UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
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Newsletter

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Disclosure Requirements of Foreign Affiliations, Collaborations and Support in Federally-Funded Research

BY STELLA SUNG AND ERIKA WILSON

INSIDE THIS ISSUE

The Federal Government has raised concerns about inappropriate foreign influence in research conducted at U.S. research institutions. The National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DoD), and the Department of Energy (DoE) have recently issued notices addressing this issue. The most notable is the letter dated August 20, 2018, from the Director of the NIH, Dr. Francis Collins, identifying three main areas of concern:

1. Diversion of intellectual property to foreign entities;
2. Sharing of confidential information by NIH peer reviewers with foreign entities; and
3. Failure by some researchers to disclose substantial resources from other organizations, including foreign entities.

As a result, Federal funding agencies have increased their efforts in ensuring compliance with reporting requirements. It is important that faculty and researchers maintain their diligence in disclosing all forms of research support, affiliations, and foreign components as required by Federal regulations.

DISCLOSURE REQUIREMENTS

Biographical Sketch: Both the NIH and NSF Biographical Sketches require that positions and appointments, including those at foreign institutions, be disclosed. List all awards, including foreign awards, in Section D of the NIH Biosketch.

Other Support: NIH requires that researchers disclose all sources of support related to all of their research endeavors. This includes resources (whether or not they have a monetary value) and/or financial support from third parties, including foreign entities. Some examples include financial support for laboratory personnel and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). Please see NIH Notice NOT-OD-19-114. NSF requires senior project personnel on proposals to disclose all sources of support, both foreign and domestic, in the Current and Pending Support section of proposal application.

NIH Applications: Applicants are required to disclose whether a project involves a foreign component in the NIH proposal on the Other Project Information Form. A Foreign Justification is needed for those projects involving activities outside of the U.S. or partnerships with international collaborators and is required to be uploaded as an attachment to the proposal application. Any use of foreign facilities or work done at a foreign site must be reported under the Facilities & Other Resources section of the Other Project Information Form. All project performance sites, including foreign sites, must be listed in the Project/ Performance Site Locations section of the NIH application.

NIH Progress Reports (RPPR): Any changes to biographical sketch or other support must be identified in each annual progress report. Section D requires project participants to be disclosed. If the project participant's primary affiliation is with a foreign organization, provide the name of the organization and country. If a portion of the grant funding is being spent in a foreign country, the dollar amount must be reported in Section E. Any foreign component(s) must be reported in Section G. This includes the name of the foreign organization, country, and description of each foreign component. NIH's definition of Foreign Component can be found in Section 1.2 of the NIH Grants Policy Statement. Please note that adding a new foreign component to the project at the award stage requires NIH prior approval and such request should be routed to the UC San Diego (UCSD) Office of Contract and Grant Administration (OCGA) for coordination.

Conflict of Interest: Researchers must comply with the Conflict of Interest (COI) disclosure requirements as outlined on the UCSD COI Office website. For more information on the COI related requirements, please see page 5.

Conflict of Commitment: The University of California requires all faculty to submit an annual Conflict of Commitment (COC) report indicating whether or not they have engaged in outside activities during the fiscal year. Outside professional activities are separated into three categories: Categories I and II include activities that must be reported and in the case of Category I, must receive prior approval before the faculty member engages in the activity.

Intellectual Property: All employees are required to promptly and fully disclose the conception and/or reduction to practice of potentially patentable inventions to the Office of Innovation and Commercialization (OIC) through the Online Invention Disclosure System.

While this article focuses on NIH and NSF regulations, all Federal agencies are providing continuous guidance on disclosure requirements and it is important that all researchers keep abreast of the updates being issued.

For questions or additional information, please contact Stella Sung at shsung@ucsd.edu or Rachel Cook at racook@ucsd.edu.

Protocol Registration and Results System (PRS) Review Comments on ClinicalTrials.gov

BY MONIQUE TEIXEIRA

There are two major points in the life cycle of a study record where the Protocol Registration and Results System (PRS) reviewers conduct reviews, at registration and results posting. When a Responsible Party "Releases" a study record on ClinicalTrials.gov, a PRS reviewer will examine the study record for errors, deficiencies, and/or inconsistencies and provide comments.

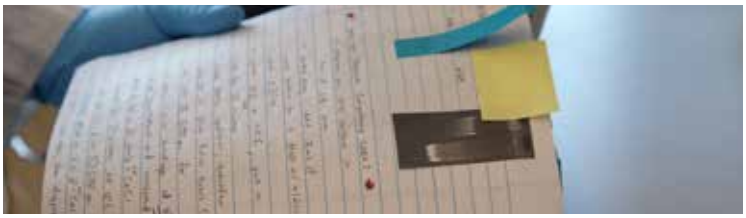
PRS Staff rely on two sets of criteria when reviewing the study record, the ClinicalTrials.gov Protocol Review Criteria for reviewing studies being registered and ClinicalTrials.gov Results Review Criteria for reviewing results postings. It is highly recommended that you read the criteria before registering or entering the results for your study record.

The PRS review for a study registration can take approximately two to five business days, and the review process for study records with results information may take up to 30 days. When PRS staff identify potential issues during review, an email notification is sent to the Record Owner, Responsible Party and the last user to update the study record with instructions for viewing the PRS review comments. To view the PRS reviewer comments, a red flag will appear next to each section and module of the study record that has at least one PRS review comment to be addressed. To read the comments, select the "Review Comments" box in the section or module. To view all PRS review comments ever received on a study record, select the "Review History" link on the Record Summary page. Then, select "Review Comments" for the version of the study record you would like to see.

The PRS review comments must be reviewed and addressed as necessary. Comments are identified as either "Major Comments" or "Advisory Comments." Major Comments must be corrected and addressed, while Advisory Comments should be addressed to improve the clarity of the record, however, are not mandated. For a study record registration, the Responsible Party must ensure "Major Comments" are addressed within 15 calendar days of the date on which PRS Staff sent the notification. For studies with results, the Responsible Party must ensure "Major Comments" are addressed within 25 calendar days of the date on which PRS Staff sent the notification. The "Corrections Expected Date" is indicated in the Record Status box on the Record Summary page.

If you have questions about PRS review comments, you can request assistance from a ClinicalTrials.gov reviewer, via email to Register@ClinicalTrials.gov.

For questions or additional information, please contact the Research Compliance and Integrity Office at ctgov@ucsd.edu, (858) 822-4939 or visit the RCI ClincalTrials.gov information webpage. There will also be an RCI training session on ClinicalTrials.gov on September 26, 2019. Keep an eye out for the registration announcement.



Single IRB: To Rely or Not to Rely…That is the Question

BY ANTHONY MAGIT

Having an Institutional Review Board (IRB) rely upon an independent IRB or an IRB from another institution for multi-site studies is consistent with human research subjects regulations and has been in practice for several years. However, the proliferation of IRB "reliance" agreements is increasing with the growth of commercial IRBs in addition to revisions to National Institutes of Health (NIH) policies and federal regulations for oversight of human subjects research (e.g. The "Common Rule). An IRB reliance agreement involves the reviewing IRB (alternatively referred to as the single IRB, IRB of record or central IRB) and the relying IRB.

Utilizing a single IRB has many perceived advantages, including the elimination of duplicate IRB reviews, reduction in protocol initiation times at relying sites and maintaining uniformity of the research protocol as modifications to protocols are reviewed by one IRB. Concerns that have been raised about centralized IRB review include the loss of local context regarding relying institutions, liability, loss of representation by the relying institution and specific knowledge about investigators and the community associated with relying institutions. Issues related to local context are addressed through reliance agreements and local context documents shared between the reviewing and relying IRBs. Ceding review to a single IRB does not eliminate all responsibilities for the relying IRB. Examples of responsibilities maintained by a relying institution include evaluating conflicts of interest, assuring appropriate human subjects training for investigators and reviewing the clinical and academic status of researchers, when appropriate.

Reviewing IRBs exist in various situations, including academic institutions, healthcare facilities or networks, commercial IRBs and Native American tribal settings. Reliance agreements can be exist between individual IRBs or through a reliance network (e.g. SMART IRB) where multiple entities utilize a common reliance agreement.

The use of a single IRB for multi-site NIH protocols is mandated for domestic sites conducting the same research protocol for NIH grant applications submitted on or after January 25, 2018, and for contract solicitations on or after January 25, 2018. Waivers for adherence to the single IRB mandate can be submitted to the NIH for extenuating circumstances, including a site being under the jurisdiction of a Native American tribal IRB. A similar mandate will become effective for all federally funded research in January 2020. Many commercial sponsors of clinical research strongly encourage the use of a single IRB. UCSD investigators serving as principal investigators for multi-site trials where UCSD is serving as the coordinating center and not directly engaged in human subjects research may consider relying upon another institution's IRB.

Investigators interested in general information regarding single IRB review can access information from the Office for Human Research Protections (OHRP) website. The UCSD Human Research Protections Program (HRPP) is currently revising the IRB reliance workflow to simplify the process for UCSD investigators. The HRPP SOPPs regarding IRB reliances provide limited information regarding the reliance process.

For additional assistance when considering a request for UCSD to serve as a reviewing or relying IRB, please send inquiries to irbrely@ucsd.edu or call the UCSD HRPP Office at (858) 246-4777.

INTERNATIONAL RESEARCH

Foreign National Export Control Requirements BY BRITTANY WHITING

When you hear the word export, most people think of a shipment to another country. But the truth is that NOT all exports are physical shipments. Disclosure of export controlled technical data or technology, whether written, oral or visual, to a foreign person in the U.S. or abroad is also an export and may require an export license. In Export Control regulations, the term foreign person refers to everyone other than a United States (U.S.) citizen, legal permanent resident, or certain protected individuals such as refugees and those with asylum. Both the Export Administration Regulations and International Traffic in Arms Regulations (ITAR) indicate that a transfer of technology or technical data to a foreign person is deemed to be an export to the home country of the foreign person. This is referred to as a "deemed export."

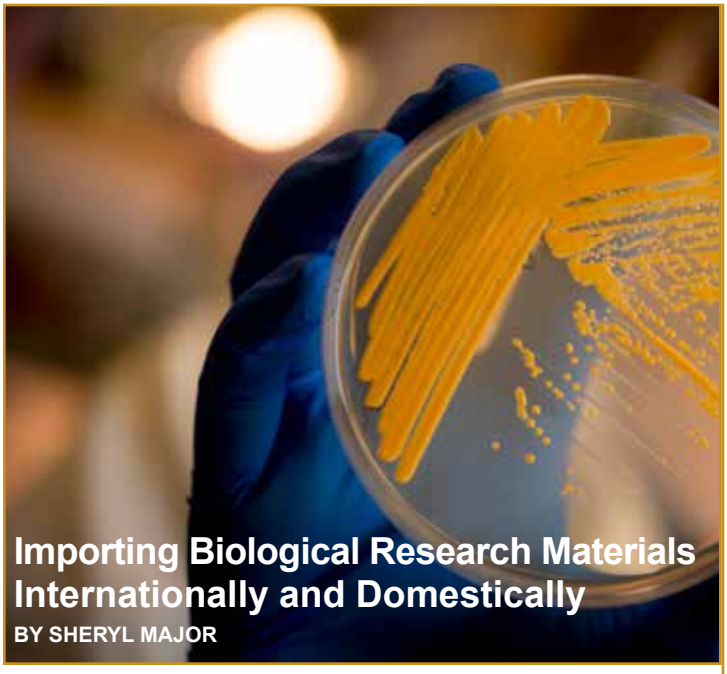
The fundamental research exception (FRE) exempts the vast majority of on-campus university research and participation by foreign persons from export control licensing requirements. The FRE covers information, but not items, that result from basic and applied research in science and engineering, at accredited institutions of higher education, located in the U.S., that is ordinarily published and shared broadly within the scientific community. It does not cover physical items, services such as training, development information, proprietary or confidential information, export-controlled information, or activities outside the U.S. The FRE also does not cover activities such as defense services, dealings with restricted entities or embargoed or sanctioned parties.

Export controls preclude the participation of all foreign nationals in research or other activities that involve export restricted technology without first obtaining a license or license exception from the appropriate government agency. There are a number of ways that UCSD addresses foreign person export license reviews. These may be triggered through contract and grant reviews of both sponsored research and unfunded agreements like Non-Disclosure Agreements (NDAs), or service agreements that may be dealing with export restricted technology, procurement of ITAR, former ITAR items referred to as 500 or 600 series technology, or hosting of foreign visitors affiliated with restricted entities.

I-129 PROCESS

As part of the sponsorship of foreign national employees for H1B and other professional visa types, the U.S. government requires a statement of whether an export license is required for that person's work at the University. Part of the department sponsorship paperwork includes an export control form that requires hiring managers to certify that the foreign person employee will not have any IT administrator access or responsibilities nor access to export restricted technology, work on awards with publication or foreign national restrictions, NDAs or be performing work on service agreements. These items are not covered by the FRE. If the hiring manager is unable to certify for information, the visa process will not proceed and they must notify the UCSD Export Control Office for an export license review to determine if a technology control plan or export license is required for that person's work. If a license is required, that person will not be permitted access to the export restricted technology until the export license is issued by the relevant federal agency, even if the visa has been approved. If a technology control plan is the preferred approach with the hiring manager, it must be implemented prior to the foreign person commencing work in that area by restricting access to export restricted technology.

Additional information on foreign national export controls are listed on the Blink Export Control Basics Webpage. For questions, please contact the Export Control Office at export@ucsd.edu or (858) 246-3300.



Importing Biological Research Materials Internationally and Domestically

BY SHERYL MAJOR

During the course of conducting your research at UCSD, you may find it necessary to import biological materials from another country, or domestically transfer them across state lines. These may be diagnostic samples from an international collaborator, environmental isolates from another state, recombinant or synthetic nucleic acids, or various plant and animal material from other countries or states. Many, if not all of these materials will require permits, issued by various United States regulatory bodies.

The predominate regulatory agencies which issue such permits to researchers are the Centers for Disease Control (CDC), the United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS), and U.S. Fish and Wildlife Service (FWS). There are also various state agencies which may require permits for your material.

In order to help you navigate potentially complex permitting requirements, you can reference the UCSD Shipping: Biological Materials Permits BLINK page to serve as guidance and overview, before navigating the applicable agency website. UCSD's page explains in detail what types of materials may be subject to permitting requirements, indicates various types of permits, and offers guidance and direction for initiating the permitting process for the CDC, USDA/APHIS, and FWS. You will also find helpful links to agency FAQs and permitting guidelines.

Even if you do not think your material will require a permit, you are encouraged to reach out to EH&S Biosafety Program for assistance and support. With obtaining importation permits comes the responsibility to: correctly identify and package materials, provide any necessary documentation requested by the permitting agency, comply with on-site inspections and interviews, and appropriately ship, package, handle, and dispose of regulated materials. The permitting process can take many paths, from an immediate issuance of a permit, to a multi-step process. Biological materials without proper permits may be stopped at international or state borders, and delayed or destroyed. EH&S Biosafety Program can help you and your lab throughout the submission of applications, agency Safety Questionnaires, on-site inspections, personnel interviews, and implementing conditions of approval.

Please visit the UCSD Shipping: Biological Materials Permits BLINK page for more details on obtaining import permits and proper shipping requirements. For questions or additional information, please contact ehsbio@ucsd.edu.

An Overview of the Regulation of Animal Research

BY THE IACUC OFFICE STAFF

Taking good care of another living being should be a given. This is true for pets and livestock, but especially important when we use animals for research purposes. While the majority of researchers are aware of this responsibility and act accordingly, there have been instances across the United States (U.S.) of mistreatment and questionable ethics in the past, including the theft of pets for use in research laboratories. The latter was exposed in a *Life* magazine article in the 1960s and resulted in a massive public outcry. Congress, encouraged by activist groups like the Animal Welfare Institute, realized that laws were needed to codify the care and use of laboratory animals. In 1966, Congress passed the first such law, the "Laboratory Animal Welfare Act." This law covered the transport, sale, and handling of animals and provided for licensing of animal dealers to prevent pet theft and their sale to research facilities as well as set high standards of care for laboratory animals with regard to their housing, feeding, cleanliness, ventilation and medical needs. Since the law was passed, those standards have been refined and adapted to new types of research, but they still apply today. The law also made the use of anesthesia or analgesic drugs for potentially painful procedures and during post-operative care mandatory.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) enforces animal research laws by inspecting laboratories and monitoring for compliance with the applicable laws. The Laboratory Animal Welfare Act, now known as the Animal Welfare Act (AWA), has been amended four times (1970, 1976, 1985, and 1991), each time elevating the standard of animal care. The amendment of 1985 was the most extensive and had two very significant results. First, an Animal Welfare Information Center was established to provide researchers with a database of alternatives to painful animal experiments. Second, each research facility in the U.S. using species covered by the AWA must register with the USDA and establish an Institutional Animal Care and Use Committee (IACUC) to review all experimental protocols involving live, warm-blooded animals (see below). Similar committees had already existed to monitor clinical trials, and the amendment now extended the same careful review to research on animals.

The definition of "animal" in the original AWA has been somewhat controversial because it only covered dogs, cats, nonhuman primates, guinea pigs, hamsters, and rabbits, but it excludes the most commonly used laboratory animals, mice and rats. While this has been repeatedly challenged by animal rights advocates, Congress recently passed an amendment to exclude permanently rats, mice and birds used in research from the AWA. However, these species are protected under another federal agency, the Public Health Service (PHS). PHS Policy requires that all institutions receiving research funds from the National Institutes of Health, the Food and Drug Administration or the Centers for Disease Control and Prevention, adhere to high standards of animal care. This covers most academic institutions that perform animal research. While PHS Policy applies only to PHS-funded research, it is broader than the AWA in that all vertebrate animals (including fish and reptiles) are covered.

The standard of care under the PHS Policy is "The Guide for the Care and Use of Laboratory Animals" (The Guide), which is published by the National Research Council and the Institute for Laboratory Animal Research. The Guide outlines rules and regulations for everything from the purchase, transport and housing of animals to experimental limitations and veterinary care. The Guide's recommendations are enforceable based on the Health Research Extension Act passed by Congress in 1985.

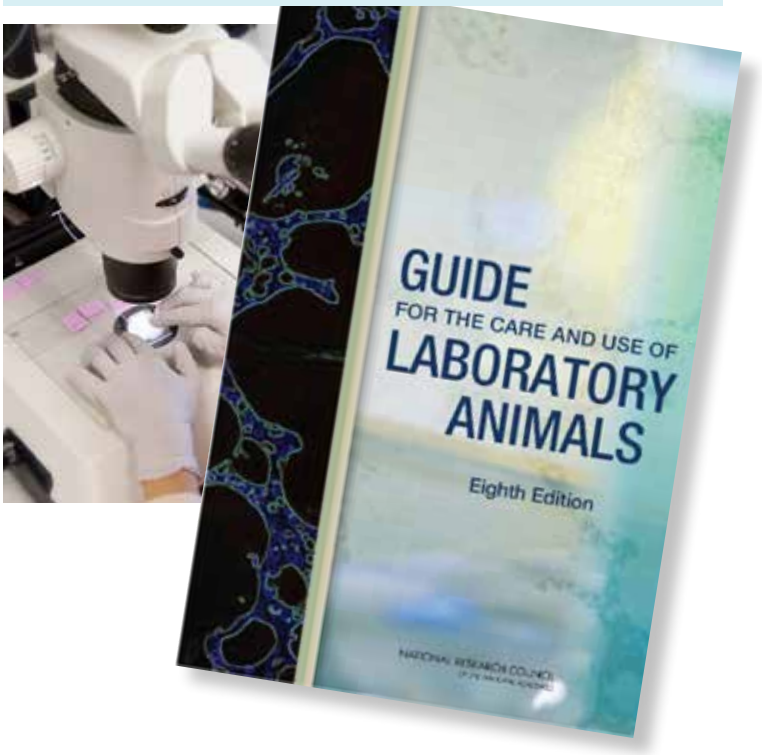
Both AWA and PHS Policy require the establishment of an IACUC which must include at a minimum one veterinarian and one member not affiliated with the institution as well as scientists and non-scientists. IACUCs require researchers to justify their need for animals, select the most appropriate species and use the fewest number of animals possible to answer a specific question, all of which is summarized in a document called an animal use protocol. IACUC approval of the animal use protocol is required before any animal work can be conducted. Protocols represent a contract between researchers and the IACUC to adhere to all rules and regulations laid out by PHS Policy and AWA.

In addition to federal requirements, there can also be state and local rules in place that govern animal research. In general, the IACUC is tasked with ensuring compliance with all applicable regulations at any given institution. It should be noted that the AWA and PHS Policy apply only to research institutions in the U.S., while regulatory oversight in other countries can be markedly different.

In 1965, the nonprofit AAALAC International (formerly known as the Association for the Assessment and Accreditation of Laboratory Animal Care) was founded with the goal to promote a uniform standard of animal care in the U.S. AAALAC International provides a service to accredit research institutions on a voluntary basis by evaluating animal care programs every three years to ensure scientists comply with the guidelines set forth in The Guide. With the ever-increasing degree of international scientific exchange and collaboration, AAALAC International has expanded since its inception and is now accrediting research and testing programs throughout the world, with over 1000 accredited institutions in 47 countries.

Even though AAALAC accreditation is voluntary, it provides a huge benefit to research institutions by assuring uniform standards of care. Many funding agencies now strongly encourage accreditation and University of California (UC) Policy requires all campuses to remain accredited, which makes it difficult to collaborate with non-accredited institutions if animal research is to be conducted there using UC funds. Therefore, while taking good care of laboratory animals is the right thing to do, it is also a crucial part of competing for research funding and establishing collaborations with other researchers.

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



Reminders from NIH about Disclosing Financial Conflict of Interests (FCOI) for Public Health Services Funded Research

BY JENNIFER J. FORD

On March 30, 2018, the National Institutes of Health (NIH) Guide Notice from Francis S. Collins, NIH Director, reminded researchers of their obligations to disclose their financial interests with respect to financial interests with foreign universities and foreign governments. Then on August 23, 2018, Director Francis Collins, advised institutions about concerns of threats to the integrity of U.S. biomedical research. There were three 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. On July 10, 2019, NIH Guide Notice issued reminders on various NIH policies, one of the policies was on Financial Conflicts of Interest (FCOI). The intent of this notice is to remind the research community about the need to report foreign activities through documentation such as financial conflict of interest. These notices makes no changes to policy requirements regarding financial conflict of interest.

The Public Health Service (PHS) regulations on Objectivity in Research provide a reasonable expectation that the design, conduct, and reporting of PHS research activities will be free from bias resulting from Investigators' financial conflicts of interest. As a public institution, UCSD employees have to be mindful of the actual and the appearance of a conflict of interest.

In order to comply with PHS regulations for Financial Conflict of Interest (FCOI), UCSD researchers with PHS-funded research must be aware of the following:

1. WHO MUST DISCLOSE:

The Principal Investigator (PI), Project Director, Senior/Key Personnel, and others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of the research.

2. WHEN TO DISCLOSE:

At the Initial proposal submission, change in funding, addition of new personnel, change in financial interest, no cost extension and at least annually.

- Submit an updated disclosure within 30 days of acquiring a new financial interest.

3. WHAT TO DISCLOSE:

All outside financial interests that meet the threshold for disclosure regardless if related to the PHS-funded research, including interests with foreign Universities and foreign governments.

- This includes interest by the researcher, their spouse or registered domestic partner, and dependent children.
- The Institution determines which financial interests are related or have the appearance of being related to the PHS-funded research.

4. DISCLOSURE THRESHOLDS:

- Income/Compensation*: Publicly traded or non-publicly traded >$5,000
- Equity:
  - Publicly traded >$5,000
  - Non-publicly traded ≥$0, including stock options that have yet to be exercised
- Travel*: Domestic and foreign travel paid for on the researcher's behalf or reimbursed to the researcher by one entity >$5,000 in the past 12 months.
- Intellectual Property: Royalties from non-UC inventions >$5,000

*Income or travel from U.S. Institutions of higher education or U.S. federal, state or local government agency are excluded from being disclosed.

5. PHS TRAINING REQUIREMENT:

Required prior to engaging in PHS funded research and at least every four years.

6. WHAT CONSTITUTES AN FCOI:

An FCOI means that a researcher's financial interests could directly and significantly affect the design, conduct or reporting of research.

- The Institution determines if a researcher's financial interest is a FCOI.
- FCOI reports are submitted to the applicable funding agency annually.

For more information about the other reminders listed in the latest NIH grant notice, please see the article in this edition entitled, "Disclosure Requirements of Foreign Affiliations, Collaborations, and Support in Federally-Funded Research."

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

Too often when the Chief Information Security Officer has to reach out to UCSD employees, it is for two reasons, either they have had something terrible happen with their computer or data, or they are doing something that will make it more likely something terrible will happen. Some of you have experienced your computer being taken off the network due to it being compromised or an account getting locked due to someone using it to send malware or spam. Before Information Technology Services (ITS) rolled out the two-step login process, ITS typically locked approximately 25-50 accounts per month. Now it is in the single digits. UCSD has approximately 30,000 staff, which means the odds are you are one of the 29,000 people who did not have their account compromised in the last year.

This does not mean you should let your guard down. ITS is finding that prominent administrators and faculty can receive upwards of 100 times the amount of spam with malware-laced attachments and phishing messages per day than the average account. If you are reading this article, you are probably being targeted. While some of these messages are very sophisticated and subtle, the majority are after the same thing, your login credentials. Below is a breakdown (categorization of the type of attacks) for one frequently attacked account:

2019/06/25 - 2019/07/24

Sort by Attack Contribution

Cryptocurrency Miner	<1%
Consumer Credential Phishing	<1%
Credential Phishing	97%
Malware	2%
Stealer	1%

While the use of the two-step login helps protect your UCSD accounts, your personal accounts are just as desirable, permitting hackers to pivot from your personal account into your family's or colleagues inbox. ITS strongly recommends that you begin using a password manager for your personal (and professional) accounts, despite using two-step login where ever possible. The campus provides a free program, called LastPass, which can be used for both work and personal accounts (you can even link your personal and University LastPass accounts). LastPass will make the hassle of passwords much less painful and make using exceptionally strong passwords trivial. Give it a try and become a security champion for another year.

For more information on LastPass, please see the LastPass website. To provide feedback on UCSD's Cybersecurity, please visit the Cybersecurity and Me website. For questions or additional information, please contact Mike Corn, Chief Information Security Officer, at mcorn@ucsd.edu or (858) 246-4223.

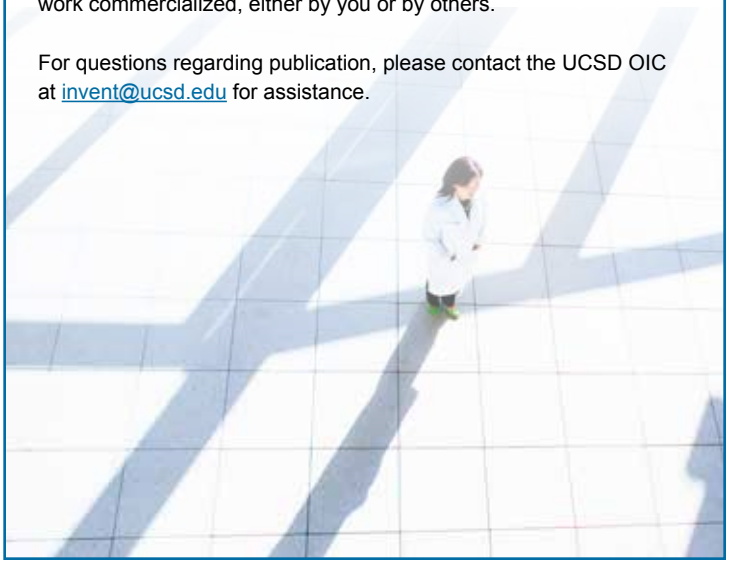
Publication Redefined: How to Protect Your Patent Rights

BY DAVID GIBBONS

When we think about publication in the academic setting, most of us think about acceptance into a peer reviewed journal. We often do not consider the many other forms of publication that occur along the way, such as posting on preprint servers (i.e. arXiv.org or bioRxiv.org), shared software workspaces (i.e. github.com or bitbucket.org), or laboratory/team websites. From an intellectual property standpoint however, the "peer reviewed" definition is much too narrow and can lead to loss of valuable patent rights in your research. Under various patent laws, a publication occurs when you share an enabling description of your idea with a third party outside of your organization who is not covered by a non-disclosure agreement. This public sharing triggers certain rules in the patent system, including the immediate loss of patentability outside of the United States (U.S.) and starting a one year clock for patenting within the U.S. In order to preserve future patent rights, research groups should establish a plan for the public sharing of information and understand the potential implications of sharing in various outlets and the timing of information release.

When considering the need to publicly disclose your research, consider the scope of the disclosure and whether the disclosure is "enabling." "Enabling", in the patent realm, means a description sufficiently detailed enough that the reader could understand the invention without the need for undue experimentation. As an example, abstracts for a conference are typically not enabling, but a full paper typically is enabled. Likewise, an invention that is realized in software could be considered enabled and published through the public sharing of source code. In order to protect the potential patentability of your work, it is advisable that you reach out to the UCSD Office of Innovation and Commercialization (OIC) at the point which you have enough data to start drafting a manuscript or wish to publicly post software. The OIC can assist you with the necessary steps to disclose and protect your work before it becomes publicly known and your patent rights diminished. This step of disclosing and protecting your research preserves your future opportunity to see the work commercialized, either by you or by others.

For questions regarding publication, please contact the UCSD OIC at invent@ucsd.edu for assistance.



EDUCATION

NEW RESEARCH COMPLIANCE AND INTEGRITY KNOWLEDGE BRIEFS!

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

CONFLICT OF INTEREST VIDEOS

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

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

EXPORT CONTROL VIDEOS

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

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

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE VIDEOS

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

Research Ethics: It's Not Just the Science

BY MICHAEL KALICHMAN

Developing new science and technology is as important as it is exciting. However, evidence continues to mount that implementation can be seriously flawed if the diversity of users is not taken into account. A recent story in the *New York Times* ("Exposing the Bias Embedded in Tech") illustrates several examples in which using historical data to train algorithms for new products can result in biased outcomes, favoring some individuals over others. For example, to develop an algorithm to assess who will be a good risk for a loan, it might seem reasonable to use existing data for past loan recipients. Although the resulting algorithm may seem an unbiased way to make decisions, training based on existing data may simply reinforce existing stereotypes or expectations. If systemic biases historically selected for particular individuals (e.g., male), then the algorithm will be biased toward that group not because they are necessarily a better risk but because they are the ones who have historically been selected. Hopefully, this is not typically the intended outcome. It is a consequence of simply not stepping back and asking about the assumptions implicit in how we develop and design new products. Just acknowledging that this is a challenge is a valuable first step, but it is insufficient. The questions we should be asking are what are our obligations and roles as scientists and engineers to meet this challenge and how can we best do so? How do we prepare ourselves, as well as the next generation, to be aware of, to value, and to address the need to be inclusive? At the very least, we can start by having this conversation with our peers, mentors, and trainees. In addition, one opportunity to think about such questions is to engage with the public through the Exploring Ethics forums convened by the UCSD-supported Center for Ethics in Science and Technology.

For additional information, please visit the Research Ethics Program website or contact the Research Ethics Program at (858) 822-2647, ethics@ucsd.edu.

Reference: The Office of Research Integrity, ori.hhs.gov/infographics

Q&A Ask the Questions . . .

Why do I keep getting emails about posting my results to clinicaltrials.gov?

Principal Investigators (PIs) may receive an email from the Research Compliance and Integrity (RCI) Office alerting them of past due study results on ClinicalTrials.gov. These reminder emails are sent to all PIs) that have not published their results on ClinicalTrials.gov in a timely manner. For applicable clinical trials, federal requirements mandate that the results be posted to the ClinicalTrials.gov website no later than 365 days after the completion of their study. It is important to note, publishing your findings in a journal article does not meet the federal requirement of publishing your results on ClinicalTrials.gov.

For additional information or assistance with entering your study results on ClinicalTrials.gov, please contact the RCI Office at (858) 822-4939, or ctgov@ucsd.edu.

How does the NIH's recent notice, "Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components" NOT-OD-19-114), impact their Financial Conflict of Interest (FCOI) policy?

There has been no change to the FCOI policy. The recent NIH notice NOT-OD-19-114 serves as a reminder to the extramural community of the requirements that are outlined within 42 CFR Part 50, Subpart F, Objectivity of Research (the FCOI regulation), which specifies the requirements for investigators to disclose to their institution their significant financial interests. The requirement to disclose includes financial interests received from a foreign institution of higher education or the government of another country. This requirement is distinct from other support and foreign components.

If you have any questions or need assistance, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

Does collaborating internationally with another researcher or foreign institution have export control requirements?

Yes, in several respects. The exchange of scientific information with researchers and administrators abroad can trigger export control requirements such as end user screening, as well as export licensing requirements potentially associated with the transfer of tangible items, proprietary technical data, software, and transfers that meet the definition of a defense service. Restricted Party Screening should be performed at the outset of any international collaboration to ensure that the collaborating entity does not appear on any of the U.S. Government's Restricted Party Lists. Please see the Restricted Party Screening for additional information. If there is any question as to whether you might be sharing research results that are not intended for publication, or you are transferring abroad any commodity or software that could be controlled under the Export Administration Regulations (EAR) or International Traffic in Arms Regulations (ITAR), you must contact the UC San Diego (UCSD) Export Control to determine the export license requirements. Finally, scholars and researchers who visit UCSD as part of the collaboration must be restricted from accessing laboratories where ITAR items or export restricted data are kept or used. A technology control plan may be an option to document the access restrictions and controls implemented to prevent unlicensed exports for foreign persons.

If you have any questions or need assistance, please contact the UCSD Export Controls Office at export@ucsd.edu or (858) 246-3300.

Who must apply for an animal use protocol with the UC San Diego (UCSD) Institutional Animal Care and Use Committee (IACUC)?

Anybody who wants to conduct a project involving research, teaching or testing on live vertebrate animals at UCSD must first submit an Animal Use Protocol and wait for approval by the UCSD IACUC before initiating any activity with the animals. Only UCSD faculty members or individuals otherwise eligible for research grants through UCSD may be the Principal Investigator (PI) on an Animal Use Protocol. All federal funding agencies also require an approved Animal Use Protocol for all vertebrate animal work listed on a grant proposal. The Animal Use Protocol represents a contract between the PI and the IACUC to conduct all animal work in compliance with all regulations, as reviewed and verified by the IACUC.

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

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Science brings society to the next level; ethics keep us there — *Dr. Hal Simeroth*