Caltech OFFICE OF RESEARCH POLICY NEWSLETTER

Spring/Summer 2024 Volume 3

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Spring/Summer 2024 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 Control, and the Office of Laboratory Animal Resources. Regulatory Committees supported by this office include the IACUC, the IRB, the IBC, the RSC, and the HESC. ORP also manages Caltech's Researcher Financial Conflicts of Interest program, Research Integrity, and Controlled Substances.

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

Important Grantee Regulatory Updates

Research Security: The Research Security landscape continues to evolve at a rapid rate. Certifications, exclusion of Malign Foreign Talent Program, Current and Pending Support and Training Requirements are all being updated by the Federal Agencies. In this newsletter, we will highlight the current training requirements and Certifications.

Training Requirements All researchers, including faculty, research staff, postdocs and graduate students, must complete <u>Responsible Conduct of Research/</u> <u>Research Integrity Training</u>. Senior or Key Personnel who are named on an NSF award will not be able to receive funds from a new award until they have completed the Research Integrity training. All graduate students are expected to complete RCR training online prior to matriculation. Postdocs are expected to complete RCR within their first month at Caltech.

Financial Conflict of Interest (FCOI) and Undue Foreign Influence (FI) training is required for senior and key personnel who receive or will receive NIH (or other Public Health Service, PHS, agency) or Department of Energy funding and must be completed every four years. The FCOI and FI training are provided by CITI and accessible via access.caltech.edu.

Certifications On November 14, 2023, the Vice Provost sent out a memo

requesting researchers complete a one time certification, which indicates that their disclosures of commitments, financial interests, biosketch and other support (as applicable) are accurate and

EVENTS	
<i>IACUC Meetings</i> July 9, 2024 August 13, 2024 September 10, 2024	<i>IBC Meetings</i> July 15, 2024 September 3, 2024
<i>IRB Meetings</i> July 12, 2024 September 13, 2024	HESC Meetings TBD
RSC Meetings TBD	ECLC Meetings TBD

complete and that they will update them as required by Caltech policy and federal regulations and to confirm that they are not participating in a Malign Foreign Talent Recruitment Program, as defined in NSPM-33. Those certifications are now included in your annual disclosure (DFIC). If you are collaborating with anyone from Russia, Iran, China, or North Korea or have a research or financial relationship (e.g., research, consulting, academic appointment) with someone or an entity from these countries, you or your collaborator may be part of a Malign Foreign Government Talent Recruitment Program (MFGTP). If you have such a relationship, you should disclose it and upload any agreement they may have with these individuals or entities either into Question #4 Biosketch and Other Support in the DFIC <u>or</u> into the Biosketch and Other Support (BSOS) system in access.caltech.edu. The Office of Research Compliance will review the agreements and let you know if the relationship is acceptable or whether it is a MFGTP. As of this year, if you are part of a MFGTP, you may not submit a proposal to NSF.

Conflict of Interest Updates

Annual COI Disclosure Period: Caltech's annual Disclosure of Financial Interests and Commitments (DFIC) submission period begins on June 3, 2024, and runs through July 31, 2024. Beginning July 1, 2024, all researchers who have not submitted their annual disclosure will be restricted from submitting sponsored research proposals. Further, individuals who have not submitted their annual disclosure cannot submit research proposals, nor will any PTA be established for new awards. PTAs will not be set up until training and COI reviews are completed. Beginning August 1, individuals who have not submitted their annual disclosure will not be eligible for an Annual Compensation Evaluation (ACE) merit increase until a disclosure has been submitted.

During the annual disclosure process, we request that you disclose all outside commitments, activities, and when applicable, financial interests that are or may be perceived to be related to your institutional responsibilities. An outside commitment is related to your institutional responsibilities when the Entity's activities or products (e.g., physical or service) broadly relate to your field of research, teaching activity, or administrative responsibility.

Biosketch and Other Support: This is a reminder to ensure that you are disclosing your professional appointments and commitments (i.e., Biosketch) as well as your other support (i.e., current and pending support) in accordance with federal requirements. The guidance documents for disclosure can be found here: <u>NSF</u>, and <u>NIH</u>. Moreover, please upload copies of correspondence and/or agreements with foreign entities (e.g., individuals or organizations from a foreign country) if you have appointments, collaboration agreements, or are otherwise providing consulting or research services. Foreign agreements and correspondences will be reviewed to identify whether they are foreign talent recruitment programs (FTRP).

Export Compliance Regulatory Updates

<u>The Bureau of Industry and Security</u> has invited Caltech to participate in their <u>Academic Outreach Initiative</u> with the goal of partnering with U.S. academic research institutions. The Initiative, which launched last June, is designed to help research universities better understand and comply with complex and ever-changing U.S. export regulations, national security and research security concerns affecting academic institutions. Faculty and staff may be asked to participate in some of these outreach sessions. Caltech OEC had a visit from BIS in November 2023 as part of the initiative.

Israel-Hamas Gaza war: Although the grim war has upended shipping and trade in this region, there are no new export compliance regulations or sanctions issued in response to this conflict to report.

Covered Entities and Government Contractor Prohibitions are imposed on government contractors by federal government agencies (DoD, NASA, GSA and FCC) through National Defense Authorizations Acts, Executive Orders, and Federal Register Notices which prohibit Caltech from purchasing or using "covered items or services" from "Covered Entities"/Restricted Parties. Here are some important ones you should be aware of:

 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: <u>Covered Entities and</u> <u>Government Contractor Prohibitions</u>

The NDAA 889 Consolidated List was revised on October 13, 2023.

- <u>Kaspersky Lab</u> (NDAA Section 1634): "Prohibition on use of products and services ..." Federal Acquisition Regulation 52.204-23 prohibits the use of products of services "for hardware, software, and services developed or provided by Kaspersky Lab and Other Covered Entities." Additional information can be found <u>here</u>.
- 3. <u>TikTok and ByteDance</u> "No TikTok on Devices" (OMB M-23-13; FAR) Restrictions on Use of ByteDance (TikTok & Lark) Social Networking Services under the FAR. Under this Act, Caltech personnel, including all faculty, postdocs, employees, and graduate students, are prohibited from downloading or using TikTok or Lark on any information technology including laptops, cell phones, software, and firmware used in the performance of a federal government contract. For more guidance, please review the Caltech Vice Provost memorandum regarding use of TikTok on campus <u>here</u>.

Restricted Party Screening: Need help with a Restricted Party Screening Result? We can help! Send an email to the Export Compliance Office <u>exportcompliance@caltech.edu</u> with your question and screening result. View the RPS Manual for additional guidance found <u>here</u>.

Research Safety Updates

Faculty are responsible for the safety of the work undertaken in their laboratories. The EH&S Office has recently updated and posted to their <u>website</u> the following documents that are intended to help Faculty run a safe laboratory:

- 1. <u>Faculty Guide on Laboratory Safety Practices</u> : This guide is to help Faculty members meet the requirements of Caltech's <u>Institute Policy on Environmental Health and Safety</u>
- 2. <u>Workplace Specific Safety Orientation</u> : This form can be used to document safety trainings conducted by Faculty and/or lab designees
- 3. <u>Safety Training Matrix for Laboratory Personnel</u> : This document is used to determine required EH&S administered trainings for researchers and Faculty

IBC Updates

The Caltech IBC continues 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.

Committee Members: Dr. Rustem Ismagilov has graciously agreed to be the IBC Chair for another year. We are grateful for his continued leadership and insight contribution to all committee matters.

We are also proud to announce that Dr. Michael Elowitz, Dr. Yu-Chong Tai, Dr. Max Coleman and Dr. Nathan Siladke have joined the committee. Furthermore, Dr. Elowitz will be stepping in to fill the role of Vice Chair. We look forward to their expertise and value their contributions to the committee.

Biosafety Awareness: We invite the research community to learn and promote the core tenets of Biosafety and Biosecurity:

• Ethical research: Being committed to conducting research in a responsible and ethical manner, with the safety of researchers, the public, and the environment as a top priority.

Office of Research Policy

• **Transparency:** Being committed to being transparent about research projects, including the potential risks and benefits. Open communication is essential for building public trust and confidence.

• **Training:** Being committed to providing researchers with the training they need to conduct their work safely and responsibly. A well-trained workforce is essential for preventing accidents and ensuring the security of research materials.

• Engagement: Being committed to engaging with the community to share information about research projects and to answer any questions they may have. Public engagement is essential for building trust and understanding.

• **Stewardship of biosafety and biosecurity:** Being committed to being stewards of biosafety and biosecurity. Recognizing the importance of protecting the community and the environment from the potential risks associated with research.

Take this time to <u>learn more</u> about the current biosafety practices at Caltech.

Training and Personnel Update Reminder: An important aspect of laboratory safety is proper training in the laboratory techniques used in the lab. The Caltech IBC reminds all laboratories to ensure their personnel are properly trained regarding the hazards of the biological agents in the lab in accordance with our policy. Any new laboratory personnel wishing to work on any project must be approved to work on the protocol PRIOR to beginning work on the protocol.

Here is a great article on "<u>Slippage</u>," written by our Assistant BSO, Dr. Leyma De Haro, which serves as a good reminder to be diligent in your training in the labs.

IRB Updates

Welcome our new IRB Members: Max Coleman, Nate Siladke, and Gaylene Ursua!

New Standard Operating Procedures (SOPs): The IRB created many new SOPs over the course of 2023/2024. These SOPs reflect the IRB's understanding and interpretation of the federal regulations that protect human participants in research, applicable state and local laws, and best practices. Investigators and staff involved in human subjects research at Caltech should familiarize themselves with these SOPs found through the <u>SOP Repository</u> in the IRB Protocol Application System (PAS) or the <u>IRB website</u>. The three most recently created SOPs are as follows: 1) Deception & Incomplete Disclosure 2) Pilot Studies 3) Venipuncture Blood Collection

IRB Policy Updates: Visit the <u>IRB website</u> to review recent IRB Policy updates.

IACUC and OLAR Updates

AAALAC Accreditation: Thank you to all the labs who prepared for and participated in the successful AAALAC accreditation site visit in early October 2023. The site visitors commended the Institute for an excellent animal care program and a final decision of Full Continued Accreditation was received from the AAALAC Council in March of 2024.

Training Reminder: The Caltech IACUC reminds all users to review their training profile in the Protocol Application System and to ensure that all required trainings are complete prior to performing work with animals. In addition, all personnel should have completed their User Profiles by filling out the Education and Experience sections in the Protocol Application System.

New Students? No Problem!: To add new students and research staff to IACUC protocols, please submit an Admin Only Amendment to the appropriate protocol. Each individual must also complete their <u>Lab animal Occupational Health</u> <u>Program (LAOHP) Medical Clearance</u> and applicable Level 1 <u>CITI Training Modules</u> before they can be approved on a protocol and before they may receive any necessary training for animal use through the OLAR veterinary group. Contact <u>vettech@caltech.edu</u> to schedule any required in-person trainings as soon as possible.

RSC Updates

The Caltech <u>RSC</u> oversees, reviews and approves the use of all radioactive materials and radiation producing machines on campus.

Office of Research Policy Grace Fisher-Adams		
Office of Research Compliance	Office of Export Compliance	Office of Laboratory Animal Resource
Mel Dereje	Adilia Koch	Karen Lencioni
COI Manager	Director of Export Control	OLAR Director, Attending Veterinarian
Megan Hayashi	Frank Rosas	
IRB & HESC Administrator	Senior Export Compliance Analyst	Office of Environmental Health & Safet
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