UC San Diego
RESEARCH COMPLIANCE AND INTEGRITY
Office of Research Affairs

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Newsletter

INSIDE THIS ISSUE

New "Cybersecurity Certification for Research" Requirement for Faculty and Researchers

BY MICHAEL CORN

No doubt many of you have read about UCSF's recent ransomware payment of $1.14 million. While there is little the University can do to stop these sorts of attacks from occurring, the University can implement systems and processes to reduce the likelihood of their success and minimize the potential impacts to our research. **Effective September 1, 2020, UC San Diego (UCSD) Information Technology Services (ITS) has launched a new required "Cybersecurity Certification for Research" (CCR) for all faculty and researchers.**

Given the breadth and variety of research activities at UCSD, securing our research cyberinfrastructure will necessitate looking at novel models for cybersecurity as research activities and data are fundamentally different from those of the standard office environment. Laboratories are filled with unusual or specialized equipment that can be challenging to secure and we must avoid disrupting the scientific workflow. We also cannot just secure laboratories that perform sensitive research or use personally identifiable information as we often see vulnerable equipment attacked opportunistically and used to pivot into the campus network. Just as wearing a mask can help protect others from COVID-19 as much as it helps you, reaching a baseline of cybersecurity everywhere possible protects all our intellectual property and research programs.

The CCR certification initiative addresses these challenges by striving for herd immunity across the University's research cyberinfrastructure and only requires a few simple steps:

1. Deploy the campus provided solutions for protecting computers from attack on every system capable of supporting the solutions and configure accounts to meet basic best practices (such as strong passwords).
2. Answer a short questionnaire about your laboratory.
3. Certify the accuracy of the information.

We also encourage, but do not require, a few additional practices whenever possible, such as using campus provided computer accounts or using the campus DUO service for Secure Shell or system access.

To assist you and your laboratory, support resources have been identified and are available at no cost to you. These consist of the ITS Research IT unit, members of the Office of Information Assurance and San Diego Supercomputer Center, and a large number of unit IT staff. Collectively this pool of resources is

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available to answer questions, help with software installation, and discuss data backup and archiving strategies. For requests for support please contact ccr-support@ucsd.edu. General questions should be sent to ccr-info@ucsd.edu.

The CCR certification is valid for two years, but you'll benefit during that time by having the security and technology professionals provide information back to you about "at risk" systems. By knowing where your laboratory is on the campus network and the sorts of instrumentation you have, the Campus IT Security Office will be able to provide you with information about systems or data sets that are attacked, along with help to resist these attacks. High risk laboratories will have their CCR certification information reviewed with suggestions for improving the laboratory's rigor against cyber threats. Faculty and researchers completing their CCR certification will receive an attestation of certification suitable for inclusion with grant proposals. The deadline for certification is June 30, 2021. Certification will be tracked and required as part of the processing of new grant proposals.

Please note that even if you're a faculty member or researcher without a large laboratory, you are still required to complete a CCR certification. An individual with a single laptop can still be at risk and ensuring your research and teaching are secured is as essential as securing a large laboratory full of sensitive instrumentation. Herd immunity requires everyone's participation.

Please visit the CCR website for general guidance and detailed information. The CCR certification request tool is available at certify.assure.ucsd.edu. More information is being added weekly to these sites. ITS is looking for two smaller units to pilot the certification process. If you are interested or would like to initiate the CCR certification process now, please contact Mike Corn, UCSD Information Security Officer at mcorn@ucsd.edu.

MANAGING ACADEMIC APPOINTEE AND STAFF COMPLIANCE WITH UC SAN DIEGO ENHANCED SAFETY

UC San Diego has developed enhanced safety requirements to promote health and safety in compliance with public health orders and UC San Diego policy during the COVID-19 pandemic. All members of the UC San Diego community, including academic appointees, are expected to follow the new requirements, including any safety protocols established by individual labs or units in furtherance of these requirements.

In addition, there are progressive engagement plans designed to guide supervisors in instances in which an academic appointee and/or staff member in your area fails to act in accordance with safety requirements. The guidelines are intended to prevent undue escalation through early intervention and behavior modification using established protocols. Please see the following links for "Pathways to Progressive Engagement Guidelines for Managing Academic Appointee and Staff Member Compliance with UC San Diego Enhanced Safety Requirements":

- **Academic Appointees**
- **Staff Members**

The Research Continuity Task Force has also developed a pathway to progressive engagement for COVID-19 related safety in research contexts. In addition to following the guidelines for progressive engagement with academic appointees, staff, and students, this document also identifies the actions that the Office of Research Affairs and Environmental Health & Safety will take to support compliance with all COVID-19 related safety requirements. This information is available at pathway-to-progressive-engagement.

By implementing the pathway for progressive engagement, UC San Diego hopes to encourage academic appointees and staff members to rethink and amend their behavior in a positive and collegial way.

For additional information, please visit the UC San Diego Return to Learn website. For research related concerns, please contact the Office of Research Affairs at research@ucsd.edu.

National Science Foundation Biosketch, Current/Pending and Foreign Disclosure Updates

BY ROSS DAMMANN

On July 11, 2019, the National Science Foundation ("NSF") issued a Dear Colleague Letter (NSF 19-200) in which they stated, "international collaboration is essential to pursuing the frontiers of science." UC San Diego also believes that scientific research and academic scholarship work best with open collaboration and is committed to having an open, welcoming campus, respecting the rights of faculty and abiding by our Principles of Community.

International research collaboration can take many different forms: A research project with a subaward to an institution in a foreign country, a multi-site clinical trial with sites and participants in a foreign country, hosting a visiting researcher from a university in a foreign country, establishing an unfunded collaboration agreement with a partner in a foreign country and other types of collaborations. For purposes of this discussion, international engagement refers to scientific research collaborations with transparent and reciprocal exchanges for mutual benefit of parties from different countries.

Recent reports and guidance from the federal government have highlighted the importance of disclosing financial interests, affiliations, activities, and relationships with foreign entities. Many federal agencies are increasing or reinforcing their existing requirements for Principal Investigators to disclose their foreign sources of support and to disclose how those sources are being used to support proposed and related research.

UC San Diego researchers who receive federal funding for research activities need to be aware of these requirements and how each federal agency interprets what is meant by foreign sources of support. Some of these federal agency requirements have been in place for some time and others are either new or are being interpreted differently and/or more rigorously than in the past. This article will focus on NSF in particular.

The above-referenced NSF Dear Colleague Letter (NSF 19-200) outlines that NSF has required senior project personnel on proposals to disclose all sources of support, both foreign and domestic, since 1978. Our (the United States) science and engineering enterprise is put at risk when another government endeavors to benefit from the global research ecosystem without upholding the values of openness, transparency, and reciprocal collaboration.

NSF has commissioned a study to assess risks and recommend possible practices for NSF and its awardee organizations to achieve the best balance between openness and security of science. For example, NSF personnel and Intergovernmental Personnel Act (IPA) Assignments detailed to NSF are precluded from participating in foreign government talent recruitment programs.

NSF recently recorded a webinar about the requirement to use an NSF-approved format for both the biographical sketch and current and pending support documents as part of proposals submitted to NSF. The webinar specifies that the two NSF-approved formats are SciENcv: Science Experts Network Curriculum Vitae, and an NSF Fillable PDF (only PDFs that are generated through use of an NSF-approved format are acceptable). This policy, outlined in the NSF Proposal and Award Policies and Procedures Guide (PAPPG) (NSF 20-1: Chapter II.C.2.f, Biographical Sketches; Chapter II.C.2.h, Current and Pending Support), goes into effect for proposals submitted or due, on or after October 5, 2020. Please note that this webinar was recorded in April 2020, and refers to the effective date of June 1, 2020 for the requirement to use an NSF-approved format in submission of the biographical sketch and current and pending support documents. Since the recording of the webinar, NSF has changed the effective date of the requirement for new proposals submitted or due on or after October 5, 2020.

Biographical Sketches must include:

- Professional Preparation: Individual's undergraduate and graduate education and postdoctoral training
- Appointments: Reverse chronological order by start date of all the individual's academic, professional, or institutional appointments
- Products: (i) up to five products most closely related to the proposed project; and (ii) up to five other significant products, whether or not related to the proposed project
- Synergistic Activities: Up to five distinct examples that demonstrate the broader impact of the individual's professional and scholarly activities

Current and Pending Support:

- Must be separately provided for each individual designated as senior personnel
- Includes all resources made available to an individual in support of and/or related to all research efforts, regardless of whether or not they have monetary value
- Includes all in-kind contributions, even if it is not intended for use on the project/proposal being proposed
- Must be provided for this project, for ongoing projects, and for any proposals currently under consideration from whatever source
- The total award amount for the entire award period covered (including indirect costs) must be provided, as well as the number of person-months (or partial person-months) per year to be devoted to the project by the individual
- If the project (or any part of the project) now being submitted has been funded previously by a source other than NSF, information must be provided regarding the last period of funding
- Concurrent submission of a proposal to other organizations will not prejudice its review by NSF.

As federal agencies become more diligent, U.S. researchers and their institutions must follow suit. Investigators and other proposal preparers are encouraged to visit the NSF sites noted in this article, and if there are additional questions, please contact the UC San Diego Office of Contract and Grant Administration (OCGA) at ocgainfo@ucsd.edu.

CONFLICT OF INTEREST DISCLOSURE FOR NON-FEDERAL PROJECTS ON THE STATE OF CALIFORNIA 700-U FORM

BY JENNIFER J. FORD

A conflict of interest (COI) disclosure is required for projects for Research, Gifts, and Services from a non-federal sponsor.

The State of California requires that the University Principal Investigator (PI), their spouse, registered domestic partners, or dependent children, disclose whether or not they have a financial interests or a position when their project is being funded or supported in whole or in part by a non-federal sponsor, such as a for-profit company or non-profit foundation, either directly or through a subaward. The State of California financial disclosure form is called the "Statement of Economic Interests for Principal Investigators" (also known as the 700-U form) and is used to comply with the Fair Political Practices Regulations as it relates to the University of California and its Principal Investigators. The 700-U form is to be completed by the PI and is required for sponsored research, clinical trials, services, research gifts,

A conflict of interest (COI) disclosure is required for projects for Research, Gifts, and Services from a non-federal sponsor.

material transfer agreements, and unfunded human subject projects. A 700-U disclosure must be submitted in Kuali COI. If the PI answers "yes" to position (3a), investment (3b) or income (3c), the PI will be required to answer supplemental questions required by the COI Independent Review Committee (IRC).

For projects with human subjects, co-Investigators and study staff assigned to the protocol that have a position or interest(s) with the non-federal sponsor, must self-report to the COI Office by sending an email to the COI Office at info-coi@ucsd.edu, requesting those specific individuals provide a COI disclosure on the 700-U form. The email to the COI office must contain the discloser's name, the name of the company the discloser has interest(s) or position, the title of the project and the IRB number.

WHAT ARE THE CATEGORIES AND DISCLOSURE DOLLAR THRESHOLDS FOR THE 700-U FORM?

The PI must disclose any direct financial relationship or position between the PI **AND** the non-federal sponsor. The disclosure categories and threshold requirements apply to the PI, their spouse, registered domestic partners, or dependent children and the non-federal sponsor within the past 12 months:

1. **Position(s) or role:** Founder, inventor, consultant, advisory board member, director, partner, manager, officer, trustee, employee, board of directors or any other position of management
2. **Investments:** Stocks, bonds, and stock options, including margin or brokerage accounts that have a value totaling $2000 or more.
3. **Income:** Salaries, consulting income, honoraria from speeches or other services that were performed, royalty payments, and stock dividends and/or interest earned, or the proceeds from any stock sales.
4. **Personal Gifts:** Gifts or the promise of a gift received from the sponsor of $50 or more, or multiple gifts from a single non-federal sponsor totaling $50 or more.
5. **Personal Loans:** Loans from the sponsor require disclosure if the outstanding balance has exceeded $500.
6. **Travel Reimbursements or travel paid for by the non-federal sponsor:** Travel expenses includes per diem, payments for transportation outside California, travel advances, lodging, and meals that were received from the sponsor.

WHEN IS COI DISCLOSURE REQUIRED FOR HUMAN SUBJECT PROTOCOLS INCLUDING UNFUNDED PROJECTS?

Investigators and study staff who are responsible for the design, analysis, conduct, or reporting of the results of research performed under a human subjects protocol, must disclose whether or not they have a financial interest in or association with the sponsor or the company supplying the materials, drugs, or devices for the project. Those financial relationships may include payments for services, equity interests or intellectual property rights. This COI disclosure requirement applies to all individuals listed in the research plan as a research team member and is applicable for unfunded research projects (i.e., internal departmental or gift funds). The policy governing disclosure is under Human Research Protections SOPP section 3.8, and applies to funded and unfunded human subject projects.

Special concerns arise when human subjects are involved, as the human subjects may be placed at additional risk because of the discloser's financial interests.

Situations that warrant additional consideration include those where an investigator or study staff have a financial interest in the sponsor or manufacturer of a product being tested in human subjects, or in which the investigator and/or study staff is the inventor of the product being used in the protocol.

When investigators or study staff have financial interest(s) in unfunded human subject projects, a manual project must be created in Kuali COI. All of the individuals

Special concerns arise when human subjects are involved, as the human subjects may be placed at additional risk because of the discloser's financial interests.

that have a position or interest(s) must self-report by sending an email to the COI Office at info-coi@ucsd.edu indicating that specific individuals must provide a COI disclosure on the 700-U form. The email to the COI Office must contain the discloser's name, the name of the company the discloser has an interest or position, the title of the project and the IRB number.

WHAT OTHER COI DISCLOSURE FORM TYPES MAY I NEED TO DISCLOSE MY NON-FEDERAL INTERESTS?

Principal Investigators, Co-Investigators and Senior/Key Personnel who have Public Health Services (PHS) funded research or research funded by an agency that has adopted the PHS COI regulations **AND** financial interest(s) greater than $5,000 in the past 12 months or any equity in a privately held company (whether foreign or domestic), are required to disclose on the federal PHS portfolio in Kuali COI. This also applies to the discloser's spouse, registered domestic partner and/or dependent children. The discloser must mark "yes" to the Federal PHS gating question screen and then on the Financial Entity screen add each entity and disclose the various types of interest(s).

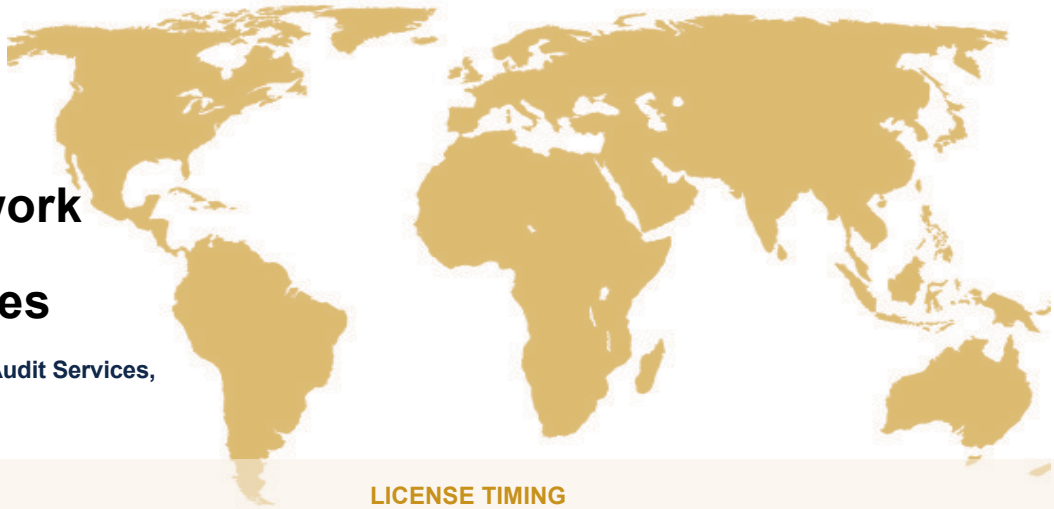
For questions or additional information, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465 or visit the Conflict of Interest Office website. Tutorials on Kuali COI are also available.

NOTIFICATION OF NEW UC SAN DIEGO INVESTIGATIONAL DRUG SERVICE FEES

BY JI SUN

Please be aware that the Investigational Drug Service (IDS) has a new fee structure for 2020 which will be effective on 10/1/2020. This fee structure will be utilized by all five UC IDS departments providing consistency among campuses. The new fees are based on current salaries, benefits and actual time required to perform given functions, and have been benchmarked against our peer institutions, to assure that they remain competitive. Studies that are already in progress, or for which we have already provided a budget estimate, will continue to be charged the old fees. For more detail, please refer to the new IDS 2020 Fee Structure on the Office of Compliance and Privacy intranet or contact IDS directly.

Federal Laws May Regulate Research/Telework From Certain Countries



UCOP Ethics, Compliance and Audit Services, Compliance Alert, Sept.2, 2020

CURRENT REQUIREMENTS

Under federal export control law, University research, telework or students participating in UC San Diego online classes from a country subject to comprehensive sanctions, including Cuba, Iran, North Korea, Syria, and the Crimea region of Ukraine, is a regulated service and may require a license[1].

For example, the COVID-19 pandemic travel restrictions are preventing some UC researchers from entering the United States to begin work. In some situations, the researchers desire to work remotely. If a researcher or student is in Cuba, Iran, North Korea, Syria, or the Crimea region of Ukraine, the University will most likely need to obtain a license before work begins. License determinations are by the location's Export Control Officer, who will review the proposed activity and apply for a specific license when one is needed.

LICENSE TIMING

License applications take 3-12 months or longer for processing by the federal government, and approval is not guaranteed. The license must be in place before the regulated service or, in the above example, before the individual begins work remotely.

CAMPUS COORDINATION

To identify UC employees who may potentially conduct research or telework from a sanctioned country, the following offices and individuals should coordinate with their local export control office, and if needed, with University counsel:

- Academic Personnel
- Graduate and Undergraduate Division Deans
- Faculty

If you have additional questions, please contact the UC San Diego Export Control Office at export@ucsd.edu.

[1] **Relevant Regulations:**
Cuba: 31 CFR 515.201(a), 31 CFR 515.564, 31 CFR 515.565
Iran: 31 CFR 560.201, 31 CFR 560.204, 31 CFR 560.410(a), 31 CFR 560, Gen. License G
North Korea: 31 CFR 510.205, 31 CFR 510.206
Syria: 31 CFR 542.207
Crimea Region of the Ukraine: E.O. 13685, dated 12/19/2014

What Qualifies as Responsible Conduct of Research Training

BY MONIQUE TEIXEIRA

Responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. While RCR training is recommended for all members of the research community, projects funded by the National Institutes of Health (NIH), National Science Foundation (NSF) and National Institute of Food and Agriculture (NIFA) have specific requirements regarding training in RCR. In addition, other programs, such as some graduate programs through UC San Diego, may require RCR training.

Often times, researchers ask what type of course qualifies to meet the requirements to be considered an RCR course. While there are no specific curricular requirements for instruction in RCR, the below topics have been incorporated into most acceptable plans for such instruction. Please note the specifics of what is acceptable may vary depending on the views of the program officer in the federal agency.

- Conflict of Interest: personal, professional, and financial
- Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- Mentor/Mentee responsibilities and relationships
- Collaborative research including collaborations with industry
- Peer review
- Data acquisition and laboratory tools; management, sharing and ownership
- Research misconduct and policies for handling misconduct
- Responsible authorship and publication
- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research or research involving vertebrate animals, may form a part of instruction in RCR, they generally are not sufficient to cover all of the above topics.

Departments are encouraged to develop their own RCR training plans in consultation with the Research Ethics Program to ensure their plans meet the format and content requirements of federal agencies. The Research Ethics Program can assist in setting goals, selecting topics to be covered, identifying useful approaches for teaching and learning, and assessing outcomes, as well as offering "Train the Trainer Workshops."

If you have taken a course that you think could qualify as RCR training, please contact the Research Compliance and Integrity Office (RCI) office and we will assist you in assessing the course. For general information on RCR training, please see the RCI Responsible Conduct of Research website. If you have questions or need additional information, please contact the RCI Office at rci@ucsd.edu or (858) 822-4939.

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, Sandra A. Brown. 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 Committee, Principal Investigators, Administrators, the IO, the RCI Executive Director 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. The Director of the Animal Care Program is also 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. Please do not hesitate to contact either office with any questions or concerns.

Changes to the ClinicalTrials.gov Applicable Clinical Trials Results Submissions

BY DIANA D. KIM

The National Institutes of Health (NIH) policy and the ClinicalTrials.gov Frequently Asked Questions (FAQs) have been updated to include a recent change in certain clinical trial results reporting requirements of the Food and Drug Administration Amendments Act (FDAAA). A Federal court has held that the submission of results information for any "applicable clinical trial" (ACT) that was initiated after September 27, 2007, or that was ongoing as of December 26, 2007, is required if the ACT studied a product that is approved, licensed, or cleared by the Food and Drug Administration (FDA) at any time, including after the primary completion date. Please see ClinicalTrials.gov FAQs for more information on ACTs. The submission of results information is required for an ACT that:

- **Was initiated after September 27, 2007, or was ongoing as of December 26, 2007**
- **Reached its primary completion date before January 18, 2017, and**
- **Studied a drug, biological, or device product that is approved, licensed, or cleared by FDA at any time, including after the ACT's primary completion date.**

If the product studied in the ACT is currently approved, licensed, or cleared by the FDA, the results information must be submitted to ClinicalTrials.gov as soon as possible. If the studied product is not currently approved, licensed, or cleared by the FDA, the results information must be submitted within 30 days after the approval, licensure, or clearance of the studied product. The FDA and the NIH can take action against Responsible Parties if required results information is not submitted, inclusive of civil monetary penalties and/or the FDA or the NIH not releasing remaining funding for a grant or funding for a future grant.

For additional information and resources, please see the Reach Compliance and Integrity (RCI) Office's ClinicalTrials.gov website and the ClinicalTrials.gov Frequently Asked Questions (FAQs). For questions, please contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.

New General Data Protection Regulation for Research Collaborative Institutional Training Initiative (CITI) Training

BY MONIQUE M. TEIXEIRA

UC San Diego faculty, students and staff now have access **at no cost** to the Collaborative Institutional Training Institute (CITI) training module on General Data Protection Regulation (GDPR) for Research and Higher Education. This module discusses the important elements of the regulation, including different categories of data and regulatory roles and when the GDPR may apply to U.S.-based organizations and researchers. This course begins with an overview of the regulation, then additional modules provide in-depth coverage on elements and topical areas, including:

- **GDPR and Human Subjects Research Considerations**
- **Legal Basis for Processing Personal Data Subject to the GDPR**
- **GDPR and Data Protection Impact Assessments**
- **GDPR and Consent for Data Processing in Research**
- **GDPR and Organizational Duties**
- **Introduction to the GDPR for U.S. Higher Education Organizations: Beyond Research**

To access the CITI module, log into your UCSD CITI account (or create a new account) and select the General Data Protection Regulation (GDPR) for Research and Higher Education course. For questions, please contact the Research Compliance and Integrity Office at rci@ucsd.edu or (858) 822-4939.

EDUCATION

RESEARCH COMPLIANCE HOT TOPICS AND TRAINING PROGRAM

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

- **New National Science Foundation (NSF) Formatting Requirements for New Proposals**

  September 23, 2020
  11:00 a.m. - 12:30 p.m., via Zoom

- **Advanced Good Clinical Practice (GCP)**

  October 21, 2020
  9:00 a.m. - 12:00 p.m., via Zoom

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

New Office of Innovation and Commercialization Senior Innovation and Commercialization Manager

BY WILLIAM DECKER

Dr. Andrei Chakhovskoi recently joined the Physical Sciences Innovation team at the UC San Diego (UCSD) Office of Innovation and Commercialization (OIC). Prior to coming to UCSD, Andrei worked as a Senior Licensing Property Officer at the Innovation Access, University of California at Davis. He was managing intellectual property in the fields of physical sciences, engineering, computer science and nanotechnology. His portfolio included one of the top 25 highest-earning engineering inventions in the entire University of California system, the Optical Network Switch. He also was responsible for plug-in hybrid automotive patent portfolio license and assisted in the creation of over 20 startup companies that licensed UC technologies.

Andrei earned his M.S. in Electrical Engineering and his Ph.D. in Physics and Mathematics from the Moscow University of Physics and Technology. Andrei worked for the Russian Academy of Sciences at the Institute of Cybernetics, and was an expert at the Russian Patent Office. Since 1992, he worked at UC Davis, first as a post-doctoral research associate, then as an Adjunct Professor at the Department of Electrical and Computer Engineering, and since 2003, as the Intellectual Property Officer. Andrei also worked as a visiting scientist at Sandia National Laboratory at Livermore, and was a consultant for the LightLab AB, a European startup company that licensed his invention related to mercury-free cathodoluminescent light bulb technology. Andrei taught classes on semiconductor physics, programming, electrical engineering and history of inventions. Andrei's list of publications consists of 50 journal articles, four patents, and over 100 conference papers and presentations.

To reach Andrei, please email achakhovskoi@ucsd.edu. For the OIC team directory, please visit the OIC page.

"Research is formalized curiosity. It is poking and prying with a purpose."
— Nora Neale Hurston

Q&A

Ask the Questions . . .

Am I required to submit results information for my Applicable Clinical Trial (ACT)on ClinicalTrials.gov?

For Applicable Clinical Trials (ACTs) that are required to be registered and with a Primary Completion Date before January 18, 2017:

- Results information is required to be submitted if the ACT studies a drug, biological, or device product that:
  - Was approved, licensed, or cleared as of the Primary Completion Date
  - Is approved, licensed, or cleared on or after the Primary Completion Date within 30 days after the approval, license, or clearance by the FDA
- For ACTs that are required to be registered and with a Primary Completion Date on or after January 18, 2017:
  - Results information is required to be submitted if the ACT studies a drug, biological, or device product regardless of the studied product's approval, license, or clearance.

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

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.

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.

What happens if I am required to disclose a conflict of interest and I do not?

For federally sponsored research, failure to file or update a conflict of interest disclosure or to comply with any conditions or restrictions imposed on the conduct of the project, may be grounds for discipline under the University Policy on Faculty Conduct and the Administration of Discipline and/or other applicable employee discipline policies. In addition, UC San Diego may be required to perform a retrospective review of past and current research projects. Furthermore, federal sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards. For non-federally sponsored research, failure to file the required Statement of Economic Interests or failure to report a financial interest may subject the individual to civil liability, including fines (Government Code sections 81000-91014) as well as University discipline.

For assistance with your conflict of interest disclosure requirements, please contact the Conflict of Interest Office at info-coi@ucsd.edu or (858) 534-6465.

I have received an email from ClinicalTrials.gov that indicates my results are now required to be posted, but previously they were not required. What does this mean?

A recent Federal Court decision, *Seife et al. v. HHS et al.* and subsequent NIH Notice, requires submission of results information for an "applicable clinical trial" (ACT) that was initiated after September 27, 2007, or that was ongoing as of December 26, 2007, if the ACT studies a product that is approved, licensed, or cleared by the Food and Drug Administration (FDA at any time, including after the ACT's primary completion date. If the results submission deadline has already passed, submit the results information as soon as possible.

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

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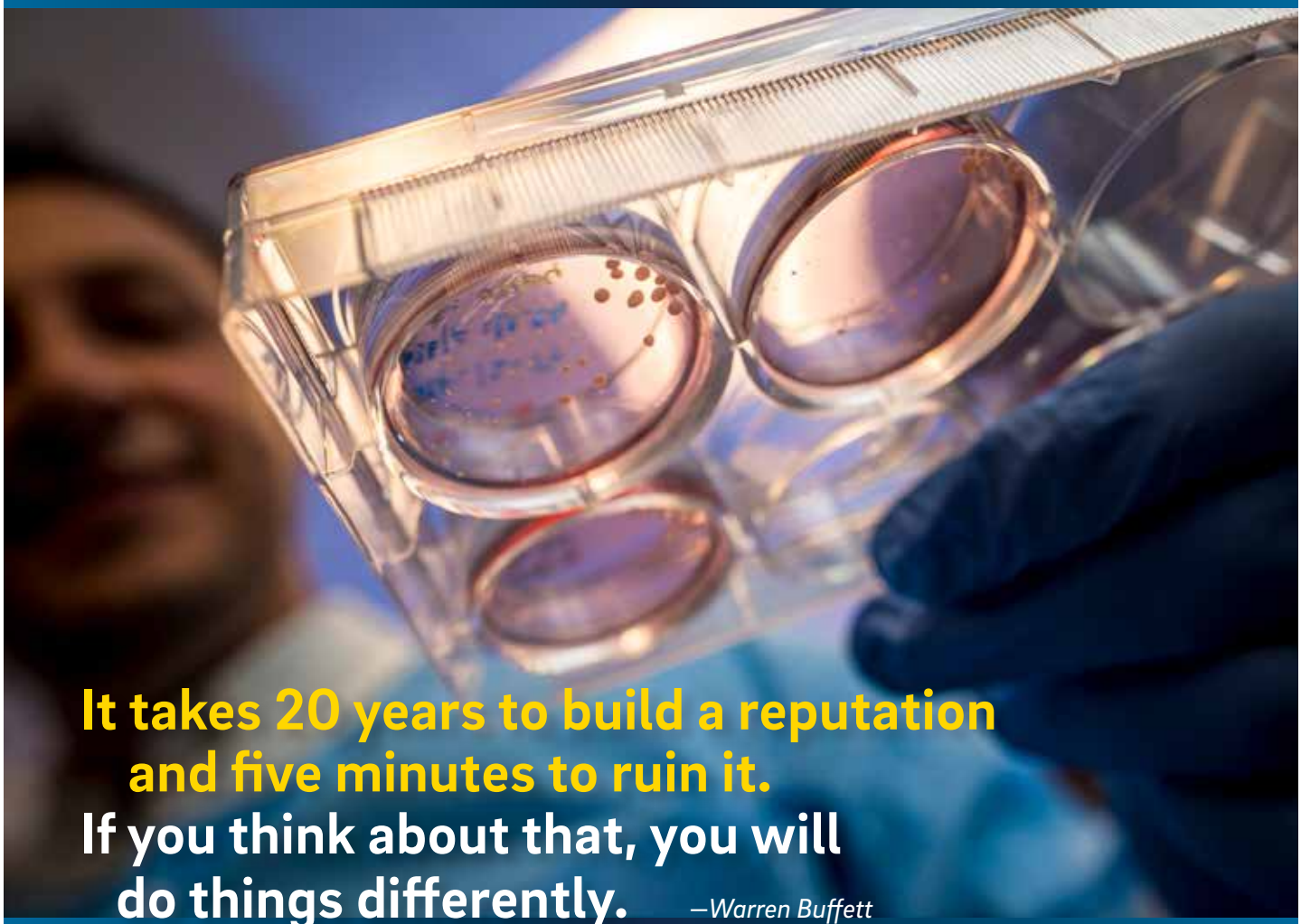

It takes 20 years to build a reputation and five minutes to ruin it. If you think about that, you will do things differently. *—Warren Buffett*

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

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