The Office of Research Compliance and Integrity (RCI) provides timely notices to the research community on important information, policies updates and regulatory initiatives and changes. See the RCI website at http://blink.ucsd.edu/sponsor/rci/index.html.

In This Issue
- Remote Work Abroad Approval Requirements
- Disclosing Financial Conflict of Interests (FCOI) for Public Health Services Funded Research
- The ClinicalTrials.gov Record Update Requirement
- Updates to the National Science Foundation Biosketch, Current/Pending and Foreign Disclosure
- Monitoring of the National Institutes of Health Good Clinical Practices Training Requirements
- Reporting Animal Welfare Concerns
- Notification of New UC San Diego Investigational Drug Service Fees
- RCI Hot Topics and Training Program

Due to the COVID-19 pandemic and changing United States (U.S.) government policies with regards to visa approvals and travel restrictions, there may be both American and foreign citizen university personnel that are unable to return to the U.S. and may need to work remotely in other countries. Remote work abroad requires approval to meet various legal and university policy requirements including Export Control, Human Resources/Academic Personnel, sponsored research grant and contract terms and Cybersecurity (these are not new UC San Diego requirements). In order to ensure that the proper controls and approvals are in place to continue research and work outside of the U.S., please contact the following offices:

Export Control:
Access by UCSD persons abroad to UCSD IT systems are exports and export licenses may be required depending on the national status, country of access and the technology. Export licensing is required for access from sanctioned countries and their nationals located in other countries like Cuba, Iran, North
Korea, Syria and Sudan. Additionally, licenses may be required for access to export restricted technology in any other country. If there are shipments abroad to support UC San Diego personnel, such as equipment or materials, an export control license review is required.

For additional information or assistance with export control related matters, please contact the Export Control Office at export@ucsd.edu.

Employment Considerations:
Employment compliance areas such as tax, health care and telecommute agreements need to be addressed. There are a number of UC San Diego offices that address these issues from your local department to certain central offices that handle specific employment areas:

➢ Staff Employees-Human Resources: Amanda Chavez, amandachavez@ucsd.edu
➢ Postdocs-Office of Postdocs & Research Scholar Affairs: Jennifer Bourque, jbourque@ucsd.edu
➢ Graduate Student Researchers (GSRs)-Grad Division: April Bjornsen, abjornsen@ucsd.edu
➢ All other academic appointments-Academic Personnel: academicpersonnel@ucsd.edu
➢ International Faculty & Scholars Office: https://ifso.ucsd.edu
➢ International Students & Programs Office: https://istudents.ucsd.edu

Sponsored Research Contracts and Grants:
If any person working abroad is also working on UC San Diego sponsored research, foreign work or foreign component pre-approval may be required depending on the funding agency and award terms. Please contact your OCGA Officer or SIO OCGA if you are aware of any personnel performing research on a Federally-funded award and working remotely in a foreign country. The Contract Officer will work with the PI and Department Fund Manager to submit any necessary notice or prior approval request to the sponsor.

Postdoctoral Scholars on NIH Awards:
If a postdoctoral scholar is required to work remotely from a foreign country in order to perform the originally approved work on an active NIH grant due to COVID-19 and no grant funds are being provided to a foreign entity, this would not qualify as a Foreign Component requiring prior approval. This is clarified in the NIH FAQs for COVID-19 Flexibilities. Guidance from other federal agencies is still pending.

If you have questions about this or other FAQs, please contact your OCGA Officer or SIO OCGA Officer. You can find additional COVID-19 related guidance at the following links:

➢ At-a-Glance summary of Federal sponsor guidance regarding COVID-19 flexibilities affecting contracts and grants: At-a-Glance Summary
➢ Links to detailed sponsor guidance regarding impacts of COVID-19 on contract and grant administration: Guidance from Sponsors and Research Partners
➢ FAQ’s related to COVID-19 impact on contracts and grants: FAQ’s

For questions related to Cybersecurity at UC San Diego, please email security@ucsd.edu.

Recently, the National Institutes of Health (NIH) posted new guidance entitled, “Protecting U.S. Biomedical Intellectual Innovation.” The NIH requires full transparency in NIH applications and throughout the life of an NIH grant, inclusive of all sources of research support, prior approval of all foreign components, and appropriate reporting and management of financial conflicts of interest. The new guidance reminds the research community about the need to report foreign activities through documentation such as 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, UC San Diego (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 directly 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.

5. Income or travel from U.S. Institutions of higher education or U.S. federal, state or local government agencies 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.

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

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**The ClinicalTrials.gov Record Update Requirement**

For studies registered on ClinicalTrials.gov, the final rule (42 CFR 11.64(a)) requires the ClinicalTrials.gov record to be updated at least annually. The annual update to the record must include the protocol amendment. However, for protocol amendments that require the changes to be communicated to the subjects in the trial, the record must be updated within 30 days of the Institutional Review Board (IRB) approval of the protocol amendment. The regulations also require some data elements to be updated more frequently. In particular, a record must be updated within 30 days of a change to any of the following:

- Recruitment Status and Overall Recruitment Status
- Completion Date

For a complete list of registration data elements that require frequent updating, please refer to ClinicalTrials.gov website’s [Frequently Asked Questions](#) page. The Responsible Party’s responsibility
to update the ClinicalTrials.gov record ends when corrections have been made and/or addressed and all required results information has been submitted if results information is required.

UC San Diego utilizes a tool called PROCoM to manage the studies registered on ClinicalTrials.gov. Responsible parties and record owners may receive notifications and reminder emails from “RCI ClinicalTrialsGov” with the email address of RCIClinicalTrialsGov@prstracker.net. These are legitimate emails used by the UC San Diego Research Compliance and Integrity (RCI) Office to provide important messages regarding specific ClinicalTrials.gov records. The replies to these messages are sent to the RCI monitored email account, ctgov@ucsd.edu.

Please see the factsheet on Annual Reporting and Updating the Study Record and the RCI ClinicalTrials.gov website. For questions or additional information, please contact the RCI Office at ctgov@ucsd.edu or (858) 822-4939.

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 the National Science Foundation (NSF) in particular.

The 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 to be submitted or due on or after October 5, 2020.

For questions or additional information, please contact the UC San Diego Office of Contract and Grant Administration (OCGA) at ocgainfo@ucsd.edu.

All investigators and staff involved in the conduct, oversight, or management of National Institutes of Health (NIH) funded clinical trials must be trained in Good Clinical Practice (GCP). The NIH clinical trial Principal Investigator (PI) has the responsibility to determine the role of each member of their study team and ensure that the study team has completed the appropriate training. All staff should complete their required GCP training before beginning work on the NIH clinical trial.
The Research Compliance and Integrity (RCI) monitors GCP training based on the information included in the grant application/proposal and the IRB application. If your NIH funded clinical trial is selected for monitoring, you may receive an email from the RCI Office asking to confirm GCP training for the individuals identified as being associated with your study. Those members of the study team who are no longer associated with the University or with your study will still be monitored to determine if they completed the required training. After the monitoring is completed, the results of the monitoring and a compliance rate will be provided to the PI.

GCP training can be completed without charge, through the UCSD CITI Program. For instructions and FAQs for the CITI training, please visit the RCI GCP FAQ page. For additional information or assistance, please contact the RCI Office at (858) 822-4939, rci@ucsd.edu.

The UC San Diego Institutional Animal Care and Use Committee (IACUC) oversees the University’s animal care and use program and is responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories, overseeing training and educational programs, and investigating animal welfare concerns. UC San Diego is committed to the humane treatment of all animals used in research and teaching. The privilege to use live animals for the advancement of science and medicine carries with it the responsibility to follow all applicable laws, policies and procedures concerning animal welfare.

Anyone who is aware of potential violations to existing animal care and use regulations or observes misuse or mistreatment of animals is strongly encouraged to report their concerns. Members of the University community are encouraged to report their concerns using any one of the following methods:

➢ Report the issue or concern to your direct supervisor.
➢ If discussing the issue or concern with your supervisor is not possible or successful, contact the IACUC Office at iacuc@ucsd.edu, (858) 534-6069 or mail code 0071.
➢ Contact the UC San Diego Hotline at 1 (877) 319-0265. Reports can be made anonymously and should include a factual description with as many of the following as possible: Date, time, location, animal species, numbers, identification of animals, personnel involved, and any other relevant details.

For additional information, please see the following:
➢ UC San Diego Institutional Animal Care and Use Committee (IACUC) Policy on Reporting Animal Concerns
➢ Reporting Animal Care and Use Concerns
➢ UCSD Hotline Information

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

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 and contact IDS directly.
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 provides 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. See the information below for the upcoming sessions:

➢ **August 19, 2020, 11:00 – 12:30 p.m., via Zoom**
   **ClinicalTrials.gov: Entering Results**

This session will provide information on how to enter study results as required by the federal regulations as well as provide tips and tricks on how to best navigate ClinicalTrials.gov and the Protocol Results and Registration System (PRS) review process. There will also be a question and answer period.

Please register by August 17, 2020, via this [UC Learning Center link](https://www.uclear.com/). Select Register in the dropdown menu. Select the radio button for the session and date, and click Submit in the lower right corner of the page. You will receive an email registration confirmation from UC Learning.

➢ **August 26, 2020, 11:00 – 12:30 p.m., via Zoom**
   **Cybersecurity, Data Use, Cybersecurity Maturity Model Certification (CMMC) and Controlled Unclassified Information (CUI)**

Michael Corn from the Office of Information Assurance will provide information on the forthcoming obligations of the Federal Cybersecurity Maturity Model Certification (CMMC) program for all UCSD researchers and the new State of California requirements for data security. Additionally, what Controlled Unclassified Information (CUI) means for the scientific flow will be discussed. Guidance on four simple practices to help protect research data and programs from ransomware and to help prepare for forthcoming CUI and CMMC obligations will be provided. There will also be a question and answer period.

Please register by August 24, 2020, via this [UC Learning Center link](https://www.uclear.com/). Select Register in the dropdown menu. Select the radio button for the session and date, and click Submit in the lower right corner of the page. You will receive an email registration confirmation from UC Learning.

To listen to recordings of past sessions, please visit the [Research Compliance and Integrity website](http://blink.ucsd.edu/sponsor/rci/index.html).

If you have any questions, please contact the RCI Office at (858) 822-4939 or rci@ucsd.edu.