UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
Office of Research Affairs

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Newsletter

INSIDE THIS ISSUE

The National Institutes of Health Reports over 500 Foreign Influence Investigations as Concern over Foreign Influence in United States Research Grows

BY REBECCA BEUTLER

Over the past year, the number of National Institutes of Health (NIH) investigations into Principal Investigators (PIs) with potential ties to undisclosed foreign governments has grown to over 500 since the NIH began their review in 2018[1]. Investigations into these Investigators are initiated from suspicion of violations of federal policies requiring investigators to disclose sources of foreign research support, conflict of interests, and potential violation of peer review integrity[2]. The majority of these compliance investigations are open and pending, while it is expected that a number will be dropped depending on what is discovered.

Of the open cases, the majority are concerned with the failure to disclose foreign grant support and/or participation in foreign talent programs. Once an investigation is initiated, cases are referred to several different agencies including the Department of Health and Human Services (HHS), Office of Inspector General (OIG) and the Department of Justice (DOJ) where they are treated as criminal or civil investigations. As a result of these investigations, to date, two criminal convictions have resulted, Xiao-Jiang Li from Emory University and Song Guo Zheng from Ohio State University (OSU).

Song Guo Zheng, MD, PhD, former chair and researcher at OSU's Division of Rheumatology and Immunology, pleaded guilty in November 2020 to making false statements on NIH award applications by minimizing his association with Sun Yat-sen University (SYSU). Zheng's plea followed an arrest made in May 2020, only one month after the NIH was tipped by Zheng's former employer Penn State. Penalties for these non-disclosures included a $3.4 million payment in restitution to the NIH and over $400,000 to OSU[3]. Currently, there are inquiries on the validity of Zheng's published works, with unreported conflicts of interest causing doubt on the integrity of his research[4]. Like Zheng, former Emory University professor Xiao-Jiang Li pleaded guilty following a NIH investigation in research misconduct and received one year's probation.

Footnotes:

1. Delfino, Theresa. "NIH Logs 500+ Foreign Influence Cases." Report on Research Compliance, vol. 18, no. 9, 26 Aug. 2021.
2. Lauer, Michael. 2021, Foreign Interference in National Institutes of Health Funding and Grant Making Processes: A Summary of Findings From 2016 to 2021, grants.nih.gov/grants/files/NIH-Foreign-Interference-Findings-2016-2018.pdf.
3. Delfino, Theresa. "Dr. Zheng Did Not Disclose Any of This." Report on Research Compliance, vol. 18, no. 9, 26 Aug. 2021.
4. Delfino, Theresa. "First Jail Term for Undisclosed Foreign Support Appealed; NIH's Lauer Laments 'Tragic' OSU Case." Report on Research Compliance, vol. 18, no. 9, 26 Aug. 2021.

UC San Diego Sponsored Project Offices Alignment Initiative

BY ROSS DAMMANN

Research Affairs is pleased to announce the launch of a deep partnership among the Sponsored Project Offices (SPOs) at UC San Diego (UCSD). Presently, the campus research administrative services are supported by several relatively independent SPOs, including the Office of Contract and Grant Administration (OCGA), Health Sciences Sponsored Projects Pre-Award Office (HS-SPPO) and Office of Contract and Grant Administration, Scripps Institution of Oceanography (SIO-OCGA). The SPOs' portfolio of work includes the management of contracts and grants (proposals and awards) and ancillary research agreements.

UCSD is committed to the highest ethical and legal standards in the conduct of research and to ensure that it supports the research community with the proper oversight and guidance to effectively carry out research. The increasing agency and regulatory requirements and potential for fines, penalties and reputational risks, made the alignment between the SPOs now more important than ever.

The SPO Alignment Initiative was adopted and launched on August 1, 2021. In addition to increasing collaboration between the SPO leaders, the SPO Alignment also includes the creation of an Executive Governance Committee (EGC). The EGC includes the Chief Financial Officer, the Vice Chancellors for Research, Health Sciences and Marine Sciences, and the Executive Vice Chancellor. The EGC will meet regularly to discuss contract and grant related issues and will find resolutions to ongoing challenges. The implementation plan for a standardized operational approach will be rolled out over three to five years and is designed to:

- Increase customer satisfaction among Principal Investigators (PIs) and research support administrators
- Decrease compliance issues and risks through improved coordination across SPOs
- Improve communication and consistent use of best practices
- Reduce staff attrition

Over the next several months, the SPOs will be working together to implement the SPO Alignment Initiative that will include discussions with research administrators, staff and faculty to identify and accomplish the following outcomes:

PROCESS ALIGNMENT:

- Develop SPO "Centers of Excellence" to draw on best practices and expert knowledge transfer from all SPOs.
- Establish Service Level Agreements with each VC area to improve and maintain service.
- Adopt the Customer Satisfaction Survey campus-wide.
- Create transparency and accountability in the delivery of data, reports and dashboards, reportable to the Vice Chancellor for Research.

TECHNOLOGY ALIGNMENT:

- Fully optimize existing technologies to allow for future growth.
- Eliminate shadow systems across SPOs and develop common business tools for the research community.
- Develop a single SPO website with campus policies, processes, and online engagement tools.

More information will be forthcoming as leaders and representatives work together on planning and implementing strategies. Importantly, research administration staff and PIs will be invited to participate in the planning process. Research Affairs looks forward to working with you on this important change for the campus.

If you have any questions or comments, please contact Ross Dammann, AVC, Office of Contracts and Grant Administration, at rtdammann@ucsd.edu.

THE SCIENCE BEHIND ATTENTION TRAINING

BY RACHEL HOMMEL

Attention is trainable. BrainLeap Technologies games were initially created and tested by UC San Diego inventors and founders Dr. Leanne Chukoskie and Dr. Jeanne Townsend, with funding by the Accelerating Innovations for Market (AIM) grant. The research study included 23 individuals, aged 9-25, with attention challenges, using their AIM award to further develop and test software programs to people with Autism Spectrum disorder.

Focusing on symptoms rather than labels, BrainLeap Technologies provides brain-training software that helps children with Autism Spectrum Disorder (ASD) improve their concentration and motor skills. It is the only research-based, gaze-driven system designed to train foundational attention skills.

"Many kids have attention challenges that can be improved by training, we can help them discover what it means to focus," said Townsend. "You just have to make training available to them. Kids can learn to control their attention. BrainLeap's current approach is to provide access to training in schools which makes it possible to help large numbers of children inexpensively and without effort to parents."

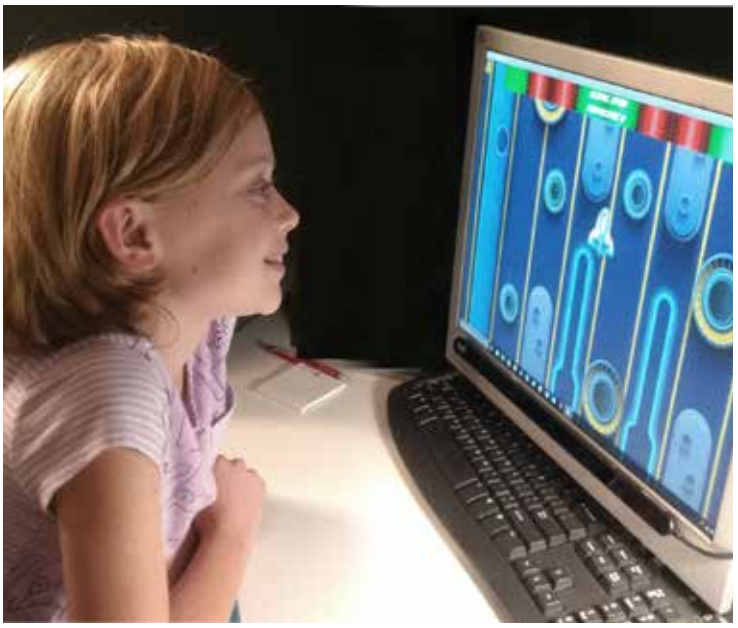
Eye movement and attention are tightly linked and share much of the same brain circuitry. The games developed by Townsend and Chukoskie gradually shape behavior using visual and auditory feedback provided in real-time. They are designed to improve the speed, accuracy, and control of eye movement and in doing so they improve the speed, accuracy and control of attention.

However, lab interventions can be very tedious and expensive, while games developed for training, therapy or education can be used in schools or at home. Chukoskie founded the UC San Diego's PoNG Center to design and develop games on a recharge basis, whether colleagues want to create a video game or design experience for research, education or therapy. The PoNG Center staff will work with the customer to meet their needs.

"Autism comes with a lot of costs. We have been able to lean into doing remote intervention," said Chukoskie. "One of things that slows and derails our method is the adherence to supervising people engaging in the lab. Since people have to come into the lab, you don't get the intensity of training you are looking for. This has been a particularly successful approach during the pandemic."

Since the pandemic, the team has worked to develop systems that can engage people on their own, managing interventions on a larger scale to make treatment broad and accessible. With funding from the National Institutes of Health, Townsend and Chukoskie are expanding research efforts to older adults via cognitive enhancement training, providing people a potentially powerful tool in the fight against dementia.

Training resistance to distraction and speed of processing, the games will help senior members learn to focus attention with internal and external distraction. Their eye-tracking, gaze-driven games



approach is more affordable than training in a lab or clinic, and all from the comfort of home.

"Attention provides an important foundation to many cognitive skills including memory. Forming a stable memory requires attention," said Townsend.

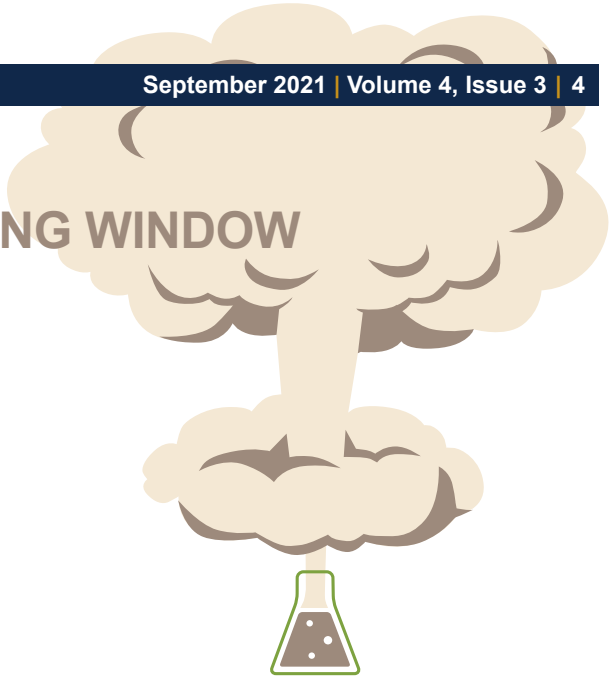
Currently, BrainLeap Technologies has partnered with incubator UbiSoft, helping make their games more playable, while targeting lower resource schools to access cutting edge software and help break the digital divide.

"We want users to see what's possible, personalization is important," said Chukoskie. "Exposure in school can help them think about what's possible."

To learn more about Accelerating Innovations to Market (AIM) and how to advance your ideas from lab to market at UC San Diego, visit https://innovation.ucsd.edu/aim. Apply by September 30, 2021! For questions, please contact aimgrant@ucsd.edu.

CHEMICAL EXPLOSION DAMAGES FUME HOODS AND BREAKS BUILDING WINDOW

BY LANCE SCOTT AND DOUGLAS HARVEY



WHAT HAPPENED?

In June of this year, a UC San Diego (UCSD) researcher had synthesized approximately 50gms of tosyl azide resulting in a major incident. Tosyl azide is an organic azide that has an explosion hazard associated with its use. The tosyl azide was in a round bottom flask and put on a Schlenk line (within a chemical fume hood) to dry the material before transferring into a glovebox. The flask was under vacuum and subsequently put on a heating

mantle which was set to slightly below the "low" setting. The researcher left the fume hood and went to an adjacent room to work. While working in the adjacent room, the researcher heard a loud explosion in the room where the tosyl azide experiment was being heated. When the researcher went into the room where the explosion occurred, there was a lot of smoke and fumes, but no observable fire.

The researcher stepped outside the laboratory and encountered two researchers from neighboring laboratories that had come out to see what had happened. They collectively shut all the laboratory doors for about 15 minutes to allow the fumes to clear the laboratory during which time they tried calling senior laboratory members, called a UCSD Environmental Health and Safety (EH&S) employees desk phone and left a voice message. Approximately 30 minutes after the incident occurred, they re-entered the laboratory to observe the extent of the damage. They turned off the vacuum pump and unplugged all electronics in the hood, activated the emergency exhaust button on the fume hoods and began cleaning up. During the cleanup, it was observed that the fume hood sash was severely damaged and nearly everything within the fume hood had been destroyed. The fume hood on the other side of the aisle as well as one of the buildings large exterior windows had a small hole blasted through it from the force of the explosion.

The incident occurred during evening hours on a weekend. The Principal Investigator (PI) was not notified of the incident until the following day. Police (9-1-1) were not notified immediately and as a result, an emergency response was not activated. Since the contact to EH&S was to an employee phone, EH&S did not receive the notification until two days after the incident.

WHAT WAS THE CAUSE?

The procedure called for drying by chemical means, but the material was heated by a heating block causing the explosion.

LESSONS LEARNED

- Incomplete hazard assessment, did not properly consider potential hazards of changing a single variable (heating of tosyl azide when the procedure calls for chemically drying).
- Deviating from procedure without PI approval. If proper channels of review had been followed the PI would have instructed researcher to never heat tosyl azide during this drying process.
- Peer-to-peer advice must follow the Mentor Method as described in the hazard control plan. This ensures that published procedures do not get overlooked or inadvertently modified through time.
- Keeping fume hood sashes closed helps ensure worker safety and can limit collateral damage to people, equipment, and the facility.

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CHEMICAL EXPLOSION DAMAGES FUME HOODS AND BREAKS BUILDING WINDOW

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- Using a blast shield is prudent even when the reaction is inside the fume hood. A blast shield adds another layer of protection.
- Follow campus emergency reporting procedures on the Emergency Response guide posted in all laboratories. All emergency notifications should go through the campus 9-1-1 system. After hours and on weekends, EH&S notifications must go to UC San Diego Campus Police Department (9-1-1). During an emergency, do not leave voice messages or text messages for EH&S as it can greatly delay the response.
- Post-incident reviews by EH&S and the campus Fire Marshal must take place before the scene is cleaned up.
- Emergency notification process was not followed limiting the ability for EH&S to report an explosion to local and state agencies.

RESEARCH SAFETY REMINDERS:

As we return to campus this fall and ramp up research, EH&S would like to remind you to review your facility, chemical inventories, check hazardous material storage locations, check equipment for leaks and safe operations, dispose of any hazardous waste, check tubing and other water connections that could cause a flood, and verify your Personal Protective Equipment (PPE) supplies. If there are any safety concerns, please contact EH&S immediately at (858) 534-3660. If facility repairs are needed, submit work orders with Facilities Maintenance Services.

As your space is reviewed, please take time to perform laboratory cleaning, decluttering and reorganization. Evaluate all items in the laboratory and if it does not have a purpose, arrange to have it disposed through the appropriate channels. Laboratories can generate waste tags for hazardous waste and universal waste and request pick-ups through the My Research Safety Online Waste Tag Program. If there is laboratory equipment to dispose of, the equipment must be Green Tagged before sending it to Surplus Sales.

Hazardous Materials: Review storage and use locations to verify the condition of all reagents and hazardous material containers. You can check your physical inventory against the labs inventory logged in the My Research Safety – My EH&S Profile. If you discover containers that have dried out, crystalized, cracked lids, developed crystals around the lid, or have developed penetrating rust please contact EH&S. If you have any concerns regarding the handling of these or any other items, please reach out to EH&S for assistance at ehsrap@ucsd.edu.

As you open shipping containers with hazardous materials inside, please do so carefully. If the material is highly toxic or has other high hazard properties, the shipping container should be opened in a fume hood. Most containers arrive on campus without damage but we have had some that have leaked or rupture during shipment. As the hazards of the material increase, additional safety measures must be implemented.

Hazard Control Plans: Review and update the lab specific sections in your hazard control plans. Follow safety procedures outlined in your laboratory's Hazard Control Plans (HCP's). HCPs inform the staff of the hazards of the material, required training, PPE, PI authorizations for use and scale up requirements. HCPs also remind staff that any changes in procedures must be reviewed by the PI or other designated senior laboratory staff.

Get "Refreshed": Review the online Lab Safety Manual and take refresher trainings. As the campus ramps up laboratory activities, research staff should refresh on both technical and laboratory safety procedures to ensure a safe transition back to research. Training reminders are now in place for online safety training courses.

PPE: Review your Laboratory Hazard Assessment Tool (LHAT) on My Research Safety to ensure all required PPE is present and in good order for all laboratory staff and students. For new laboratory coats, safety glasses and laboratory coat laundry, please contact our PPE office. Laboratory coat fitting is now done by appointment only.

Required Reporting: It is critical for employees to immediately report all fires, explosions, significant injuries, spills and exposures to EH&S. The best way to contact EH&S for any of these types of events is by calling 9-1-1 on campus or (858) 534-HELP (4357) from off campus. Emails or voice messages are not an appropriate communication method to report serious incidents. UCSD Police Department will reach out to EH&S to initiate appropriate emergency response actions. There are federal, state, and local reporting requirements for fires, explosions, large spills, and injuries so timely notification of EH&S is critical.

Remember, it is all employees' responsibility to immediately report imminent hazards, threats, fires, explosions, injuries or emergencies to the following:

- UC San Diego Police: 9-1-1 from campus phones; other phones (858) 534-4357 (534-HELP)
- Your supervisor or department head, and Department Safety Officer
- EH&S: (858) 534-3660, weekdays, 8 a.m. – 4:30 p.m.; 9-1-1 after hours and on weekends

If you are not sure how to report, please call Campus Police 9-1-1 or (858) 534-HELP. For additional information, please see:

- Campus Emergencies https://blink.ucsd.edu/safety/emergencies/campuswide/index.html
- Emergency Guide https://blink.ucsd.edu/safety/emergencies/preparedness/guide.html

FDA Notices of Noncompliance Continue to be Issued

BY MONIQUE TEIXEIRA

The Food and Drug Administration (FDA) has issued their first Notice of Noncompliance (Notice) to an individual Responsible Party (RP) of a clinical trial for failing to submit results as required by federal law. This marks the first time the FDA has issued a Notice to an individual investigator as opposed to a drug manufacturer. Potential sanctions include civil monetary penalties of up to $12,103 per a day the clinical trial is in noncompliance and potential loss of Health and Human Service (HHS) funding to the study and/or the institution.

The most recent Notice was issued to a Los Angeles surgeon who failed to submit results for his clinical trial. The clinical trial was completed in June 2018 and federal law required the results to be posted by July 2019. The FDA issued the surgeon a Pre-Notice of Noncompliance in July 2020 about the failure to post results and the surgeon responded in November 2020 that he was very busy and short-staffed. As a result, the FDA issued a Notice of Noncompliance on August 31, 2021, with the opportunity to remedy the noncompliance by submitting the required clinical trial results information within 30 calendar days from the date the Notice was received. The Notice indicated that if the results are not submitted within 30 calendar days, the FDA may seek civil monetary penalties. The surgeon promptly posted the results on ClinicalTrials.gov.

At UC San Diego, the individual Principal Investigator serves as the RP and is responsible to update the ClinicalTrials.gov record. The FDA Pre-Notices and Noncompliance Notices are sent the RP indicated on the ClinicalTrials.gov record. If you receive an FDA Pre-Notice of Noncompliance or Notice of Noncompliance letter, please contact the Research Compliance Office and Integrity (RCI) Office as soon as possible at ctgov@ucsd.edu or (858) 822-4939. The RCI Office also routinely follows up with a RP if it is discovered that the RP's clinical trial is not in compliance with the ClinicalTrials.gov reporting requirements.

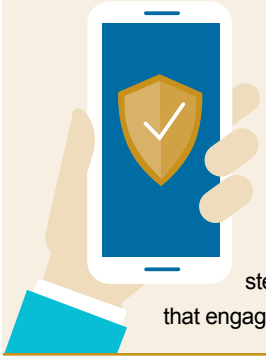
For additional information, inclusive of videos, factsheets and Frequently Asked Questions (FAQs), please visit the RCI ClinicalTrials.gov webpage. For assistance, please contact the Research Compliance and Integrity Office at (858) 822-4939, ctgov@ucsd.edu.

CYBERSECURITY CERTIFICATION PROGRAM FOR RESEARCH

BY MICHAEL CORN

In response to the continuing onslaught of major cybersecurity breaches within the commercial and governmental sectors, the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DoD), Department of Energy (DoE), and other funding agencies are reexamining the cybersecurity obligations they place on funding recipients. The urgency for this was underscored by the Biden administration's recent executive order requiring the entire Federal Government to "modernize national cyber defenses." While the DoD, DoE, and Homeland Security may be pursuing this most aggressively, Universities will continue to see new requirements for cybersecurity practices in Federal solicitations and new scrutiny leveled at research programs that receive Federal funding.

In response, UC San Diego has created a novel self-certification program for researchers that can help researchers gain a competitive edge when putting together grant proposals. The Cybersecurity Certification for Research (CCR) program provides researchers with a few highly effective, yet simple steps that will both provide enhanced system and data security as well as better enable researchers to benefit from the campus investment in cybersecurity. Upon completion of the program, the researcher will receive a certification letter suitable for inclusion with contract or grant proposals.



For researchers without large technical infrastructure, the CCR program can be completed in under 30 minutes. Researchers with larger laboratories and complex technical infrastructure can delegate the technical steps to any staff member. Further, laboratories that engage in high value vaccine or DoD sponsored research will have their submissions reviewed by a team of Information Technology (IT) and security professionals that will provide additional recommendations and guidance to strengthen and enhance their laboratory security.

Recently, the CCR program process has been refined and will:

1. Collect contact information so we can reach you when we detect an attack on your research
2. Collect a small amount of information about your lab and the nature of your research, to help us identify environments at higher risk so we can offer appropriate support
3. Ask you to install two small pieces of software on equipment capable of supporting them: a contemporary anti-malware program, and software that identifies vulnerabilities in the operating system. These act both to protect you and to detect the spread of malware should it successfully attack an unprotected system. These are provided at no-cost to researchers and research staff.

To date nearly $200 million of sponsored research is being protected by the CCR. If you have questions about how you can become certified, or need any assistance in deploying software and understanding your own risk profile, please contact the CCR program by emailing ccr-support@ucsd.edu.

Please also note that there will be a CCR training session on October 20, 2021, from 11:00 a.m. to 12:30 p.m. Michael Corn, Chief Information Security Officer, and his team will walk through the certification process and attendees will be prepared to quickly and easily improve their overall cyber-resilience. Register via the UC Learning Link. Please send any workshop questions to rci@ucsd.edu.

NATIONAL HISPANIC HERITAGE MONTH

BY MADELEINE PALEY

Each year, Americans observe National Hispanic Heritage Month from September 15 to October 15. This includes celebrating histories, cultures and contributions of American citizens whose ancestors came from Spain, Mexico, the Caribbean and Central and South America. This observation started in 1968 as Hispanic Heritage Week and was expanded in 1988 to cover a month-long period. The beginning date of September 15 is the anniversary of independence for the Latin American countries of Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua. Other countries, such as Mexico and Chile, also celebrate their independence days in mid-September (September 16 and September 18, respectively). Columbus Day or Día de la Raza also falls within National Hispanic Heritage month, on October 12.

While National Hispanic Heritage Month is a time to celebrate, it is also an opportunity to support future generations through investments in educational programs and resources. The National Hispanic Heritage Month webpage outlines kids and family events, performances, panels and content available via streaming. To learn more about opportunities to support local Latinx-owned business in San Diego county, please see the San Diego Tourism Authority Blog, Walk the Block blog, and the San Diego County Hispanic Chamber of Commerce.

At UC San Diego, the Latinx Leadership Program empowers students with leadership skills and exposure to real life entrepreneurial experiences. The program is open to all Latinx students with priority given to trans, nonbinary and womxn-identifying students who will receive leadership training, coaches, and assistance with summer internship opportunities. The program is run by the Office of Innovation and Commercialization through The Basement.

UC San Diego is making progress toward becoming a Hispanic-Serving Institution (HSI). With nearly 22% full-time Latinx undergraduate student enrollment as of Fall 2020, UCSD is now considered an Emerging HSI. The university's goal is at least 25% full-time Latinx undergraduate enrollment, making the university eligible for HSI designation by the U.S. Department of Education. Throughout this month and all year, it is important that UC San Diego reflects on the importance of Latinx and Hispanic faculty, students, staff and researchers.

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

TECHNOLOGY CONTROL PLAN: WHAT IS IT AND WHY IS IT NECESSARY?

BY MICHAEL M. MILLER

A "Technology Control Plan" (TCP) is an agreement between UC San Diego and its faculty, staff, and students describing minimum security procedures and requirements to manage or prevent access to export-controlled items, materials, equipment, technologies, information, technical data or know-how. Adherence to TCP procedures reduces risk and prevents the violation of export control laws and regulations or sanctions. A TCP is often viewed as a "roadmap" of how UC San Diego controls technology specific to the International Traffic in Arms Regulations (ITAR), Export Administration Regulations (EAR), US Treasury, Office of Foreign Assets Control sanctions and the National Industrial Security Program Operating Manual (NISPOM) Rule to ensure both the Principal Investigator (PI), team members, and other "custodians" of controlled resources understand their obligations and responsibilities. A TCP is not a replacement of UC San Diego policy or existing security mechanisms, but an enhancement to existing practices.

The UC San Diego Export Control Office (ECO) reviews activities to determine when a TCP is necessary. There are several types of TCP's, based upon what is being controlled (physical items, technical information, processes, methods, etc.):

- Facility (or Lab) specific TCP includes protocols for complex lab environments, often with multiple, simultaneous export-controlled projects and/or multiple restricted items in-use or in inventory, and/or complex foreign-person visitors or collaborations. The TCP identifies facility procedures and requirements to generate, maintain, access or transfer technical data to authorized persons, while ensuring foreign persons do not inadvertently gain access. This TCP is intended to manage an entire lab, research group or facility and is preferred for environments where university equipment is used by multiple research teams on both fundamental research or restricted activities.
- Project-Specific TCP includes protocols for a single activity or project of limited duration. The TCP identifies facility procedures and requirements to generate, maintain, access or transfer technical data to authorized persons within the UC San Diego environment, while ensuring foreign persons and other unauthorized persons do not inadvertently gain access. The TCP identifies allowable parameters or thresholds and conditions that require the ECO input, such as international use of export-controlled items or equipment. This TCP is intended to manage a specific project, process or activity that can be easily compartmentalized and does not necessarily require research performance.
- Custody, Access or "Use" Agreement includes protocols for a single department, unit, group, PI, or lab to maintain custody of a restricted item, material, equipment, technology, technical data or information. The TCP identifies the restricted commodity, specifies citizenship allowable for access, and situations when ECO guidance is required. This TCP is primarily used for commodities subject to an NDA, or export-controlled commodities purchased on the open market, such as defense articles or dual-use commodities.
- Foreign Person Employee TCP is necessary when UC San Diego is required to obtain a US Government-issued license for a foreign person employee access authorization or technical assistance. Access authorization must be obtained for all foreign persons who require access to ITAR-controlled defense articles and/or technical data in the performance of their job responsibilities. This TCP describes internal controls to prevent unauthorized access, including the allowable scope of the activity, description of export-controlled technology, allowable interactions and collaborations, limitations on direct interactions with other countries, limitations on residence outside of the United States, and other required permissions for the transfer of technical data. The TCP serves as the official UC

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TECHNOLOGY CONTROL PLAN

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San Diego certification that the technical data is within scope of the employment authorization and describes the authorized role and responsibility, and conditions of the US Government approval.

- ► Visitor Control Plan. This TCP is for foreign visitors from restricted entities or sanctioned countries. This agreement between the University, PI, and visiting scholar outlines the roles and responsibilities for hosting a foreign visitor with an affiliation of a Part 744 entity, to include Denied Persons, Entity and Unverified Lists, and entities that are on the China Defense Universities Tracker. Foreign visitors are only authorized to participate in fundamental research. They are prohibited from accessing proprietary, or confidential information, data, equipment, or technology. In some cases, the EAR prohibits transfer of all technologies to foreign persons with an affiliation with certain denied entities, including EAR99 technologies. This Visitor Control Plan helps to ensure that there are no violations of the export control regulations.

TCP security procedures are intended to be customized depending upon variables of the lab, project or other commitments. All TCP's include the following:

- Statement of Institutional Commitment
- Commodity Jurisdiction and Classification of Technologies
- Physical Security
- Information Security
- Personnel Security
- Role and Responsibilities
- Project Completion Requirements
- Annual Assessment and/or Monitoring Criteria

To learn more about determining if your visitor has an affiliation with an entity of concern, please visit the UC San Diego Export Control Office Restricted Party Screening webpage.

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

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 contract with UC San Diego to perform 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 Public Health Services (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 REQUIREMENTS

- **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.

RESEARCH COMPLIANCE CORNER:

WORD TO THE WISE

CLINICAL RESEARCHERS SENTENCED TO FALSIFYING TRIAL DATA

A federal judge sentenced Eduardo Navarro, a nurse practitioner and sub-investigator. and Nayade Varona, an assistant study coordinator, at Tellus Clinical Research, a clinical research site, in connection with their participation in falsifying data in two clinical trials for irritable bowel syndrome. Navarro was sentenced to 46 months in prison and Varona was sentenced to 30 months in prison. They were also ordered to pay $2,134,503 in restitution. They admitted "… they agreed with one another and others to falsify data in medical records…" and fabricated medical records to make it seem like there were subjects participating in the trials when they were not.

"The falsification of clinical trial data puts the health and safety of the public at risk," said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division. "The Justice Department will continue to work with its partners at the Food and Drug Administration (FDA) to investigate and prosecute anyone who engages in this conduct."

For additional information, please read the Department of Justice announcement.

FIVE CHARGED IN VIOLATION OF ARMS EXPORT CONTROL ACT

A federal grand jury returned an indictment charging five defendants of conspiring to unlawfully export defense articles to Russia. If convicted, each face up to 20 years in prison. The charge alleges that in violation of the Arms Export Control Act, Elena Shifrin, Vladimir Pridacha, Boris Polosin, Vladimir Gohman, and Igor Panchernikov, exported thermal imaging riflescopes and night-vision goggles to Russia without a license.

According to the court documents, in a multiyear scheme, they purchased dozens of thermal imaging devices, most of which cost between $5,000 and $10,000 and are controlled by the International Traffic in Arms Regulations, from sellers across the United States using aliases and falsely assuring the sellers that they would not export the items from the United States. They did not obtain the required export licenses to export defense articles to Russia and they falsely stated on export declaration that the contents were non-export-controlled items. The items were exported using aliases and false addresses to co-conspirators in Russia.

For additional information, please read the Department of Justice announcement.

FORMER PROFESSOR PLEADS INNOCENT TO INDICTMENT ALLEGING CHINA TIES

A former University of Arkansas Professor, Simon Ang, pleaded innocent to a total of 55 counts of wire fraud linked to his ties to China and the use of University research facilities. According to the court document, the wire fraud counts relate to payments made to a limited liability company set up by the professor as well as the University salary payments made to the professor in which the professor "instructed researchers that he supervised at the University of Arkansas to conduct research and work on behalf of the companies he was affiliated with China."

The indictment also states that the professor received a one-time Thousand Talent Program grant and that he received money from the Chinese government that was deposited into Chinese bank accounts controlled by him, which he failed to disclose to the University or U.S. funding agencies. The Federal Bureau of Investigations (FBI) stated that the professor would have been made ineligible for federal

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RESEARCH COMPLIANCE CORNER:

WORD TO THE WISE

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research grants he pursued due to his "close ties" to the Chinese government and Chinese companies. The University suspended the professor after his arrest and subsequently fired him.

For additional information, please read the news article.

RESEARCHER AT UNIVERSITY ARRESTED FOR WIRE FRAUD AND MAKING FALSE STATEMENTS ABOUT AFFILIATION WITH A CHINESE UNIVERSITY HAS BEEN ACQUITTED

Anming Hu, an Associate Professor in the Department of Mechanical, Aerospace and Biomedical Engineering at the University of Tennessee, Knoxville (UTK) was arrested in February 2021 on a federal indictment and charged with three counts of wire fraud and three counts of making false statements. The indictment alleged that beginning in 2016, Hu engaged in a scheme to defraud the National Aeronautics and Space Administration (NASA) by concealing his affiliation with Beijing University of Technology (BJUT), a university in China. Federal law prohibits NASA from using appropriated funds on projects in collaboration with China or Chinese universities. As alleged in the indictment, Hu's false representations and omissions to UTK about his affiliation with BJUT caused UTK to falsely certify to NASA that UTK was in compliance with this federal law. Hu's trial began in June 2021 and ended after jurors couldn't come to a unanimous decision on counts of wire fraud and making false statements, leading the judge to declare a mistrial. He potentially faced up to 20 years in federal prison and a fine up to $250,000 on each of the wire fraud counts, and up to five years in prison on each of the false statement counts. Hu however was acquitted with the U.S. District Judge writing, "the government has failed to provide sufficient evidence from which any rational jury could find, beyond a reasonable doubt, that defendant had specific intent to defraud NASA by hiding his affiliation with BJUT from UTK."

For additional information, please read the Department of Justice announcement.

SENIOR NASA SCIENTIST SENTENCED TO PRISON FOR MAKING FALSE STATEMENTS RELATED TO CHINESE THOUSAND TALENTS PROGRAM PARTICIPATION AND PROFESSORSHIP

Meyya Meyyappan, a senior National Aeronautics and Space Administration (NASA) scientist, was sentenced to 30 days in prison and a $100,000 fine for making false statements to the Federal Bureau of Investigation (FBI), NASA's Office of Inspector General (NASA OIG), and the United States Attorney's Office (USAO). In his position at NASA, Meyyappan was subject to certain statutory, regulatory, and agency restrictions and reporting requirements regarding, among other things, outside employment, travel, and compensation. Meyyappan was interviewed by the FBI, NASA OIG, and the USAO, and Meyyappan falsely stated, among other things, that he was not a member of the Thousand Talents Program and that he did not hold a professorship at a Chinese university while in fact Meyyappan was a member of the Thousand Talents Program and held a professorship at a Chinese university, funded by the Chinese government.

NASA scientist was sentenced to 30 days in prison and a $100,000 fine

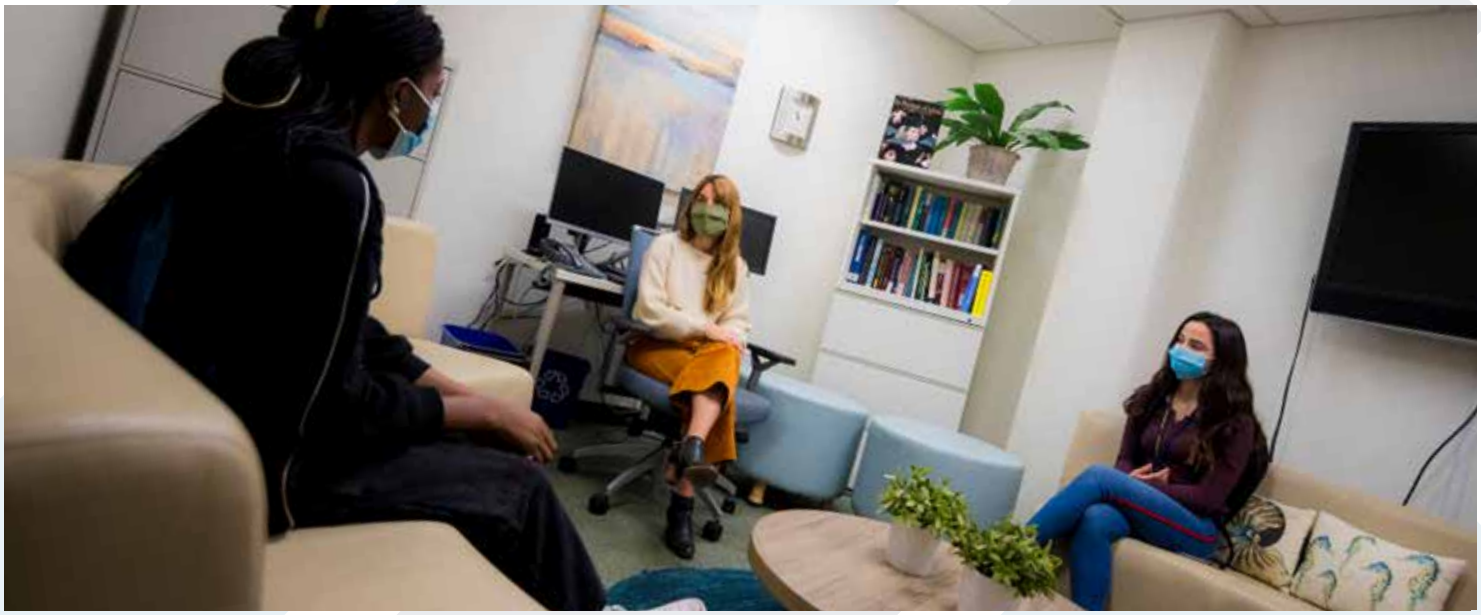
For additional information, please read the Department of Justice announcement.

VAN ANDEL RESEARCH INSTITUTE REACHES SECOND SETTLEMENT TO PAY $6.6 MILLION TOTAL IN FINES IN VIOLATION OF THE FALSE CLAIMS ACT

The Van Andel Research Institute (VARI) reached a second settlement with the Department of Justice (DOJ) in response to allegations of violations of the False Claims Act. The recent allegations center around the failure of VARI to disclose foreign support for two of their federally funded Principal Investigators (PIs). The first settlement was reached in December of 2019, in which VARI paid $5.5 million in response to similar allegations. VARI was accused of allegedly not disclosing foreign collaboration efforts between a VARI investigator, nondisclosure of transfer of biological research samples from a foreign entity, and nondisclosure of an invitation that a VARI faculty received to join a foreign talent program.

The NIH requires all grant recipients to report and obtain approval for all foreign components. This includes any support regardless of financial value. As seen in the case of VARI, institutions are held responsible for the investigation and reporting of potential violations of the false claims act and potential risks of foreign involvement.

For additional information, please read the Department of Justice announcement.



WHY IS IT IMPORTANT TO ACCURATELY DISCLOSE IN KUALI COI FOR PUBLIC HEALTH SERVICES FUNDED RESEARCHERS?

BY JENNIFER J. FORD

The Public Health Service (PHS) regulations on "Objectivity in Research" are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS research activities will be free from bias resulting from a researcher's financial conflict of interest (FCOI). The National Institutes of Health (NIH) requires full transparency in NIH applications and throughout the life of an NIH grant, inclusive of all sources of research support, in the biosketch, other support, and the reporting and management of significant financial conflicts of interest. A researcher's financial relationship with, or interest in, a company must be made and updated within 30 days of acquiring or discovering any new significant financial interest and/or change in an existing significant financial interest.

UC San Diego's Independent Review Committee (IRC) on Conflict of Interest strives to manage conflicts of interest by increasing the visibility and transparency of the conflict of interest review process. The review performed by the IRC is based on the COI disclosure information provided by the researcher in the Kuali COI system. The accurate disclosure of a researcher's financial relationship with, or interest in, a company, is key to the IRC review and will help to assure the public of the integrity of research results.

Human Subject research, including clinical trials, poses special situations that require close scrutiny. UC San Diego is responsible for ensuring that human subjects are fully informed and not placed at additional risk because of financial interests on the part of the researcher(s). If a potential conflict of interest is disclosed, the IRC's strategies for management of conflicts of interest are directed at ensuring integrity, protecting human subjects, and maintaining public trust. Since the informed consent document is considered the principal means by which to advise potential human subjects of risks associated with their participation in a study, when appropriate, a conflict of interest disclosure is included in informed consent. For sponsored research projects with Human Subjects and the project is submitted in Kuali Research system, while there is a section in the Kuali IRB system to disclose conflict of interest information, researchers are required to disclose their conflicts in Kuali COI only. For Researchers participating in the human subject studies, however, does not use the Kuali Research system, the Researcher must disclose their interest(s) in the required for both the IRB in Kuali IRB and to the COI Office in the Kuali COI system.

In December of 2019, ProPublica wrote an article, entitled "Federally Funded Health Researchers disclose at least $188 Million in conflicts of interest. Can you trust their findings?" ProPublica created an NIH database (which was made public for the first time) that indicates researchers have reported more than 8,000 "significant" financial conflicts, potentially influencing their work. Throughout this article, ProPublica cites examples of potentially incomplete conflict of interest (COI) disclosures. The public and the scientific community are served best by researchers and physicians, who are being open and transparent in accurately and timely disclosing their financial interest(s).

For more information on how to disclose conflict of interests in the Kuali COI system or what to disclose, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

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 session has been scheduled:

- **Cybersecurity Certification for Research: Achieving Cyber-Resilience in Your Research Program**
  October 20, 2021 | 11:00 a.m. - 12:30 p.m. | via Zoom (to register, click on this link)

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

Collaborative Institutional Training Institute (CITI) Modules Available for Researchers at UC San Diego

Through the Collaborative Institutional Training Institute (CITI), the University of California San Diego (UCSD) offers a variety of free training modules for all UCSD faculty, students, staff and affiliates. The CITI training modules meet certain training requirements, as well as provide an excellent supplement for research related education and training.

Specific funding agencies, departments and/or sponsors may require certain CITI training courses. Completion certificates can be easily viewed and shared with reviewing entities. Please see below for a list of training courses offered through UCSD's CITI account.

Training Topic	CITI Modules	Applicability
Good Clinical Practices (GCP)	• CITI GCP* (also available in Spanish) • GCP Social and Behavioral Research Best Practices for Clinical Research*	Meets NIH requirements that Investigators and staff involved in the design, conduct, oversight, or management of a NIH funded clinical trial complete GCP training.
Human Subjects Research	• Biomedical Research* • HIPAA Research Privacy • Public Health Research • Research Involving Children • Social and Behavioral Research* • Spanish Language Biomedical Modules	For Principal Investigators and Key personnel conducting human subjects research.
Responsible Conduct of Research (RCR)	• Biomedical RCR • Humanities RCR • Physical Science RCR • RCR for Administrators • RCR for Engineers • Social and Behavioral RCR	For study personnel participating in projects funded by the NIH, NSF, and NIFA. *Note: requirements differ per grant agency, please see UCSD RCR webpage for requirements.*
Lab Animal Research	• Antibody Production in Animals • Aseptic Surgery • IACUC Chairs, Members and Coordinators • IACUC Community Member • Investigators, Staff, and Students • Reducing Pain and Distress in Laboratory Mice and Rats • Working with animals in research settings (specific courses available for varying species)	For Investigators, study staff, scholars and students conducting animal research with varying animal models.
Export Controls	• CITI Export Controls	For researchers, staff, students and scholars at UCSD.
Other	• Clinical Research Coordinator • Clinical Trial Billing Compliance • FDA Inspections: From Site Preparation to Response	For Principal Investigators and Key personnel conducting clinical and FDA regulated research.

* Basic and refresher courses are available

For more information, please visit the Research Compliance and Integrity Office's required and recommended training page.
If you have any questions, please contact the RCI Office at rci@ucsd.edu, or (858) 822-4939.

Q&A

"A good education is a foundation for a better future."

— Elizabeth Warren

Ask the Questions . . .

I have submitted a publication to a journal and the journal has placed an embargo on the publication. Can I wait until after the embargo is lifted to post the study results (that are included in the publication) to ClinicalTrials.gov?

No, ClinicalTrials.gov does not provide extensions or waive "late results" findings for a publication that has been submitted to a journal and has been embargoed. The requirements for submission to ClinicalTrials.gov are separate from those related to publishing. ClinicalTrials.gov requires results to be posted to ClinicalTrials.gov no later than one year after the study's Primary Completion Date, as described in 42 CFR 11.44(a). Fines and penalties for late results may include civil monetary penalties of up to $12,103 per a day the study is in noncompliance, loss of Health and Human Service (HHS) funding to the study and/or UC San Diego and/or public notices of non-compliance.

It is the responsibility of each Responsible Party to check with the journal to determine the journal's individual policy. Please note that the International Committee of Medical Journal Editors, as well as several separate Journal editorials, have made clear that submission of results to ClinicalTrials.gov will not constitute "prior publication" for the purposes of manuscript consideration.

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

What is the Public Health Services (PHS) Financial Conflict of Interest (FCOI) training requirement?

The FCOI regulations include requirements for mandatory and ongoing conflict of interest (COI) education and training. All PHS researchers, as defined by the rule, must complete training prior to beginning work on a PHS funded project with a Notice of Award. Either the UC Learning (SumTotal) system or the UC San Diego COI Office will email the applicable researcher when the PHS FCOI training is required.

For more information regarding PHS FCOI training, please review the COI Office website.

I was told I need a Technology Control Plan (TCP) and/or a Visitor Control Plan (VCP) by the Export Control Office. What does this mean?

A TCP is an agreement with UC San Diego describing the minimum necessary security procedures and requirements to prevent access to export-controlled items, materials, equipment, technologies, information, technical data or know-how. A VCP is a type of TCP describing the minimum necessary security procedures relating to the activities of a foreign person visitor with an identified relationship with an entity of concern (such as denied entities, unverified-list entities, or entities enumerated on the China Defense University tracker) and outlines the security responsibilities of the Principal Investigator (PI) or host and the visiting scholar. A foreign person is defined as any person who is not a US Citizen, permanent resident, refugee or asylee. Dual citizens of the U.S. and another country are not considered foreign persons. A foreign person is assigned a VCP when it has been determined that the visiting scholar has a current or previous relationship with an entity of concern, and intends to participate in research activities. The PI, host, and visiting scholar are responsible to review and comply with the provisions of the VCP, which ensure that the visiting scholar does not have access to export-controlled research, restricted research, technology or proprietary information. The PI or host, visiting scholar, and the Director of Export Control sign the VCP. The VCP is in effect until the end of the visiting scholar's appointment. Foreign persons are prohibited from returning to their home country with items or information subject to export controls. It is important to note that a TCP is not an authorization to export. Any items that are exported out of the country need to be reviewed by the UC San Diego Export Control Office to ensure there are no license requirements.

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

RESEARCH COMPLIANCE AND INTEGRITY

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