animal."

PHS Policy defines an animal as "Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes." This includes all vertebrate animals but excludes, for example, insects, mollusks and worms. For the AWA, "The term animal includes, with certain exceptions, any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet, specifically excluding birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research." This excludes a large fraction of research animals that are covered under PHS policy.

UC San Diego is both PHS-assured and USDA-registered which means that an animal use protocol and IACUC oversight are required for work with any animal meeting either of the definitions above, i.e. any live vertebrates. It should be noted that there is ongoing discussion among regulatory and accrediting groups to include cephalopods (squid, octopus, cuttlefish, etc.), which do not currently require IACUC approval. The IACUC Office will keep the research community informed about any new developments or changes to the regulations.

For questions about your particular research or circumstances or general assistance, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

EDUCATION

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 will offer 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. The following sessions has been scheduled:

► **Conflict of Interest (COI) - Navigating Kuali COI and COI Disclosure Requirements**
June 24, 2020
11:00 a.m. - 12:30 p.m., via Zoom

► **ClinicalTrials.gov - Results**
August 19, 2020
11:00 a.m. - 12:30 p.m., via Zoom

Information on registration and additional sessions will be provided soon. For questions, please contact rci@ucsd.edu.

Research Compliance and Integrity Knowledge Briefs!

Some of the core areas within the Research Compliance and Integrity Office have created short informational videos for UC San Diego researchers and staff on a variety of topics, policies and procedures. The videos can be accessed through UC Learning.

CONFLICT OF INTEREST VIDEOS

1. **Roles and Services of the Conflict of Interest (COI) Office**:
   Provides an overview of the roles and services of the Conflict of Interest (COI) Office.
2. **What is a Conflict of Interest (COI) in Research and Other Related Activities**:
   Provides information on what is a conflict of interest in research and other related activities.
3. **700U Conflict of Interest (COI) Disclosure**:
   Provides the State of California Statement of Economic Interest 700U disclosure for researchers.
4. **Public Health Services (PHS) Financial Conflict of Interest (FCOI) Disclosure**:
   Provides information on the Public Health Services Financial Conflict of Interest (PHS-FCOI) form for researchers.
   Note: This video does NOT SATISFY PHS mandatory training.
5. **Non-PHS 9510 Conflict of Interest (COI) Disclosure**:
   Provides information on the Non-PHS (Public Health Services) federal disclosure of financial interests for researchers.
6. **What Happens When a Conflict of Interest (COI) Disclosure is Submitted to the Independent Review Committee (IRC)**:
   Provides information on what happens when a Conflict of Interest (COI) disclosure is referred to the Independent Review Committee (IRC).

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

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE VIDEOS

Links to various Institutional Animal Care and Use Committee (IACUC) informational videos are available on the Investigator menu in the Animal Use Protocol System (AUPS). For questions or additional information, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

EXPORT CONTROL VIDEOS

1. **Export Control for Restricted Parties**:
   Provides an overview of Restricted Party and Sanctions Screening and answers the "what, when and how" regarding the responsibility of researchers to screen all potential collaborations, awards, agreements and financial transactions with foreign entities or persons against US government watch lists.
2. **Restricted Party Screening**:
   The U.S. government restricts collaborating with or shipping to certain individuals or organizations. In this video you will learn what a restricted party is, when to screen for them, and how the screening is done here at UC San Diego in order to maintain compliance with United States Export Control Regulations.
3. **Export Control for Temporary Exports**:
   Provides information about Temporary Exports (exported goods which will return to the U.S. within (1) year) including the various ways to ship or hand-carry goods internationally and the trade, duty and tax implications and exemptions of the various methods. It also covers required Electronic Export Information filing (EEI) for Temporary Exports.
4. **Foreign National Export Control Considerations**:
   Provides information about what qualifies as an export (disclosures of "controlled" technical data or technology, whether written, oral or visual to a "foreign person" in the U.S. or abroad) and how to know when an export license is required. It also provides an overview of Fundamental Research Exemption (FRE) and the conditions under which they may or may not apply to your export.

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

Q&A

"Research means that you don't know, but are willing to find out."

—Charles Kettering

Ask the Questions . . .

I recently started a new company and the company has limited resources. Can I use University resources (for instance, equipment or facilities) when they are not being used for University purposes?

University resources should not be used for a private or personal purposes. Per BFB-BUS-20, University employees shall not use University property or property in the care and custody of the University for personal purposes. Equipment procured through the federal government under a grant or contract must only be used for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project. Once the equipment is no longer needed for the project, the University can use the equipment for other projects, but in this order of priority:

➢ Research funded by the agency that funded the purchase of the equipment;
➢ Research funded by other federal awarding agencies;
➢ Non-federally funded projects.

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

What if there is Personal Identifiable Information, trade secrets, or confidential information on my ClinicalTrials.gov study documents. Do I still have to upload the documents?

Yes, the documents must still be uploaded to ClinicalTrials.gov. However, if there is information that includes personal identifiable information, trade secrets, and confidential information (e.g., exploratory endpoints), the documents should be redacted prior to uploading. For more information and instructions on how to redact documents, please review the Research Compliance and Integrity Factsheet: ClinicalTrials.gov Instructions for Uploading Study Documents and Redaction Guide.

I am conducting research that involves animals. My grant application asks for UC San Diego's AAALAC accreditation date and Public Health Service (PHS) Assurance number. Where can I find these?

For animal research, all current assurance and accreditation numbers and dates can be found on the IACUC website. UC San Diego is USDA registered, PHS assured and AAALAC accredited.

For assistance or additional questions, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

How can I satisfy National Institutes of Health's (NIH) Responsible Conduct of Research training requirement that requires in-person attendance during the COVID-19 pandemic?

The NIH issued guidance permitting online training for training that typically requires a face-to-face instruction in the midst of the declared public health emergency. A variety of online training can be completed through the Collaborative Institutional Training Institute (CITI) program at no cost. For instance, training such as the Responsible Conduct of Research (RCR) that typically involve an in-person instruction can be completed on CITI. The CITI RCR training satisfies 4 hours of the recommended 8 hours of training. Additionally, the UC San Diego Research Ethic Program has developed and implemented an online version of the Scientific Ethics course.

For more information, please visit the Research Compliance and Integrity (RCI) training page or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

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