University of California Office of the President Issues a New Research Data Policy

BY LAURA SCHULLER

The University of California (UC) Research Data Policy (Policy) was issued on August 9, 2022, and went into effect on July 15, 2022. This Policy applies to all research data generated or collected during the course of University research. The Policy intends to clarify the ownership of and responsibility for research data generated during the course of University research, encourage active data management and sharing practices, and provide guidance with respect to procedures when a researcher leaves the University.

UC’s commitment to protecting research data reflects its mission to expand public knowledge and responsibility as the owner of research data. The origin of the ownership of University research data goes back to 1958 in UC Regulation No. 4 of Academic Personnel Manual 020, which simply states, “... notebooks and other original records of the research are the property of the University.” The Policy helps to clarify this simple statement.

While the University asserts ownership of research data through the Policy, it also recognizes that the researchers provide scholarly leadership pertaining to research data. The researchers continue to:

➢ Choose the nature and direction of their investigations
➢ Maintain and use the research data they generated or collected in the course of their University research to pursue future research
➢ Publish their results
➢ Share their findings with scientific and academic communities

Guidance on certain procedural components of data management that are not covered in the Policy as well as UC San Diego implementing procedure for the Policy will be forthcoming.

For additional information, please see the UC Office of President’s Frequently Asked Questions about Policy and the UC San Diego Guidelines on Access and Management of Research Data on Blink.

For questions, please contact the Research Compliance and Integrity (RCI) Office at rci@ucsd.edu or (858) 822-4939.
Updated Informed Consent Form and Assent Templates

BY BEN MOOSO

After a lengthy period of development, fine tuning, and stakeholder input, the UC San Diego (UCSD) Office of IRB Administration (OIA) is pleased to announce the launch of our new Informed Consent Form (ICF) and assent templates. The new templates can be downloaded from the OIA forms page. In addition to updating the OIA main ICF template, we’ve updated our adolescent and child assent templates to match. We have also created an Exempt Information Sheet template to be used with Exempt studies (e.g. surveys, interviews, focus groups, etc.) where there will be interactions with subjects.

Why did OIA make the new templates?
There were a number of reasons for issuing new templates. First, the previous templates had not been updated since the initial release of the Revised Common Rule in 2019. It is safe to say, OIA has learned a lot about the workings of the Revised Common Rule, the intent of the regulators, and the consent process since then, so it was time for an update to reflect that new knowledge. Second, there have been changes here at UCSD (the IRB’s name change from the Human Research Protections Program (HRPP) to OIA, the update of the UCSD Health Policy (UCSDHP) 340.1, “Investigational Drugs, Devices, and Procedures ”, an increase in the use of electronic consent, etc.) that necessitated updates to the language in the documents. Third, OIA wanted to provide more template text for researchers to minimize the guess work in crafting an ICF and assents that will be acceptable.

So what changed in these new templates?
The child assent template stayed essentially the same. However, the main ICF and adolescent assent templates received the majority of the updates. The most notable change is the formatting of the documents. While we generally kept the same question and answer format, the sections are now all numbered, and the fonts and organization of the document have been updated to provide a better flow when going through the document with a subject.

Another major change is that we’ve combined the Social/Behavioral and Biomedical ICF templates into one document which can now be used for adult subjects, adult subjects requiring surrogate consent, and parental permission for minor subjects. What used to be four separate templates has been combined into one.

As mentioned earlier, the OIA has also provided a lot more template text for researchers. This is probably most notable in the risks section (Section 9) as OIA has provided template text for the most common procedures where researchers had struggled to write descriptions in the past. Additionally, in the section on confidentiality (Section 10) OIA has included new standard language to inform subjects participating in certain biomedical studies about how their participation in a qualifying study will be linked to their medical record, if they have one, and that a medical record will be created for them if they don’t have one already in compliance with UCSDHP 340.1.

Is there anything we should pay particular attention to with these new templates?
Please pay special attention to the instructions throughout the documents written in red text. These will tell you exactly what information the IRB is looking for in these sections or when to include template text that has been added. Following the instructions in red will help to reduce the number of times the submission goes back and forth between OIA and the researcher.

As always, the number one issue the OIA sees with submissions is consistency. Please ensure that the information included in the ICF and any assents are consistent with what is described in the study protocol and Kuali application.

Is there a Rady Children’s Hospital San Diego (RCHSD) version of this form?
Not yet. The OIA is working with the RCHSD research office to develop a joint UCSD/RCHSD version of the form. We will send another announcement and post the joint form on our website when it is ready.

For questions or additional information, please contact the OIA at irb@ucsd.edu.
Effective January 2017, the National Institutes of Health (NIH) policy requires registration and results reporting for all NIH funded clinical trials. Applicants seeking NIH funding need to submit a plan for the dissemination of NIH funded clinical trial information and awardees are obligated to adhere to its dissemination plan through the terms and conditions of the award. Since the NIH is responsible for ensuring that NIH-funded clinical trials are reported on ClinicalTrials.gov, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) conducted an audit to determine whether the NIH ensured that NIH-funded clinical trials complied with the federal reporting requirements for results reporting by reviewing a sample of clinical trials for which federal law and NIH policy required the results to be reported. OIG found that the NIH did not ensure that all clinical results were reported in accordance with federal requirements.

OIG identified several reasons for the noncompliance such as the NIH not having adequate procedures for ensuring that responsible parties submitted the results of clinical trials, taking limited enforcement action in case of noncompliance, and continuing to fund new research of responsible parties that had not submitted the results of the completed clinical trials.

OIG made the following 3 recommendations for the NIH in the report:
1. Improve its procedures to ensure that responsible parties of NIH-funded clinical trials comply with requirements to submit results to ClinicalTrials.gov in a timely manner.
2. Take enforcement actions against responsible parties that are late in submitting trial results or do not submit results.
3. Work with the responsible parties to understand their challenges related to ClinicalTrials.gov and implement procedures to address the challenge.

For more information, please see the OIG report. Please also see the factsheet on ClinicalTrials.gov Requirements and the Research Compliance and Integrity (RCI) Office ClinicalTrials.gov webpage. For questions or additional information, please contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.
THE STAKES ARE HIGH
Research Laboratory Operational Security
BY ERIC S. DEAN

During the 1960’s, while conducting analytical reviews of failed combat operations, the term OPSEC (Operational Security) was coined by the United States (U.S.) Department of Defense. Since that time, the OPSEC process derived from those reviews has been adopted worldwide by industry, governments, and research laboratories. Simply put, OPSEC is the process of protecting individual pieces of data that could be grouped together to give the bigger picture (aggregation). The OPSEC process includes five steps:

1. **Identifying Critical Information (CI):** CI is information about activities, intentions, capabilities, or limitations that an adversary seeks in order to gain a technological, economic, political or military advantage. CI may be Classified or Unclassified and is often Controlled Unclassified Information (CUI) that, when collected in the aggregate, could be grouped together to give the bigger picture. For a research laboratory, CI answers the questions that an adversary may ask when determining how to clone, counter or defeat a technological advantage.

2. **Identifying the Threat:** Foreign governments, foreign companies, and even competing U.S. companies pose a significant threat to U.S. research facilities based on economic or political interests, competing ideologies, military capabilities, and many other factors.

3. **Assessing Vulnerabilities:** Studying your operations from an adversarial perspective (how could someone gain unauthorized access to your critical information) will help you determine how well your CI is protected.

4. **Analyzing the Risk:** For U.S. research laboratories, loss of CI could have serious, and sometimes grave economic, diplomatic or national security implications.

5. **Developing and Applying Countermeasures:** To protect CI produced or managed by a research laboratory, OPSEC is incorporated along with traditional physical security measures. OPSEC does not replace other security disciplines, it supplements them. Although every research laboratory is unique and will require varying levels of security, a few examples of research laboratory OPSEC best practices include:

   - **Implement a Technology Control Plan (TCP).** A TCP is a formal agreement describing minimum security procedures and requirements to manage or prevent access to export-controlled items, materials, equipment, technologies, information, technical data or know-how. Each member of the research team will read and sign the TCP. Adherence to TCP procedures reduces risk and helps prevent the violation of export control laws, regulations and sanctions.

   - **Provide for positive access control that is appropriate for the specific research environment, such as entry and visitor logs.**

   - **Increase situational awareness of laboratory personnel (e.g., knowing who is in the laboratory, identifying suspicious contacts and activity).**

   - **Encourage the reporting of suspicious contacts, theft, or vandalism.**

   - **Restrict off-hour access to laboratories, if appropriate.**

   - **Ensure personnel do not post information regarding specific research projects on internet web sites, social media venues, or other information technology systems not located inside the controlled work environment.**

   - **Position displays containing CI in a manner that will prohibit viewing from outside the work center. This includes sight lines that are visible at a distance where binoculars or similar devices could make the information viewable.**

   - **Advise research personnel not to discuss CI on a cell phone or in a room where a cell phone or similar device is present. Personnel should not discuss the project’s CI outside the controlled work center where they may be overheard.**

   - **Do not allow research materials that contain CI to be taken outside of the access-controlled work area except when necessary to conduct approved project work (i.e. transit to sponsor facility for testing, etc.).**

   - **Instruct personnel not to respond to information requests from anyone that is not directly involved with the research or activity.** Report suspicious activities and requests to the Facility Security Officer (FSO).

   - **Inspect and inventory materials removed from the laboratory.** There are many other security measures and countermeasures that may apply to a specific research laboratory or activity. A good OPEC/Security plan is tailor-made to meet a laboratory’s unique requirements.

   - **The UCSD Export Control Office (ECO) identifies and manages export risks in support of the research activities of university faculty, staff, scholars and students. ECO personnel are specially trained to help navigate export regulations and protect CI through the development of TCP’s and other countermeasures that may be appropriate.**

For assistance or additional information, please visit the UCSD Export Control Office website or contact the ECO at export@ucsd.edu.
UC San Diego’s Animal Care and Use Program

BY THE IACUC OFFICE

UC San Diego’s Animal Care and Use Program is comprised of three main entities, the Institutional Animal Care and Use Committee (IACUC), the IACUC Office and the Animal Care Program (ACP), all working under the leadership of the Institutional Official (IO) and Vice Chancellor for Research, Dr. Corinne Peek-Asa. The IO is the individual who, as a representative of senior administration, bears the primary responsibility for UC San Diego’s Animal Care and Use Program, is responsible for resource planning and to ensure alignment of the Animal Care and Use Program goals with the institution’s mission. The IO is also the individual who has the authority to sign the institution’s Public Health Service (PHS) Animal Welfare Assurance, making a commitment on behalf of the University that the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals will be met.

The IACUC oversees the University’s Animal Care and Use Program, facilities and procedures, and ensures the appropriate care, use and humane treatment of animals used for research, testing and education. The IACUC is also responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories, overseeing training and educational programs, and investigating animal welfare concerns. The IACUC serves as a resource to faculty, investigators, technicians, students and staff, providing guidance in planning and conducting all animal use procedures in accordance with the highest scientific, humane, and ethical principles. The members of the IACUC are appointed by the IO and are from general campus, Health Sciences and Scripps Institution of Oceanography.

The IACUC Office is one of the core offices of the Research Compliance and Integrity (RCI) program in Research Affairs. The IACUC Office is the administrative, regulatory, and compliance arm of the campus-wide Animal Care and Use Program. The IACUC Office team members include experienced regulatory compliance and animal welfare specialists who provide support and serve as advisors to the IACUC, Principal Investigators, Administrators, the IO, the Assistant Vice Chancellor for Research Compliance and Integrity and overall campus. For additional information regarding the IACUC Office, please visit the IACUC website or email iacuc@ucsd.edu.

The ACP is a team of highly trained individuals dedicated to the humane care and use of animals, including the Director of the Animal Care Program and the Attending Veterinarian. ACP is responsible for animal acquisitions and procurement, vivarium management including animal housing and husbandry, veterinary services and animal use training. To learn more about ACP, please visit the ACP Website.

The IACUC Office and ACP staff are here to help. Together, these entities are responsible for the health and well-being of all vertebrate laboratory animals used at UC San Diego and work cooperatively to help facilitate research while optimizing animal welfare.

Do not hesitate to contact either office with any questions or concerns.

Facilitating Responsible Research, Innovation and Education for Global Excellence

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

rci@ucsd.edu | 858-822-4939
coi@ucsd.edu | 858-534-6465
export@ucsd.edu | 858-246-3300
iacuc@ucsd.edu | 858-534-6069
U.S. Department of Health and Human Services Review the Management of Foreign Financial Interests by National Institutes of Health (NIH) Grantees

BY BEC BEUTLER

In June of 2022, a report by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) was published highlighting the risks and potential solutions to the increasing issue of foreign threats to research integrity. Per Federal HHS requirements, recipients of National Institutes of Health (NIH) grants are responsible for disclosing foreign financial interests and support, and grantee institutions are responsible for providing education and oversight to ensure that all disclosures to NIH are accurate. Since 2018, concerns regarding foreign influence have been raised by federal funding institutions and efforts have increased to encourage and enforce the disclosure of foreign interests.

In order to determine how institutions that received NIH funding ensured proper disclosure from their investigators as well as what processes were in place to review said disclosures, OIG conducted a survey of NIH grantees with the goal of determining how grantee institutions ensure that all disclosures are completed and accurate. OIG reached out to 773 grantees who received NIH funding in Fiscal Year 2020 with survey questions regarding the policies surrounding disclosure of foreign interests and support, how the grantees reviewed foreign interests and what actions are taken to address failure to report foreign support. Of the 773 grantees contacted to complete the survey, 617 provided responses.

It was found that many of the grantees surveyed failed to not only meet all the Federal requirements of disclosure of foreign interests, but also did not conduct the required training and oversight to prevent non-compliance with HHS funding requirements. The results of the survey are the following:

➢ 69% of grantees failed to require that their investigators disclose at least one foreign financial interests and support. A majority of grantees that did not require this were smaller institutions that had under $10 million in NIH funding in FY2020.
➢ 45% of grantees did not comply with Federal Conflict of Interest (FCOI) requirements to disclose all of their equity interests in non-publicly traded foreign entities.

Survey showed failure to disclose foreign financial and equity interests, approximately 50% of grantees did not require disclosure of foreign in-kind support or participation in foreign talents programs.

➢ Almost half of grantees did not require their investigators with NIH funding to disclose in-kind resources, foreign professional affiliations, and participation in foreign talents programs.
➢ Almost 25% of grantees did not train their investigators on disclosure of foreign financial interests, going against HHS requirements.
➢ 10% of grantees did not perform FCOI reviews of their investigators.

With this survey, OIG is able to identify gaps in grantee institutions’ knowledge and provide guidance to increase foreign disclosure compliance. Highlighted in the report were a number of recommendations to help strengthen oversight that revolves around education, review of investigators disclosures, creation of mandated policies, and increased accessibility of institution disclosure reporting platforms and processes. OIG also provided suggestions for NIH to educate on and enforce Federal disclosure requirements as well as ensure the review of investigators disclosures by their institutions. Additional suggestions include the requirement of institutions to provide training to investigators as well as modify their reporting process to help distinguish foreign financial support in financial interest and other support disclosures.

For more information, please read the U.S. HHS Office of Inspector General Report. For questions or additional information, please visit the Research Compliance and Integrity (RCI) International Research webpage or contact the RCI Office at rci@ucsd.edu or (858) 822-4939.
Every year, there are two months where Americans celebrate and pay tribute to individuals with disabilities. March is Development Disabilities Awareness Month. Beginning in 1987, first recognized by President Reagan, this Awareness Month is a chance to celebrate the over 6 million individuals in the United States that have a developmental disability. According to the Centers for Disease Control and Prevention, developmental disabilities include autism spectrum disorders, cerebral palsy, attention deficit/hyperactivity disorder, learning or intellectual disabilities, hearing loss, and vision impairment. Through a campaign each March, the National Association of Councils on Developmental Disabilities (NACDD), Association of University Centers on Disabilities (AUCD) and National Disability Rights Network (NDRN) join forces to highlight the ways in which people with and without disabilities unite to form strong communities. The 2022 social media campaign was called “Worlds Imagined,” and was focused on how the world is changing as we move through and beyond the pandemic. This year’s campaign highlighted intersectionality and disability, as well as how people with intellectual disabilities and developmental disabilities (ID/DD) are living longer and more productive lives than ever before. Please see the NACDD website for more information and to view the 2022 Resource Guide, including videos, toolkits, news articles, etc.

October observes National Disability Employment Awareness Month to pay tribute to the accomplishments of individuals with disabilities whose work keeps America’s economy strong. This month is to reaffirm our commitment to ensuring equal opportunity for all citizens. This effort to educate the public about the issues related to disability and employment began in 1945, when Congress enacted Public Law 176, declaring the first week of October each year as National Employ the Physically Handicapped Week. In 1962, the word “physically” was removed to acknowledge the employment needs and contributions of individuals with all types of disabilities. In 1988, Congress expanded the week to a month and changed the name to National Disability Employment Awareness Month. The Department of Labor chose “Disability: Part of the Equity Equation” as the 2022 theme for this Awareness Month, recognizing the vital role people with disabilities play in making our workforce diverse and inclusive. For more information about this year’s theme, visit the Department of Labor website. Additionally, the Law Library of Congress has compiled guides to commemorate observations, including a comprehensive inventory of the Public Laws, Presidential Proclamations and congressional resolutions related to Disability Employment Awareness Month.

Each year in October, UC San Diego hosts events to create awareness and recognize the value of our diverse workforce. Please visit the Disability Awareness Month Blink page for more information. Additionally, Disability Counseling and Consulting, a division of Human Resources, provides disability management and job accommodation consultation services to UC San Diego faculty and staff who have a medical condition (physical or mental) that interferes with their ability to work or return to work. The Human Resources Department at UC San Diego also offers courses and trainings to learn more about issues associated with employee disabilities.

For questions or additional information, please contact the Research Affairs Equity, Diversity and Inclusion Committee at vcr-edi@ucsd.edu.
Conflict of Interest (COI) Office Guidance on Outside Personal Consulting Agreements

BY JENNIFER J. FORD

The UC San Diego (UCSD) encourages its faculty to participate in activities that contribute to their profession and to the outside community. Personal consulting is a professional activity related to a person’s field that is undertaken with an outside party, usually for a fee-for-service. Although outside consulting arrangements are personal, language in consulting agreements can create conflicts with the obligations of a faculty member to UCSD. Faculty members and other researchers may engage in consulting with outside entities as long as UCSD facilities and resources are not utilized, and the consulting activities do not interfere with their teaching and research responsibilities to UCSD. All UC San Diego employees have a duty of confidentiality related to UC San Diego business (i.e., data, inventions, copyright, software, equipment, or information, etc.).

The UCSD Conflict of Interest (COI) Office developed a guide on outside personal consulting agreements to assist faculty, staff and students (who are employees at UCSD), with issues to consider when entering into personal outside consulting agreements. UCSD does not review or sign personal consulting agreements and this guide is not to be taken as legal advice (faculty may wish to seek personal legal advice prior to signing any such agreement). The COI Office in consultation with other UCSD institutional offices has developed sample contract language that can be included in a personal consulting agreements.

Considerations for Outside Personal Consulting Agreements:

- Employee Obligations under UC Patent Agreement/Acknowledgment: All employees of the University sign a Patent Agreement/Acknowledgment as a condition of employment. Under the University Patent Policy, employees agree to disclose all inventions and patents to the University, and to assign them to the University, except those resulting from permissible personal consulting activities for faculty, staff and students.

  Often outside personal consulting agreements have language that requires assignment of patentable discoveries and/or other intellectual property to the company. Such a requirement might stand in direct conflict with obligations already made to the University and possibly with the obligations made by the University to sponsors of research. Faculty, staff or students (who are UCSD employees) who engage in consulting are advised to consider the terms of any proposed agreement with a company carefully to ensure that no conflict exists with existing obligations. It is also recommended that the company be informed of faculty, staff and students (who are UCSD employees) obligations to the University.

- Compromising Future Research Funding: Great care must be taken not to compromise future research funding. Although consulting agreements are personal, if such agreements are not properly formulated, they can jeopardize future University research programs and related funding. Companies employing consultants may desire commercial access to inventions made during the course of the consulting arrangement and often will seek rights to future yet-to-be-developed inventions made at the University related to the consulting activity. An agreement to provide such rights to future research results would preclude the University from providing comparable rights to other companies that sponsor University research. Most potential sponsors would refuse to fund research if their access to resulting inventions were denied because of prior obligations made through a consulting arrangement.

- Acceptance of Confidential Information: It is not uncommon that a company will disclose proprietary information to a consultant. In doing so, the company will want assurances that this information will be kept confidential. Confidentiality can be tricky for a faculty member, staff, and students (who are UCSD employees) involved in open, free exchanges of information in a public university setting. Disclosure of proprietary information, either intentionally or unintentionally, may be actionable under criminal as well as civil law. Therefore, it is essential to limit the amount of confidential information received when consulting and to have the company agree to clearly identify such proprietary information by marking it as “confidential.” Consulting agreements should always include a statement about the transmission of proprietary information and a no-fault statement regarding unintentional disclosure.

- Disclosing Financial Conflict of Interest: Under the California Political Reform Act of 1974, a Principal Investigator must disclose whether or not there has been any consulting activity with a company when accepting funding for research from that company. The National Science Foundation and the Public Health Service also require disclosure of consulting income under specified conditions. An existing or prior consulting arrangement might require that proposed funding be reviewed and approved by appropriate campus officials for possible financial conflicts. UC San Diego requires Conflict of Interest disclosure be made in Kuali COI.

- Reporting Personal Consulting Activities for Conflict of Commitment: Under University policy (APM-025 / APM-671), certain faculty are required to submit annual reports on their outside professional activities, which includes personal consulting, in UC OATS.

If you have COI questions or need additional information about COI, please contact the COI Office at (858) 534-6465 or info-coi@ucsd.edu.
The UC San Diego (UCSD) Office of IRB Administration (OIA) has undergone a number of staffing changes in the last year with the majority of our current staff having been hired since January 2022. While OIA continues to be managed by our two directors Ben Mooso (OIA Director) and Dr. Anthony Magit (OIA Medical Director), recent changes have also brought the OIA three new members of the OIA leadership team:

**KACEY PRATT, Assistant Director**

Kacey Pratt has been with the UCSD IRB office for 10 years, previously serving as the analyst for the oncology committee and more recently, the neuroscience committee. She has been working in the field of IRB administration for nearly 15 years on both the east and west coasts. In her spare time, she enjoys the performing arts and spoiling her dogs.

Kacey began her role as OIA Assistant Director in April 2022. In her new role, Kacey oversees the team of analysts supporting the six IRB committees and the Stem Cell Research Oversight Committee (SCRO). As Assistant Director, Kacey’s role also includes general oversight of the OIA along with the Directors.

**DAN GONZALEZ, Non-Committee Supervisor**

Dan has been part of the University of California system for over 16 years and has extensive experience overseeing human subjects research. After completing 10 years at the UC Los Angeles IRB, Dan joined the UCSD OIA in 2018.

Formerly serving as the Reliance Manager, Dan has now taken the role of Supervisor for the non-committee group, overseeing minimal risk research reviewed at the Exempt and Expedited levels, as well as reviewing administrative determinations of Non-Engagement and Not Human Subjects Research (NHSR). Dan is passionate about protecting the rights and welfare of humans participating in research and is proud to be part of a community that sparks discoveries that advance society. During his free time Dan enjoys playing soccer and golf, but most importantly spending time with his wife and two children.

**CARMEN THOMPSON, Reliance Supervisor**

Carmen Thompson joined the UCSD OIA in August 2022 as the IRB Reliance Supervisor. As Reliance Supervisor, Carmen oversees and works alongside the team of analysts conducting administrative and local context reviews of studies submitted for reliance on external IRBs and executing reliance agreements. Prior to joining UCSD, she worked at WCG IRB for 8 years as our IRB liaison. There she worked with all levels of the organization to improve relationships with institutional clients. In that role, Carmen began working directly with researchers and research teams with the implementation of the New Common Rule. Her interest in the field of IRB led her to obtaining her CIP certification in 2018. Prior to her working in the field of IRB, she worked in marketing and communications in the pharmaceutical industry. Carmen currently lives in Puyallup, WA, with her husband, children and the cutest Malshi ever named Luna. She enjoys cooking, walking Luna, and Zumba.

To contact any member of the OIA, please visit the [OIA Contact Us page](#).
Former University of Kentucky Assistant Professor Found to Have Engaged in Research Misconduct

It was determined in an investigation by the University of Kentucky (UK) with oversight from the Office of Research Integrity (ORI) that a former research-track assistant professor at UK engaged in research misconduct in Public Health Service (PHS) funded research. Stuart G. Jarrett, Ph.D., at the UK College of Medicine was found to have intentionally, knowingly, or recklessly falsified and/or fabricated images included in four PHS-supported published papers and three PHS grant applications. In both the publications and grant applications, western blot images and confocal microscopic images were manipulated. In one publication, it was determined that Western blot images were repeatedly reused, manipulated, and relabeled to falsify experiment results. Additionally, it was found that confocal microscopic images were manipulated by inserting a blank image in order to falsely represent the controlled experiment in both the publications and the three grant applications.

Former University of Arkansas Professor Sentenced for Lying about Patents in China

The U.S. District Court sentenced a former University of Arkansas engineering professor Simon Ang to 366 days in a federal prison for making a false statement to the Federal Bureau of Investigation (FBI) regarding his status as an inventor. Specifically, Ang denied the existence of patents for his inventions in China. The FBI, the U.S. Department of State’s Diplomatic Security Service (DSS), NASA Office of Inspector General and Air Force Office of Special Investigations conducted an investigation by looking at Ang’s patent history and interactions with research agencies in the United States to determine if Ang violated the University’s requirements including conflict of interest and outside employment. In particular, the University of Arkansas owns all inventions created by those subject to the policy and it requires individuals to promptly provide “full and complete” disclosures of inventions. While the patents did not have any monetary value, Ang did not disclose the Chinese patents to the University and knowingly denied being the inventor. Ang also did not disclose several talent awards from the Chinese government on the University’s annual conflict of interest disclosure forms. For more information, read the Department of Justice Announcement.

Former University of Florida Professor Charged with Stealing Federal Grant Money

A biomedical engineering professor at the University of Florida has been charged with wire fraud and making false statements to an agency of the United States. It is alleged that Lin Yang fraudulently obtained $1.75 million in federal grant money from the National Institutes of Health (NIH) to conduct research for the Chinese government. Yang was responsible for administering the grant funding in compliance with applicable federal law and institutional policies as the principal investigator for the NIH grant. Despite the requirement to disclose his foreign research support and financial conflicts of interest “including his ownership of, or interest in, a foreign company”, Yang’s disclosures to NIH contained false statements and omissions regarding his foreign affiliations and research endeavors with a foreign government and company. Particularly, he hid his conflicts of interest including his business in China that he promoted by disclosing that its products were the results of years of research supported by US government funding. Yang also concealed his participation in China’s Thousand Talents Program in affiliation with a research University in China called Northwestern Polytechnical University. Yang fled China in August 2019. For more information, read the Department of Justice Announcement.

For a period of four years, Jarrett is debarred from procurement of transactions covered under the Federal Acquisition Regulation and is prohibited from serving in any advisory capacity. The publications in question will also be retracted. For more information, please read ORI’s Case Summary.
Research Supervision Required for Texas Biomedical Research Institute Professor Following Admission of Research Misconduct in Non-Human Primate Studies

An investigation conducted by the Texas Biomedical Research Institute (TBRI) and the Office of Research Integrity (ORI) found that a Professor and Director at TBRI participated in research misconduct using Public Health Service (PHS) funds. Deepak Kaushal, Ph.D., was found to have falsified and fabricated experimental methodology included in one published paper and two grant applications submitted for PHS funding. It was found that Kaushal falsified and fabricated the numbers of animal subjects, the number of weekly doses of treatment, and the time interval between doses in studies with non-human primates.

After Kaushal’s admission of misconduct, he entered into a Voluntary Settlement Agreement in which he agreed to having his research supervised for one year by a committee at his home institution. Outlined in a supervision plan provided to ORI, the supervision committee will be responsible for confirming the integrity of any experiments conducted by Kaushal. Additionally, he will voluntarily exclude himself from serving any advisory role to PHS or abstract. Lastly, Jiang is required to exclude herself from serving in any advisory or consultant capacity to PHS. For more information, read ORI’s case summary.

Ohio State University Makes Two Findings of Research Misconduct

After numerous allegations of research misconduct, inquiries into Dr. Carlo Croce’s laboratory at Ohio State University (OSU) has led to two research misconduct findings as well as removal of Croce from his endowed chair position. By April 2020 when findings were made, a scientist in Croce’s laboratory, Flavia Pichiorri, was found to have engaged in nine cases of falsifying figures in three different publications, one of which was published while she was in Croce’s laboratory. In a report made in October 2021, a second scientist in Croce’s laboratory, Michela Garafalo, was found to have engaged in 11 cases of research misconduct, including plagiarism in seven cases and four cases of image falsification in eight publications that were published while she was in Croce’s lab. It was recommended by OSU that both Pichiorri and Garafalo be banned from rehire at the University.

In an investigation conducted by OSU related to Croce, it was concluded that Croce did not conduct research misconduct, but rather had an inappropriate lack of oversight and mentorship in his laboratory. Following the investigation, Croce was removed as endowed chair due to the repeated mismanagement of his laboratory. In response to these findings and subsequent actions, Croce filed a lawsuit against OSU board of trustees but ultimately lost in court. Currently he is involved in an additional lawsuit in Ohio in which he argues that the OSU investigation committee had conflicts of interest in his investigation.

As a result of all three Research Misconduct investigations, it was recommended that publications be retracted or corrected from their respective journals. It is unclear whether the U.S. Office of Research Integrity (ORI) will take further action on the three investigated researchers. For more information, please read Nature’s News Feature.

ORI Determines That Former University of California, Los Angeles Assistant Researcher Fabricated and Falsified Grant Application Data

Following an investigation done by the University of California, Los Angeles (UCLA) and the Office of Research Integrity (ORI), it was found that the Respondent, Janina Jiang, M.D., Ph.D., knowingly and recklessly falsified and/or fabricated flow cytometry results that were included by Jiang in eleven grant applications. The former Assistant Researcher at David Geffen School of Medicine, engaged in misconduct by manipulating the flow cytometry results in a way that they were incompatible with the raw experiment data.

As a result of the investigation, Jiang entered into a Voluntary Settlement Agreement to a required supervision of her research for a period of three years including required submission of a supervision plan. During the supervision period a certification that the data provided by Jiang are based on actual experiences is to be confirmed by the supervisory committee prior to the submission of application for PHS funds, report, manuscript, or abstract. Lastly, Jiang is required to exclude herself from serving in any advisory or consultant capacity to PHS. For more information, read ORI’s case summary.
EDUCATION

Research Security Videos

In January, the White House Office of Science and Technology Policy published Federal Agency Guidance for Implementation of National Security Presidential Memorandum (NSPM) 33. The guidance suggests agencies harmonize disclosure requirements to the extent possible and utilize digital persistent identifiers. It outlines consistent consequences for non-disclosure and guides agency information sharing. It outlines more specifics on how research organizations awarded more than $50 million a year are to meet requirements for a research security program covering cybersecurity, foreign travel security, research security and export control training.

The University of California Office of the President in conjunction with several campuses developed a Research Security Video Series available on YouTube, comprised of four short videos covering Disclosures, Talent Recruitment Programs, International Collaborations and Data Security. This video series is intended as a resource for our research community and is not mandatory.

Direct links to Research Security Video Series on YouTube:
- Disclosures: Conflicts of Interest & Conflict of Commitments (4 min 40 seconds)
- Talent Recruitment Programs (3 min 55 seconds)
- International Collaborations (3 min 50 seconds)
- Data Security (3 min 30 seconds)

If you have any questions, please contact the UC San Diego Research Compliance and Integrity Office at rci@ucsd.edu or (858) 822-4939.

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

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

- Cybersecurity Certification for Research: Achieving Cyber-Resilience in your Research Program
  October 19, 2022, 11:00 a.m. – 12:30 p.m.
  via Zoom (to register, click on this [link])

Do you have research compliance questions?
Join RCI Office Hours every Tuesday from 11:00 a.m. - 12:00 p.m. Sign up at calendly.com/ucsdrcioffice.

For questions, please contact rci@ucsd.edu.
Is a financial interest automatically a conflict of interest?

For federally sponsored research, having an outside financial interest is not automatically a conflict of interest. It is also important to remember that some financial interests are of such low value and/or limited duration that they do not meet the definition or threshold of disclosable financial interests or are so small or inconsequential that the research support from the sponsor can be accepted with no further action. Disclosed financial interests and resulting conflicts of interest may be reduced, eliminated, or managed so that the research project can be accepted and funded by the proposed sponsor.

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

Are there consequences for not submitting the required results information on ClinicalTrials.gov?

There are potential legal consequences for the Responsible Parties if they do not comply with the requirements to submit registration and results information on ClinicalTrials.gov. The consequences may include civil or criminal actions, civil monetary penalties, and grant funding implications. Below are some examples of available agency and journal sanctions:

- Food and Drug Administration Amendments Act (FDAAA): Public notices of noncompliance and violations, withholding of federal funds, FDA sanctions, and civil monetary penalties of $13,237 per day.
- National Institutes of Health (NIH): Suspension or termination of NIH grant or contract funding and consideration in future funding decisions.
- International Committee of Medical Journal Editors (ICMJE): Refusal of publication in member medical journals following ICMJE policy.

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

What are the consequences for not complying with the National Institutes of Health (NIH) policy for disclosure of Foreign Interests and Other Support?

If an institution discovers that the PI or other Key personnel failed to disclose Other Support information, an updated Other Support form must be submitted as soon as it becomes known, but no later than 30 days after it is known. If the NIH discovers that Other Support was not disclosed properly, consequences include withdrawing approval of the Principal Investigator or key personnel listed on the NIH award, imposing specific award conditions, disallowing costs and withholding future awards including the possibility of suspending or terminating the award. For additional information, see the NIH Grants Policy Statement, Section 8.5.

For questions or assistance related to Foreign Interests and Other Support, please contact the Health Sciences Sponsored Project Pre-Award Office at vchsgrants@health.ucsd.edu or email your HS PPO analyst directly.

What should I do if I receive an Interinstitutional Assurance for animal research from an external institution with which I am collaborating?

If you will be performing NIH funded animal research at UC San Diego as part of a collaboration with an outside entity that does not have its own animal care and use program, and the outside entity is the prime NIH awardee, UC San Diego can serve as the Assured Institution for the animal research. Once you receive the signed Interinstitutional Assurance from your collaborator, please route the completed form (sections I and IIA should be completed) to the UC San Diego Institutional Animal Care and Use Committee (IACUC) Office at iacuc@ucsd.edu with the relevant UC San Diego IACUC approved protocol number on which the animal work will be performed. The IACUC Office staff will confirm the approval date of the protocol and obtain the signature of the IACUC Chairperson as well as the Institutional Official and return the signed form to you as soon as possible. Please work with the Office of Contracts and Grants Administration to ensure there is an agreement in place between the outside entity and UC San Diego.

For additional information, please see OLAW instructions regarding Interinstitutional Assurances. For assistance, please contact the IACUC Office at iacuc@ucsd.edu or (858) 534-6069.

My laboratory conducts only Fundamental Research, do I need to be concerned with operational security (OPSEC)?

Yes. Skilled collectors may use multiple pieces of information that are not controlled by regulations to produce an aggregate that may be controlled or restricted.

For additional information, please contact the Export Control Office at export@ucsd.edu.