UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
Office of Research Affairs

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Newsletter

INSIDE THIS ISSUE

What are the Disclosure Differences Between Conflict of Commitment (COC) and Conflict of Interest (COI)?

BY JENNIFER J. FORD

WHAT IS CONFLICT OF COMMITMENT (COC)?

A conflict of commitment (COC) occurs when a University employee's commitment and time to an outside activity interferes with the employee's performance of University duties. The Academic Personnel Manual (APM) 025 and 671, "Conflict of Commitment and Outside Activities of Faculty Members," clarifies a faculty member's commitment to the University and outlines reporting guidelines for compensated and uncompensated outside professional and non-professional activities. Every faculty member covered by APM 025 and 671, must provide a COC annual disclosure in November for the previous fiscal year (July 1 to June 30). The reporting is required in UC OATS.

WHAT IS CONFLICT OF INTEREST (COI)?

A conflict of interest (COI) refers to situations in which financial or other personal considerations may compromise or have the appearance of compromising an employee's professional judgment in administration, management, teaching, research and other professional activities. If the employee has an interest in a company that is providing funding for the employee's research or other University activity or the research might directly and significantly affect the interest of an employee responsible for the conduct of the research, a COI may exist. For any active or pending research activities, University employees will need to submit an updated disclosure within 30 days of acquiring a new or change in an interest(s) in Kuali COI. There are various COI Disclosure Requirements, for instance, Public Health Service (PHS) funded research (i.e., National Institutes of Health (NIH) and those agencies and sponsors that have adopted the PHS COI regulations) require a COI disclosure of income, stock, stock options and depending on the sponsor start-up companies must be disclosed regardless of their value. The time period for COI disclosure is within the last 12 months of certifying and signing the disclosure in Kuali COI.

WHY DOES PROPER DISCLOSURE FOR COC AND COI MATTER?

At the University, investigators are obligated to disclose their financial conflicts of interests for some federal agencies such as NIH and National Science Foundation (NSF) as well as the state of CA requires investigators to disclose whether or not they have interest(s) with companies and non-profit organizations funding their research and

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other related activities, such as, services or gifts. The federal government has raised concerns about inappropriate foreign influence in research conducted at U.S. research institutions. The NIH, the NSF, the Department of Defense (DoD), and the Department of Energy (DoE) have been issuing notices addressing this issue for the past several years. The three main areas of concern: diversion of intellectual property, sharing of confidential grant applications during peer review and failure by some researchers to disclose substantial resources and interests from other organization, including foreign governments and foreign Universities. The federal government has been reminding the research community about the need to report foreign activities through documentation such as financial conflict of interest, biosketches, other support and conflict of commitment. Please refer to the Federal governments for improper or lack of disclosure for NSF Findings and for NIH Findings. All Federal agencies are providing continuous guidance on disclosure requirements and it is important that all researchers keep abreast of the updates being issued.

Given this heightened scrutiny, it is critical to ensure that faculty COC and COI disclosures are current and consistent. The Research Compliance and Integrity (RCI) Office conducts routine reviews of COC and COI disclosures to determine if the necessary financial interests and outside professional activities have been properly and consistently disclosed in accordance with both the COC and COI requirements. As part of the review process, education regarding the disclosure process is provided. For questions regarding these RCI reviews, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

WHAT ARE THE DIFFERENCES BETWEEN COC AND COI DISCLOSURES?

Conflict of Commitment	or	Conflict of Interest
UNIVERSITY OF CALIFORNIA OATS	System	kuali
Academic Personnel Office	Responsible Office	Conflict of Interest Office
APM 671 / APM 025	Governing Policies	UCSD (PPM 200-13), UCOP (APM 028), PPSM 82, Funding agencies (700-U, PHS/NIH, NSF)
Identify and manage outside professional activities to avoid conflicts of commitment	Purpose	Protect the objectivity of research and comply with policies and regulations
Prior approval to engage in category 1 activities and annual reporting of time and earnings for category 1 and 2 activities	Disclosure Requirements	Protect the objectivity of research and comply with policies and regulations
Category 1: Prior to Engagement Category 2: Annually July 1st to June 30th	Timing	Proposal and/or award stages and dependent on funding

For questions related to conflict of commitment, please contact the UC OATS team at esr-oats@ucsd.edu. If you have COI questions or need additional information, please contact the COI Office at (858) 534-6465 or info-coi@ucsd.edu.

National Institutes of Health (NIH) Notices of Noncompliance for ClinicalTrials.gov

BY MONIQUE M. TEIXEIRA

For grant applications submitted on or after January 18, 2017, the National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting.

This applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions.

Compliance with this policy is a term and condition of the grant award and issues of noncompliance may include sanctions such as public notices of noncompliance and violations, withholding of NIH funding and possible civil monetary penalties.

The NIH has begun issuing noncompliance letters to Responsible Parties. These noncompliance letters indicate the study has not been registered or results have not been published on ClinicalTrials.gov. The letter asks the Responsible Party to provide a reasoning and any supporting information for consideration within 30 days from receipt of the letter.

If any member of the study team receives an NIH letter of noncompliance, please contact the Research Compliance and Integrity Office (RCI) as soon as possible at ctgov@ucsd.edu or (858) 822-4939. RCI will assist you with the NIH response. For additional information please visit the RCI ClinicalTrials.gov webpage.

Learn about the Updates to the University of California Policy on Copyright Ownership

BY SKIP CYNAR

WHY SHOULD I CARE ABOUT COPYRIGHT OWNERSHIP AT THE UNIVERITY OF CALIFORNIA (UC)?

Intellectual property (IP) is a product of our mind. Copyrights, one form of IP, protect the original expressions of our ideas. The framers of the United States (U.S.) Constitution thought this was so important, that they crafted the Patent and Copyright Clause of the Constitution (IP clause; Article I Section 8 | Clause 8) in order to send a clear message that the U.S. welcomed and rewarded innovation: "[The Congress shall have power] To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

The founding fathers understood that in order to instill innovation, our fledgling nation would have to support unparalleled intellectual property rights. Intellectual property rights are fundamental rights, providing for automatic copyright protection for any "original work of authorship" "fixed in any tangible medium of expression" (17 U.S.C. § 102. Section 102 of the U.S. Copyright Act). Copyrightable works include literary works, musical works, dramatic works, choreographic works, pictorial and sculptural works, motion pictures and other audiovisual works, sound recordings, and architectural works, not to mention software code.

Understanding what rights are protected and who owns or can claim an interest in those rights at the UC is the purpose of the UC Office of President's Policy on Copyright Ownership. This policy applies to all employees and students of the University of California and at all University of California locations. The new 2021 policy streamlines the language of the 1992 policy (15% fewer words) and addressed several areas of potential ambiguity. The 2021 copyright policy has been rewritten to:

- Expand and clarify the pool of works eligible for copyright ownership. The policy defines "Scholarly & Aesthetic Works" more broadly and also clarifies that software is a work for which eligible employees may own the copyright. Some common examples of Scholarly & Aesthetic Works include software, scholarly papers, books, short stories, course materials (including lecture notes), musical compositions/ arrangements and recordings, lyrics, architectural drawings, visual works of art, dance choreography, and other artistic creations, among others, regardless of the medium in which those works are fixed or disseminated. It is worth emphasizing that copyright does not protect "mere facts" or ideas.
- Expand the pool of those eligible to own copyrights. The new definition of "Academic Authors" is simplified to "Employees who have a general obligation to create copyrightable scholarly or aesthetic works."
- Set a limitation on the University's ownership to works made with "Significant University Resources." The 1992 policy used a broad definition of "University Resources", that allowed UC to assert copyright ownership when the University's resources contributed to the development of the copyright work. In the 2021 policy there is a new key limitation such that the level of University resources must be "significant" and beyond the support provided to "similarly-situated authors." For the purposes of this definition, the usual support provided by the University and generally available to 'similarly-situated Academic Authors' includes customary administrative support, library facilities, office space, personal computers, access to computers/networks, and salary.
- Clarify copyright ownership by graduate students. The revised policy provides clarity regarding copyright ownership by graduate students of their theses, dissertations, and other copyrightable works.

Wondering whether course materials are covered under this revised policy? Broadly, yes. However, ownership of course materials are specifically covered by a separate system-wide 2003 Policy on Ownership of Course Materials. This 2003 policy, which supplements the Copyright Ownership policy, addresses copyright ownership in greater detail for print, digital, and audio-visual course materials prepared for instructional purposes. For copyright ownership questions specific to course materials (including online course materials), please refer to the 2003 Policy on Ownership of Course Materials.

Wondering whether research data is covered under this new revised copyright ownership policy? Generally, no, meaning in general, research data often will not, by itself, be protected by copyright, as copyright does not protect mere facts or ideas. However, efforts are currently underway to draft a system-wide policy specific to rights and responsibilities in research data. Development of this policy will follow the standard UC policy review process.

If you are curious about the origin of IP rights in the United States, including copyright, please review the "Origins and Scope of the Power."

For specific questions regarding copyrights or other intellectual property questions, please contact UC San Diego's Office of Innovation and Commercialization at innovation@ucsd.edu.

UC Policies related to Copyrights:

2021 Policy on Copyright Ownership (full text of the new 2021 policy)
2003 Policy on Ownership of Course Materials
2005 Policy on Use of Recordings of Course Presentations

DATA SECURITY: How to Manage Visiting Scholars and Students

BY MICHAEL CORN

As UC San Diego's (UCSD) Cybersecurity Certification for Research (CCR) initiative continues to roll out across campus and the health system, several researchers have asked how to address students and visiting scholars working in their laboratories. While not ideal, students and visiting scholars often use personally owned equipment for which the University cannot provide security software. In addition, students and visiting scholars do not always recognize that their use of personal Gmail, Dropbox, or Github accounts lack the protections for research data and intellectual property offered by University services.

In addition, if a student or visiting scholar is using their personal equipment or accounts and then leaves the University, it can be a challenge for the Principal Investigator (PI) to ensure that all of the data has been returned and/or fully deleted. It is important that PIs spend the time to document how they expect students and visiting scholars to handle data and maintain their personal computers when used in the UCSD research environment. Unfortunately, there have been ransomware incidents in UCSD laboratories due to the lax security of personally owned devices.

To assist, the CCR initiative has created an electronic form that informs students and visiting scholars of their obligations and provides the PI with a documented agreement, digitally signed by the student and/or visiting scholar attesting to their agreement to comply with the security obligations of University and the specific practices detailed by the PI. The form is available at labworker.assure.ucsd.edu. Once the form is completed, the person completing the form, the PI listed on the form and the Office of Information Assurance, will receive a copy of the signed form. The completed form should be retained by the PI.

The form acknowledges the following:

- Handling laboratory data in a manner consistent with the wishes of the PI, including destruction or return of any data stored by the student or visiting scholar
- Ensuring that their laptop encrypts its drive so that a lost or stolen laptop does not result in stolen research data
- Installing security patches in a timely fashion and running a licensed antivirus program

It is the PI's obligation to ensure that the students and visiting scholars are told where to store and how to handle research data (for example, that it is only to be stored where you authorize it, and not in personal accounts).

The CCR initiative provides direct support to PIs and their laboratories by establishing simple security practices that support data integrity, reproducibility, and resilience from cyberattacks. For questions or assistance, please contact Mike Corn, Executive Director/CISO, at mcorn@ucsd.edu or the CCR team at ccr-support@ucsd.edu.

SHIPPING BIOLOGICS? AVOID FINES AND PENALTIES BY WORKING WITH THE EXPORT CONTROL OFFICE

BY TAMARA HEMINGWAY

Princeton University's recent settlement agreement with the Commerce Department's Bureau of Industry and Security (BIS) for violations of the Export Administration Regulations (EAR) provides several important lessons for anyone engaged in research involving biological materials.

On February 1, 2021, Princeton University was ordered to pay a civil penalty of $54,000 and submit to BIS the results of two audits, one to be conducted internally and another to be conducted by an independent third-party, to settle charges of 37 instances of exporting an animal pathogen and various recombinants to international locations, including Australia, Belgium, Canada, China, France, Hungary, India, Israel, Japan, Singapore, South Korea, Switzerland, and the U.K., without the required licenses. The charges resulted from a voluntary self-disclosure made by Princeton after it discovered the unlicensed shipments, which occurred between November 2013 and March 2018 and were valued at $27,000 in total.

APPLICABLE REGULATIONS

Potentially dangerous biological products are currently controlled under four Export Control Classification Numbers (ECCN) on the Commerce Control List (CCL) for chemical and biological weapons reasons (CB) due to their potential for weaponization. A license is required to ship these materials to any destination outside of the United States.

ECCN 1C351 controls human and animal pathogens and "toxins," including viruses, such as Ebola virus and Yellow fever virus; bacteria, such as Clostridium botulinum and Francisella tularensis; and toxins, such as Aflatoxins, Cholera toxin, and Shiga toxin.

ECCN 1C354 controls plant pathogens including bacteria, such as Xanthomonas albilinean; fungi, such as Synchytrium endobioticum; and viruses, such as potato spindle tumor viroid.

These controls apply to the whole organism, isolated cultures, and other living material deliberately inoculated with the controlled agent. It's important to recognize that, unlike some of the entries found on the Centers for Disease Control (CDC) and Animal and Plant Health Inspection Service (APHIS) Select Agents lists, even very small quantities and attenuated strains are controlled under the EAR.

ECCN 1C353 controls genetic elements and genetically modified organisms. Broadly speaking, this ECCN applies to any genetically modified organism that contains, or any genetic element that codes for, a gene specific to materials controlled under ECCN 1C351 and 1C354. Genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation. "Genetic elements" include, chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part.

ECCN 1C991 controls vaccines, immunotoxins, medical products, diagnostic and food testing kits, also for chemical and biological weapons reasons, but to more limited destinations. This ECCN is slightly less restrictive and allows the export of medically important products related to the materials in ECCNs 1C351,1C353, and 1C354, as long as the products meet the definitions and comply with the strict requirements of 1C991. Most notable of these requirements is prior Food and Drug Administration (FDA) approval.

For a complete list of controlled items, exceptions, and related definitions, please refer to EAR 15 CFR §§730-774 or contact the UC San Diego Export Control Office at export@ucsd.edu.

VALUE OF VOLUNTARY SELF-DISCLOSURE

"Voluntary self-disclosure is a mitigating factor in determining what administrative sanctions, if any, will be sought by Office of Export Enforcement (OEE)."

According to the Proposed Charging Letter, Princeton faced a maximum civil penalty of up to or the greater of $307,922 per violation or twice the value of the transaction forming the basis of the charge, denial of export privileges, and debarment. Had these violations been determined to be criminal in nature, the responsible parties could have faced penalties as high as $1,000,000 per violation along with a prison sentence up to 20 years.

Instead, Princeton was ordered to pay $54,000, twice the total value of the offending exports. The relative leniency shown to Princeton was likely because the university discovered the violations as part of its regular export control procedures, voluntarily self-disclosed them, and fully cooperated with OEE during the resulting investigation. These actions are important evidence of a culture of compliance supporting a well-designed export control program at Princeton.

IMPORTANCE OF A ROBUST EXPORT CONTROL PROGRAM

With the U.S. Government increasingly turning its attention to universities and research facilities in its effort to stem the loss of valuable U.S. technologies, a robust export control program is particularly critical.

In response to the Princeton settlement, the OEE Special Agent in Charge of the New York Field Office issued the following statement, "This action demonstrates that the Office of Export Enforcement will continue to leverage our unique authorities as enforcers and regulators of our nation's export control laws to investigate possible violations by research institutions and hold them accountable when appropriate." While this statement may be intended to put the export community on notice, BIS is also taking steps to foster an increased understanding of, and compliance with, the complex regulations over which it has oversight. Immediately following the Princeton settlement, BIS released a valuable training video to assist the exporting community with identifying which biological materials are controlled and applying for a license to ship them to international destinations.

Export control regulations are an important part of ensuring the national security of the United States and the world. Compliance is a shared responsibility and this includes taking the necessary steps to correct mistakes when they happen. The UCSD Office of Export Control is here to assist you with navigating these challenging regulations. If a license is required, the Office of Export Control will need to apply for the license on your behalf.

If you have any questions or need assistance, please contact the UCSD Export Control Office at export@ucsd.edu.

Principal Investigators Who Have Funding from NASA Must Submit a Certification to OCGA Assuring No Funding Activity with China

BY MARY MANSFIELD

Do you have a current grant, contract, or subaward from the National Aeronautics and Space Administration (NASA)? Are you planning a proposal for an NASA solicitation? If so, please be aware that you are required to review, sign, and submit a Univerity of California Office of the President (UCOP)-specific Certification to the Office of Contracts and Grants (OCGA). The UCOP certification is required due to the "NASA Restrictions on Funding Activity with the Peoples Republic of China (PRC)." This restriction is included in NASA grants and contracts, and it prohibits NASA from funding any joint scientific activity with China.

THE AWARD TERMS AND CERTIFICATIONS FOR CONTRACTS DIFFER FROM THOSE REQUIRED FOR GRANTS AND COOPERATIVE AGREEMENTS

For **NASA contracts,** UC San Diego's (UCSD) obligation is to assure that UCSD does not enter into written contracts or subcontracts with China for the performance of any part of the NASA scope of work. This representation is made as part of the proposal and award certifications. Additionally, per UC policy, the Principal Investigator (PI) should separately certify that they will not enter or cause The Regents to enter into a contract or subcontract with China to perform the scope of work of a NASA-funded contract. This Certification must be collected by OCGA before The Regents can accept a NASA contract.

For **Assistance Awards (Grants and Cooperative Agreements),** NASA requires entities submitting proposals in response to a solicitation to provide an assurance that it "will not participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level or at any subrecipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement." This assurance requirement imposes an award restriction which is broader than the "contracting with China" restriction under NASA contracts and extends to individuals performing part of the NASA-funded Scope of Work who have an affiliation with China or a Chinese-owned company. At the award stage, the PI should complete a questionnaire on their own behalf and on behalf of all other UC participants performing part of the NASA grant scope of work ("Participants") to help determine whether anyone has an affiliation with China that would preclude their participation, whether funded or unfunded or on-campus or remote. If the PI does not know the answers for any Participant, the PI should obtain the necessary information directly from the Participant(s). PIs should consult with OCGA if an affiliation with China is indicated for any project Participant.

NASA has not defined what constitutes an "affiliation." However, the following situations are likely to preclude a person from participating in a NASA-funded scope of work:

- The receipt of substantial financial support from China, other than scholarships.
- Present or committed employment relationships with China.
- Present or committed student status in China.

If no affiliations with China are indicated on the questionnaire described above, the PI should complete a Certification attesting that bilateral participation, collaboration, or coordination with China, whether funded or unfunded, will not be performed as part of their NASA-funded award, and submit this Certification to OCGA.

KEY POINTS RELATED TO THE NASA RESTRICTION:

- Applies to activities described in the scope of work of a NASA award.
- Does not restrict individual involvement based on citizenship or nationality.
- Does not prohibit dissemination of data/results arising from a NASA project.
- Does not disqualify UCSD from using the Fundamental Research Exclusion under the export control regulations.
- Does not apply to "general scientific discussions."
- Does not apply to the purchase of commercial and non-developmental items, including the purchase of IT systems by the University under research awards.

FREQUENTLY ASKED QUESTIONS

NASA has published a series of frequently asked questions (FAQs) to help their internal and external research community better understand the restrictions. The FAQs apply to both NASA contracts and grants. Example questions include:

- What about my graduate student, post-doctoral fellow, or other investigator on my team who is not at a Chinese institution but is a Chinese citizen?
- May I travel to China to attend conferences?
- May I use Chinese data (e.g., from ground stations) to perform scientific research?
- If I conduct NSF funded research in the PRC and/or with scientists affiliated with a PRC institution, am I barred from getting a NASA grant?

Please visit the OCGA NASA page or contact your UCSD Contract Officer to obtain the questionnaire and certifications for completion. If you have questions about whether a particular situation would be prohibited, contact your OCGA Office who will consult the NASA program officer.

For more information contact Mary Mansfield mamansfield@ucsd.edu.

THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE REVIEW OF ANIMAL USE PROTOCOLS

BY THE IACUC OFFICE

The UC San Diego Institutional Animal Care and Use Committee (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, and overseeing training and educational programs. Reviewing animal use protocols is one of the most important responsibilities of the IACUC as the review is meant to assure the implementation of the criteria established in the Public Health Service (PHS) Policy, the Animal Welfare Regulations (AWRs), and the Guide for the Care and Use of Laboratory Animals. In its review of protocols, the IACUC's primary goal is to ensure animal welfare as well as compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

Once protocols are submitted to the IACUC, they are extensively pre-reviewed by Animal Care Program (ACP) veterinarians, IACUC Office analysts and Environment Health & Safety (EH&S) specialists. Questions from pre-reviewers are sent to the Principal Investigator (PI) and alternate contacts in a "Missing Information" email, along with instructions about how to respond and resubmit the protocol for review by the IACUC. This extensive pre-review is meant to help facilitate a more efficient review by the IACUC.

Mechanisms by which protocols may be reviewed are defined by federal regulations and depend on the nature of the protocol or amendment. The IACUC always attempts to review protocols by the most efficient mechanism possible. Please see the protocol review mechanisms below:

➤ **FULL COMMITTEE REVIEW (FCR):** Protocols are reviewed at a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that for proposals reviewed by the full committee, a simple majority vote of the members present is required for approval.

➤ **DESIGNATED MEMBER REVIEW (DMR):** One or more qualified IACUC members are assigned to review a protocol outside of FCR. This may only occur after the entire IACUC has been notified of the protocols eligible for DMR and has been given at least two business days to call for any of the protocols to be reviewed by FCR.

➤ **DESIGNATED MEMBER ADMINISTRATIVE REVIEW (DMA):** Changes to a protocol may be approved administratively if they meet the criteria for an administrative approval.

➤ **VETERINARY VERIFICATION AND CONSULTATION (VVC):** An Amendment to a protocol can be administratively approved in consultation with a veterinarian designated by the Attending Veterinarian, who is authorized by the IACUC to review and verify that the proposed amendment conforms to specific approved IACUC policies or documents.

For details about which types of protocols are eligible for which type of review, please review the IACUC Policy 39 - IACUC Protocol Review Process.

If you have questions or concerns regarding protocol reviews, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069. The IACUC Office staff is here to assist you.

Monitoring, Audits, and Inspections of Clinical Research

BY DIANA D. KIM

Clinical research is subject to monitoring reviews, audits, and inspections by internal or external entities to ensure the protection of human research subjects and data integrity.

Monitoring is a continuous process of overseeing the progress of a study that may be conducted by study monitors, sponsors, or contract research organizations (CRO). The goal of monitoring is to make sure that the study is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOP), Good Clinical Practices (GCP), institutional policies, and applicable regulatory requirements.

Similar to the scope of a monitoring review, an audit is a systematic and independent examination of study-related activities and documents to assess whether the study-related activities were conducted and the data were recorded, analyzed, and reported accurately in accordance with the protocol, SOP, and GCP. An audit assesses study compliance at a given moment in time and may be conducted by internal entities such as one of the UC San Diego's institutional offices or by external entities such as sponsors and CROs.

An inspection is an official regulatory audit of the study related documents, facilities, records, and other resources by the regulatory authorities. Inspections for both routine oversight activities and specific for-cause activities assess whether the investigator and/or the sponsor are conducting the study according to applicable statutory and regulatory requirements. The Food and Drug Administration (FDA) Bioresearch Monitoring Program (BIMO) is one of the regulatory agencies and it inspects investigators, sites, IRBs, sponsors, CROs, and nonclinical labs. FDA warning letters may be issued to a responsible individual such as the Principal Investigator about the violations of regulatory significance that the FDA has documented during its inspections.

Monitoring is a continuous process of overseeing the progress of a study that may be conducted by study monitors, sponsors, or contract research organizations (CRO).

For sample self-assessment tools, please see the Office of Compliance and Privacy's Intranet site (you will need to login with your AD credentials). For more information on what to expect during an inspection, please refer to the Research Compliance and Integrity (RCI) Office factsheet on Ten Rules for Researchers to Survive an Inspection.

For additional information or assistance, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

EDUCATION

NEW Collaborative Institutional Training Initiative (CITI) Training "FDA Inspections: From Site Preparation to Response"

UC San Diego offers a variety of training opportunities at no cost for the research community through the Collaborative Institutional Training Institute (CITI) program. CITI is comprised of various learning modules. CITI is designed to educate and provide a resource to researchers and staff. A new training module has been added available for all UCSD affiliates, "FDA Inspections: From Site Preparation to Response." This course will identify what is subject to Food and Drug Administration (FDA) inspection and what is off limits, define the regulations and guidelines applicable to the FDA clinical investigator inspection process and discuss the clinical site team's roles and responsibilities during an inspection.

Please see the UC San Diego RCI Research Compliance Training page for links to the required and recommended training for researchers and research staff.

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

RESEARCH COMPLIANCE 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:

- **Export Control 101: Basics You Need**
  April 17, 2021
  11:00 a.m. - 12:30 p.m., via Zoom (to register, click on this link)

- **Study Coordinator 101**
  May 19, 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.

Q&A

"An investment in knowledge pays the best interest."

— Benjamin Franklin

Ask the Questions . . .

What should I do if I discover that something was shipped without an export control review?

Please contact the UC San Diego Export Control Office at export@ucsd.edu immediately to provide complete details of the transaction for further review and analysis.

Do I need to disclose the following as a potential conflict of interest?

- **An unpaid research collaboration with a foreign university.** When you are not compensated and do not receive anything of monetary value (besides your UC San Diego salary) no conflict of interest disclosure is required.
- **A university will pay me directly to participate on a research project, as a consultant, peer review journal, hiring committee, or advisory board.** If you are conducting or proposing PHS-funded research (i.e., NIH and those that have adopted the PHS FCOI regulations) and the payments are from a foreign university, foreign organization or foreign government total $5,000 or more in any 12 month period, you must disclose this on your annual PHS financial disclosure in Kuali COI.

If there are any questions, please contact the Conflict of Interest Office at info-coi@ucsd.edu.

What biological materials are export restricted?

The UC San Diego Export Control Office maintains a handout on export restricted biologicals, and the last two pages contain an alphabetized list for your easy reference.

If there are any questions, please contact the Export Control Office at export@ucsd.edu.

My department's Academic Personnel contact indicated that if a faculty member's APM 025/671 category I pre-approval activity has implications for conflict of interest, research being conducted outside of University or foreign activities, the request needs to be reviewed by the Research Compliance and Integrity Office (RCI). What does the RCI Category I review entail?

When RCI receives a request for a faculty member's Category I pre-approval activity from the department, RCI evaluates the conflict of interest, research outside of the University, foreign entity, and intellectual property implications as well as the risk to the University. As necessary, RCI makes referrals to the Conflict of Interest Office, Export Control Office, and/or Office of Innovation and Commercialization. RCI will enter their review information in the "Notes" section of Outside Activity Tracking System (OATS). For questions regarding Category I requests, please contact the academic personnel staff in your department or Academic Personnel Services.

For more information on the RCI review, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

What is required if I want to use funding administered by UC San Diego to perform research involving live vertebrate animals at a foreign institution?

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. Institutions outside the United States (U.S.) that receive PHS funds directly through a grant or contract award are to use the Animal Welfare Assurance for Foreign Institutions (Foreign Assurance). The Foreign Assurance also applies to institutions outside the U.S. that receive PHS funds indirectly (as a performance site through a primary institution). The UCSD Institutional Animal Care and Use Committee (IACUC) also requires that the Principal Investigator provide the IACUC Office with a copy of the foreign IACUC (or IACUC-equivalent) approval letter in original language and English translation. Finally, the foreign institution must be AAALAC-accredited. If not AAALAC-accredited, the physical ownership of animals must be ceded to the foreign institution.

If you need assistance or additional information, please contact the UC San Diego IACUC at iacuc@ucsd.edu or (858) 534-6069.

I understand I am required to publish my clinical trial results on ClinicalTrials.gov within one year of the primary completion date of my study, but how long does it generally take a study team to enter/upload the results?

Each study has various amounts of results data that must be analyzed and published depending on the number of primary and secondary outcome measures of the study, but the initial entry of summary results information into Protocol Registration and Results System (PRS) can take as long as 40 hours. It is important that you plan accordingly.

For questions or assistance related to ClinicalTrials.gov, please contact the Research Compliance and Integrity (RCI) office at (858) 822-4939 or ctgov@ucsd.edu.

RESEARCH COMPLIANCE AND INTEGRITY

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