Caltech
OFFICE OF RESEARCH POLICY NEWSLETTER

Winter 2025
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Winter 2024 - 2025 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

The Office of Science and Technology Policy published its long-awaited research security program guidelines on July 9, 2024. The Guidelines confirm the four mandatory program elements necessary for a compliant research security program: (1) Cybersecurity; (2) Foreign Travel Security; (3) Research Security Training; and (4) Export Control Training. Caltech will be releasing our Research Security Program Guidelines early next year.

We are seeing several new award terms related to research security that researchers should be aware of:

(1) **Controlled Unclassified Information (CUI)**. Caltech does not generate CUI. Unless previously approved by the Provost Office, Caltech may not receive CUI. If receipt of CUI is approved, it must be used and stored in compliance with US Government cybersecurity requirements.

(2) **Foreign Travel Reporting Requirements.** Federal awards may have a requirement to report business travel, personal travel or both, to countries of concern or to all countries, prior to travel. The requirement may apply to senior/key personnel only or to all personnel (including graduate students, postdocs, staff) working on a project. PIs must be aware of their specific reward requirements and ensure compliance. The Provost Office must approve if the requirement includes travel reporting for students and postdocs. Please contact the Office of Research Security (ResearchSecurity@caltech.edu) for guidance.

EVENTS

IACUC Meetings January 14, 2025 February 11, 2025 March 11, 2025	**IBC Meetings** February 4, 2025 March 4, 2025
IRB Meetings January 10, 2025 March 07, 2025	**HESC Meetings**
RSC Meetings TBD	**ECLC Meetings** TBD

(3) **Foreign Person Restriction from Participation on a Project.** Caltech does not accept restrictions on personnel eligible to perform research. If an award has a restrictive term, Caltech will normally include an additional award term allowing us to terminate the project. Acceptance of these terms must be approved by the Provost Office.

Conflict of Interest Updates

Annual COI Disclosure Period: All Caltech researchers are required to submit an annual disclosure in Caltech's Disclosure of Financial Interests and Commitments (DFIC) system. The submission period ended on July 31, 2024; however, individuals who have not submitted are urged to submit immediately. Please note that individuals who still have not submitted their annual disclosure are not eligible for their Annual Compensation Evaluation (ACE) merit increase until a disclosure has been submitted. Further, individuals who have not submitted their annual disclosure cannot submit federal research proposals and no PTA will be established until FCOI training and conflict of interest (COI) reviews are completed and any actual conflicts of interest are managed.

Malign Foreign Talent Recruitment Programs (MFTRPs): In August, DARPA affirmed the prohibition on covered individuals' participation in MFTRPs along with the related certification requirements under CHIPS Sec. 10632(a).

In light of MFTRP concerns, we request all researchers upload copies of any correspondence and/or agreements with foreign entities (e.g., individuals or organizations from a foreign country) to the Biosketch and Other Support section of their Disclosure of Financial Interests and Commitments (DFIC) disclosure or directly to the Biosketch and Other Support (BSOS) application available in access.caltech.edu. Examples of such "agreements" include appointment letters, collaboration agreements, or consulting and research service agreements. The uploaded materials will be reviewed for compliance with MFTRP restrictions.

Biosketch and Other Support (BSOS): The BSOS application that can be reached via Caltech's Access has been updated to better align with the Common Form. Please take a moment to review your profile in BSOS to ensure compliance with federal requirements for disclosing professional appointments and commitments (Biosketch) as well as other support (current and pending). The guidance documents for disclosure can be found here: NSF, and NIH. Additionally, please note that supervisors now have access to view the DFIC disclosures of their direct reports from their BSOS profile.

Export Compliance Regulatory Update

BIS Revisions to the Entity List

The Entity List identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. To learn more and for information on how to screen your party against the Restricted Party List, please visit:

Link: Federal Register 89 FR 68544

Research Safety Updates

Safety Survey – Now Active On December 2, a campuswide communication was sent with a link to the 2024 **Caltech Campus Safety Program** Survey. This survey will remain open through December 23. To better understand and enhance the Caltech campus safety program, please take a few minutes to share your experiences and views. And please encourage your laboratory members to complete the survey as well. EH&S staff, along with the Institute Environmental Health and Safety Committee, will use results from this survey to assess the efficacy of and improve Caltech's environmental health and safety programs. Your participation is voluntary, anonymous, and very much appreciated. **Reminder - Important Onboarding Procedures** All new Personnel must be adequately onboarded in all aspects of working at Caltech, including the unique hazards associated with laboratories. Before researchers can begin any work in a laboratory, please ensure that you review all laboratory-specific emergency procedures with them, including utilizing Caltech's emergency number ext. 5000 (from Caltech landline) or 626-395-5000 (from cell phone) in the event of an emergency, injury, or exposure on campus.

Take time to introduce all new personnel to all hazards (chemical, biological, radiation, laser, physical, etc.) that may be present in your laboratory. Here are helpful resources for onboarding:

1) [Faculty Guide on Laboratory Safety Practices](#): This guide outlines the onboarding process for new researchers

2) Caltech's Research Safety Programs: The [Chemical Hygiene Plan](#), [Biosafety Manual](#), [Laser Safety Manual](#), [X-Ray Safety Manual](#), and the [Radiation Safety Manual](#) are all resources to help inform and educate researchers on mitigating these risks in the lab

3) Assist new students in identifying all EH&S administered [safety trainings](#) that they may need to complete

4) Provide them with laboratory-specific training on the tasks they will conduct

5) Document and maintain accessible records of [laboratory-specific training](#) provided for review by EH&S

For any questions, please reach out to: safety@caltech.edu or ext. 6727

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.

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.

NIH Guidelines Update for Gene Drive Modified Organisms (GMDO): The NIH has updated their [Guidelines](#) for recombinant and synthetic nucleic acids. All experiments involving GMDO, including microorganisms, animals, and plants will now be conducted at a minimum of Biosafety Level 2 containment.

Policy Update regarding Synthetic Nucleic Acids and Nucleic Acid Synthesis Equipment: Effective immediately, Caltech researchers will only be able to purchase synthetic nucleic acids >200 nucleotides from vendors on an approved vendors list. A current list of approved vendors can be found here. Note that this list may be updated from time to time, so please confirm before you submit your purchase.

In accordance with the US Department of Health and Human Services (HHS) [Framework for Nucleic Acid Synthesis Screening](#), we should only procure synthetic nucleic acids from providers that have implemented designated screening practices. This screening is targeted at reducing biosecurity risks by screening purchases of nucleic acid orders to identify sequences of concern (i.e. regulated biological agents and toxins, sequences contributing to pathogenicity or toxicity) and to assess customer legitimacy.

This framework and corresponding requirements went into effect October 26, 2024, but a grace period of six months was offered to allow recipients of federal funds to comply. The current requirement applies to sequences > 200 nucleotides. However, that threshold will be lowered to sequences > 50 nucleotides in 2026. More information will be provided prior to the change in requirements.

Additionally, nucleic acid synthesis benchtop equipment can only be purchased from providers that implement customer screening protocols to ensure purchases are from a verified customer.

If you would like to use a vendor not on the approved vendor list, please contact the BSO, Manali Doshi, at mdoshi@caltech.edu for more information. Please note, however, that some vendors will not be approvable for use of federal funds.

You may contact the IBC Office at ibc@caltech.edu if you have any further questions.

Dual Use Research of Concern Update: Beginning in May 2025, the scope of [Dual Use Research](#) will expand significantly, with a larger list of applicable agents and toxins, an increase in potential experimental outcomes of concern, and a requirement that all future federal funding applications are assessed for relevant research projects. Questions regarding

the applicability of this policy to your research projects will be requested during your Annual IBC/Biosafety Assessment and the initial grant application process.

IRB Updates

Welcome our new IRB Member: Jonathan Katz!

IRB Policy Updates: The IRB made major updates to the IRB Policy during its September meeting. Visit the IRB website to review the recent updates.

New Standard Operating Procedures (SOPs): In addition to Policy review, the IRB reviewed all current and three new SOPs. Investigators and staff involved in human subjects research at Caltech should familiarize themselves with SOPs found through the SOP Repository in the IRB Protocol Application System (PAS) or the IRB website. The three most recently created SOPs are as follows: 1) Elements of the Protocol Application 2) Exempt Research Amendments 3) Unanticipated Problems & Adverse Event Reporting

IACUC and OLAR Updates

Custom Monoclonal Antibodies: If you are procuring custom monoclonal antibodies from a third party, you need IACUC approval prior to purchase. Please contact iacuc@caltech.edu and see the IACUC SOP on Antibody Procurement for further information.

New OLAR Recharge Rates: OLAR has completed a cost study to develop new recharge rates based on actual current costs. These new per diem and technical services rates are anticipated to be finalized soon and in effect as of Jan 2025. The rates will be posted to the OLAR website once finalized.

Protocol Review: One of the most comment noncompliance pitfall is researchers not being aware of the protocol requirements. We highly suggest that all lab members routinely review their protocol(s) and are aware of all amendments and changes made to the protocol(s) to prevent any disruption to the research.

Training Reminder: The Caltech IACUC reminds all users to review their training profile in the Protocol Application System and to ensure that all required training is 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 Lab Animal Occupational Health Program (LAOHP) Medical Clearance and applicable Level 1 CITI Training Modules 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 vettech@caltech.edu to schedule any required in-person trainings as soon as possible.

RSC Updates

The Caltech Radiation Safety Committee (RSC) oversees, reviews and approves the use of all radioactive materials and radiation producing machines on campus. If you have questions for the committee, please reach out to RSC@caltech.ed .

Office of Research Policy

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