UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
Office of Research Affairs

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Newsletter

INSIDE THIS ISSUE

INTERNATIONAL RESEARCH AND ENGAGEMENTS

BY ANGELA MCMAHILL AND MICHELLE FRANKLIN

UC San Diego believes that scientific research and academic scholarship work best with open collaboration, and it is committed to having an open, welcoming campus, respecting the rights of faculty and abiding by our Principles of Community. As a global research University, we are proud to have hundreds of faculty and educators from around the world teaching in our classrooms. At the same time, UC San Diego must protect research integrity, address the federal government's increasing concerns about foreign entities unduly influencing United States (U.S.) research and adhere to the guidelines and policies the government puts in place.

It is important for the UC San Diego research community to be aware of evolving federal regulations that may impact international research collaborations. Below are some examples:

1. NATIONAL INSTITUTES OF HEALTH

► The National Institutes of Health (NIH) issued a statement on protecting the integrity of U.S. biomedical research (August 23, 2018) and a reminder on NIH policies regarding proper disclosure of other support (July 10, 2019).

► The NIH is continuing its investigation into researchers who may have failed to properly disclose their foreign research collaborations. To date, the NIH has sent inquiry letters to over 75 U.S. Universities and 200 researchers and has made at least 12 referrals to the Department of Justice for potential criminal prosecution.

2. NATIONAL SCIENCE FOUNDATION

► The National Science Foundation (NSF) released the commissioned JASON report to enhance its understanding of the threats to basic research posed by foreign governments that have taken actions that violate the principles of scientific ethics and research integrity (December 11, 2019).

► The NSF created a new Research Security Chief position to ensure the security of its research while maintaining an open international collaboration (March 2, 2020).

3. DEPARTMENT OF DEFENSE

► The Department of Defense (DOD) issued a letter to the research community on the importance of securing U.S. research (October 10, 2019).

► The DOD's has engaged its Office of Inspector General (OIG) to evaluate foreign influences. The objective is to determine whether there is appropriate monitoring and mitigating foreign influence into the DOD's research and development programs (January 6, 2020)

4. DEPARTMENT OF ENERGY

► The Department of Energy (DOE) modified Order 142.3a, requirements to include foreign national reporting on all non-U.S. citizens working on DOE funded awards (December 13, 2019).

Across the U.S., there have been well publicized cases of researchers who have either been terminated or resigned from their University positions due to their failures to disclosure international research collaborations, as well as a high dollar research settlement with a research institution. In addition, there are multiple criminal prosecutions of researchers related to foreign collaborations.

Following are examples of criminal prosecutions:

► University of Tennessee Mechanical, Aerospace and Biomedical Engineering Professor charged in a federal indictment with making three counts of wire

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CONTINUED FROM PAGE 1

fraud and three counts of making false statements on ties to China (February 27, 2020)

► Harvard Nanoscientist and Chemistry Chair arrested for false statement regarding funding (Talents Program) from Chinese government (January 28, 2020)

► Harvard Medical Researcher arrested at airport for allegedly smuggling cancer research to China (January 2, 2020)

► Emory Professor fired for allegedly failing to disclose income from China is now facing criminal charges for theft of grant funds (November 2019)

► University of Kansas researcher indicted for fraud for failing to disclose conflict of interest (COI) with Chinese University (August 2019)

► UCLA Adjunct Professor of Electrical Engineering found guilty and faces 219 years in federal prison for conspiring to export semiconductor chips with military applications to China (June 2019)

► Former Los Alamos National Laboratory scientist indicted for false statements about his involvement with the Chinese Talents Program (May 24, 2019)

To stay in compliance with foreign disclosure requirements, it is recommended that researchers disclose any external support (whether financial, compensated or not) or an engagement that would be acknowledged in public presentations or publications, should also be made in grant applications, annual reports and closeout summaries, and in University-related conflict of interest and conflict of commitment disclosure forms (as required).

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

Exception Request to Conduct Research Outside the University

BY DIANA D. KIM

The University of California Policy, "Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University", requires all employees who receive any part of their salary through the University or whose activities use any University resources or facilities, to submit their proposals for extramural support through the appropriate contracts and grants office. This requirement ensures that there is compliance with University policies and guidelines.

Conducting research outside the University means that the employee is included on a proposal, grant application and/or award for research through an institution other than UC San Diego (and there is no agreement executed through UC San Diego). Exceptions to the requirement to submit proposals and awards through the University must be submitted in advance of the activity and require approval by the Vice Chancellor for Research (VCR). The new UC San Diego Policy PPM 150-82, "Implementing Procedure for UC Policy, Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University", provides an outline of the procedures in obtaining an approval of the exception request.

An exception request can be submitted by providing a memo that includes the information below to the Research Compliance and Integrity (RCI) Office at rci@ucsd.edu. The request must include an endorsement by the Department Chair or Dean (this can be done by a signature on the memo or by an email confirmation). The review process can only be initiated with the Department Chair or Dean's endorsement.

- A list of the specific proposals, grant applications, and awards that the requestor wishes to be on outside of the University. For each proposal, grant application, and award, the requestor should provide the proposal title, agency, grant time period, their anticipated role, and their anticipated time commitment.
- The rationale/justification for the request, including anticipated benefits to the University.
- An explanation for why the requested activity will not interfere with the requestor's duties and responsibilities to the UC San Diego campus.
- Information on how the requestor will maintain a clear distinction and separation between the requestor's service to the University and service to the external party.
- An affirmation from the requestor that all University personnel, research, and intellectual property policies will be followed and that the University name will not be used by the external party without prior University approval.

The VCR will consider a number of factors to see if an exception request is permissible. The VCR will determine whether there exists a compelling reason to grant an exception, the degree of overlap in and/or conflicts with research and/or responsibilities between the proposed activity and the requestor's University duties and responsibilities, the adequacy of the separation between the requestor's University obligations and the proposed extramural activities, the risk that the proposed activity may result in a violation of University policy, and the justifications for the request.

Please see the new UC San Diego RCI Exception Request webpage that includes applicable policies and instructions on how to apply for an exception to conduct research outside the University.

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

Kuali Research Go Live Brings Changes

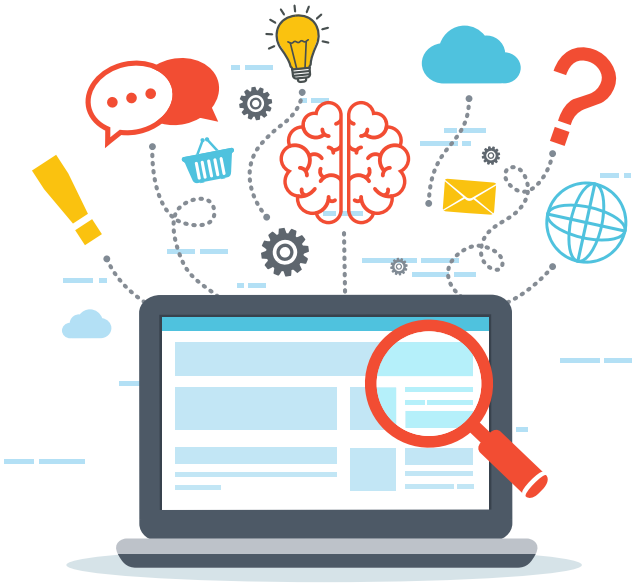
BY LINDA COLLINS

Kuali Research was successfully launched on January 21, 2020. The launch included Proposal Development, Institutional Proposal, Negotiations and Award and replaced the former Electronic Proposal Development (ePD) and Coeus Institute Proposal and Award system.

While there have been successful system-to-system (S2S) submissions to the National Institute of Health (NIH), Department of Defense (DOD), Department of Energy (DOE) and National Science Foundation (NSF) using the detailed budget functionality, we acknowledge there are further refinements that can be made to the system for a more seamless and straightforward user experience. We also understand that the use of S2S and detailed budget is a significant change which may take users time to fully understand all the nuances and feel comfortable completing. **In an effort to support the research community with these changes, users have until June 30, 2020, to fully adopt the functionality of the S2S and detailed budget.** Users however are highly encouraged to adopt as quickly as possible.

While we can celebrate the momentary success of the launch of this large initiative, we know there is still more work to do and we look forward to partnering with our subject matter experts to continuously improve the user experience. A group of subject matter experts from across Health Sciences, Marine Sciences and Academic Affairs have been selected by the Research Information Systems Advisory Group, who govern Kuali Research, with the charge to review various business process questions and system change requests to ensure that changes to the business process and system are fully usable and adoptable to the entire campus.

For additional information and/or to connect with client support, please visit the Kuali Research Blink page.



WHO IS RESPONSIBLE TO ENSURE THAT RESPONSIBLE CONDUCT OF RESEARCH TRAINING HAS BEEN COMPLETED?

BY MONIQUE TEIXEIRA

Responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Projects funded by the National Institutes of Health (NIH), National Science Foundation (NSF) and National Institute of Food and Agriculture (NIFA) have specific requirements regarding training in RCR.

Regardless of the funding source, if RCR training is required, the home department for an extramural training award is responsible for tracking the completion of the requirement. It is important that you maintain the documentation of course completion. Documentation of the training is subject to review by the funding agency and UC San Diego Research Compliance and Integrity upon request.

There are a number of options to satisfy the RCR training, below are some options:

OPTIONS	AVAILABILITY	FEDERAL AGENCY REQUIREMENTS
Research Ethics Program Core Courses	Everyone	All
Ethical Challenges of Research Workshops (Office of Postdoctoral & Visiting Scholar Affairs)	Postdoctoral Scholars only	All
Academic Integrity Tutorial	Undergraduate Students only	Only meets NSF And NIFA requirements, does not meet standard of face-face training for NIH
Medical Students Research Ethics Workshop	Medical Students	All
CITI RCR Education Courses	Everyone with a UCSD affiliation	Only meets NSF And NIFA requirements, does not meet standard of face-face training for NIH
Scripps Institution of Oceanography (SIO) SIOG232 or SIOB273 classes	All UCSD graduate students. *May require SIO Department authorization	Only meets NSF and NIFA requirements, does not meet NIH requirement

For general information on RCR training, please see the Research Compliance and Integrity (RCI) Responsible Conduct of Research website. If you have questions or need additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

THE COMMERCIAL IRB OPTION

BY KIP KANTELO

The UC San Diego (UCSD) Human Research Protections Program (HRPP) office recently provided information regarding the evolution of single Institutional Review Board (sIRB) arrangements. As of January 20, 2020, federally-supported multisite human subjects research must use an sIRB. Industry and other sponsors are increasingly using sIRB arrangements as well. Under the 21st Century Cures Act, the Food and Drug Administration will likely have to adopt a similar requirement for research that it regulates.

A sIRB review is when one IRB performs the ethical/scientific review for multiple sites. That IRB might be:

- The IRB of one of the institutions involved
- A central IRB created by the funding agency or a consortium of institutions
- A commercial IRB not tied to any one institution.

Over the past 15 years, the HRPP has offered the use of commercial IRBs for certain projects. Like many peer institutions, the UC system has master agreements with the two major commercial IRBs, Advarra and WCG.

The HRPP has been updating its administrative requirements for relying on commercial IRBs. These updates have been prompted by feedback from the UCSD research community. The goal of these updates has been to simplify requirements while ensuring that UCSD can effectively carry out its oversight and subject protection responsibilities.

ELIGIBILITY FOR COMMERCIAL IRB REVIEW:

Any use of a commercial IRB for UCSD research requires registration with and authorization from HRPP. The following types of studies are eligible to be sent to a commercial IRB. Please note that HRPP and other central offices do not pay the fees charged by commercial IRBs.

- Phase II-IV industry-authored and –sponsored clinical trials of drugs or biologics
- Industry-authored and –sponsored clinical trials of devices
- Federally-funded studies for which the commercial IRB has been centrally contracted (for example, the use of Advarra by the National Institutes of Health-supported AIDS Clinical Trials Group).
- Expanded access to investigational products under an IND or IDE held by the manufacturer or other external sponsor (for example, intermediate group expanded access protocols)

Certain Phase I clinical trials of drugs or biologics are also eligible. Other studies may also be eligible by exception. More details about these limited situations are available in the updated procedures.

INITIATING THE PROCESS:

HRPP has simplified the document set required to register and request a commercial IRB review. The Principal Investigator (PI) initiates the request via the UCSD IRB portal as a new project with the following core items:

- Commercial IRB Reliance Facesheet
- Commercial IRB Screening Checklist
- Master Protocol
- Informed Consent Template
- Current approval letter for the overall study from the IRB of Record (if available)

Based on the checklist and depending on the project, the PI may need to upload additional selected subject-facing documents. HRPP then conducts an administrative check for eligibility and completeness before clearing the study. This does not involve a UCSD IRB review.

Once cleared, the PI submits to the commercial IRB according to its procedures and using its system. Advarra and WCG will not accept submissions from UCSD without clearance from HRPP.

In parallel, the PI must identify and submit for any required ancillary reviews. For example, this might include Conflict of Interest, Radiation Safety, Biosafety or Cancer Center Scientific Review. Reviews for Coverage Analysis, Industry Contracting and Rady Children's Research Administration, will still be triggered by the application to HRPP.

INITIATING THE STUDY:

Once the commercial IRB review and ancillary reviews are completed, the PI will update the documentation in the UCSD IRB portal. The HRPP will do a final administrative and quality control check. Again, this does not involve a UCSD IRB review. Upon completion of this check, HRPP will issue documentation that the external review is valid for UCSD.

ONGOING COMMUNICATION:

The PI still needs to keep complete records of communications with the commercial IRB, but PIs no longer need to submit every communication to HRPP in parallel. The PI will still need to provide HRPP with annual continuing reviews, PI changes and other select events or decisions by the commercial IRB.

CONCLUSION:

Commercial IRBs have been and continue to be an important tool for human research protections at UCSD. HRPP has been working to simplify administrative aspects of the process. Piloting of this updated process has been a success, and has identified additional areas of improvement.

For questions or assistance with commercial IRB reviews or other sIRB arrangements, please contact the UCSD HRPP at irbrely@ucsd.edu.

Kuali Conflict of Interest (Kuali COI) Commonly Asked Questions

BY JENNIFER J. FORD

Kuali COI went live on January 21, 2020, and has integrated disclosure notifications for external proposals and awards with Kuali Research (KR). The Conflict of Interest (COI) Office wanted to provide information about the commonly asked questions being received about Kuali COI:

- For approximately the first year, to reduce the burden on the Researchers, we purposely did not trigger a COI disclosure for every research project into Kuali COI on the first day of go-live. Therefore, there will be instances where the COI Office already collected a paper COI disclosure and Kuali COI is requesting another disclosure.
- 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.
- Every University employee with an AD account will have a "My Disclosure" screen and "Create Disclosure" button. Only when a record is created and/or saved in KR after January 21, 2020, will the Kuali COI system determine if a COI disclosure submission is required and prompt an email notification.
- The Notification button in the KR Proposal Development (PD) on Key Personnel tab does not notify the key personnel for Kuali COI. This Notification button in KR is only to notify the PI to certify the proposal.
- For Researchers that have submitted a positive disclosure (have interest(s)) for either a federal or non-federal sponsored research project and their COI portfolio (disclosure) is under review by the COI Office, the Researcher's entire COI portfolio (disclosure) is locked and cannot be edited/updated by the Researcher (or their Delegate). If the Researcher receives a notification to update their disclosure for a new proposal/award or if the Researcher needs to their update financial interests previously reported, the Researcher or their Delegate will need to contact the COI Office at info-coi@ucsd.edu (or click "Submit a ticket", if WalkMe is enabled on your computer) and request their disclosure be returned to the Researcher in the Kuali COI system.
- For federally sponsored research, i.e., NIH, NSF, etc., there will be instances where Researchers will be asked to disclose in Kuali COI for proposals/awards sooner than their annual federal reporting period. For federal research, Researchers will be required to engage in Kuali COI at the time of proposal and to re-affirm at the time of award. For projects that are completed but have not been closed in Kuali Research, Researchers may receive a disclosure notice.
- For non-federal (700-U) sponsored research, i.e., for-profit and non-profit sponsors), if anyone other than the Principal Investigator (PI) is listed as "Key Personnel" in Kuali Research, the Kuali COI system will send an email requesting disclosure and the 700-U form will not render as a 700-U form is not required. There is no action for the Co-Investigators. While Kuali re-programs the system, we recommend that only the Principal Investigator be listed on the "Key Personnel" tab in Kuali Research. This recommendation does not apply for prime funding from a federal agency.
- The outlined red boxes on either the "700-U projects" 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 non-federal (700-U) projects, the FPPC requires 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 email the Researcher outside the Kuali COI system. The Researcher can complete part 3 of the 700-U for each required project.
- There are two ways research administrators can have visibility into Kuali COI to determine a Researcher's COI disclosure status:
  - In KR 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.
  - 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 cannot proceed past the non-federal projects, until the Researcher has verified and submitted for the non-federal project (s).
  - The Delegate must communicate to the Researcher outside the Kuali COI system when the Delegate has finished their portion of the 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.
  - No email notifications are sent when Delegates are added or removed from Kuali COI.
  - The COI Office does not have access to view which Researcher has Delegates assigned.

We welcome your feedback and recommendations about the Kuali COI system. To learn more, please watch the Kuali COI Video and review the content on the Kuali COI Website. For questions, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

INTERNATIONAL RESEARCH

Working and Traveling Overseas: Systems Access, Security, and Data

BY MIKE CORN AND BRITTANY WHITING

Recently, UC San Diego's Information Technology Services (ITS) Office has been made aware of an increased level of scrutiny on individuals leaving the United States (U.S.) have been receiving from Federal agencies at airports. This appears to be largely, but not exclusively, focused on individuals traveling to countries known to be involved in the theft of U.S. intellectual property. In an era where international collaborations are the norm for most scientific programs, many UC San Diego (UCSD) faculty may find themselves in a situation where they are asked by Federal agents, "what data are you taking with you" and "do you have authorization to take this data out of the country?" If you are traveling internationally, please keep the following in mind:

- **Reduce Cyber Risk:** Minimize the data you have physically with you. Remove data from your laptop that is not needed. The UCSD International Travel Security Blink page provides guidance and resources to help reduce your cyber risk and protect UCSD data during international travel.
- **Obtain Export Clearance for UCSD Items being Handcarried or Shipped Abroad:** All shipments, hand carry of items or technology abroad are exports regulated by the U.S. government. Per the UC Export Control Policy, all UC Faculty, Academic Appointees, Staff, Students (including student employees), non-employee participants in University programs (e.g., visiting scholars, vendors, and contractors) exporting or handcarrying UCSD items abroad are required to work with the UCSD Export Control Office so export license reviews are completed and any required documentation is completed prior to travel abroad, including export licenses or hand carry letters detailing the export authorization. More information on international shipping and hand carry information is detailed on the Export Control website. Export licensing can take 6 weeks or longer to obtain approval from the U.S. government and must be in place prior to travel abroad or export shipments.
- **Ensure Your Trip is Registered:** Please see the UCSD travel preauthorization requirements. Business Travel Accident Insurance coverage is automatic if you book travel with Connexxus, UC's business travel booking program. If you book through another source, then you must register for insurance. For additional information, see the Blink Business Travel Accident Insurance page.
- **Consult the U.S. Department of State's Travel Advisory Website and Register with U.S. STEP:** For U.S. nationals it is advised that they register their trip with the U.S. State Department's Smart Traveler Enrollment Program (STEP) which is a free service to allow U.S. citizens and nationals traveling and living abroad to enroll their trip with the nearest U.S. Embassy or Consulate. The recent evacuations of U.S. citizens back to the U.S. from Wuhan, China, the epicenter of the novel coronavirus outbreak, are an example of why these registration systems are so important.
- **Cooperate with Federal Authorities:** Customs and Border Protection (CBP) Officers are responsible for border security, including counterterrorism, customs, immigration, trade, and agriculture. CBP performs inspections, intelligence analysis, examination, and law enforcement activities including apprehension, detention and arrest relative to arrival and departure of persons, conveyances and merchandise at ports of entry. It is the officer's duties to protect the U.S. homeland, enforce federal laws, and efficiently facilitate legitimate trade and travel.

  CBP's legal search authority including search of electronic devices is outlined here. You may be asked questions about your travel and the items you are carrying or your checked baggage. **Be honest and respectful to the agency representative and the role he/ she plays on the agency's behalf. Make sure you understand each question asked before answering. If you do not understand the question, ask for clarification first.**

  Specific information on traveler guidance is detailed on CBP's website. The U.S. government has a series of Trusted Traveler Programs that allow members to use expedited lanes at the U.S. airports, and when crossing international borders.

  Be sure your department and PI is aware of your international travel. If you are traveling as part of U.S. government funded research, ensure that your award authorizes travel and that foreign component has been authorized by the agency. Additionally you may be required to report your foreign collaborations for your research abroad to the agency. With the increased focus on foreign influence, individuals who plan on working abroad need to work with their department to ensure the work abroad request has been vetted and approved, otherwise, you may not be able to access certain critical research systems while traveling internationally.

For IT Security questions, please contact Mike Corn, Chief Information Security Office, mcorn@ucsd.edu, (858) 246-4223. For export control information, please contact the UCSD Export Control Office at export@ucsd.edu or (858) 246-3300.

Interinstitutional Research Involving Animals

BY THE IACUC OFFICE

When institutions collaborate on research involving live vertebrate animals, the responsibility for ensuring compliance with all applicable rules and regulations can be complex. When research is performed at off-site locations, or conversely, when outside institutions conduct research on the UC San Diego campus, the university is still subject to oversight by agencies such as the U.S. Department of Agriculture (USDA); the National Institutes of Health, Office of Laboratory Animal Welfare (NIH OLAW); and AAALAC International.

IACUC REVIEW REQUIREMENTS

All proposals involving housing or use of vertebrate animals for the purpose of research, testing or teaching, must be reviewed and approved by the UC San Diego Institutional Animal Care and Use Committee (IACUC) prior to initiation if any of the following apply:

- The research is conducted by or under the direction of UC San Diego personnel in connection with his or her UC San Diego responsibilities.
- The study uses UC San Diego property, facilities, or resources to support or carry out the activity.
- The name of UC San Diego is used in applying for funds (intra or extramural) as an awardee or performance site.

In the case of interinstitutional research, the IACUC will review each proposed collaboration on a case-by-case basis. Approval for the collaboration will depend upon whether or not UC San Diego is the prime awardee, as well as the PHS assurance, AAALAC accreditation, and USDA registration status of the collaborating institution.

If the collaborating institution is PHS-assured and AAALAC-accredited, a UC San Diego IACUC protocol may not be required, but a copy of the other institution's IACUC protocol and approval letter must be provided to the IACUC Office for grant congruence verification.

GENERAL COLLABORATION EQUIREMENTS

- If animal work will be performed at a location that is not owned, operated, or leased by UC San Diego, the location must be listed as a performance site in the UC San Diego grant (i.e., subaward or subcontract). This includes facilities where custom antibodies will be produced.
- Ensure that the institution where animal work is performed is AAALAC-accredited and PHS-assured. If work will involve USDA regulated species, the institution must also be registered as a Research Facility with the USDA.

In general, the IACUC will not allow collaborations with institutions that do not have the necessary assurances, accreditations or registrations but each situation will be reviewed on a case-by-case basis.

If you are considering a collaboration with an outside institution, please contact the IACUC Office for guidance at iacuc@ucsd.edu or (858) 534-6069.

WHEN IS A WRITER NOT AN AUTHOR?

BY MICHAEL KALICHMAN

Research misconduct may come to mind first when thinking about ethics and research, but some of the most significant ethical dilemmas are not as clear cut as lying, cheating, or stealing. Many of the choices we make in science are more nuanced, often resulting in passionate disagreement about the best course of action. One such case is questions about authorship. For example, research manuscripts must be sufficiently well-written both to pass peer review and to effectively communicate with other members of the research community, but not all researchers have the ability to write well. The result is that individuals with good writing skills are sometimes recruited to write a manuscript even though they had little or nothing to do with the planning, conduct, analysis, or interpretation of the research. The proper way to credit such contributions does not lend itself to easy answers. Instead, it is important for members of a research team to have open conversations about how to handle such cases. Doing so may help not only answer this specific question, but also better prepare the researchers to address other aspects of responsible authorship.

- **Should someone who was involved only in the writing of a research manuscript ever be credited as an author of the manuscript?**
- **Should someone who was involved only in the writing of a research manuscript be credited in the acknowledgements?**
- **If someone is hired to write a manuscript, should it be acceptable for them to ask to not be named as an author or in the acknowledgements because they don't feel confident about the quality of the research or the ways in which the named authors might modify the manuscript after it has been written?**

Members of the UC San Diego research community are encouraged to have conversations about this case as well as many others posted on the website of the Research Ethics Program. For additional information, please visit the Research Ethics Program website or contact the Research Ethics Program at (858) 822-2647, ethics@ucsd.edu.

EDISCLOSURE SURVEY POINTS TO SUCCESS

BY WILLIAM DECKER

In recent months, the Office of Innovation and Commercialization (OIC) has surveyed its recent inventors on how well its new eDisclosure system has satisfied their needs as inventors. Recall that, as a condition of employment or as a result of the use of the university's research facilities, funds or resources, inventors are required to sign the UC patent agreement. This agreement requires a disclosure of all inventions from employees and other relevant personnel.

The UC San Diego (UCSD) eDisclosure system provides the campus with the ability to take in and process in an efficient and effective manner between 400 and 500 invention disclosures a year. Having recently changed vendors who provide us with the web-based service, we wanted to know what inventors think of the system. We asked over 400 inventors who were named on technology disclosures to OIC from April 1, 2019, to September 30, 2019, to respond to our survey. We received 62 responses (a 15% response rate). Of the inventors who responded, the percentage that were aware of the eDisclosure tool was 55%. Of those that were aware of the tool, 88% had attempted to submit a disclosure using the system. Of those who had used the system, 70% said they enjoyed the experience.

We received a number of positive comments as well as constructive criticism that helped us launch an improvement effort centered on addressing two key themes, simpler is better and more information is better. Over the next few months, OIC is striving to implement changes that fit these themes.

For questions or assistance related to invention disclosures or intellectual property, please contact OIC at innovation@ucsd.edu.

What is the Difference Between Freedom of Information Act and California Public Records Act Requests?

BY SCOTT SAGLE

Have you ever received a California Public Records Act (CPRA) or Freedom of Information Act (FOIA) request? They can be highly sensitive and complex. Below is some general guidance to help you understand how these requests are managed on campus and what to do if you receive one.

The FOIA is a federal law that allows the public the right to request access to records from any federal agency (e.g., NIH, NASA, DOD). The FOIA does not apply to UC San Diego directly, but university records may become accessible under FOIA if they are in the possession of a federal agency. When an FOIA request seeks information that originated from an outside entity (e.g., grant proposal from a researcher), the agency notifies the outside entity and gives them a chance to object. These notifications generally go to the Principal Investigator (PI) and the contract officer. Policy & Records Administration (P&RA) assists PIs with understanding the FOIA process, identifying information that may be exempted under FOIA, and working with federal agencies to identify information that should be withheld.

The CPRA is a state law that provides the public with a right of access to governmental records. As a public institution, UC San Diego must disclose records to the public upon request unless a legal exemption applies. CPRA requests are managed by P&RA directly. P&RA contacts relevant researchers or other record holders, identifies responsive information, determines what must be disclosed, and communicates with the requester. We provide instructions and guidance when reaching out to faculty and staff on these requests.

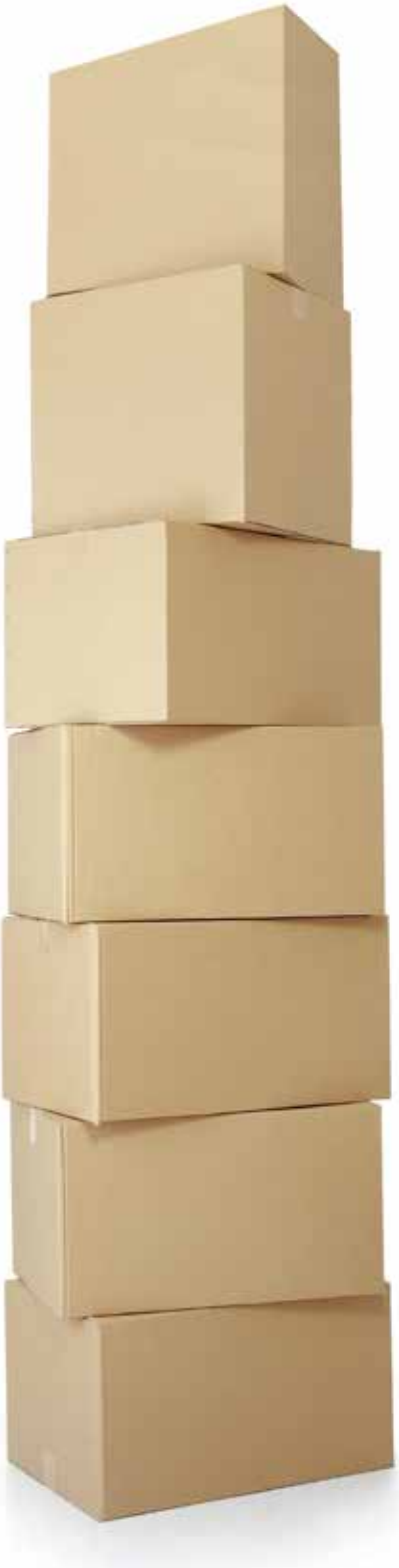
HOW DO I HANDLE THESE REQUESTS?

If you receive notification of a public records request via a federal research sponsor or other federal agency, FOIA applies. If you receive a request directly from the requester (e.g., a citizen, a reporter, or a company), this is probably subject to CPRA. In both cases, strict legal deadlines apply: contact P&RA immediately for assistance.

For assistance with FOIA, CPRA, or other information disclosure inquiries, please contact Policy & Records Administration (P&RA) at publicrecords@ucsd.edu or (858) 534-3393 / (858) 534-3394.

Foreign Gifts and Contracts Reporting under Section 117 of the Higher Education Act

BY JEFFREY WARNER



Recent news has highlighted certain universities that are under investigation by the U.S. Department of Education (DOED) for failing to report foreign gifts and contracts worth hundreds of millions of dollars. The basis for this reporting requirement is outlined in this article and highlights UC San Diego's efforts to comply.

The UC San Diego receives $500M annually in federal student financial aid programs, including grants and scholarships, graduate fellowships, loans and work-study. As a Title IV-eligible university, we are required to report any foreign gifts or contracts that exceed an aggregate of $250,000 in value from the same foreign source. To comply with Section 117 of the Higher Education Act (HEA) of 1965, UC San Diego is required to submit to the Secretary of Education, DOED, reports about gifts, contracts/grants and any ownership interest in, or control over our institution from any foreign source.

The HEA defines a foreign source as:

- a foreign government, including an agency of a foreign government;
- a legal entity, governmental or otherwise, created solely under the laws of a foreign state or states;
- an individual who is not a citizen or a national of the United States or a trust territory or protectorate thereof
- an agent, including a subsidiary or affiliate of a foreign legal entity, acting on behalf of a foreign source.

The HEA requires institutions to conduct due diligence in making the determination as to whether an entity providing funding is a foreign source. As affiliate relationships are not always obvious, UC makes the determination based on the information supplied by the sponsor/donor from UC curated databases.

Within the UC system, each campus is responsible for preparing its own report for the HEA. UC San Diego develops its report through a collaborative process involving multiple offices across the campus. The Office of Contract and Grant Administration (OCGA) and Audit and Management Advisory Services (AMAS) currently coordinate the data collection/validation effort and works with the following departments to collect the necessary gifts, contracts and grants:

- Office of Contract and Grant Administration
- Office of Innovation and Commercialization
- Scripps Institution of Oceanography Office of Contract and Grant Administration
- Gifts
- Real Estate
- Enrollment Management
- Health Sciences Business Contracts Extension
- Health Sciences International
- International Patient Program
- University Extension

The HEA requires that we provide type of activity, name of foreign source, country of foreign source, contact for the department receiving the funding, and amount of funding received from the foreign source. After data is collected and reconciled into one report, UC San Diego's Financial Aid Office is responsible for submitting it to the DOED.

UC San Diego's HEA reporting relies on the accuracy of the information entered into the systems of the respective offices required to provide data for the report (e.g., Kuali Research, Blackbaud, etc.). It is critical that the reports to the DOED are accurate as they are authorized to undertake a civil action against an institution if an institution fails to comply with the HEA Section 117 requirements, which is the basis of their recent actions against certain universities. Institutions that knowingly or willfully fail to comply with the HEA Section 117 must reimburse the U.S. Treasury for the full cost of obtaining compliance.

For additional information, please refer to the UC Office of the President Higher Education Act Section 117 Foreign Source Reporting Memo. If you have any questions, please contact Jeff Warner, Director, OCGA Ancillary Research Agreements, at jswarner@ucsd.edu or 858-534-6721.

EDUCATION

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

The UC San Diego Research Compliance and Integrity Office is pleased to offer the Research Compliance Hot Topics and Training Program (Program) to all UC San Diego faculty, staff and students. The Program will offer training through a variety of forums, including workshops, videos, newsletters and other activities, and is designed to serve as an educational resource to assist the UC San Diego research community with the complexities of conducting research. The following sessions have been scheduled:

- **POSTPONED DUE TO COVID-19: Other Support, Biosketches, and Disclosing a Foreign Component with NIH, NSF, DOD, or DOE (previously March 25, 2020)**
- **Research Related HIPAA Inclusive of Data Access, Use and Storage**
  April 28, 2020, 12:00 p.m. - 1:30 p.m.
  ACTRI Auditorium

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

Research Compliance and Integrity Knowledge Briefs!

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

CONFLICT OF INTEREST VIDEOS

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

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

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE VIDEOS

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

EXPORT CONTROL VIDEOS

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

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

"Research is creating new knowledge."
—Neil Armstrong

Q&A Ask the Questions . . .

What if my project involves human subjects and I am not the Principal Investigator and/or the project is unfunded, do I still need to submit a conflict of interest disclosure?

Special concerns arise when human subjects are involved, as the research subjects may be placed at additional risk because of an Investigator's financial interests. Situations that warrant additional consideration by the Conflict of Interest Independent Review Committee (IRC) include those where an Investigator has a financial interest in the sponsor or manufacturer of a product being tested in human subjects, or in which the Investigator is the inventor of the product.

In such situations, the IRC maintains that any research involving human subjects must be free of conflict of interest and recommends that individuals who have independent roles in projects and who are responsible for the design, analysis, conduct or reporting of the research performed (or to be performed) under a human subjects protocol shall not concurrently receive any compensation from the sponsor or other entity supplying materials, drugs or devices for the project, including honoraria and consulting fees, during the course of the study. However, the IRC will also consider other factors such as:

- The Investigator's role in the project.
- Whether the Investigator is involved in subject selection, including prescreening for inclusion/exclusion criteria.
- Participation of the Investigator in the consent process. Investigator participation in clinical treatment of subjects, separate from the research interventions or procedures.
- The design of the clinical study; whether it is a single-site, investigator-initiated study or a multicenter study with oversight provided by a sponsor or other third party.

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

We would like to collaborate with an external institution on research involving live vertebrate animals. How do I know if the institution is PHS-assured, AAALAC-accredited and USDA-registered?

To confirm if the external institution is PHS-assured, AAALAC-accredited and/or USDA-registered, please review the following websites:

- Domestic Institutions with PHS Approved Animal Welfare Assurance
- Foreign Institutions with PHS Approved Animal Welfare Assurance
- Directory of AAALAC Accredited Organizations
- List of Active USDA Licensees and Registrants

UC San Diego may only work with external sites that are AAALAC-accredited and PHS-assured. If work will involve USDA regulated species, the institution must also be registered as a Research Facility with the USDA. If you need assistance or additional information, please contact the UC San Diego IACUC at iacuc@ucsd.edu or (858) 534-6069.

When must the Responsible Conduct of Research (RCR) training be completed?

The requirements of when RCR training must be completed differs between all three federal funding agencies:

The National Institutes of Health (NIH) highly encourages that initial instruction during pre-doctoral training occurs as early as possible in graduate school. The completion of training should be consistent with the responsible conduct of research plan included in the NIH proposal.

The National Science Foundation (NSF) does not specify when the training must be completed but a plan must be in place at the time of proposal submission.

The National Institute of Food and Agriculture (NIFA) requires the training be completed before participation or payment from the project.

For more information and course options, please visit the RCR webpage or contact the RCI office at rci@ucsd.edu or (858) 822-4939.

What does it mean to conduct research outside of the University?

Conducting research outside of the University means that an employee is included on a proposal, grant application and/or award for research through an institution other than UC San Diego and there is no agreement administered by the University.

Under the UC Policy "Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University," employees are required to obtain an exception request when conducting research outside of the University. Employees must submit an exception request prior to submitting a proposal, grant application and/or accepting an award from an external entity. The new UC San Diego Policy, "Implementing Procedure for UC Policy, Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University," provides an outline of the procedures in obtaining an approval of the exception request.

For more information, please visit the RCI Exceptions Request webpage or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

RESEARCH COMPLIANCE AND INTEGRITY
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(877) 319-0265
A confidential service to handle reports of potential fraud, waste, misuse of assets or other compliance issues