UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
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Newsletter

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The National Science Foundation Feels the Effects of an Increase in Foreign Influence Investigations

BY REBECCA BEUTLER

At a hearing with the United States (U.S.) House of Representatives Science Committee on October 5, 2021, multiple testimonies were given to address the issue of balancing open science in U.S. research with the increasing need for security against foreign threats. Notably, National Science Foundation (NSF) Inspector General, Allison Lerner, expressed a concern over the growth of allegations regarding researchers failing to disclose foreign support when applying for NSF funding. Lerner states, "these cases now make up 63% of our portfolio, which is a huge growth in a very short period of time."

Since foreign influence cases were first brought to Lerner's group in late 2017, the number of cases has grown exponentially. In a semiannual report released in May 2021, it was stated that there are 131 active investigations, with 31 new cases being opened since the previous report was last published. Since 2019, the NSF has suspended 24 awards and terminated 16 awards where scientists and institutions were in violation of NSF's disclosure policy. Nine researchers have been banned from receiving federal grants, and five have been stricken from NSF's roster of grant application reviewers. Approximately $8 million has been recovered from 23 grantees who were found to be in violation of disclosure rules. These violations include the non-disclosure of foreign funding and association with foreign talent recruitment programs.

In comparison, since the U.S. government's China Initiative began three years ago, the National Institutes of Health (NIH) has been a leader in investigating foreign influence cases in U.S. biomedical research. Taking a proactive approach, the NIH has identified 540 scientists that may have violated NIH disclosure rules, and have requested 95 institutions to investigate a number of their researchers.

This large increase in investigations can be associated with the increasing number of Federal Bureau of Investigations (FBI) queries, which Lerner confirmed there has been a 1000-fold increase in the number of FBI requests to NSF. Concerns surrounding the increase in foreign efforts to access U.S. funded research has resulted in an increased effort by FBI to monitor foreign ties. It is the hope of Maria Zuber, Vice President for Research at the Massachusetts Institute of Technology, and other representatives that the collaborative involvement of the FBI with academic institutions and government funding agencies will bridge the culture between the two groups and aid institutions in investigative work that they are not normally equipped to do.

For additional information, please read Science Insiders Report or watch the full U.S. House of Representatives Committee on Science, Space, & Technology Hearing. For questions or additional information, please visit the RCI International Research webpage or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

Meet the New Office of IRB Administration Director

Ben Mooso
Director for the Office
of IRB Administration (OIA)

On November 1, 2021, Ben Mooso has assumed the role of Director for the Office of IRB Administration (OIA). Ben comes to UC San Diego from UC Davis where he had served as Associate Director of IRB Administration for the past three years. A California native who grew up in the Los Angeles area, Ben is a UC Davis graduate where he earned his bachelor's degree in Biochemistry and Molecular Biology. Immediately after attaining his degree Ben began his work in bench science studying prostate and bladder cancers and how the PI3K-Akt-mTOR pathway could be employed to treat them. Along the way, he earned his master's degree from California State University, Sacramento in Biological Science with an emphasis in Molecular and Cellular Biology. Ben then transitioned to working for the Veterans Affairs Medical Center IRB in Sacramento for a year before going back to UC Davis where he worked for the Emergency Medicine Department as a Research Compliance Analyst. Ben eventually transitioned to the UC Davis IRB as Associate Director where he led the office in adopting the Revised Common Rule, revising policies to be consistent with other offices around campus to reduce researcher burden, and new initiatives to increase inclusivity in human subjects research. Ben is excited to be joining the UC San Diego community and looks forward to working closely with the OIA team, researchers, and leadership in furthering the UC San Diego research mission.

Ben can be reached at bmooso@ucsd.edu.

Notification of New UC San Diego Investigational Drug Service Fees

BY JI SUN

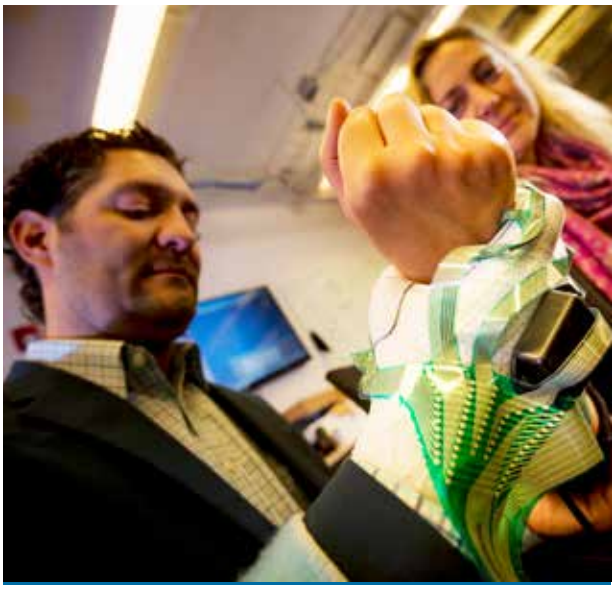
Please be aware that the Investigational Drug Service (IDS) has a new fee structure for 2022, which will become effective on January 1, 2022. This fee structure will be utilized by all five University of California IDS departments providing consistency among campuses. The new fees are based on current salaries, benefits and actual time required to perform given functions, and have been benchmarked against our peer institutions, to assure that they remain competitive. Studies that are already in progress, or for which we have already provided a budget estimate, will continue to be charged the old fees.

For additional information, please refer to the new IDS 2022 Fee Structure on the Office of Compliance and Privacy intranet or contact IDS directly.

CAN AN INVESTIGATOR HAVE FINANCIAL INTERESTS AND STILL PARTICIPATE IN RESEARCH?

BY JENNIFER J. FORD

A conflict of interest may occur when an opportunity arises for an investigator to influence University business decisions, for instance in a research project, which may result in personal financial gain and potentially compromising the integrity of research by the investigator with the financial interest.



SOME OF THE MOST COMMON CONFLICT OF INTEREST ISSUES IDENTIFIED ARE:

- Consulting agreements while also having basic research, gifts, services, clinical trials, or other human subject research
- Equity ownership in an investigator's start-up company
- Stock options in investigator's participation as a scientific advisory board member of a company
- Management positions in outside entities
- Visiting professor positions at foreign institutions
- Foreign travel with foreign institutions or companies
- Small business grants (SBIR/STTR) with investigators who are the inventor and/or founder

Having a financial interest is not automatically a conflict of interest. It is important to remember that some financial interests are of such a low value and/or limited duration that they do not meet the definition or threshold of disclosable financial interests.

What Happens After an Investigator Discloses a Financial Interest?

Once a financial disclosure is submitted to the Conflict of Interest Office (COI) office, the investigator's financial disclosure form is reviewed by the COI Office. The COI office must apply the applicable COI policies and regulations based on the investigator's specific University sponsored activity or other related activity, i.e., gifts, service, material transfer agreements, etc. Depending on the scope and nature of the disclosure and/or project, the conflict of interest may need to be reviewed by the Independent Review Committee (IRC) on Conflict of Interest. The IRC is a committee of faculty members from disciplines all across the campus and functions as the principal advisory committee to the Chancellor for conflict of interest related to research and other related activities. The charge of the IRC is to review situations where a potential, perceived, or real conflict of interest exists by virtue of financial interest and determine whether these interests constitute significant conflicts of interest that must be eliminated, reduced, or managed before research support can be accepted. Depending on the funding agency of the research, the specifics of the investigator's interest(s), the conflict of interest may have to be reported by the COI office to the funding agency.

THE IRC REVIEWS FOCUS ON THREE AREAS:

- The actual or the appearance of a conflict of interest
- The risk for bias by the conflicted investigator
- The risk to the reputation of the conflicted investigators and the University

If the IRC determines that the research support may be accepted, they then also recommend to the Chancellor appropriate strategies for the management of any significant conflict of interest. The IRC applies management strategies that have evolved over time, based on their prior experience, and the appearance of new types of conflicts. The oversight role of the IRC endeavors to safeguard the interests of the University and individual researchers with conflict(s) and ensure compliance with state and federal government regulations and policies. With appropriate management, often research that may technically have a conflict of interest is permitted to proceed with management strategies.

The IRC's most common management strategies are disclosure in publications, presentations, to the research team, ensuring protection of students and postdoctoral scholar, and, if human subjects are involved, disclosure in the informed consent. Once the IRC has made their decisions, the COI Office informs the applicable institutional office to ensure funds are released to the investigator.

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

KUALI IRB TIPS AND TRICKS FROM OFFICE OF IRB ADMINISTRATION

BY BEN MOOSO

With the implementation of Kuali IRB in July of this year, a lot has changed in how our researchers interact with the IRB. We have been developing Knowledge Base Articles (KBAs) to address many of these changes so that researchers have access to this information day or night without having to contact the Office of IRB Administration (OIA). The KBAs can be found here. We regularly edit or add KBAs based on the feedback and questions from the research community. Below are some of the common questions OIA has received with the answers and references to more information.

1. **When will I receive the IRB stamped documents? Where can I find the IRB stamped documents?**

   The Kuali system automatically applies a stamp to the PDF versions of the Informed Consent Form (ICF), assent forms and recruitment materials when a new study, amendment, or renewal is approved. As such, there will not be a separate email from OIA or Kuali that contains the stamped documents. To ensure that the ICF is stamped, please be sure that the clean version is uploaded as a PDF and that its attachment type in Kuali is listed as "Informed Consent/Parental Permission" or "Recruitment Materials." Once the submission is approved in Kuali, the stamped document can be found by navigating to the "Supporting Information" section of the study application and clicking on the document to download it. For more information on this topic, please see our KBA here.

2. **How do I respond to IRB reviewers and/or action items?**

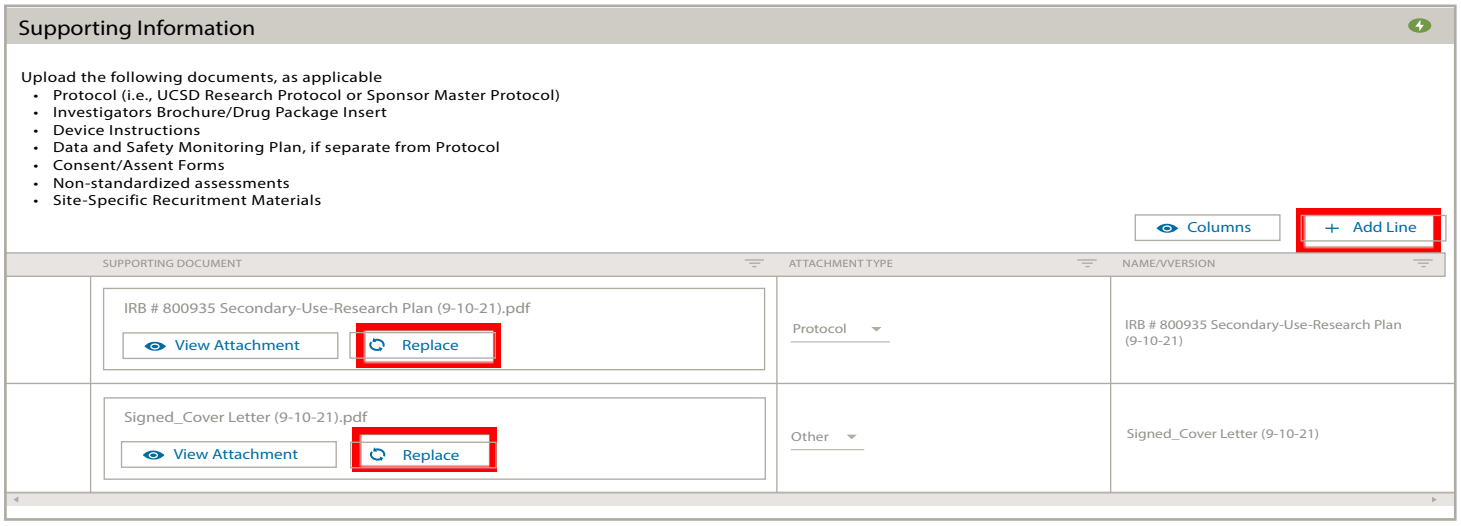
   When a study is being reviewed, the reviewer(s) may have questions or changes in the form of action items. Once they have compiled their action items, they will return the submission to the study team to be addressed. Kuali will automatically generate an email notification when this happens. To review and respond to the action items, the study team should open the submission in Kuali by logging in and clicking on the study title. Once open, a yellow circle with a number in it will appear in the menu on the left-hand side of the screen showing which sections have action items to be addressed. The study team can either click on any of the section headings in the left-hand menu or scroll through the application to get to these sections. Each item in the application where there is an action item to respond to will have the words "Action Items" with a yellow circle with a number in it indicating that there is something for the study team to address. To open the action items, click on the words "Action Items" and the right-hand menu will open and display the action items to be addressed. When the study team is ready to reply to an action item, click on the "reply" link in the action item to enter a comment. For more information on this topic, please see our KBA here.

3. **When should I replace a document in Kuali versus uploading a new document?**

   When amending documents in the "Supporting Information" section of the Kuali application, the study team has the option to either click the "+ Add Line" button at the top of the table showing all of the current supporting documents or click the "Replace" button that appears for each document (see the red boxes in the screenshot below). The study team should only use the "+ Add Line" button when uploading a new document that will be going to the IRB for the first time. The study team should always use the "Replace" button when they're uploading a new version of a document that has already been uploaded into Kuali.

4. **I need help getting access to Kuali IRB. How do I get help?**

   Access to Kuali IRB requires access to the University's Business Systems. Getting this access depends on who needs the access and their role in relation to UC San Diego. There are several KBAs here which explain how to get Business



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Systems access. With rare exceptions, Kuali IRB access is intended only for faculty, staff or students of UC San Diego and/or Rady Children's.

5. Why do I have to submit a transfer amendment when nothing is changing?

The legacy e-IRB Services and Kuali IRB are vastly different systems and do not "talk" to one another. As such, prior to the Kuali IRB Go Live earlier this year, shell studies were created in Kuali IRB based on information in the legacy system at that time. These shell studies contained very basic information about studies (e.g. protocol number and study title) but much of the information could not be transferred due to technological issues. This means that every study which was in the legacy system and will continue past July 2022 has to go through the process of transferring that data. UC San Diego OIA determined the best way to do this was during renewal through the transfer amendment process. So why did we call it a transfer amendment? Like all systems, Kuali IRB has only a limited number of submission "types" for us to choose from. Given that limited selection, calling it a "transfer amendment" made the most sense. For more information about transfer amendments, please see our KBA here.

6. How should I answer the question in Kuali IRB, "Will identifiable information transmitted over the internet be encrypted?"

This question is located in the "Privacy/Confidentiality" section of the Kuali application and can be confusing as it comes right after several questions about Protected Health Information (PHI). The IRB asks several questions related to the topic of Privacy and Confidentiality in this section to determine the study's risk level, the level of review that is required, and ultimately whether privacy and confidentiality provisions of the various regulations, laws, and policies, as applicable, are met. In thinking about this question, it is important to remember that "identifiable information" means more than just PHI. "Identifiable Information" which is sometimes also referred to as "Personally Identifiable Information (PII)" is any information for which a person's identity is readily identifiable. This could be a survey with someone's name or email address in it, the video recording of an interview, or a PHI dataset that contains any of the 18 HIPAA identifiers. In thinking about how to answer this question, think about all the data that will be transmitted over the internet. If any of it will be identifiable, then the answer should probably be "yes" and the study team will need to take measures to ensure this is the case. If the answer is "no", there should be a reasonable justification for why (e.g. the data, should confidentiality be compromised, do not pose any risk to the subject's reputation, employability, legal standing, mental or physical well-being, etc.). On the other hand, if no data will be transmitted over the internet or all the data will be transmitted in a format without identifiers, then the study team can select the option for "Not applicable."

While these are some of the common issues and questions OIA is receiving, additional information is available through our KBAs. As always, please contact the OIA anytime at irb@health.ucsd.edu with any questions.

The National Institutes of Health is Now Verifying ClinicalTrials.gov Registration and Reporting

BY DIANA D. KIM

All National Institutes of Health (NIH) funded clinical trials are required to be registered and have the results submitted on ClinicalTrials.gov per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information." The system validation in the electronic Research Administration (eRA) Human Subjects System (HSS) will result in an error for grant recipients upon submission of a Research Performance Progress Report (RPPR) when the clinical trial registration and/or results reporting are overdue.

- **Registration:** Grant recipients will receive a warning if they are not in compliance at 21 days after the enrollment of the first study participant. An error is then generated if the clinical trial registration is more than 30 days past this date. The registration error for RPPR is resolved when the trial is registered on ClinicalTrials.gov and the ClinicalTrials.gov identifier (NCT#) or the ClinicalTrials.gov registration receipt is submitted on the Human Subjects Clinical Trial Information (HSCT) form.
- **Results reporting:** Grant recipients receive an error if the results are overdue by more than 12 months after the clinical trial's actual primary completion date. The results reporting error is resolved when results are submitted on ClinicalTrials.gov or by providing a ClinicalTrials.gov receipt for either a "Good Cause Extension" request or a "Certification of Delayed Submission of Results Information" on the HSCT form.

Grant recipients will receive an error at the time of RPPR submission, and the award will be prevented if the requirements are not met at the time the award per NOD-OD-22-008. For additional information regarding ClinicalTrials.gov, please visit the Research Compliance and Integrity ClinicalTrials.gov webpage or contact RCI at ctgov@ucsd.edu.

EXPORT CONTROLS: Activities with Entities Affiliated with a Foreign Military, Intelligence or Security Agency

BY MICHAEL J. MILLER

Engagement with entities affiliated with a foreign military, intelligence or security agency require compliance with United States (U.S.) export control laws and regulations. Many such entities are enumerated in 15 CFR Part 744 of the Export Administration Regulations (EAR) as either a denied or unverified entity. However, there are other entities not included in Part 744 that participate in military-civil fusion (MCF) programs that integrate military and civilian research and development efforts into higher education system. The China Defence Universities Tracker is a database of Chinese institutions engaged in military or security-related science and technology research as part of MCF (hereafter called "Unitracker" entities). Engagement with a Unitracker entity or person is not always problematic so long as the activities comply with U.S. export control laws and regulations.

U.S. researchers hosting scholars or engaging in research collaboration affiliated with Unitracker entities must consider the following:

1. **Is the entity you are collaborating enumerated on both the Unitracker and Part 744 List?**

   Unitracker entities also enumerated on either the Denied Entity or Unverified List require compliance with Export Administration Regulations, which are more-strict for these entities. Denied entity or Unverified List parties are prohibited from receiving some or all items subject to the EAR without a license, which includes "technology" defined as "Information necessary for the "development," "production," "use," operation, installation, maintenance, repair, overhaul, or refurbishing (or other terms specified in Export Control Classification Numbers (ECCNs) on the Commerce Control List (CCL) that control "technology") of an item." This impacts certain visiting scholar activities, in addition to operation of certain research equipment. These parties present a greater risk for diversion of weapons of mass destruction programs, terrorism, or other activities contrary to U.S. national security or foreign policy interests.

2. **Is the entity you are collaborating a Military end-use or End-Users? (or) Does the entity support a Military end-use or End-Users?**

   Activities that directly support entities enumerated on Supplement No. 7 to Part 744 - Military End-User List or military end-uses, or in any way support an entity that collaborates with the Chinese, Russian or Venezuelan Military, or supports entities supporting the Military-civil fusion integration require a license prior to export, deemed-export, or the release of specific technology, including release to foreign visitor researchers in the U.S. There are also restrictions and a few named entities listed in 15 CFR 744.22 that restrict exports for particular military-intelligence end uses or end users in Burma, China, Cuba, Iran, North Korea, Russia, Syria, and Venezuela.

> **"Engagement with a Unitracker entity or person is not always problematic so long as the activities comply with U.S. export control laws and regulations."**

3. **Do you participate in proprietary, export controlled or sensitive research?**

   Unitracker entities actively pursue research engagement with persons at U.S. universities and have been identified worldwide diverting research, technology, and items. Researchers with access to proprietary information, such as that provided by a sponsor in furtherance of a non-disclosure agreement, are cautioned against the release of proprietary technology to scholars with an affiliation with a Unitracker entity as they are not permitted to access proprietary information or materials, or engage in export-controlled or sensitive research. Attempts to engage in such activities must be reported to the Export Control Office.

   U.S. researchers hosting scholars or engaging in research collaboration affiliated with Unitracker entities must consider the following required security measures for visitors affiliated with a Unitracker entity:

► **Research Participation:** Allowable research activities are limited to "Fundamental Research" as defined in 15 CFR 734.8, which are free of access, dissemination, publication, or foreign participation restrictions. Fundamental research is distinguished from other research by the ability to publish research results.

► **Equipment Use:** Unitracker foreign visitors are permitted to operate research equipment to the extent a license is not required but must not receive training or instruction on the methods and procedures or access to technical information required to install, maintain, repair, overhaul or refurbish the equipment. The visitor cannot access export-controlled items or equipment. The visitor is only permitted access to publicly available items, technology (i.e., information, technical data), and software.

► **Non-Sponsored Research Activities:** Unitracker foreign visitors seeking to augment domestic activities (e.g., using UC San Diego resources to perform foreign research on U.S. soil) may be unallowable depending on various factors. Please contact the Export Control Office before facilitating Unitracker service requests.

► **Information Access:** Information access must be limited to publicly available items, technology (i.e., technology or technical data), and open-source software. Transfer of export-controlled or proprietary items, technology, or software is not permitted. Unitracker access to the UC San Diego Library and Blink, and services provided by UC San Diego to students and guests are allowable so long as the UC San Diego system contains only publicly available information or technology.

► **International Exports and Shipments:** The visitor is NOT permitted

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to take or return to their home country with ANY University-owned items, non-public technology, or software without a U.S. Government-approved export license.

► **Imports:** Imports of items or information into the United States for the visitor may require a U.S. Government approved import license.

► **Access Prohibited to UC San Diego Research Data that has not been Publicly Released:** Research data is the property of UC San Diego. The Principal Investigator is the steward of research data owned by the University and any other data acquired or used during research. Please visit the UC San Diego's Guidelines on Access and Management of Research Data for a complete description of UC San Diego's Guidelines on access and management of research data. The visitor may not be furnished with information technology accounts that facilitate access to UC San Diego research data.

► **Tangible Research Materials:** Unitracker visitors do not retain ownership of research data or tangible research materials. When a visitor departs UC San Diego, tangible research materials shall remain at the University. Subject to any third-party restrictions, tangible research materials may only be transferred with the approval of the Vice Chancellor for Research, generally under a Material Transfer Agreement (MTA) between the University, the Principal Investigator, and the home institution or employer of the visitor.

► **Research Data (that is not a Tangible Research Material):** Except in the case of tangible research material, the visitor may export self-generated research data produced at UC San Diego only when the data is released into the public domain or is otherwise not subject to export control license requirements.

► **Foreign Component Reporting:** Investigators with federally funded research may be required to report foreign affiliations, visitors, foreign participation, and participation in foreign-funded activities.

► **Violations:** Faculty, students, scholars, staff, and visitors must take steps to ensure they do not violate export control regulations or economic sanctions. Consequences can be severe and include both civil and criminal penalties for the individual and University, up to $1 million per violation, and may face imprisonment for criminal cases.

If you have questions, need assistance, or suspect a violation has occurred, please contact the UC San Diego Export Control Office at 858-246-3300, export@ucsd.edu.

REPORTING ANIMAL WELFARE CONCERNS

BY THE IACUC OFFICE

The privilege to use live animals for the advancement of science and medicine carries with it the responsibility to follow all applicable laws, policies and procedures concerning animal welfare. UC San Diego is committed to the humane treatment of all animals used in research and teaching. All Principal Investigators (PIs) who use live animals for research or teaching must assure that their lab will adhere to the animal use protocol approved by the Institutional Animal Care and Use Committee (IACUC). The UC San Diego IACUC oversees the University's animal care and use program and is responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories, overseeing training and educational programs, and investigating animal welfare concerns.

Federal law and Public Health Service (PHS) Policy require the IACUC to investigate all reports of animal welfare concerns, that reports can be made anonymously and that there will be protection from reprisal or discrimination. Anyone who is aware of potential violations to animal care and use regulations or who observes misuse or mistreatment of animals is strongly encouraged to report their concerns. Reports can be made by phone, email, campus or postal mail. Reports can also be made through the UC San Diego Whistleblower hotline at (877) 319-0265.

The IACUC encourages anyone with an animal welfare concern to first address their concern with their supervisor. If discussing the concern with their supervisor is not possible or not successful, the IACUC should be contacted through one of the methods listed at the end of this article. Reports should contain as much information as possible so the IACUC can adequately investigate the concern. Details such as the time, date, and place of the event of concern, names of people involved, the species and number of animals affected, and any other details that may help the IACUC investigate, should be included in the report. Reports can be made anonymously by withholding the name of the reporting party or by requesting anonymity in the report.

Posters that outline the UC San Diego policy on Reporting Animal Concerns are posted at the entrance to each animal facility and in animal use areas. Reports can be submitted to the IACUC Office at iacuc@ucsd.edu, (858) 534-6069 or mail code 0071, or the UC San Diego Hotline at (877) 319-0265. For additional information, please see the following:

- UC San Diego Institutional Animal Care and Use Committee (IACUC) Policy on Reporting Animal Concerns
- Reporting Animal Care and Use Concerns
- UCSD Hotline Information

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

RESEARCH COMPLIANCE CORNER:
WORD TO THE WISE

A UNIVERSITY REPAYS NATIONAL SCIENCE FOUNDATION $1.3M AND SUSPENDS RESEARCHER AFTER FINDINGS OF MISMANAGEMENT

The University of Texas at Austin (UT Austin) conducted an internal investigation involving a Principal Investigator (PI) with four National Science Foundation (NSF) awards after being notified of a potential misuse of federal funds. The investigation found that the PI failed to consistently verify and document participant eligibility and failed to consistently track and report participants to NSF. It was also found that the PI paid mentors using "participant support costs" and paid ineligible participants.

UT Austin agreed to repay the NSF $1.3 million, which was the full amount of the four awards at issue. The PI was required to reimburse one-third of the misappropriated funds and appoint a Co-PI with fiduciary responsibilities for all his remaining grants. The actions against the PI included a letter of reprimand, a one-year suspension without pay, a loss of endowment, reduction in compensation, ineligibility to serve as a PI on any new proposals for three years, and completion of research integrity training. For additional information, please read the NSF Semiannual Report to Congress.

THE UNIVERSITY OF WASHINGTON SETTLES WITH DEPARTMENT OF JUSTICE OVER ALLEGATIONS OF A FALSIFIED GRANT APPLICATION

The University of Washington (UW) will pay more than $800,000 in settlement fees over falsification allegations made by the Department of Justice. According to the settlement agreement, allegations were made against Mehmet Sarikaya, a Professor at UW's Materials Science and Engineering Department, for misrepresenting the involvement of two researchers on National Science Foundation (NSF) grant documents. Following a whistleblower complaint regarding the work and personnel listed on the grant application, it was found that the two researchers did not participate in any work for the $1.4 million grant.

"This is an expensive, but critical, lesson that researchers must accurately report who worked on a project, as well as the results from their research" said U.S. Attorney, Nicholas Brown. As a result of the misrepresentation, UW has agreed to pay $400,000 in restitution and $400,000 in penalties under the False Claims Act. UW has declined to comment on any disciplinary action for Sarikaya, but he remains a professor at the University. For more information, read the Department of Justice announcement.

AIR WAR COLLEGE PROFESSOR PLEADS GUILTY TO LYING ABOUT CHINESE TIES

Xiaoming Zhang, a civilian professor at the Air War College (AWC), Alabama, has pleaded guilty to making false statements to a federal agent. During his tenure at AWC, Zhang would travel to China on a regular basis for work-related purposes, for research and to visit family living there. While in China, Zhang developed a relationship with a known foreign official working with the Shanghai Municipal Government. Records indicate that Zhang met with the official in person on approximately six occasions and exchanged approximately 40 emails with him from December 2012 to January 2017. During this period, Zhang became aware that the official was using, or attempting to use, their relationship to gain access to sensitive information in Zhang's possession as well as to contact other potentially valuable individuals. Zhang failed to report the relationship with the foreign official and made multiple misleading or false statements to authorities to hide his relationship with the Chinese official. Zhang faces a maximum of five years in prison at sentencing. For more information, read the Department of Justice announcement.

$1.3 MILLION
PRISON TERM
$800,000

YOUR DATA IS NOT NECESSARILY THE TARGET

BY MICHAEL CORN

Federal granting agencies have taken note of the explosion of cybersecurity attacks rocking higher education and health care. From community colleges, major healthcare systems, to large research universities, ransomware in particular has shaken the federal government and higher education with a threat that's not merely financial, but borders on existential. However, often I am approached by faculty and/or researchers who tell me they feel the concerns about ransomware are overblown for their research because, after all, like many research programs they use either public data or data not involving human subjects. Unfortunately, this incorrect belief is the result of a fundamental misunderstanding about the goals of a ransomware attack.

Ransomware is malicious software (aka malware) that converts all the files on a system into a format that requires a special password to access them. The files are generally not stolen, but held "hostage" until a ransom is paid, at which time the password may (or may not) be provided, allowing the researcher to restore the files to their original state. Most importantly, ransomware, unlike other forms of attack, is not an attempt to steal valuable data such as intellectual property or banking information, but rather to deny you access to something you hold valuable.

For the researcher, this can mean the inability to access any stored data, papers, analyses, regardless of format, preventing publications, grant proposals, and student theses for weeks at a time. Imagine the impact of not being able to do any work for an entire month in the middle of grant writing season. Adding insult to injury, it is also not uncommon that the password for accessing your files does not function, thus your data maybe permanently lost. Worse still, paying a ransom only encourages further ransomware attacks on you and other UC San Diego researchers.

UC San Diego, like every other university, sees daily ransomware attacks aimed at individual laptops and laboratories across the institution. The persistent threat of ransomware is one of the reasons all Federal funding agencies are adding expanded cybersecurity obligations to grants and contracts. Whether it is the Department of Energy, National Aeronautics and Space Administration, Department of Defense or in Data Use/Sharing agreements with private firms, new and sometimes significant security provisions are now quite common.

In order to help the campus research community prepare for and respond to the cybersecurity risks, we strongly encourage researchers to engage with our Cybersecurity Certification for Research initiative (CCR), described at assure.ucsd.edu. The CCR is a program that ensures the minimum set of highly effective security measures are in place in your research program, measures that significantly reduce the likelihood of ransomware and that greatly reduce the impact when it does occur.

A recording of a workshop on completing the program is available on the Research Compliance and Integrity Office website. In addition, you can join our Research IT team for CCR office hours every Thursday from 1:00 to 2:00 p.m., on Zoom. See CCR Office hours for additional information and Zoom details.

By receiving the CCR certification, the researcher's laboratory will be postured to easily meet some of the forthcoming security standards Federal agencies are releasing and the researcher can provide the CCR certification award letter with grant applications to help demonstrate cyber resilience in their research program to granting agencies.

For additional information or questions, please contact Michael Corn, Chief Information Security Officer, at mcorn@ucsd.edu.

CLINICALTRIALS.GOV CERTIFICATION OF DELAYED SUBMISSION OF RESULTS

BY DIANA D. KIM

For Applicable Clinical Trials (ACT) that are subject to the Final Rule, the standard deadline for submission of results information is no later than one year after the primary completion date. Responsible parties can submit a "certification for delay" on the Protocol Registration and Results System (PRS) for a delay of up to two years from the date of the submission of a certification for delay, if either of the following apply:

1. Certify Initial Approval: An unapproved, unlicensed, or uncleared product studied in the clinical trial is still under development by the manufacturer, or
2. Certify New Use: Marketing approval will be sought within one year after the primary completion date of the trial for a new use of an approved, licensed, or cleared product that is being studied in the clinical trial.

A certification for delay must be submitted prior to the standard deadline for submission of results information (i.e., at least the day before), and it is considered late if it is submitted on or after the date of the standard submission deadline of results information. After ClinicalTrials.gov reviews the certification, the ACT's Results Expected Date is automatically assigned to be a maximum of two years from the date of the submission of the certification for delay.

The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) can take action against Responsible Parties if required results information is not submitted, inclusive of civil monetary penalties and/or not releasing remaining funding for a grant or funding for a future grant. Please see the ClinicalTrials.gov Frequently Asked Questions (FAQs) and the Research Compliance and Integrity Office (RCI) factsheet on Instructions for Publishing Results and Adverse Events.

For questions or additional information, please visit the RCI ClinicalTrials.gov website or contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.

NEW UPDATES TO CLINICALTRIALS.GOV MODERNIZATION EFFORTS

BY REBECCA BEUTLER

In August of 2019, the National Library of Medicine (NLM) initiated a modernization effort of ClinicalTrials.gov to improve the site functionality. With input from stakeholder engagement, product development, and infrastructure enhancements, the NLM has made progress in the modernization effort while still upholding the regulations set for researchers.

The NLM working group had three main goals to reach with modernization:

1. Ensure that Clinical trial information is current, complete, and reliable,
2. anyone can easily find and use information about clinical trials, and
3. trial info, resources, and tools provide value to the research ecosystem all while minimizing the disruption to users of the current system.

To reach these goals while also ensuring that the current site is functional, the NLM has a timeline in which the beta site will be released in parallel to the current site. With feedback from users, features will then be added and improved until the beta site is made the primary site. These timelines and goals will be applicable to both the Protocol Registration and Results System (PRS) site and the public facing site.

In late December 2021, the first beta release of the ClinicalTrials.gov website will introduce the following changes:

- A new home page with a simple search with different underlying search technology
- A search results page with filters to refine search results
- A redefined study record page with an in-record navigation menu
- Updated background information about ClinicalTrials.gov and clinical research studies

The next release for both the PRS system and public facing site is expected to include additional features based on user input. For more information on these modernization efforts, please review the full report. Please note, with these modernization efforts, policies regarding registering and posting results on ClinicalTrials.gov are unchanged.

For any questions regarding ClinicalTrials.gov requirements, please visit the website, or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

EDUCATION

National Native American Heritage Month and the Importance of Land Acknowledgment

BY MADELEINE PALEY

Land Acknowledgment: The UC San Diego community holds great respect for the land and the original people of the area where our campus is located. The university is built on the un-ceded territory of the Kumeyaay Nation. Today, the Kumeyaay people continue to maintain their political sovereignty and cultural traditions as vital members of the San Diego community. We acknowledge their tremendous contributions to our region and thank them for their stewardship.

November was National Native American Heritage Month. Beginning in 1990, this heritage month is a time to celebrate rich and diverse cultures, traditions, and histories and to acknowledge the important contributions of Native people. National Native American Heritage Month is also a time to educate the public about tribes and to raise a general awareness about the unique challenges Native people have faced both historically and in the present. To learn more about National Native American Heritage month, visit the official government webpage and the National Congress of American Indians webpage. To learn more about the work being done at UC San Diego, visit the Native American Heritage Month Blink page and Intertribal Resource Center webpage.

The University of California San Diego is built on the unceded territory of the Kumeyaay Nation, land that has immense history. Today, the Kumeyaay people continue to maintain their political sovereignty and cultural traditions as members of the San Diego community. UC San Diego acknowledges their contributions to this region and hold great respect for the land and the original people of the area where our campus is located.

It is important for all members of the UC San Diego community to understand the history that has brought us all to reside on this land. The Native Governance Center highlights that, "land acknowledgements do not exist in a past tense, or historical context: colonialism is a current ongoing process, and we need to build out mindfulness of our present participation." To learn more about land acknowledgment and how to develop a land acknowledgment statement, visit the Native Governance Center resource page.

For questions or additional information, please contact the Research Affairs Equity, Diversity and Inclusion Committee at vcr-edi@ucsd.edu.

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

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

- **NIH 021-73 Updates**
  January 12, 2022, 11:00 a.m. – 12:30 p.m.
  via Zoom (to register, click on this link)
- **IRB Town Hall**
  January 19, 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 here: calendly.com/ucsdrcioffice.

For questions, please contact rci@ucsd.edu.

Q&A

Ask the Questions . . .

How do I submit my conflict of interest (COI) disclosure for research and other related activities?

All conflict of interest (COI) disclosures for research and other related activities must be submitted in Kuali COI. A Kuali COI disclosure is created from two sources, either from Kuali Research (for sponsored research, services, and unfunded agreements) or a manual project in Kuali COI (made by the COI Office) and is triggered when a record is created in Kuali COI for specific sponsors and activities.

More information about Kuali COI can be found at https://blink.ucsd.edu/sponsor/coi/kualicoi.html.

What is the China Defence Universities Tracker and can I Collaborate or Export to Universities and Entities on this Tracker?

The China Defence Universities Tracker (Tracker) is a database of Chinese institutions engaged in military or security-related science and technology research. The Tracker includes entries on nearly 100 civilian universities, 50 People's Liberation Army institutions, China's nuclear weapons program, three Ministry of State Security institutions, four Ministry of Public Security universities, and 12 state-owned defense industry conglomerates. The Tracker provides risk related information regarding the entity and/or institution. Caution should be used before engaging in research related activities with any entity or institution included on this list.

For additional information or assistance, please contact the UC San Diego Export Control Office at export@ucsd.edu.

If one part of my project in a National Institutes of Health (NIH) grant application meets the NIH definition of a clinical trial, but the remaining parts do not, is my entire NIH grant application considered a clinical trial?

Yes, even if only one part of your project meets the NIH definition of a clinical trial, your entire grant application will be considered a clinical trial. This applies even if other parts of the project do not fall under this definition. For more information, please see the notice of NIH definition of a clinical trial and the NIH FAQs.

Additional information regarding training and reporting requirements for NIH clinical trials can be found at UC San Diego's Research Compliance and Integrity Office website.

We would like to collaborate with an external institution on research involving live vertebrate animals. How do I know if the institution is Public Health Services (PHS) assured, AAALAC accredited and U.S. Department of Agriculture (USDA) registered?

To confirm if an 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.

Does National Institutes of Health permit online training to meet the Responsible Conduct of Research training requirement?

The National Institutes of Health (NIH) announced in early 2020 that training in the Responsible Conduct of Research (RCR) can be completed online during the declared COVID-19 public health emergency. The online training is permitted through December 31, 2021, even if the declared public health emergency is rescinded before then. These flexibilities apply to all awards requiring instruction in RCR and grant recipients do not need to seek prior approval for the online training.

For more information, please visit the NIH Guide Notice and the UC San Diego Research Compliance and Integrity Office website for additional information regarding the NIH (and other agency) RCR training requirements.

RESEARCH COMPLIANCE AND INTEGRITY

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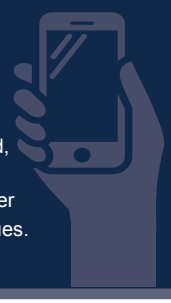

UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY

Facilitating Responsible Research, Innovation and Education for Global Excellence

Compliance starts with you!

Be honest.

Be responsible.

And if you don't know – **ask!**

- ClinicalTrials.Gov
- Conflict of Interest
- Dual Use of Research Concern
- Export Control
- Good Clinical Practices
- Institutional Animal Care and Use Committee
- Research Misconduct
- Responsible Conduct of Research

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