ENTERPRISE SYSTEM RENEWAL FINANCE SYSTEMS STABILIZATION PROGRESS

BY ALLORAH PRADENAS

Two years ago, UC San Diego implemented our new finance systems during a stressful pandemic. While our systems are now functioning as intended, the campus community is still adjusting to this new way of operating. In our recent quarterly survey of Oracle users and faculty/researchers, we heard resoundingly that while there has been slight progress in the majority of areas, overall this stabilization period has taken too long and caused an immense amount of frustration. Staff with fiscal oversight or job responsibilities have been profoundly impacted. Some Principal Investigators and faculty are not consistently receiving financial reports or have only recently been able to track their grant spending sufficiently. Everyone across the campus, regardless of whether they are located in departments, central offices, or labs/centers, is working incredibly hard to make this a better situation for our university.

The additional stress of the finance systems implementation during a public health crisis has hurt many faculty, researchers, and staff, morale is low. In order to address these concerns due to the extended stabilization period, we are taking the following actions to:

1. **Provide support teams for cleanup.** For departments that need assistance with expense cleanup efforts, we are providing support teams to help. For the majority of departments, our fiscal staff are proficiently operating in our finance systems, however, cleanup of past expenses and transaction errors is essential for our financial reports to display accurate information as well as to ensure data quality management in our systems. We are leveraging the support teams across academic Vice Chancellor areas first. It might take some time to get to all departments that need assistance. We thank you for your continued patience while we prioritize our teams for those departments who have the most need at this time.

2. **Invest in staffing.** Staffing ratios will be evaluated and adjusted as needed during this transition. In our current state, finance work is taking longer. Tasks that seemed simple in past systems feel time consuming and burdensome now. In some areas, we were not staffed appropriately to ensure continuity of services during this transitional time period. It might take some time to get to all departments that need assistance. We thank you for your continued patience while we prioritize our teams for those departments who have the most need at this time.

CONTINUED ON NEXT PAGE
Department of Energy (DOE) and National Nuclear Security Administration (NNSA) Interim Conflict of Interest (COI) Policy

BY JENNIFER J. FORD

On December 20, 2021, the Department of Energy (DOE) and National Nuclear Security Administration (NNSA) published an Interim Conflict of Interest Policy. This policy closely resembles the existing federal Financial Conflict of Interest (FCOI) program required for those applying for and receiving funding from Public Health Service (PHS) agencies, such as the National Institutes of Health (NIH).

DOE/NNSA provided awardees 180 days to implement a process for those applying for and receiving DOE/NNSA funding. The UC San Diego Conflict of Interest Office is working with University of California Office of the President (UCOP) on developing a process to implement these new requirements and will provide more details for the campus research community soon.

Investigators and key personnel applying for or currently receiving DOE/NNSA funded research should be aware of the following:

► The dollar thresholds and disclosure requirements are similar to the PHS FCOI regulations. It is recommended Investigator’s review this summary.

► The policy will require disclosure of Significant Financial interests that relate to an Investigator’s institutional responsibilities (e.g., research, teaching or service). This means that the Investigator may need to disclose financial interests that do not relate to their DOE funding but are related to their professional responsibilities to UC San Diego.

► The definition of a Significant Financial Interest can be found within the interim DOE COI policy which is slightly broader than PHS FCOI policy.

► Investigators are advised to keep track of any personal Significant Financial Interests. Since the initial disclosure period will cover the preceding 12 months, the disclosing Investigator will need to be able to accurately report on those financial interests.

► Pending clarification from the DOE, reimbursed for sponsored travel related to an Investigator’s institutional responsibility will need to be reported.

► Unless we receive clarity from DOE, this means the dollar threshold change may have to apply to all PHS-funded (i.e., change from $5,000 threshold to zero-dollar threshold).

► The DOE policy has specific certification language that the Investigator will need to certify in Kuali COI.

► DOE/NNSA requires mandatory COI training. The Ethics and Compliance Briefing for Researchers (ECBR) by UCOP will satisfy the mandatory DOE COI training requirement. DOE and NNSA awards will not be able to be released until the training has been completed by all Investigators listed as senior key personnel. It is recommended that Investigators check and complete their ECBR Training.

DOE/NNSA COI disclosures will not be required until a campus process is implemented in Kuali COI and communicated to the research community. UCOP’s anticipates updating the PHS FCOI policy to incorporate the DOE interim COI policy soon. If you have questions or need additional information, please contact the Conflict of Interest Office at (858) 534-6465 or info-coi@ucsd.edu.

Enterprise System Renewal Finance Systems Stabilization Progress

In order to address this, we are conducting an analysis lead by the Office of Operational Strategic Initiatives (OSI) to benchmark according to several factors, including grant complexity and type, junior versus senior staff levels and experience, and staff ratios to balance workloads. These benchmarks will be shared with departments to ensure staffing is adequate and sufficiently funded.

3. Optimize processes and systems. While it was anticipated that we would require a period of time to learn and adapt to the new systems before we could begin to realize efficiencies, we are not satisfied with the process time delays and system inefficiencies. We are committed to sustained and in-depth process review directly with end users in order to ensure optimization as a long-term goal. We know current processing times are unacceptable for many units. Our commitment is to reduce inefficient processes and deliver improved system functionality over the next several years.

Vice Chancellor and Chief Financial Officer Pierre Ouillet and his Enterprise System Renewal leadership team are truly sorry this delayed stabilization period has caused so much pain and instability. The extended timeline and slower than anticipated progress has been upsetting to all of us. As we turn this next corner and refocus our efforts, we ask for kindness with your campus colleagues who are trying their best despite being overburdened. Thank you to faculty and staff for your exceptional resilience. We remain extremely dedicated to our university mission and the success of our institution. Progress updates are posted weekly on the financial management website, which include resolutions and timelines for resolving the remaining finance system-related issues as well as survey results from the campus community feedback.

If you have any questions or comments, please contact Allorah Pradenas, Program Manager, Finance Systems Stabilization, at apradenas@ucsd.edu.
The National Institutes of Health (NIH) released notice NOT-OD-22-044, which details the NIH policies on maintaining confidentiality and integrity in the peer review process as well as possible actions that the NIH and other offices may take when parties violate these rules.

This notice applies to Project Investigators, Key Personnel, Peer reviewers and NIH National Advisory Council (NAC) members.

As the NIH peer review process is completed via online systems, the NIH prohibits the following activities in the review process:

► Accessing or attempting to access a secure government computer system used to support the NIH review process by an unauthorized individual, or assisting such an individual gain access to a system;
► Improper use of these systems, applications, data or information. This includes communicating, delivering, or transmitting information to any person not authorized to receive such information;
► Sharing of government-issued login credentials to gain access to a secure government computer system used to support the NIH peer review process.

In order to preserve the confidentiality of a NIH peer review, Principal Investigators, Key Personnel, officials of applicant organizations, and other individuals acting on their behalf are prohibited from:

► Contacting a reviewer in order to request or provide information related to the review, to attempt to influence the outcome of the review, or to access information related to the review unless provided directly to them through NIH communication channels
► Sending information related to the project under review directly to the reviewer

Guidance is also provided for NIH Advisory Council members to ensure peer review meetings are closed to the public and reviewed documents are confidential. The following actions are prohibited:

► Accessing or attempting to access a closed session unless authorized
► Disclosing grant applications, and associated confidential information with any other individual unless authorized
► Disclosing information about the committee deliberation and discussions to any other individual, unless authorized
► Disclosing confidential information to individuals who have declared a conflict of interest with that application or proposal
► Recording or transcribing committee deliberations, discussions, evaluations, or documents
► Using information in a grant application for personal benefit
► Disclosing procurement information prior to the award of a contract

It is required that every NIH peer reviewer certify a Security, Confidentiality and Nondisclosure Agreement. This certifies that they understand that any false statement or representation may be subject to criminal, civil, or administrative penalties.

Participants and stakeholders are expected to report violations to the Designated Federal Office (DFO). Per NOT-OD-22-044, if there is a breach of integrity in the NIH peer review process, the following actions may be taken:

► Notifying or requesting information from the individual's institution
► Terminating review service for a reviewer
► Deferring or withdrawing an application submitted by an individual's institution
► Terminating grant, cooperative agreement, or award
► Notifying the appropriate Federal agencies such as the NIH Office of Management Assessment, U.S. Department of Health and Human Services Office of Inspector General and U.S. Department of Justice for additional action

To test your knowledge on Security and Confidentiality in NIH Peer review, please visit the NIH Quiz on this notice’s content. For questions or additional information, please visit the NIH Notice NOT-OD-22-044 or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.
Research Ethics Program

BY CAMILLE NEBEKER

The UC San Diego Research Ethics Program is a campus resource that provides education and consultation services. Our overarching goal is to cultivate an organizational culture that promotes inquiry and conversation about ethical and responsible research practices. Our team also conducts research to learn about the ethical and social implications of technologies used in health research. Below is a description of the educational programs and services available to our UC San Diego colleagues.

We invite you to join our ongoing efforts to cultivate an ethical and responsible campus culture. Please complete this brief survey to join the Research Ethics Program network.

EDUCATION

Formal and informal training in research ethics is an important aspect of the professional development of scientists and engineers. The rules, cultures and disciplinary differences are sometimes obvious and other times nuanced and it is important to know how to navigate and discriminate between hard and fast rules and not so clear conventions. Research ethics education may also be a requirement of a funding agency and our courses are designed to satisfy federal training requirements for Responsible Conduct of Research (RCR).

The UC San Diego Research Ethics Program offers a variety of courses, workshops, and seminars. The topics covered are those associated with RCR, which includes, for example, conflict of interest, mentor/mentee responsibilities, data management and research subject protections (see: NIH RCR requirements). In addition, education may focus on more specialized topics including, for example, digital health (e.g., artificial intelligence, predictive analytics), gene editing and stem cell research.

SERVICES

CONSULTATION: The purpose of consultation is to clarify ethical challenges, possible courses of action, and strategies for mitigating future challenges. Consultations are a pathway to clarifying and resolving disputes, possible misunderstandings, or questionable research practices. Consultation might focus on regulated areas of research such as conflict of interest and research subject protections as well as unregulated aspects of research including collaborations, authorship and mentor/mentee relationships.

PUBLIC/COMMUNITY ENGAGEMENT: Public engagement is an important part of discussing complex ethical issues, particularly in emerging areas of technology (e.g., robotics, pervasive sensing). The Research Ethics Program faculty are experienced in staging public forums to promote discussion of complex ethical issues. Unique challenges include, but are not limited to, designing research that will involve vulnerable populations and returning results to research participants. Our faculty also have a role in communicating with the public through interviews with journalists and publishing op-ed pieces.

POLICY DEVELOPMENT: Assistance is available to research groups, schools/departments, and the University in the development of policies, guidelines, or procedures that support the ethical and responsible conduct of research. This assistance may involve drafting materials and/or providing guidance.

RESEARCH

Research is strengthened through the conduct of both normative analysis and empirical research designed to study and inform best practices. Our research has received extra and intramural support for over 20 years. Current research is carried out with support from the National Institutes of Health, National Science Foundation and Patient Centered Outcomes Research Institute. Areas of interest include:

► Creating/testing decision-making tools to support ethical artificial intelligence/digital health research,
► Fostering ethical and responsible research environments, and
► Informing participant communications including informed consent and return of results, and
► developing ethically sourced health data repositories.

In addition to leading research programs, our faculty support researchers by contributing to grant proposals. This includes addressing ethical issues proactively and/or developing aims to conduct research on ethical issues that are either central to or a part of clinical and translational research projects. In addition, our Research Ethics Program faculty contribute to career development and fellowship proposals that require plans for research ethics education or addressing ethical challenges.

RESEARCH ETHICS PROGRAM

► Contact us with questions or requests for services: Research Ethics Program
► Twitter: @UCSD_EthicsProg
► Subscribe to the UCSD Bioethics Seminar Mailing Lists: Seminar Mailing Lists
► Email us about San Diego Research Ethics Consulting Services: sdrec@ucsd.edu
GUIDANCE FOR REQUESTING A CERTIFICATE OF CONFIDENTIALITY FOR A UCSD CLINICAL STUDY

BY REBECCA BEUTLER

In an effort to provide additional protection for human subjects participating in clinical studies, the National Institutes of Health (NIH) can provide a Certificate of Confidentiality (CoC) to cover studies of a sensitive nature (e.g. illegal/illicit behaviors). CoCs protect against harm to the subject’s reputation, employability, status or situations that put them at risk of criminal or civil liability except under circumstances in which researchers uncover imminent harm to another (e.g. child or elder abuse). The CoC affords such protections by requiring study teams to not release the subject’s identifiable information, including in cases where a subpoena, Freedom of Information Act (FOIA) request or Public Records Act (PRA) request is received. For studies funded by the NIH and Center for Disease Control (CDC), the CoC is automatically issued as part of their award to the institution. For studies funded by non-NIH or CDC agencies, or unfunded studies, a CoC may still be obtained from the NIH by request.

All NIH CoC requests through UC San Diego must be routed to the UC San Diego IRB office via the NIH’s CoC request website. To request a CoC, the following should be completed:

► Navigate to the NIH’s CoC request website.
► Identify the funding source by selecting the appropriate choice from the drop-down menu and click “Next.”
► Answer questions 2-6 and click “Next.”
► Enter project title, start and end dates, description.
► Under “Institution and Performance Site Details” enter the following information:
  a. Name of Institution: UC San Diego or UC San Diego Health
  b. Institution Address: 9500 Gilman Drive, La Jolla, CA 92093
  c. Name of Institutional Official: Gary Firestein
  d. Email Address of Institutional Official: irb@ucsd.edu
► Under “Principal Investigator and Other Key Personnel” enter the name of the PI and any key personnel.
► Under “Administration of Drugs” enter any drugs that will be administered as a part of the study, if applicable.
► When everything is complete, click the “Submit for Verification” button.

For more information on NIH CoC, please visit the NIH’s Electronic Research Administration Certificate of Confidentiality Resource System. Additional guidance can be found on UCSD’s Office of IRB Administration Guidance page or contact the IRB office at irb@ucsd.edu.
Updates from the Office of Contract and Grant Administration on its Redesign and Restructuring Efforts

BY ROSS DAMMANN

The Office of Contract and Grant Administration (OCGA) supports the collaborative and interdisciplinary research culture that makes UC San Diego one of the leading research institutions in the world. Therefore, it is critical to deliver the best customer service to researchers, business officers, and administrative staff.

As of June 1, 2022, OCGA will complete its yearlong redesign and restructuring effort to create smaller, more agile, and resilient teams. The redesign focuses on delivering positive customer experiences and improved service quality and efficiency by leveraging its staff’s expertise and deploying existing and emerging customer-centric technologies. The changes to OCGA reflect the ongoing commitment to continuously finding better ways to improve services for the UC San Diego research community.

The new operating model shifts from the “Department Model,” in which officers were assigned to departments and tasked with learning the intricacies and protocols of multiple funding agencies to a “Specialist Model” with a strong focus on small expert teams supporting the three highest impact functional areas:

**PROPOSAL REVIEW AND SUBMISSION:**
As an effort to support a 40% growth in proposals over the last six years, OCGA has streamlined processes to support compliance with Proposal Submission Timeline. OCGA’s dedicated proposal team will consist of experts proficient in sponsor policies and processes across the various federal and non-federal sponsors.

**AWARD NEGOTIATION AND EXECUTION OF AGREEMENTS:**
To provide researchers and research administrators with expertise in award negotiation, facilitate the appropriate application of sponsor policies, and improve the turnaround times on award processing, OCGA created smaller, more agile, sponsor-segmented teams. Each team is equipped with experts, knowledgeable and experienced in fulfilling the full range of responsibilities required to address these complex and difficult negotiations. This will ensure that awards and agreements are rigorously reviewed and completed within reasonable expectations.

**CLIENT EXPERIENCE:**
Through OCGA’s review of customer satisfaction surveys and direct feedback from the research community, OCGA has developed a new client experience team focused on providing relevant, timely, and accurate responses to basic research administration questions, as well as support for Kuali Research. The new Client Experience team will leverage UCSD Services and Support Research portal and the Research Administration Activity Dashboard to ensure client inquiries are promptly addressed. Client Experience Agents can be reached at researchadmin@ucsd.edu.

As a result of the new model and campus investment in additional resources, OCGA expects the campus research community will experience improvements in the timeliness, accuracy, and quality of services in support of UCSD’s $1.5 billion research enterprise, and the acceleration of research productivity. We greatly appreciate your patience as we continue to incorporate your feedback for greater efficiency.

For more information about this new model and links to OCGA resources and tools, please visit the OCGA website. If you have any questions, please contact Ross Dammann, Assistant Vice Chancellor for OCGA at rtdammann@ucsd.edu.
Electronic Digital Signature Options for the National Institutes of Health Other Support Documents

BY RACHEL COOK

As of January 25, 2022, the National Institutes of Health (NIH) requires all Other Support documents to be electronically certified and signed by the discloser. There has been confusion on both sides of the aisle on how to implement this requirement, what program can be used, how will the Sponsored Projects Office and NIH review this requirement, how the institution’s Authorized Organization Representative should respond to the NIH when contacted for confirmation and/or verification that the Other Support was certified and signed correctly, and how to remain in compliance with the institutional policies for certified e-signatures.

At UC San Diego, there are two ways to certify the Other Support documents with an e-signature: Sign using DocuSign or Adobe Acrobat Professional.

DocuSign at UC San Diego requires the discloser to log in through Single Sign On. Once there, the program allows you to drag and drop the document that needs to be signed. The discloser can be both the host and signer. There is also an option that permits the host to forward an email to the person that needs to sign. For each step in the process, an email will be generated notifying the discloser (and host) that a document needs to be signed and when it is completed. Once completed, download the document and it will show that it has been signed and all the signatures are valid in Adobe Acrobat. It is important that when the document is downloaded, the Certificate of Completion is also downloaded and saved for audit purposes. Please do not use the Certificate of Completion to Electronic Research Administration (eRA) Commons or Application Submission System & Interface for Submission Tracking (ASSIST). Please see below of an example of the e-Signature and the Certificate of Completion.

Adobe Acrobat Professional has the “Fill & Sign” tool to add signatures, but only allows for a signature with no certification process or audit trail of who actually signed the document and when. If using Adobe Acrobat Professional, make sure to select the “Certificates” tool which will allow you to either select the Digitally Sign option or the Certify (Visible Signature) option. Both of these options will work, but the latter of these two is the preferred choice. Please see below for an example of the e-Signature using the Certify (Visible Signature) option and the Signature Properties showing who and when this was digitally signed.

Flatten your PDF once certified and signed. Once the Other Support has been certified and signed, the PDF needs to then be “flattened” in order to add all of the Other Support that is being submitted into one PDF and uploaded into eRA Commons. Note per the NIH FAQ, “all applicants and recipients must maintain supporting documentation to reasonably authenticate that the appropriate individual signed the form. Recipients must make the documentation available upon request in accordance with 45 CFR Part 75.364.”

There are two easy ways to “flatten” your PDF. The first is to print the document to PDF. This works in most cases, but not all due to embedded security features. When the program will not allow you to print to PDF, then the other option is to open up a browser window and drag and drop the file into the open browser. This will open the file in your browser, select the option to print to PDF, will remove all security features and allow you to save, add to other documents, and upload into eRA Commons or ASSIST.

For questions or additional information, please contact your UC San Diego Sponsored Projects Office.
Federal Cybersecurity Regulations Target Researchers

BY MICHAEL CORN

As we approach the fourth month of the Russian invasion of Ukraine, I thought it would be useful to reflect on how this conflict impacts UC San Diego (UCSD), and specifically researchers at UCSD. Most of us recall the dire warnings about the Russians launching massive cyberattacks to coincide with the invasion (roughly 80% of all ransomware originates in eastern Europe) and indeed there have been a number of serious episodes generally attributed to Russian state actors. While Russia has obviously used their cyber capabilities against Ukraine (see the article, "Tracking Cyber Operations and Actors in the Russia-Ukraine War") there has been wide reporting of attacks against Finland and the United Kingdom as well as European allies (see the articles, "Cyberattacks on the Rise since the Start of the Ukraine Invasion" and "U.S. Russia Malware Cyberattacks").

However, it is reasonable to question why, in the middle of a major war, Russia would bother with attacking one of the thousands of US universities, let alone the one furthest from Moscow in the continental United States. Obviously I will not hazard a guess at what logic drives Russian military cyber doctrine. What is interesting though is that many of the attacks launched against Ukraine were not attempts to hold data for ransom, or to steal military secrets, but merely to execute a scorched earth policy of wanton destruction. Data “wipers” seem to be the preferred munition. Have we seen these? What kind of threat have we found since the start of the war?

As part of our normal threat assessment process, UCSD IT Security began preparing for the worst case by building alerts and custom real-time reports that focused on network traffic originating from the general region of Russian, Ukraine, Crimea and Belarus. Similarly UCSD IT Security looked at authentications from these regions, essentially who was logging into UCSD systems and services, and were these logins “normal.” That is, was the same account used to login from Russia and San Diego at nearly the same time. We went as far as to contact many of these account holders to confirm that they actually were overseas.

As a result of this closer examination, UCSD IT Security have identified over 1000 locations (IP addresses) probing and doing reconnaissance of the campus network. We block these from connecting to the campus as we uncover them and share this intelligence with our counterparts throughout the University of California system. Those 1000 locations generated millions of connections and probes of the campus, entirely blind to the value of the system being probed. In a world where a brutal cyberattack can be launched with a few keystrokes, with the goal, not of data theft, but data destruction, every system and every research lab at UCSD is both at risk and a target.

This brings us to how Federal agencies are responding to the “new normal” in the cyber landscape. Across the country, universities are responding to the release of the National Security Presidential Memo 33 (NSPM-33). Earlier this year, the National Science and Technology Council released their guidance on the implementation of NSPM-33. NSPM-33 is a broad document covering much more than cybersecurity, but with regard to cyber, it introduces 14 technical practice requirements that will be applicable to all research programs. NSPM-33 follows the example led by the Department of Defense in that it requires institutional certification that these practices are implemented and being met by covered programs. Under the leadership of the Vice Chancellor for Research, UCSD has formed a working group to address the requirements of NSPM-33, which will be working throughout this calendar year on the issue.

All change takes time. The obligations of NSPM-33, and responding to the very real threat to researchers we see launched at UCSD computing resources will require change in computing practices even in the smallest laboratory working with the entirely public data. Fortunately, UCSD is better prepared than many schools, and over $200 million dollars in research programs have participated in the campus Cybersecurity Certification for Research (CCR) initiative which aligns almost directly with the NSPM-33 requirements.

The CCR asks only for the most minimal practice changes to the laboratory environment, and all of the data collected can be provided by anyone delegated by the Principal Investigator. The CCR program while significantly raising the bar on general research cybersecurity, represents a gentle on-ramp to the elevated requirements of NSPM-33 and prepares researchers for further requirements many of the funding agencies are exploring.

For questions or additional information, please contact Mike Corn, Executive Director, Chief Information Security Officer at mcorn@ucsd.edu. For assistance with the CCR, please visit assure.ucsd.edu or email ccr-support@ucsd.edu.
Participation in Proprietary and Export-Controlled Activities

BY MICHAEL MILLER

“Access” to certain proprietary, export-controlled, or restricted items, materials, equipment, software or the “release” of technology may require compliance with United States (U.S.) export control laws, regulations or sanctions. Access or release may constitute a “deemed-export”, defined as the release to a foreign national in the U.S. of “technology” or “source code” required for the “development,” “production,” or “use” of the controlled item, material, equipment software or technology.

While most deemed-exports involving academic activities are exempt from many export control requirements, there are inevitably situations and variables requiring compliance, and in certain cases, licensing, and the implementation of access restrictions in a Technology Control Plan. The UC San Diego Export Control Office (ECO) assists the UC San Diego research community to understand and navigate the complex regulatory landscape of trade, export and security controls. The primary trigger of most export controls within the academic community are foreign person access to items and activities that are proprietary or defense-related. Proprietary items and technologies are those not already public or allowed to be made public and include:

- Activities subject to a non-disclosure agreement (NDA)
- Items, materials, equipment, software or technology, covered by an NDA, data or software use agreement or otherwise limited by agreement terms and conditions
- Research results and other information that cannot be disseminated or released into the public domain without prior authorization
- Processes, methods, designs, formulae, etc., that are not public, generated by, or provided to the university
- Defense and related items and technologies are identified by whether they were specially designed for a military application and include a variety of military, space, and defense-related-technologies. Defense-related flow-through programs require careful evaluation to ensure the activities are not in furtherance of proprietary or militarily restricted program.

Foreign person participation in activities that involve access or release of proprietary or defense technologies may trigger an export control requirement and depending upon the nationality of the foreign person and country of origin of the technology, a license may be required.

Allowable participation in activities involving access and/or release to proprietary or defense technologies varies according to the relationship the foreign person has with UC San Diego and U.S. Government approval requirements. The UC San Diego ECO facilitates deemed-export reviews for employees, students and visitors to determine if participation in, or access to proprietary activities and items require compliance, licensing, or other mitigators.

If you or a foreign person are unsure as to the regulatory requirements associated with an activity or have any export control related questions, please contact the ECO at export@ucsd.edu.

Definition of an “Animal” for Institutional Animal Care and Use Committee 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, circumstances or general assistance, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.
The National Institutes of Health Updates the Requirement for Instruction in the Responsible Conduct of Research

BY DIANA D. KIM

The National Institutes of Health (NIH) Fiscal Year 2022 Updated Guidance on requirement for instruction in the Responsible Conduct of Research (RCR) (NOT-OD-22-055) reaffirms the principle that education in RCR is a fundamental element of research training. In particular, the updated guidance provides new recommendations on the format, frequency and timing, and topics of instructions in RCR.

► Format: While substantive face-to-face interaction among participants and faculty remains a key feature of RCR training, video conferencing that promotes discussion, active learning, engagement, and interaction can be partially* used to meet the requirement for RCR instruction. Exceptions include short-term research training or unusual and well-justified circumstances.

* At this time during the declared public health emergency, RCR training can be fully completed online and grant recipients do not need to seek prior approval to do so.

► Frequency and timing: RCR training is to be undertaken at least once during each career stage and no less than once every four years. However, reference to the previous requirement for 8 contacts hours has been removed. Institutions are to consider the value of ongoing and discipline-specific training as researchers progress in their careers.

► Subject matter: Additional topics have been included in discussion of RCR.

➢ Conflict of commitment, in allocating time, effort, or other research resources
➢ Safe research environments (those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
➢ Collaborations with investigators and institutions in other countries
➢ Peer review, including the responsibility for maintaining confidentiality and security in peer review
➢ Data analysis, laboratory tools (for analyzing data and creating or working with digital images), and recordkeeping practices, including methods such as electronic laboratory notebooks
➢ Secure and ethical data use and data confidentiality

Institutions are to incorporate the updated requirements for RCR instruction for the 2022-2023 academic year as well as in new and renewal application for research training, career development, research education, and dissertation research grants beginning with September 25, 2022, due dates.

For additional information, please refer to the last NIH Guide Notice on the requirement for instruction of RCR, NOT-OD-10-09. Of note, unless changed by NOT-OD-22-055, the requirements of NOT-OD-10-09 remain in effect. For questions, please contact the Research Compliance and Integrity Office at rci@ucsd.edu or (858) 822-4939.

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

The UC San Diego Research Compliance and Integrity (RCI) 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 training program session has been scheduled:

► Export Control 101: The Basics You Need
June 15, 2022, 11:00 a.m. – 12:30 p.m.
via Zoom (to register, click on this link)

Do you have research compliance questions? Join RCI Office Hours every Tuesday from 11:00 a.m. - 12:00 p.m. Sign up at calendly.com/ucsdrcioffice.

For questions, please contact rci@ucsd.edu.
Juneteenth is a nationally celebrated holiday in the United States commemorating the end of slavery in America. The holiday originated in Galveston, Texas in 1865, nearly nine decades after the founding of the United States and more than two years after President Lincoln signed the Emancipation Proclamation, when enslaved Black Americans finally received word that they were free. Juneteenth honors the end to slavery in the United States and is considered the longest-running African American holiday.

In June of 2021, on the 156th anniversary of the last slaves being freed in Texas, President Biden signed into law Juneteenth National Independence Day, creating a federal holiday to commemorate Juneteenth. Today, Juneteenth commemorates African American freedom and celebrates education and achievement. In addition to a time of rejoicing, it is a time for reflection, assessment, and improvement. It is a long overdue truthful acknowledgement of a painful period in American history that shaped and continues to influence society today. To learn more about Juneteenth, see the official Juneteenth website and the President’s Proclamation of making Juneteenth a federal holiday.

Following President Biden’s declaration of Juneteenth as a federal holiday, UC President Michael Drake announced Juneteenth as a new UC holiday, observed at the end of June in 2021 and to be celebrated according to the federal calendar starting in 2022. At UC San Diego, to assist in the mission of finding solutions to end systemic racism and anti-blackness, UCSD’s Office for Equity, Diversity, and Inclusion developed the Strategic Plan for Inclusive Excellence, which includes resources such as the Chancellor’s 21-Day Antiracism Challenge along with an allyship initiative aimed at educating and supporting white campus community members in continuing anti-racism work. Please visit the Office for Equity, Diversity, and Inclusion website for additional information on various initiatives and anti-racism resources.

If you have questions or would like to learn more about the Research Affairs EDI Committee, please visit our website or contact vcr-edi@ucsd.edu.

New Collaborative Institutional Training Initiative (CITI) Training “Health Disparities: Promoting Equity and Diversity in Clinical Research”

BY REBECCA BEUTLER

The Collaborative Institutional Training Institute (CITI) offers a variety of training modules that are available for all UCSD faculty, students, staff and affiliates. A new online course, Health Disparities: Promoting Equity and Diversity in Clinical Research, has been made available for all UCSD employees. This module provides education on health disparities affecting groups of people in research, as well as provides strategies for designing and conducting research that addresses implicit bias. Additionally, resources are provided from National Institutes of Health (NIH) and the National Institute on Minority Health and Health Disparities (NIMHD). At the end of the training and completion of the quiz, a certificate is provided.

Please see the UC San Diego Research Compliance Training page for links to the required and recommended training for researchers and research staff. For questions or additional information, please contact the RCI Office at rci@ucsd.edu, (858) 822-4939.
**RESEARCH COMPLIANCE CORNER: WORD TO THE WISE**

**Office of Research Integrity Makes Misconduct Finding Against Vice Chancellor for Research at University of North Carolina**

The Office of Research Integrity (ORI) found that Terry Magnuson, Vice Chancellor for Research at the University of North Carolina (UNC) at Chapel Hill, engaged in research misconduct. ORI found that Magnuson intentionally, knowingly, or recklessly plagiarized text from three online articles and a one published paper in a grant application to National Cancer Institute (NCI).

Magnuson entered into a Voluntary Settlement Agreement of a 22-month supervisory program that requires his proposals for Public Health Service funding to be first submitted to UNC’s School of Medicine and Office of Research to review to “check for plagiarism and ensure compliance with acceptable scientific practice for citation of prior work.” Although Magnuson was reappointed to his position after an administrative review, he ultimately resigned after UNC faculty pushed for accountability. For more information, read the [ORI Misconduct Finding](https://www.orcnt.org/misconduct-finding).

**Former University of Wisconsin-Milwaukee Professor to Plead Guilty to Wire Fraud**

On February 11, 2022, it was announced that University of Wisconsin-Milwaukee (UWM) professor Yue Liu, had been charged with a two-count information with wire-fraud and engaging in an unlawful monetary transaction. The wire fraud charge carries a penalty of up to 20 years in prison and a maximum fine of $250,000. The second charge, unlawful monetary transaction, carries up to 10 years in prison and a maximum fine of $250,000.

In an investigation conducted by the Federal Bureau of Investigation, the Criminal Investigation Division of Internal Revenue Service, and Immigration and Customs Enforcement of the Department of Homeland Security, it was found that Liu was promising foreign students that they would be a part of a fake program he controlled, which would pay UWM expenses. By devising and executing this scheme to fraud, Liu obtained more than $1.1 million from foreign students and visiting professors which he used for personal purposes. Liu has signed a plea agreement, but has not formally entered a plea in this matter. For more information, read the [Department of Justice Announcement](https://www.justice.gov/opa/pr/university-of-wisconsin-milwaukee-professor-pleads-guilty).

**Coca-Cola Chemist Sentenced to Prison for Passing Can Secrets to China**

A chemist who worked at Coca-Cola Company, Xiaorong “Shannon” You, was sentenced to 14 years to prison for stealing trade secrets and passing them to a Chinese company. You was granted access to the proprietary information on various chemicals, formulas, and processes through her work at Coca-Cola and Eastman Chemical Company. She then sold the stolen confidential information to Weihai Jinhong Group, which was backed by the Chinese government’s Thousand Talents program. Evidence showed that she intended to benefit not only the foreign company, but also the governments of China including the province of Shandong, city of Weihai, and the Chinese Communist Party.

The trade secrets were related to a bisphenol-A-free (BPA-free) coating for the inside of cans. Owned by companies including Dow Chemical Company, PPG Industries, Sherwin-Williams Company, and Eastman Chemical Company, the trade secrets collectively cost about $120 million to develop. You and Weihai Jinhong Group received millions of dollars in Chinese government grants to set up a new BPA-free coating company in China. In addition to stealing trade secret, You was convicted of economic espionage and wire fraud. For more information, read the [Department of Justice Announcement](https://www.justice.gov/opa/pr/coca-cola-chemist-sentenced-prison-passing-can-secrets-china).

**Duke-National University of Singapore Researcher Pleads Guilty to Spying on the United States for Russia**

On February 16, 2022, a scientist at Duke-National University of Singapore (Duke-NUS), pled guilty to spying on a United States (U.S.) informant on behalf of the Russian Government. It was found that the Scientist, Hector Alejandro Cabrera Fuentes, lived a double life between Singapore and Russia, where he had two separate families. During one of his frequent trips between Singapore and Russia, he was recruited by a Russian agent in 2019 who instructed him to spy on a Federal Bureau of Investigation (FBI) informant in Miami, Florida. The Department of Justice (DOJ) reported that he had met with Russian officials in Moscow at least five times between May 2019 and February 2020.

After pleading guilty, Fuentes may be jailed for up to 10 years. His position at both the National Heart Centre Singapore (NHCS) and Duke-NUS Medical School has since been terminated. For more information, read the [Strait Times article](https://www.straitstimes.com/singapore/uncle-sam-gets-second-helping-as-duke-national-university-of-singapore-researcher-pleads-guilty-to-spying-on-the).

**Former Novartis-Affiliated Researcher Convicted of Conspiracy to Steal GlaxoSmithKline Trade Secrets**

Gongda Xue, a scientist who worked at a research institute in Switzerland affiliated with Novartis, was convicted of conspiracy to steal trade secrets from GlaxoSmithKline (GSK) where his sister, Yu Xue, worked. Both Gongda Xue and Yu Xue conducted sensitive and confidential cancer research as part of their work. While working for their respective entities, Gongda Xue and Yu Xue exchanged proprietary information on research into anti-cancer products.

Gongda Xue founded Abba Therapeutics AG in Switzerland and Yu Xue and her associates created Renopharma, Ltd., in China. Both companies sought to develop their own biopharmaceutical anti-cancer products. Renopharma, in particular, received direct funding and support from the government of China. Evidence showed that Renopharma attempted to re-brand GSK products under development and sell them for billions of dollars. Internal projections by Renopharma showed that the company could be worth as much as $10 billion based upon the stolen information. The FBI arrested Yu Xue and her associates and seized funds in a Renopharma bank account as well as e-mails containing stolen data. Gongda Xue was extradited from Switzerland to the United States. For more information, read the [Department of Justice Announcement](https://www.justice.gov/opa/pr/former-novartis-affiliated-researcher-convicted-conspiracy-steal-glaxosmithkline-trade-secrets).
Office of Research Integrity Makes Misconduct Finding Against Former Post-Doctoral Researcher

The Office of Research Integrity (ORI) found that Shuo Chen, a former postdoctoral researcher in the Department of Physics at the University of California, Berkeley, engaged in research misconduct. ORI found that Chen intentionally, knowingly, and/or recklessly falsified data and methods by “altering, reusing, and relabeling” data to represent images and falsified images, figure legends, and text descriptions in a grant application to the National Institute of Neurological Disorders and Stroke (NINDS).

Chen agreed to a Voluntary Settlement Agreement of a one-year period of supervision without admitting or denying ORI's findings of research misconduct. The supervision plan is to include a committee of two to three senior faculty members to provide oversight and guidance in all of Chen’s funding applications to the Public Health Service. For more information, read the ORI Misconduct Finding.

ORI Makes Two Research Misconduct Findings at Albert Einstein College of Medicine

The HHS Office of Research Integrity (ORI) made two findings or related research misconduct with Hui Bin Sun, former professor, and Daniel Leong, a research technician. It was found that Sun and Leong reused and relabeled western blot and histological image data included in sixteen grant applications submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Heart, Lung, and Blood Institute between 2013 to 2019. Both Sun and Leong did not admit to falsifying and/or fabricating data, but agreed to settlement terms. In 2016, Leong left Einstein voluntarily prior to ORI's investigation. In 2019, Sun was terminated following findings of the investigation.

Under the settlement agreement, Sun will participate in a 12-year supervision program in which senior faculty members at his institution would have to provide oversight on a quarterly basis if he should apply for funding by any Public Health Service. Leong had agreed to a four-year government wide exclusion, and at its conclusion he will be subject to a four-year government wide exclusion, and at its conclusion he will be subject to a four-year long supervision period with similar requirements as Sun’s. For more information, read the ORI findings regarding Sun and Leong.

University of Kansas Professor convicted of Wire-Fraud

Under the now defunct Trump-era China Initiative, a tenured professor from the University of Kansas (KU) was convicted with four counts of wire-fraud following a two-week long court case. Chemistry professor Feng Tao was charged with government allegations that he failed to inform the Department of Energy, KU, and other funding agencies that he was employed by the Changjiang Scholars Program as a Distinguished Professor at Fuzhou University.

The purpose of the China Initiative was to combat China’s attempts to steal American technology and trade secrets. But rather than charge researchers with espionage charges, it has led to catch-all investigations into any connection to China, including failures to disclose ties to China on grant-related forms. Tao was the first defendant in about two dozen charged under the China Initiative, and his verdict has led to the attention of civil rights activists who are concerned with the targeting of Chinese Americans. A sentencing date for Tao has yet to be set, but his legal team is looking to get the verdict overturned, noting the judges significant issues with the evidence in the case. For more information, read the NPR article on the case.

Southern Illinois University Professor Found Guilty of Tax Charges

An applied Math professor from Southern Illinois University (SIU), Mingqing Xiao, was found guilty of tax charges, but was found not guilty of committing grant fraud. Xiao was accused of lying to the National Science Foundation (NSF) and SIU about his affiliations to Chinese funding agencies and Shenzhen University. Additionally, he was charged with violating tax laws by not reporting a Chinese bank account used to support his research in China. Upon deliberation, all fraud charges were dropped but he was convicted on four tax charges. Sentencing is scheduled for August 11, 2022, and these charges can result in a maximum of 5 years in prison and a large fine. For more information, read the Science Insider article on the case.

Retirements in Health Sciences Sponsored Project Pre-Award Office

Erika Wilson Thanhdieu Rich

BY RACHEL COOK

The Health Sciences Sponsored Project Pre-Award Office (HS SPPO) would like to officially announce the retirement of two key individuals. Erika Wilson, Senior Director and Thanhdieu Rich, the longest-serving Senior Grant Analyst, are retiring as of June 30, 2022, after long careers at UC San Diego. Erika started working at UC San Diego in 1981 and Thanhdieu in 1988. We are sad to see them leave, but are excited for them and their new adventures in retirement.

Congratulations, but know you will both be missed by the UC San Diego research community!
Q & A

Ask the Questions . . .

What happens if I am required to disclose a conflict of interest and do not?

For federally sponsored research, failure to file or update economic interests forms or to comply with any conditions or restrictions imposed on the conduct of the project may be grounds for discipline under the University Policy on Faculty Conduct and the Administration of Discipline and/or other applicable employee discipline policies. Furthermore, federal sponsors may suspend or debar an Investigator from receiving future awards.

For non-federal sponsored research, failure to file the required Statement of Economic Interests or failure to report a financial interest may subject the individual to civil liability, including fines, as well as University discipline (Government Code sections 81000-91014).

Where do Investigator’s submit their COI disclosure forms? Investigators must complete and submit disclosure in the Kuali COI system.

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

How do I know if my activity or technology is proprietary?

Proprietary technologies are distinguishable by whether everything about the technology is published and fully accessible within the public domain, such as in a public library or patent office. Ask yourself, “Does the public domain include enough information to recreate the technology”? If the answer is yes, then it is within the public domain. For purposes of export controls, technologies without all steps, processes, methods, formulae, and other characteristics and variables completely published and readily accessible, where a company retains an ownership interest are proprietary.

Can a corporate sponsor approve foreign person access to proprietary technology? No, only the authorized federal agency or department of the U.S. government with licensing jurisdiction of the regulated commodity can authorize a deemed-export. A corporate sponsor with proprietary ownership of a technology cannot license access to the technology.

For export control related questions, please contact the UC San Diego Export Control Office at export@ucsd.edu.

When must an informed consent form be posted to ClinicalTrials.gov for clinical trials initially approved on or after January 21, 2019, per 45 CFR 46.116(h)?

To satisfy 45 CFR 46.116(h), the 2018 requirements state that an informed consent form must be posted to ClinicalTrials.gov after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject. Informed consent forms posted prior to this 60-day time frame do not satisfy the 45 CFR 46.116(h) requirements.

The last study visit is considered the last study visit that occurs because of the study visit, and would not have happened as part of routine clinical care. The investigator’s continued collection of the clinical data from the follow-up clinical visits is not considered to be a study visit for the purposes of 45 CFR 46.116(h).

For more information please visit the Office for Human Research Protections Guidance on Informed Consent Posting or contact the Research Compliance and Integrity Office at rci@ucsd.edu or (858) 822-4939.

I have never written an animal protocol before. How can I get help?

There is a wealth of information on the Institutional Animal Care and Use Committee (IACUC) website. Look for the “What You Need to Know” section, click on the links and read the brief articles. In addition, when you log into the Animal Use Protocol System (accessible from the IACUC’s website), there is a “Best Practice for Writing Animal Care and Use Protocols” presentation under “Additional Resources” section.

Before responding to the questions on the protocol form, read all of the questions first so you know what information is requested in each section. The IACUC Office staff have over 80 combined years of experience in research with animals and are happy to provide assistance.

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

Does video conferencing meet the updated National Institute of Health’s requirement for instruction in the Responsible Conduct of Research?

The updated National Institutes of Health (NIH) requirement for instruction in Responsible Conduct of Research (RCR) does not omit the in-person meeting component. Video conferencing that allows for effective “face-to-face” discussion is considered acceptable, but it cannot be the only means for meeting the requirement for RCR instruction. Flexibilities in the method of instruction of RCR remain in place during the declared public health emergency. At this time, RCR training can be fully completed online and grant recipients do not need to seek prior approval to do so. Please see NIH Notice NOT-OD-22-055 for more information.