Enterprise System Renewal Finance Systems Stabilization Progress

BY ALLORAH PRADENAS

UC San Diego’s research funding continues to grow, which is an impressive achievement for our campus. With on-going anticipated research growth, our research community of faculty and staff experience increasing workloads to ensure sponsor compliance and integrity. In addition to these increases in workload, we know our finance system implementation has slowed down our ability to produce sponsor reports and operating in the finance systems is taking longer than before. While system optimization work is underway, we are very aware that the taxing workload puts enormous pressure on our staff and retaining and attracting staff continues to be an issue for many departments. It is necessary to provide additional support in a variety of ways to address staff turnover and change fatigue.

We remain committed to reducing inefficient processes and delivering improved system functionality over the next several years.

As part of the optimization efforts, we are listening directly to department staff to better understand the pain points and opportunities for efficiency with our finance systems. Based upon the campus community’s feedback, we are focused on these three priorities:

1. **Optimize processes and systems.**
   Some of the main concerns we have heard from our Oracle users are issues with functionality, such as incompatibility with other systems and slow screen-loading times as well as concerns with inefficient approval workflows and financial report accuracy and usability.

   a. **Functionality.** We are focused on leveraging automation of processes and building integrations to allow for more local control, whenever possible. For example, with the launch of our new Graduate Student Accounting Setup Automation, we reduced department staff wait time for setting up graduate student payments from several weeks to one day. Additionally, we launched the Project & Awards Data Update Application (PADUA) that allows department staff to update Oracle project information, real-time and in bulk, which reduced wait time from two weeks to a few minutes.

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Enterprise System Renewal Finance Systems Stabilization Progress

b. **Approval Workflows.** We have streamlined the Oracle approval notifications to save department staff time. The new email notifications feature more detailed information about transactions so approvers can take advantage of the ability to approve via email and do not need to login to Oracle to approve.

c. **Financial Reports.** We have launched and enhanced major reports and dashboards in the Business Analytics Hub, including the Project Management Dashboard, which offers fund managers one place to review all faculty startup and retention funds or their department’s operating funds, analyze a researcher’s portfolio, and close out expired projects. To address data accuracy concerns, reports have been streamlined and redesigned to ensure balance calculations are leveraging consistent logic. The Financial Accountability Blink webpages were launched to support fiscal staff with data accuracy, which includes step-by-step guides to running reports and how to correct data issues in source systems.

d. **Future Enhancements.** Upcoming system and process enhancements are focused on streamlining processes, improving customer experience, and reducing errors. For example, the Oracle Project Portfolio Management (PPM) General Projects Contract Billing Redesign, which has already launched two of five total phases, will improve the billing process for department users billing on general projects by creating more timely customer invoicing and more flexibility with invoice and accounting needs as well as reducing manual errors.

Another example is the UCPath Salary Cost Transfer enhancement that is a custom tool to significantly streamline and simplify salary cost transfers. These enhancements will reduce the transactional burdens to maintain accurate financial accounting.

3. **Develop better training and communications.** Another critical piece of feedback from the campus community was the need for strengthened finance training and streamlined communications. With increased turnover, department staff are feeling the weight of training newer staff in addition to their regular job duties. We are conducting a needs assessment for finance training and developing finance training infrastructure and governance to ensure campus needs are heard and addressed. We also want to ensure that all systems improvements and process efficiencies are properly disseminated into training materials and communicated to the staff who need to know.

While these types of improvements take time to achieve, we are optimistic that the continued focus on optimization of our systems and support of our department staff will move our campus into a better position to manage our sponsored research funds and their future growth. 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.
Restrictions on the Use of Potential Native American Graves Protection and Repatriation Act (NAGPRA): Cultural Items in Research

BY LAURA SCHULLER

On January 1, 2022, the University of California (UC) finalized the Policy on Native American Cultural Affiliation and Repatriation. The purpose of this policy is to prioritize the repatriation of Native American Cultural Items (including human remains), in accordance with the federal Native American Graves Protection and Repatriation Act and its accompanying regulations (jointly referred to as, NAGPRA), and the California Native American Graves Protection and Repatriation Act (CalNAGPRA). This policy was created to increase the knowledge of the fundamental human rights of Native Americans and Native Hawaiians to their ancestral cultural items. It highlights the restriction on the use of identified or potential cultural items in research, instruction, or other use, without appropriate tribal approvals. While the restrictions from the policy may impede ongoing or planned research, they are necessary to increase repatriation, accountability and transparency.

WHICH ITEMS ARE SUBJECT TO THIS RESTRICTION?

➢ All Native American human remains and ethnographic or archaeological objects subject to NAGPRA or CalNAGPRA, regardless if cultural affiliation has been established and regardless if the items has been determined to meet the definition of “Cultural Item” under federal and state regulations.
➢ Note that CalNAGPRA § 8013(c) states, “Because it may not be clear whether Native American objects are Cultural Items, all museum collections of Native American ethnographic or archaeological objects shall be included in the preliminary summary.”
➢ While some Native American materials housed by UC (e.g., beads, lithics, faunal remains, and baskets) were not included in the past under UC NAGPRA inventories and summaries, CalNAGPRA now requires these items to be included to ensure determinations are made in consultation with Native American Tribes.

WHICH TRIBES MUST PROVIDE APPROVAL?

➢ If cultural affiliation has been determined, all culturally affiliated Tribes must approve.
➢ If cultural affiliation has not been determined, all Tribes whose aboriginal lands/aboriginal territory of tribal lands overlap with the location where the materials originate must approve.

HOW DO RESEARCHERS SECURE APPROVALS?

Researchers should contact the UCSD Campus Repatriation Coordinator, Eva Trujillo at e7trujillo@ucsd.edu for a list of Tribes than are needed for approval. All requests for tribal approval must include a clear and easily understood explanation of the duration, type, nature and extent of research being requested and the potential impact on the human and cultural items. Vice Chancellor of Resource Management and Planning, Gary Matthews will consider the following factors in reviewing the requests:

➢ Evidence of tribal consolation and authorizations
➢ Tribal input
➢ Efforts to maintain high standards of care and respect for all human remains and/or cultural items

For more information, please visit the UCSD Native American Graves Protection and Repatriation Act webpage.
New Conflict of Interest Office Hours for Kuali COI Questions

BY JENNIFER J. FORD

The Conflict of Interest (COI) Office will host Kuali COI Office Hours every Wednesday from 11:00 a.m. - 12:00 p.m. beginning January 4, 2023. The UC San Diego research community can sign up and have an experienced COI team member provide one-on-one guidance on submission of COI disclosures in Kuali COI as well as other conflict of interest related questions. To sign up, please visit www.calendly.com/ucsdcoioffice. The sessions are for 15 minutes, however, the time can be extended. The appointment confirmation will include a direct link to the zoom session. For questions on scheduling for COI Office Hours, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

Kuali COI is the UC San Diego system of record for COI disclosures for research and other related activities (i.e., gifts, services, material transfer agreements, human subject studies, etc.). Kuali COI has an integrated disclosure notification process for external proposals and awards with Kuali Research (KR).

There are three types of COI disclosures in Kuali COI: (1) Federal PHS (i.e., NIH, DOE, and non-profits that follow the PHS FCOI regulation); (2) Federal Non-PHS (i.e., NSF, CIRM and UC Programs) and (3) 700-U disclosure (i.e., for-profits and non-profits)

Kuali COI is programmed to request the Researcher disclose in Kuali COI for one of the three COI regulations, based on number of combined factors: the sponsor, prime sponsor, award mechanism, and the anticipated activity type. Below are some answers to Kuali COI commonly asked questions:

➤ When logged in to Kuali COI, the Researcher must click the blue “update disclosure” button to start the disclosure process.

➤ If the Researcher does not see this button, then within Kuali COI the Researcher (or their Delegate) must request the COI office to return your Kuali COI portfolio for the Researcher to update. Click the brief step-by-step tutorial on how to request the Researcher’s portfolio to be returned.

To complete the disclosure process in Kuali COI, every Researcher must click through all the screens and click “submit.” Every time the Researcher submits a new portfolio version is created. The Researcher is reaffirming that their interests are up-to-date, appropriate edits were made, and there are no interest(s) impacting existing projects previously disclosed.

➤ Researchers and their added Delegates will receive a Kuali COI email from “Kuali Notifications no-reply@kuali.co.” The Kuali COI email signifies that there is at least one proposal or award record requiring a COI disclosure submission by the Researcher in the Kuali COI system.

➤ For federally sponsored research, the Researcher must submit their disclosure at least annually, even if the Researcher has no new updates of interest(s) and/or no new federal projects. The Kuali COI system will notify the Researcher before and at the time of expiration. The Researcher must keep their Kuali COI portfolio active, especially if the Researcher has active federal awards. If you have interest(s), you must update existing interest(s) in Kuali COI at least annually.

➤ Every Researcher starts on the “700-U Forms” screen even if the Researcher does not have any activities with these entities. There are two screens in Kuali COI that list projects that may require review. If the Researcher does not see a red box on the “700-U Forms” page, click next until the Research is on the “Federal Project Declaration” page.

➤ The outlined red boxes on either the “700-U Forms” screen or the “Federal Project Declaration” screen means that there are data elements missing that must be entered on that screen before moving on to the next screen.

➤ For federally sponsored research, there will be instances where Researchers will be asked to disclose in Kuali COI for awards sooner than their annual federal reporting period. For projects that are completed but have not been closed in Kuali Research, Researchers may receive a disclosure notice in Kuali COI.

➤ For non-federal (700-U) sponsored research, if anyone other than the Principal Investigator (PI) is listed as “Key Personnel” in Kuali Research, the Kuali COI system will not send an email requesting disclosure. The 700-U form is not required for senior key personnel except under a human subject study (whether funded or unfunded), the conflicted Researcher must report their interest(s) in Kuali IRB. The Kuali IRB system will notify the COI office once the COI question in Kuali IRB is checked. The COI office will create a manual project in Kuali COI to render a disclosure for the human subject study.

➤ For non-federal (700-U) projects, the FPPC (state regulators) require part 1 and 2 of the 700-U form be completed by the Researcher. We recommend the Researcher add support staff as a “Delegate” in Kuali COI (see instruction link below). The Delegate can complete these two parts on the 700-U form and then notify the Researcher in Kuali COI. Kuali COI will send the Researcher an email stating the Delegate has completed their portion. Then then Researcher can complete part 3 (the declaration of interests) of the 700-U for each required project.

➤ There are two ways research administrators have visibility into Kuali COI to determine a Researcher’s COI disclosure status on a given KR project:
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➢ In KR Proposal Development (PD), proposal preparers have visibility to Kuali COI statuses on the “Key Personnel” tab. Each key person listed will have their own COI status lines under their name.
➢ In KR Award, those that have access to the KR record have access to Kuali COI statuses on the “Contacts” tab. Each key person listed will have their own COI status lines under their name.
➢ For consistent visibility into the Kuali COI system and to receive the same email notifications as the Researcher, support staff can be added as a delegate by the Researcher in the Kuali COI System.
➢ Click the instructions on how a Researcher adds a Delegate. There are instructions for how the Delegate can view and enter data.
➢ Other information about the Delegate process functions in Kuali COI:
  ♦ The Researcher must verify, review, and certify their COI disclosure in the Kuali COI system. Their Delegate will not be able to certify and submit.
  ♦ If a Researcher has non-federal projects (700-U) and federal projects, the Delegate can proceed past the non-federal projects to review the federal projects.
  ♦ The Delegate communicates with the Researcher inside the Kuali COI system when the Delegate has finished their portion of the data entry and review.
  ♦ Currently, only one auto-generated email from Kuali COI is sent to the discloser (and their Delegate(s)), and the COI office will have to follow-up with the discloser. In the future, Kuali COI will be able to set-up automatic follow-up emails.
  ♦ Researchers can add as many Delegates as they need.
  ♦ Delegates can be assigned as a Delegate for as many Researchers as necessary.
  ♦ E-mail notifications are sent when Delegates are added or removed from Kuali COI.
  ♦ The COI Office does not have access to view or permission to edit which Researcher has Delegates assigned.
➢ The “notification” button within the KR PD in Key Personnel tab does not notify the key personnel to submit in Kuali COI. This notification button in KR is only to notify the PI to certify the KR PD proposal.

Protocol-Grant Congruence Verification for Animal Research

BY THE IACUC OFFICE

Federal funding agencies like the National Institutes of Health (NIH), the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA), and some private extramural funding agencies require a “congruence verification” before funding is released. The NIH Grants Policy Statement states, “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the Institutional Animal Care and Use Committee (IACUC).” The Office of Laboratory Animal Welfare, which oversees the care and use of research animals in Public Health Service funded research, defines congruence as “agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC.” It is left to the grant recipient institutions how to implement this congruence verification.

At UC San Diego (UCSD), for animal research, the congruence review is performed by the IACUC Office. The Sponsored Project Offices (OCGA, HSSPO and SIO OCGA) generally contact the IACUC Office when a Just-in-Time (JIT) notice is received or when funding for a grant is imminent. The IACUC Office compares grant and animal use protocols and provides a confirmation to the Sponsored Project Office, which will then provide the assurance to the funding agency. If congruence cannot be verified, the IACUC Office and Sponsored Project Office will work with the Principal Investigator (PI) to determine how to modify the grants or protocols and ensure a timely release of funds.

If UCSD is the primary recipient of the grant, but funds are used to pay for animal work conducted at other institutions, congruence review also covers animal use protocols from those institutions. The other institutions must provide the relevant documents to the UCSD IACUC Office. All subcontract locations must be AAALAC accredited, as required by IACUC policy 21 on Inter-Institutional Research. No expenditures for activities with live vertebrate animals may be charged to an NIH grant if there is not a valid IACUC approval.

To prevent delays during the congruence verification, PIs should routinely amend their animal use protocols to match any new or supplemental grant proposals. When a new grant is submitted, a review of the protocols for all performance sites listed on the grant should be conducted to ensure the fundamental components of the proposal, such as animal species, major experiments and procedures and experimental compounds, are listed and approved.

The COI Office welcomes your feedback and recommendations about the Kuali COI system. For more tutorials, please review the content on the Kuali COI website. For questions or assistance, please contact the COI Office at info-coi@ucsd.edu or (858) 534-6465.

For additional information regarding grant congruency or IACUC processes, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.
How and When are Prohibited Pathogens and Toxins Subject to Export Controls?

BY IVÁN I. HERNÁNDEZ

The words "anthrax," "smallpox," "terrorism," and "ricin," have sparked fear among the international community as their descriptions fill the headlines of biological warfare as an emerging threat of the 21st Century. Events such as the inhumane sarin chemical weapons Ghouta attack in 2013, the 2003 conviction of Dr. Thomas Campbell Butler, of Texas Tech University for illegally exporting Yersinia pestis to Tanzania, and the 2021 settlement of Princeton University for allegations that it sent various strains and recombinants of animal pathogens to various overseas institutions, bring to light the imminent consequences of the misuse of dangerous biological agents.

As a global economic and political leader, the United States (U.S.) has been front and center in international accords across the globe that aim to suppress the spread of biological agents that, in the hands of the wrong actors, could be used for deleterious purposes including bioterrorism.

Domestically, the United States has codified under 15 CFR 774 controls of certain pathogens and toxins that are deemed a threat for exploitation in the development of chemical and biological weapons. To that end, the country’s export control laws have been instrumental. In the U.S., export controls refer to federal government regulations that restrict the transfer of certain materials, technology or software abroad or to non-U.S. persons in the U.S.

The question of how these export control regulations impact universities is focal to academia’s central mission to produce disseminable research. One the one hand, most life science research which is published and considered fundamental research is not subject to export controls. This means that much of the research in university laboratories is not subject to export controls if it is fundamental research, a rather technical construct meaning “basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons” (15 CFR §734.8(c)). The U.S. Bureau of Industry and Security (BIS) provides an illustration of fundamental versus non-fundamental research:

- University based research on bacillus anthracis that has restrictions on publications of scientific and technical information resulting from the research (non-fundamental research)
- University based research on vectors for salmonella typhi which is published broadly (fundamental research)

At UC San Diego, export control triggers that would warrant a review of life science research by the Export Control office can be summarized as follows:

- A Principal Investigator’s (PI) acceptance of publication or foreign national restrictions on their research;
- Planning to transfer of non-publicly available technology/software/technique to an international student or scholar in the PI’s laboratory;
- Planning to work with materials that are listed on the U.S. Munitions List;
- Planning to ship or take samples or materials that are controlled on the Commerce Control List or U.S. Munitions List abroad.

Specifically, life science research that involves prohibited pathogens or toxins can come under the purview of two jurisdictional authorities as follows:

- ITAR (International Traffic in Arms Regulations), which control “Biological agents and biologically derived substances specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment, or damage crops” (USML Category XIV(b)).
- EAR (Export Administration Regulations), which enumerate the controlled pathogens and toxins under various export control classification numbers (ECCNs).

As previously noted, most life science research qualifies under the fundamental research exclusion (FRE), posing no export control issues. On the opposite end, under the ITAR, work that involves any of the enumerated biologicals and biologicals is a full stop, and it requires a review by the UC San Diego Export Control Office to determine any licensing requirements for the work to proceed.
Under the jurisdiction of the EAR, research that qualifies under the FRE is typically designated as EAR99, obviating the need for a license from BIS in most cases.

Higher levels of controls under the EAR for life science research appear under the following ECCNs:
- ECCN 1C350. Chemicals that may be used as precursors for toxic chemical agents.
- ECCN 1C351. Human and animal pathogens and “toxins.”
- ECCN 1C353. Genetic elements and genetically modified organisms.
- ECCN 1C354. Plant pathogens.
- ECCN 1C991. Vaccines, immunotoxins, medical products, diagnostic and food testing kits.
- ECCN 1E001. Technology for the development or production of the controlled biological agents.
- ECCN 1E351. Technology for the disposal of controlled biologicals.
- ECCN 2B352. Equipment capable of use in handling biological materials (e.g., Nucleic acid assemblers and synthesizers).

The manifests that bring focus to controlled pathogens and toxins under the EAR are ECCNs 1C351, 1C353, 1C354 for controlled agents, and 1E001 and 1E351, for their related technology. Notably, there is a worldwide license requirement for exports of controlled biological agents listed in ECCNs 1C351, 1C353 and 1C354, or for “deemed exports” for the release of technology in the US subject to the EAR to a foreign national. Export controls apply regardless of quantity or attenuation, including small quantities of the controlled pathogens or toxins. Genetic elements could include chromosomes, genomes, plasmids, transposons, and vectors, associated with the pathogenicity of the microorganisms.

Importantly, mere handling of the prohibited pathogen or toxin is insufficient to trigger a deemed export license requirement. A controlled “technology” must be released to a foreign national in order for the export control regulations to trigger one of the two requirements for export control rules to apply, the other being, the application of a publication or toxin is insufficient to trigger a deemed export license.

The second prong would not be met, and therefore the results of the research would qualify as fundamental research, if the technology released to the foreign national on how to grow, maintain, quality check a pathogen was in the public domain, and there was an expectation that the results of said research would be published. This scenario would effectively eliminate the need for a deemed export license.

As a corollary, all stakeholders involved in life science research should take note of the following recommendations in order to facilitate and ensure compliance with export controls:

Foreign National restrictions (deemed export). Assess or inquire whether foreign nationals are required to obtain an export control license to access controlled technology in the U.S.
- A foreign person working in a laboratory researching vaccines or other biologicals, accessing controlled technology and proprietary information.

Prevent data release. What is the institution’s risk potential for releasing research data?
- Sharing information to a foreign national on how to grow, maintain, quality check, or dispose of biological agents that is not in the public domain.

Reevaluate technology. Monitor project changes and staff reassignments to reevaluate the need of technology being transferred.

Shipping. An export control license is required for shipping a controlled biological agent internationally.

Lastly, not all pathogens and toxins are regulated by export controls. It will be important to identify the factors that prevent pathogens and toxins to fall within the scope of the export control regulations in order to avoid over-restricting a researcher’s work. The following are examples of biologicals not controlled under EAR:

- (1) Pathogen or toxin not on CCL (Commerce Control List); (2) gene fragments (must be whole gene with ORF); (3) chromosome fragments; (4) E. coli Nucleic acid sequences (unless sequence code for verotoxin); (5) publicly available technology; (6) project that arises during fundamental research; (7) data already published or will be published.

For questions or assistance in determining whether your research requires a license or other export control consideration, please contact the UC San Diego Export Control Office at export@ucsd.edu.
Knowledge Base Articles (KBAs) are an important part of the transition from the legacy eIRB system to Kuali. These articles help provide additional instruction and guidance about how to use the Kuali system. The research knowledge base containing KBAs for all of UC San Diego (UCSD) research can be found here.

We wanted to highlight three new KBA documents published by the UCSD Office of IRB Administration (OIA) to help users better navigate the Kuali IRB system. These KBAs are related to Administrative Determinations, Amendments, and Renewals. As always, these KBAs provide step-by-step directions and tips to using the Kuali IRB system. They do not provide guidance on submission types or when a submission might be necessary. For guidance questions, please review our guidance web page or submit a ticket by emailing irb@ucsd.edu.

ADMINISTRATIVE DETERMINATIONS

The OIA generally has five types of administrative determinations it can make:

- A study is not human subjects research:
  - This determination means that the study either does not qualify as “research” according to the Federal definitions that IRBs use or that it does not involve “human subjects” as defined in the same Federal regulations. IRB review is not required.

- UCSD/Rady Childrens Hospital San Diego (RCHSD) is not engaged in the human subjects research:
  - This determination means that while the study is human subjects research, the activities being performed by UCSD/RCHSD personnel do not engage the institution(s) in the research. IRB review is not required.

- The research qualifies for an exempt determination:
  - This determination means that the study is human subjects research, but all of the activities fall into at least one of the six Federal categories of Exemption. Per UCSD PPM 100-5, the UCSD IRB is required to review these studies to make sure that they meet Exempt criteria and conform to local requirements.

- The research will rely on a non-UCSD IRB for review:
  - This determination allows the UCSD IRB to cede our review to a non-UCSD IRB for the oversight of the study.

- The research involves indefinite plans or delayed onset:
  - This determination means that the study Principal Investigator (PI) has certified to the UCSD IRB that their study will involve human subjects research and that they will not involve human subjects until IRB approval has been granted, but they cannot make a full submission to the IRB because there is preparatory work that has to be done first. These are most appropriate when there is an impending funding deadline, just-in-time request, or an award needs to be released so that non-human subjects research activities can take place.

The newly developed KBA on this topic walks users through how to submit each of the five types of determination applications above.

AMENDMENTS

Throughout the life of a study, it may be necessary to make changes to the study application or any of the study documents (e.g. protocol, consent form, recruitment materials, etc.). The process by which these changes are submitted to the IRB for review is called an amendment. The newly developed KBA on this topic walks users through the process of submitting an amendment and some particular nuances of how to use the Kuali IRB system.

RENEWALS

Some studies require ongoing review by the IRB to ensure the safety of subjects. In order to facilitate this ongoing review, researchers must submit a renewal application to the OIA. The newly developed KBA on this topic walks users through the process of submitting a renewal application.

Not seeing a KBA to walk through a process and want to suggest OIA create one? Email OIA at irb@ucsd.edu to let us know.
Reliance Transfers to Kuali Institutional Review Board (IRB): Common Issues

Greetings from the UC San Diego Office of IRB Administration Reliance Team!

The Reliance Team would like to thank you for your patience while they process a large influx of transfer amendment applications. During the review of transfer amendments for studies where the UC San Diego (UCSD) IRB relies on an external IRB, we have noticed some recurring issues listed below that are requiring revisions to projects and are causing additional delays and resubmissions in the review process.

Incorrect Submission Type

Submissions that have submission type as “Automatic conversion from eIRB” are incorrect. The correct submission type should be “Admin Determination or Registration” followed by selecting “Request to Rely on a non-UCSD IRB”. Once the submission type is corrected, additional sections that need to be added and completed are: Local Context, Reviewing IRB, and Characteristics. These can be “unlocked” for editing by clicking “Add/Remove Section” from the right-hand menu within the amendment and then clicking the checkboxes for each corresponding section.

Newer Documents in the Supporting Information Section

The initial shell created in Kuali automatically (if a shell was created), did not include any study documents. As such, the Reliance Team has requested that transfer amendments include only the most recent IRB-approved documents that were accepted/acknowledged by OIA in the eIRB system along with a brief update of the status of the research, update to Study Personnel and funding, as applicable. Documents required for an external reliance review transfer are research plan/protocol, clean version of consents/assents and recruitment materials.

When newer documents are submitted, those applications are being returned with action items for every document that does not align with eIRB and creating additional processing time. Newer documents can be submitted after the transfer amendment is complete, if they either meet our criteria for amendment submissions or require ancillary review such as Office of Coverage Analysis Administration review.

Unnecessary Documents

Applications to request that the UCSD IRB rely on an external IRB do not require the submission of subject facing materials, data collection tools, external IRB rosters or translated materials.

If you have a transfer amendment for an external reliance in queue to be processed, please consider reviewing the application(s) to ensure that your application(s) do not have any of the common errors listed above. Your assistance in ensuring your transfer amendment did not include these errors will improve our review times and we can get through the applications quicker.

For questions or assistance, please email irb@ucsd.edu.

The Office of Institutional Review Board Administration

Winter Closure 2022

Please note the following regarding the Office of Institutional Review Board (IRB) Administration (OIA) operating schedule in December. Please keep these adjustments in mind when preparing IRB submissions.

As always, IRB meeting dates are available here. For information about handling urgent changes or emergency use of investigational products without IRB approval, please see the end of this message.

On behalf of the OIA staff and IRB members, we wish you all the best. Happy Holidays!

December 23, 2022 - January 2, 2023: UC San Diego, including the OIA, will be closed for winter holidays and will re-open Tuesday, January 3, 2023. Please submit all renewals that need to occur prior to January 16, 2023 by November 30, 2022 to ensure that they are renewed in a timely fashion and do not expire.

Note: You may implement changes to research to eliminate an apparent immediate hazard to a subject without obtaining prospective IRB approval. Changes made in those circumstances must subsequently be reported to the IRB within 5 days.

You may make emergency treatment use of investigational products according to the appropriate Food and Drug Administration (FDA) instructions for drugs or devices (including permission from the FDA as required).

If you are considering emergency treatment use from December 23, 2022 - January 2, 2023, please contact the IRB at 858-229-8978. Such emergency uses must be reported to the IRB within 5 days.
THE UC SAN DIEGO RESEARCH ETHICS PROGRAM

BY CAMILLE NEBEKER

The UC San Diego Research Ethics Program (REP) is entering its 25th year and that is cause for celebration! We kicked off our celebration in September by honoring the founding Director of the REP, Dr. Michael Kalichman and Assistant Director, Dr. Mary Devereaux. Both Mike and Mary were instrumental in developing and delivering educational programs across the UC San Diego campus to elevate awareness about ethical and responsible research practices. Since its launch in 1997, the REP has educated thousands of students, trainees, faculty and staff to cultivate a culture of responsible and ethical research at UC San Diego. In addition to being a local resource, the REP supports the San Diego Research Ethics Consortium, which include several surrounding academic institutions. The REP continues to be recognized both nationally and internationally for its innovative ethics education and research on the ethical and social implications of emerging technologies.

The REP offers several sections the Scientific Ethics course each quarter. To do this, we rely on our faculty who are accomplished scientists as well as research and bioethics scholars. To learn about our faculty, please visit: https://ethics.ucsd.edu/about/faculty/index.html. If you are interested in taking a course or would like to consider teaching a section of Scientific Ethics for the REP, please contact ethics@ucsd.edu.

In addition to offering our Scientific Ethics course, the REP has launched new initiatives with a goal of building campus capacity to promote ethical and responsible research. These include the Research Ethics Grand Rounds and Ethics at the Table (EAT). Our recent Research Ethics Grand Rounds featured Dr. Perri Klass, Professor of Journalism and Pediatrics at New York University (NYU) and Co-Director of NYU Florence. Her presentation touched on key issues within her new book entitled, The Best Medicine: How Science and Public Health Gave Children a Future. Our Research Ethics Grand Rounds are scheduled quarterly and accessible via zoom and in person. Learn more here. Ethics at the Table or EAT involves snacks and is a lab-level conversation that can be a formal presentation, or an informal discussion related to the lab’s research ethics interests. To request an EAT visit at your lab, contact us at ethics@ucsd.edu.

For questions or additional information, please email ethics@ucsd.edu.
The ClinicalTrials.gov Protocol Registration and Results System (PRS) recently added new help documents to assist study teams in completing the Brief Summary within the Study Description module when creating a record on PRS. A well written Brief Summary provides a brief description of the study that the general public can easily understand.

PRS provided the Plain Language Checklist of best practices for writing lay research summaries inclusive of the following tips:

➤ The purpose of the research should be clear to the intended audience.
➤ The words should be easy to understand.
➤ The numbers should be meaningful with context such as “high” or “low” and “better” or “worse.”
➤ Structure the summary so the readers can easily locate the information needed.

PRS also provided the following template to write a brief study description in plain language:

The goal of this [type of study: observational study or clinical trial] is to [learn about, test, compare, etc.] in [describe participant population/health conditions]. The main question[s] it aims to answer are:

- [Question 1]
- [Question 2]

Participants will [describe the main tasks participants will be asked to do, treatments they’ll be given and use bullets if it is more than two items].

Once a record is created and submitted for PRS review, PRS staff review the record for errors, deficiencies, and/or inconsistencies. Following the PRS tips and templates for registration will help in avoiding the record being sent back with comments that must be addressed before the record can be registered and posted. It is helpful for record owners to keep the research plan and the informed consent form handy when registering a study on ClinicalTrials.gov to help with the Study Description module. Please note that the Brief Summary cannot be identical to the Detailed Description in the Study Description.

Please see the Research Compliance and Integrity Office (RCI) ClinicalTrials.gov webpage for more information and resources. For questions or additional information, please contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.
Former Texas A&M Professor Pleads Guilty to Making False Statements to NASA

A former Texas A&M University scientist, Zhengdong Cheng, pleaded guilty to making false statements to the National Aeronautics and Space Administration (NASA) and agreed to repay NASA the funds awarded to him to conduct research on the International Space station. Cheng was initially charged with defrauding the government and making false statements under the now abandoned China Initiative. At the hearing, Cheng admitted to failure to disclose to NASA the work for two Chinese Universities on both the grant application and the award agreement, which went against a clause attached to NASA's 2010 annual spending bill which prohibited NASA from providing funds to any research that involved Chinese entities. Cheng’s failure to disclose his work with two Chinese Universities, the Guangdong University of Technology and Southern University of Science and Technology, resulted in the repayment of the award to NASA valued at $86,876, as well as a $20,000 fine. For more information, read the science.org article.

Federal Indictment of Three Individuals for the Alleged Selling of Export Controlled Data to China

Three individuals were recently charged with Violations of the Arms Export Control Act, Violation of the International Traffic in Arms Regulations, Violation of the Defense Acquisition Regulations System (DFARS), and wire fraud in a federal indictment. The indictment alleges that between January 2012 to January 2018, Phil Pascoe, Monica Pascoe, Scott Tubbs, and Quadrant Magnetics, LLC., conspired to send technical drawings that were related to end-use items for military systems for the U.S. Department of Defense (DOD) to a China-based company with an approved export-license from the U.S. Government. Rare earth magnets sold to DOD must be produced and magnetized in the U.S. or an approved country under the DFARS specialty metal clause and China is not an approved country. In violation of the DFARS, Quadrant Magnetics allegedly imported and sold magnets smelted and magnetized in China to two U.S. companies for DOD use in the F-16,F-18, and other defense assets. For more information, please read the Department of Justice announcement.

Misconduct by Former NIH Postdoctoral Fellow Brings Three-Year Supervision

The Department of Health and Human Services Office of Research Integrity (ORI) recently announced findings of research misconduct against Ritankar Majumdar, a former postdoctoral fellow in the National Institute of Health’s (NIH) intramural research program. Majumdar was found to knowingly or recklessly falsify and/or fabricate data in one published paper, one manuscript, three Public Health Service (PHS) grant applications, and fifteen presentations. ORI found that Majumdar falsified and/or fabricated electron microscopic images, presenting them “from the same source and falsely relabeling them to represent different experimental results”, immunoblot image data, and time-lapse confocal microscopic image data for nuclear envelope vesicle formation by falsely presenting still images in reverse order from the original movies.

Majumdar entered into a Voluntary Settlement Agreement and agreed to have his PHS supported research supervised for three years. Prior to the submission of an application for PHS support and prior to participation in any capacity in PHS-supported research, Majumdar is to submit a plan for supervision to ORI that includes a committee of two to three senior faculty members with expertise in his research but who are not supervisors or collaborators. Majumdar will also not be allowed to serve as a reviewer or advisor to PHS during this supervisory period. For more information, please see the Federal Register.
Canadian Psychiatrist Guilty of Research Misconduct

The Department of Health and Human Services Office of Research Integrity (ORI) found that Romian Mizrahi, Associate Chair in the Department of Psychiatry at McGill University, committed research misconduct by intentionally, knowingly, or recklessly falsifying data in a grant application submitted for U.S. Public Health Service (PHS) funds in 2018. ORI found that Mizrahi selectively included and excluded the PET scan data of research participants to show a greater response in the patient group versus the healthy volunteers in the application.

Mizrahi entered into a Voluntary Settlement Agreement and agreed to have her research supervised for one year. Also, prior to the submission of an application for PHS support for a research project and prior to participation in any capacity in PHS-supported research, Mizrahi is to submit a plan for supervision. This supervision plan will include a committee of two to three senior faculty members at the institution who are familiar with Mizrahi’s field of research who will review in advance each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research where Mizrahi is involved. Mizrahi agreed to other related requirements and has also agreed to not serve as a PSH advisor during the supervisory period. For more information, please read ORI’s Case Summary.

Convictions Reversed for U.S. Chemical Engineer Accused of Hiding China Ties

Feng ’Franklin’ Tao, chemical engineer at the University of Kansas, was indicted by the Department of Justice (DOJ) in August 2019 for failing to disclose on a conflict of interest form that he was working on at Fuzhou University in China. He is considered to be the first academic researcher to be arrested under the former China Initiative.

Tao was also indicted by the DOJ for not disclosing the links to China while receiving federal funding from the National Science Foundation and the Department of Energy. He was found guilty on three counts of wire fraud and one count of making a false statement. In September 2022, the judge overturned the wire fraud convictions on the basis that the DOJ’s evidence was “legally and factually insufficient.” The judge stated that while Tao was deceptive in not disclosing the activities with Fuzhou University in China, there was not an alleged scheme to defraud. Tao awaits sentencing for the one count of making a false statement. For more information, please read Nature News.

Ohio State University Professor Allegedly Fails to Disclose Foreign Government Support, Institution Pays Over $875,000

In a settlement made between Ohio State University (OSU), and the U.S. Army, National Aeronautics and Space Administration (NASA), and National Science Foundation (NSF), OSU paid $875,689 for allegations of failing to disclose an OSU professor’s foreign affiliations and support to these federal funding agencies. Between November 2012 to August 2020, it was found that the Principal Investigator (PI) failed to disclose foreign support, including employment at a foreign university, participation in a foreign talent program, and funding from a foreign government’s natural science foundation.

Universities, institutions and researchers are required to make certain disclosures when applying for federal grants so that the government can assess whether to fund their research and development. Failure to do so can result in large penalties to the PI’s Institution.

The Department of Justice indicated that it will hold accountable applications who undermine the integrity of the grant process by knowingly failing to submit complete and truthful applications. For more information, please read the Department of Justice announcement.
Research Affairs Compassionate Action Circle: MOVING FROM AWARENESS TO ACTION

BY MADELEINE PALEY

In October, the UC San Diego Office of Research Affairs (ORA) Equity, Diversity and Inclusion (EDI) Committee held the Research Affairs Compassionate Action Circle: Moving from Awareness to Action. This event centered around Barbara Love’s framework on liberatory consciousness. Love’s framework is used to “maintain an awareness of the dynamics of oppression characterizing society without giving in to despair and hopelessness about that condition and enabling us practice intentionality about changing systems of oppression.”

The four components of Love’s framework are Awareness, Analysis, Accountability, and Action/Allyship. Awareness is the capacity to notice what is going on in the world around us and questioning those observations. Analysis means asking if our reality moves toward liberation or away from it. Accountability is asking what needs to happen in order for our reality to move toward liberation, and what role we can play in it. Action/Allyship refers to the support we provide each other in mirroring our liberatory intentions back to each other, and the assistance we provide each other in our learning.

Led by Dr. Ellen Beck, Faculty Director in Academic Affairs, and Dr. K. Wayne Yang, Professor of Ethnic Studies and Provost of John Muir College, October’s EDI event asked where each individual in attendance felt UC San Diego was on Barbara Love’s framework just two years after the murder of George Floyd and pushed attendees to ask where work needs to be done. Small breakout groups led to important discussions about individuals, immediate teams, and the University at large.

The event concluded with a discussion about Bettina Love’s video explaining the difference between allies and co-conspirators in the fight for justice. In the video, Love explains the difference between an ally and a co-conspirator with an example about two activists, a black woman, Bree Newsome, and a white man, James Tyson, as they removed a confederate flag in South Carolina. In the storytelling, Love indicates that Newsome was tasked with climbing the pole and removing the flag while Tyson waited at the flagpole base to ensure Newsome’s safety and assist with the climbing gear. When the police arrived and planned to tase the pole to get Newsome down, Love notes how Tyson went from an ally who was standing in support to a co-conspirator by placing his hand on the poll to ensure they did not tase it. Co-conspirators must be unapologetically anti-racist, committed to listening and learning, willing to cede power while using privilege to invite others to lead, uncompromising in providing high-quality education for black children and prepared to take political risks to advance their needs. In order to advance on Barbara Love’s liberatory consciousness framework, we must be more than allies, we must be co-conspirators.

For more information on ORA EDI events, visit the EDI Committee Blink page. For questions or additional information, please contact the Research Affairs Equity, Diversity and Inclusion Committee at vcr-edi@ucsd.edu.
Research Security Videos

In January, the White House Office of Science and Technology Policy published Federal Agency Guidance for Implementation of National Security Presidential Memorandum (NSPM) 33. The guidance suggests agencies harmonize disclosure requirements to the extent possible and utilize digital persistent identifiers. It outlines consistent consequences for non-disclosure and guides agency information sharing. It outlines more specifics on how research organizations awarded more than $50 million a year are to meet requirements for a research security program covering cybersecurity, foreign travel security, research security and export control training.

The University of California Office of the President in conjunction with several campuses developed a Research Security Video Series available on YouTube, comprised of four short videos covering Disclosures, Talent Recruitment Programs, International Collaborations and Data Security. This video series is intended as a resource for our research community and is not mandatory.

Direct links to Research Security Video Series on YouTube:
- **Disclosures: Conflicts of Interest & Conflict of Commitments** (4 min 40 seconds)
- **Talent Recruitment Programs** (3 min 55 seconds)
- **International Collaborations** (3 min 50 seconds)
- **Data Security** (3 min 30 seconds)

If you have any questions, please contact the UC San Diego Research Compliance and Integrity Office at rci@ucsd.edu or (858) 822-4939.

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RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

The UC San Diego Research Compliance and Integrity (RCI) Office continues 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:

- **IRB Town Hall**
  
  January 18, 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](http://calendly.com/ucsdrcioffice).

For questions, please contact rci@ucsd.edu.
Who are the UC San Diego ClinicalTrials.gov Protocol Registration and Results System Administrators?
The Research Compliance and Integrity (RCI) Office serves as the Protocol Registration and Results System (PRS) Administrators at UC San Diego. The RCI Office helps with all things ClinicalTrials.gov related such as the following:
• Administer the PRS system
• Track registration of protocols and informed consent forms (for applicable studies)
• Notify study teams for upcoming updates and/or results

For questions related to ClinicalTrials.gov, please contact the RCI Office at (858) 822-4939 or ctgov@ucsd.edu.

Can a University employee participate in a University decision if they have a personal financial interest that may be affected?
A University employee has a personal financial interest in a decision if it is reasonably foreseeable that the decision will have a material financial effect on the employee or their immediate family. If so, the University employee is prohibited from participating or influencing the University decision(s). The University employee must promptly inform with their supervisor of the conflict. The University employee’s supervisor will need to determine whom at the University will oversee, perform the tasks (if feasible) and make the University business decision.

To learn more about conflict of interest guidance for UCSD employees, click here.

What are some misconceptions about the export control of pathogens and toxins?
The following are common misconceptions about export controlled pathogens and toxins:
• Some people believe attenuated strains are not controlled. This is false. Attenuated strains can still be controlled.
• Some people believe minimal quantities are not controlled. This is false. Any quantity of a controlled biological is still controlled.
• Some people believe their research materials and equipment are not controlled if the project is fundamental research. This is false. Fundamental research exclusion does not apply to physical/tangible items.
• An international collaborator doesn’t have access to this material. This is for medical research to help eradicate infectious disease or to provide treatment.
• National Institutes of Health or Department of Health and Human Services already know about this research, why do I need permission from another U.S. government agency? These are separate concerns controlled by separate governmental departments. Material that may no longer be regulated under the Select Agent Regulations may nonetheless be regulated under export control regulations.

For more information, please contact the Export Control office at export@ucsd.edu.

For what animal species must I submit an Animal Use Protocol?
You need to submit an animal use protocol if you are conducting research, training or testing using any vertebrate animal. Although the definition of “animal” differs slightly between Public Health Service (PHS) Policy and the United States Department of Agriculture’s (USDA) Animal Welfare Act, all vertebrates are covered and UCSD requires an animal use protocol for any of the activities mentioned above. The IACUC ensures the campus is in compliance with all applicable regulations by applying the USDA and PHS regulations to all vertebrate animal use on campus for teaching and research.

If you are unsure, please feel free to contact the IACUC Office for guidance regarding your particular animal model at (858) 534-6069, or iacuc@ucsd.edu.

Q&A
Ask the Questions . . .

“Education is the most popular weapon which you can use to change the world.” —Nelson Mandela