Caltech
OFFICE OF RESEARCH POLICY NEWSLETTER

Fall 2022/Winter 2023

Welcome to the ORP Newsletter!

The Office of Research Policy is responsible for providing research compliance support and training to faculty, students and staff in order to comply with federal, state and local regulations as well as Caltech policies. ORP includes Caltech's Office of Research Compliance, the Office of Export Compliance, and the Office of Laboratory Animal Resources. Regulatory Committees supported by this office include the IACUC, the IRB, the IBC, and the HESC. ORP also manages Caltech's Researcher Financial Conflicts of Interest program, Research Integrity, and Controlled Substances.

This newsletter will be issued two times a year, highlighting important regulatory changes, changes in institute policy, upcoming educational events, and committee meetings. We hope you find this informative and useful!

Important Grantee Regulatory Updates

Data Sharing: The Library is supporting campus implementation of the new NIH Data Management and Sharing Policy, which goes into effect on January 25, 2023. Please see the Library webpage for more information on the policy. The Library will be sharing more information about policy compliance at upcoming presentations, as well as posting further resources for researchers. Do you have questions about the policy? Please e-mail data@caltech.edu.

The Office of Science and Technology Policy (OSTP) also recently issued a memo in August regarding expected Data Sharing for federally funded projects.

Research Integrity Training: Both NSPM-33 and the CHIPS and Science Act of 2022 (P.L. 117-167) (CHIPS Act), require Research Integrity training for all investigators at all career stages. A new training module is being built for faculty and staff researchers. All postdocs and graduate students will continue to be required to complete the CITI RCR training available through access.caltech.edu.

Transparency Requirements: FCOI: NIH issued NOT-OD-22-210 Financial Conflict of Interest and Other Support: Reminders as a follow-up to the June 2022 OIG report that concluded that institutions did not require disclosure of outside relationships with international academic institutions. Note there will be a few new changes to your disclosure questions this year in the Disclosure of Financial Interests and Commitments (DFIC also known as COI Disclosure) in access.caltech.edu– more to come!

All investigators (including graduate students) must disclose financial conflicts of interest and commitments. Graduate student disclosure will begin Fall 2023.

Transparency Requirements: Biosketch/Current & Pending/Other Support: The Caltech International Collaborations website has been updated to include new information about NSF and NIH proposal disclosures and charts. Note that the Caltech-specific checklists in PDF format have been removed temporarily while we await the new federal forms, requirements expected to be out in a few months.

The NSF, on behalf of the National Science and Technology Council (NSTC) Research Security Subcommittee of the OSTP, posted the *draft* model forms for use by senior personnel, including draft common instructions for the Biographical Sketch, Current and

Pending (Other) Support, and a spreadsheet summarizing the data elements for each of these, as well as a pre-and post-award chart of where information must be disclosed. **FOR NSF, YOU MUST USE ONLINE SciENcv as of October 23, 2023.**

Digital Persistent Identifier: The National Science Foundation (NSF) will soon begin crunching several large databases to see whether there are scientists who failed to disclose ties to foreign institutions in their grant applications. All investigators with federal awards should obtain an ORCiD (a digital persistent identifier-DPI) to ensure you have a single profile and your information will not be confused with another investigator with the same or similar name. 84% of Caltech faculty already have an ORCiD!

Research Security: The CHIPS and Science Act of 2022 (P.L. 117-167) (CHIPS Act) was signed into law on August 9, 2022. It is designed to boost US competitiveness, innovation, and national security. The law provides subsidies to manufacture semiconductors in the U.S., boost science and technology research and address China's anti-competitive trade practices. These funds also come with strong guardrails. Of particular note to grantees regarding Research Security:

- Establishes and Empowers NSF Research Security and Policy Office.
- Requires all researchers be trained on best practices. Establishes a Research Security and Integrity Information Sharing Organization that will serve as a clearinghouse for institutions and researchers to identify efforts that may compromise research security.
- Prohibits participation in any *malign foreign talent recruitment program by universities and researchers involved with research and development awards from Federal agencies*.

Research Security: Safeguarding Science Website The National Counterintelligence and Security Center (NCSC) launched a website dedicated to research security: https://www.dni.gov/index.php/safeguarding-science. The site provides a research security toolkit.

Export Compliance Updates

Export News: U.S. Government agencies implement new international engagement regulations in response to current global events, national security concerns and foreign relations policies

Sanctions News: U.S. AND ITS ALLIES RESPOND TO RUSSIAN INVASION OF UKRAINE. Earlier this year, the United States and its allies released sanctions and export controls in response to Russia's invasion of Ukraine. This includes blocking sanctions on most major Russian banks including Russia's central bank, asset freezes on Russian elites, and a broad set of restrictions on exports of technology to Russia. For updates on the current sanctions, please visit:
https://researchcompliance.caltech.edu/export/sanctions_embargoes

Current U.S. Relationship with China? It's Complicated.   New U.S. "chip" export regulations casts a wide net on advanced computing and semiconductor items to address U.S. national security concerns and to curtail its reliance on foreign made critical components. On October 7, 2022, the Bureau of Industry and Security (BIS) published a new interim final rule that imposes controls on "certain advanced computing and semiconductor manufacturing items, supercomputer and semiconductor end use, and end-users." This rule applies when engaging with the People's Republic of China (PRC) (directly or indirectly) in semiconductor development and manufacturing of advanced computing and semiconductor chips. The restrictions apply to transactions to and from China of chips, commodities containing these chips, fabrication equipment for supercomputers and semiconductors. Please contact the export office before engaging with the PRC to assess the implications of these new requirements on your transaction, including procurements, development and fabrication activities, import/export of items to or on behalf of the PRC. Visit is us at:
https://researchcompliance.caltech.edu/export.

Section 889 of the John S. McCain National Defense Authorization Act prohibits government contractors from providing the federal government with telecommunications or video surveillance equipment, systems, or services and prohibits government contractors from using these prohibited items or services. To view the current prohibited Chinese and Russian companies list, please visit this page: https://researchcompliance.caltech.edu/export/nationsection-889

IBC Updates

This past year, the Caltech IBC continued to oversee, review and approve the use of recombinant DNA and RNA, pathogens, human materials and other potentially infectious material, as well as transgenic animals, insects and plants on campus.

Importing/Exporting Biological Materials: We have established a new webpage regarding importing / exporting biological materials and its requirements. https://researchcompliance.caltech.edu/export/shipments

IRB Updates

New Protocol Application System: The Institutional Review Board (IRB) protocol application system (PAS) will be coming **ONLINE on January 27, 2023** and available at access.caltech.edu. To accommodate the transition, the old system will be **OFFLINE all day January 26, 2023**. The new system has several upgraded features that will help with protocol management and training. It is integrated with several existing institute databases (IACUC PAS, grants, training, etc.) and will soon be integrated with the IBC. All existing protocols will be transferred into PAS and we will work with labs to ensure all data is accurate. We will be in touch with instruction and training leading up to the go live date.

Updated SOPs: The Caltech IRB Standard Operating Procedures (SOPs) describe the procedures related to IRB review, management and function. IRB members and researchers should reference the SOPs to enhance compliance with federal, state, and local requirements, and best practices. The Caltech IRB SOPs can be found on the IRB website.

IACUC and OLAR Updates

AAALAC Accreditation: 2023 is the year we will renew our AAALAC accreditation. You will receive more information as the time for our site visit approaches, likely in the Fall.

New Rates: OLAR will be instituting new per diem and service rates in January or February 2023.

Update User Profiles: The Caltech IACUC requests that all labs ensure that their personnel complete their User Profiles by filling out the Education and Experience sections in the Protocol Application System. This is required in preparation for the AAALAC re-accreditation process in 2023. As a reminder, to add new students and researchers to IACUC protocols, Lab animal Occupational Health Program (LAOHP) Medical Clearance must be obtained and specified CITI Training Modules must be completed.

Reduced Regulatory Burden for USDA Species: The Caltech IACUC implemented the new review timeline for USDA protocols in 2022. The USDA changed the requirement for the ongoing renewal and review of IACUC protocols to decrease regulatory burden. Their timeline now follows the same timeline as required by the PHS/OLAW. All protocols must be renewed every three years, and annual reviews will be submitted each year.

New Species on Campus: Government agencies extended their animal care and welfare oversight to include invertebrate animals, including the oversight over cephalopods in the new version of the Guide. AAALAC has provided guidelines on the care and welfare of cephalopods in research. The IACUC has incorporated these guidelines in the Standard Operating Procedures and the IACUC charter to include oversight of cephalopods. We now have cephalopods on campus!

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