Caltech

OFFICE OF RESEARCH POLICY NEWSLETTER

Fall 2025 - Winter 2026
Volume 5

In this issue:

Fall 2025-Winter 2026 Office of Research Policy Newsletter

The Office of Research Policy (ORP) includes Caltech's Office of Research Compliance, Office of Research Security, 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 oversees Caltech's Research Security Program, including Conflicts of Interest and Export Control, Caltech's Research Integrity Program, and Caltech's Controlled Substances Program.

This newsletter is issued two times a year, highlighting important regulatory changes, changes in Institute policy, and upcoming educational events and committee meetings. It has been a very busy year this year, so this newsletter is a bit longer than usual. Please use the index on the left to navigate to sections that are relevant to you.

Important Grantee Regulatory Updates

This year has been a very busy year for changes in grantee proposals and post award terms and conditions. Some of the changes have been specific to the research committees (IACUC and IBC), so please review these sections of the newsletter. More broadly, we are seeing significant changes across the research security and foreign engagement landscape. Note that not every agency is implementing these changes in the same way, so please reach out to our offices if you have questions or need assistance.

EVENTS	
IACUC Meetings October 14, 2025 November 11, 2025 December 9, 2025	***IBC Meetings*** October 7, 2025 November 4, 2025 December 2, 2025
IRB Meetings October 31, 2025	***HESC Meetings*** October 30, 2025
RSC Meetings TBD	***ECLC Meetings*** TBD

(1) **Disclosures.** All agencies have implemented a requirement that grantee applicants and awardees complete an annual financial interest and commitment disclosure (see below) and that they appropriately and accurately report appointments and commitment in their Biosketch and any Other Support as required by their sponsor. NIH issued a requirement for Institutions to have an Other Support Policy and ensure that researchers were aware of their obligations to report other sources, both monetary and in-kind, received for research. Please visit this Other Support Policy Page.

(2) Controlled Unclassified Information (CUI) or Export Controlled Data or Materials. Caltech does not generate CUI or Export Controlled Data or Materials. Unless previously approved by the Office of the Provost, Caltech may not receive such information, data or materials either. If receipt and use of such materials is approved, it must be used and stored in compliance with US Government cybersecurity requirements, including abiding by the Cybersecurity Maturity Model Certification (CMMC) Program requirements (effective 11/10/25) and University Research Cybersecurity Requirements (Pending).

(3) **Foreign Travel Reporting Requirements.** Federal awards may have a requirement to report business travel, personal travel, or both, to countries of concern (China-PRC-including Hong Kong and Taiwan, Russia, North Korea, Iran, and others as the list may change) or to all foreign 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 Office of the Provost must approve travel reporting if the requirement includes travel reporting for students and postdocs. Please visit the International Travel Webpage and/or contact the Office of Research Security (ResearchSecurity@caltech.edu) for guidance.

(4) **Foreign Person Restriction from Participation on a Project.** Caltech does not accept restrictions on personnel eligible to conduct research. If an award has a restrictive term, Caltech will normally include an additional award term allowing us to terminate the project should any Caltech personnel be denied participation. Acceptance of any term restricting foreign personnel from participation must be approved by the Office of the Provost.

(5) **Publication.** Federal sponsors are becoming increasingly concerned about foreign collaborations giving rise to publications funded by the US. As an example, on September 5, 2025, the Select Committee on the Chinese Communist Party issued a report citing to several publications related to DOD awards. Researchers should take care not to include authors (foreign or domestic) who have not contributed substantially to the paper and should not include anyone gratuitously as an author or in the acknowledgements if they have not contributed. Likewise, authors should not cite gratuitously to federal funding, if none was used in support of the reported research. Several sponsors have issued new terms and conditions (even on renewals of existing awards) restricting collaborators in foreign countries from conducting or collaborating on research or collaboratively writing a publication stemming from the federally funded research. If you have questions or concerns about your research collaboration, please contact researchsecurity@caltech.edu.

(6) **Federal Risk Evaluation and Mitigation.** Many of these requirements regarding foreign research relationships stem from a federal agency review of risk and establishment of a risk mitigation plan. A risk mitigation plan may require a researcher to implement any of the above requirements or even end a collaboration with a foreign collaborator. On May 5, 2025, the Department of Defense/War (DOD) issued an updated Risk Matrix.

(7) **Training.** Over the last several months multiple agencies have increased their training requirements. Training includes Research Security Training, Conflict of Interest Training, Research Integrity Training, and more. A Training Matrix is available for researchers to check, by agency for current training requirements.

(8) **Executive Orders.** Executive Orders issued in the last few months are directly related to research and grants enterprise: Improving Oversight of Federal Grantmaking and Restoring Gold Standard Science.

Conflict of Interest Updates

(1) **Annual COI Disclosure Period:** Caltech's annual Disclosure of Financial Interests and Commitments (DFIC) submission period for researchers began on June 2, 2025, and ran through June 30, 2025. During this period, researchers were required to disclose all outside commitments and activities, and, when applicable, financial interests that are or may be perceived as related to their institutional responsibilities. The DFIC continues to accept disclosures; however, effective July 1, 2025, researchers who have not submitted their annual disclosure will be restricted from submitting sponsored research proposals and no new PTA will be established for new awards until disclosure is complete.

(2) **Foreign Engagement Review:** To comply with federal sponsor requirements regarding participation in Malign Foreign Government Talent Recruitment Programs (MFTRPs), the annual DFIC certifications have been updated to include a affirmation that the investigator is not a party to a MFTRP. Additionally, the DFIC and the Biosketch and Other Support (BSOS) applications allow researchers to upload documents related to foreign or hybrid (foreign and domestic) entities. This update enables a researcher to submit relevant documentation such as letters of appointment, collaboration agreements, consulting contracts, email

correspondence, or other materials related to consulting or other outside engagements for Caltech review to ensure it is not an MFTRP. If a researcher is found to be participating in a MFTRP, they will be ineligible to propose for or receive U.S. federal funding unless they terminate the MFTRP.

Import & Export Compliance Regulatory Updates

(1) **Caltech Openness in Research and Export Control Policies.** Copies of these policies are now found here and in the Faculty Handbook.

(2) **New Entity Restrictions and Emerging Technologies.** In the first half of 2025, the Department of Commerce's Bureau of Industry and Security (BIS) added more than 90 entities to its Entity List across China, Pakistan, Iran, South Africa, the UAE, and Taiwan. No entities were removed during this period. The action specifically targets entities involved in technological domains highly relevant to our research community, such as: Artificial Intelligence, Quantum Computing, Advanced Semiconductors, and Missile and Uncrewed Aerial Vehicle (UAV) programs. These designations have direct consequences for research at Caltech. All interactions with a listed entity now require a BIS license.
On June 24, 2025, the Department of Defense/War (DOD) updated its list of prohibited entities under Section 1286 of the National Defense Authorization Act. This update added several new universities and research institutions from China, Iran, and Russia. The list includes foreign institutions and some foreign talent programs that have been confirmed as engaging in problematic activity or posing a threat to the national security interests of the U.S. as described in the same provision. Under federal law, researchers cannot use the MFTRP exemptions for activities if they are related to 1286-listed entities. Entities on the 1286 List are considered military end users, and U.S. law requires a federal license to collaborate with or share (ship, mail, or transfer) anything with a 1286-listed entity, with a presumption of denial, i.e. the U.S. government will almost certainly deny a license.

(3) **Personnel Screening and Research Security.** To ensure compliance and safeguard Institute research, all collaborators, visiting scholars, visitors, volunteers, guests and external affiliates, whether domestic or foreign, who are visiting for more than 2 weeks, should be onboarded and screened using the **Visitors Access Request (VAR)** system, found in the access.caltech.edu suite of applications. If you are planning to host a visitor in your lab or with your research group for a short term (less than 2 weeks), you should, at a minimum, run a Restricted Party Screening (RPS). Caltech has a subscription to Descartes Visual Compliance and anyone from the Office of Research Security can run an RPS for you or provide you access to the Visual Compliance application to run on your own.

(4) **Tariffs.** Rules and the application of tariffs and waivers have been unpredictable this year. Please visit this Best Practices Website for information current as of August. The Export Compliance Manager is available to assist you in navigating these rules.

(5) **Federal Prohibition on Specific Foreign-Made Drones in Research.** Effective December 22, 2025, federal contractors and recipients of federal awards will be prohibited from using federal funds to purchase a prohibited Unmanned Aircraft System (UAS) and prohibited from using a prohibited UAS in the performance of a government contract. (FAR 52.240-1) A prohibited UAS is one manufactured or assembled by entities on the FASC-maintained list of American Security Drone Act-covered foreign entities. The federal contractor must ensure any effort or expenditure associated with a prohibited UAS is consistent with a corresponding exemption, exception, or waiver determination expressly stated in the contract. Please consider your UAS inventory and whether the manufacturer is on the foreign entities list. Feel free to reach out for assistance.

Research Safety Updates (from the Office of Environmental Health and Safety- EH&S)

(1) **Website.** Updated manuals: To support research activities and ensure compliance with state and federal regulations, Caltech EH&S provides comprehensive manuals, essential forms, and a variety of safety programs tailored to our research community. These resources can be easily found on the left menu of the EH&S Research Safety Onboarding webpage.

(2) **Instrument Disposal or Relocation.** Decommissioned/decontaminated materials or instruments prior to disposal: When purchasing large equipment or specialized instruments - especially those that contain lasers, radioactive materials, hazardous gases, or chemicals - researchers should always plan for the instrument return or disposal with the vendor to ensure safe and compliant removal at the end of its use.

(3) **Laboratory Hazardous Waste Training.** Annual Laboratory Hazardous Waste Training is required for all researchers and faculty with laboratories that generate hazardous waste. This training is required by federal law under the Resource Conservation and Recovery Act (RCRA) regulations to primarily ensure that employees understand how to safely handle, store, and dispose of hazardous waste. To access the training: click here to sign in, go to My Assignments, and select the Hazardous Waste Training learning plan to launch the course.

(4) **Caltech CampusOptics.** What is It? A centralized online Campus EH&S Management System. How Does it Work? This is a platform that allows Caltech personnel to access and review workplace safety profiles, incidents, inspections, or reported safety concerns. This tool centralizes campus-wide safety data and provides metrics to drive proactive Environmental Health and Safety responses, track laboratory and shops' inspection reports and corrective actions, identify trends in safety related incidents, and improve the overall campus interface with Environmental Health and Safety. Test Drive HERE and click on the Caltech CampusOptics link under Self Service. Contact safety@caltech.edu if you would like a demo or have any problems accessing the platform.

Administrative Committee on Biosafety (IBC, BOC, and IRE) Updates

(1) **IBC, BOC, and IRE.** The Caltech Administrative Committee on Biosafety (ACB) oversees, reviews and approves the use of recombinant DNA and RNA, pathogens, human materials and other potentially infectious material, as well as transgenic or infectious animals, insects and plants on campus. The ACB has been reorganized to provide clearer oversight over biosafety and biosecurity. The ACB is now comprised of the following three sub-committees:

- The *Biological Oversight Committee (BOC)* reviews and approves research and teaching that (1) involves the use of infectious biological and biohazardous agents and toxins not covered by the NIH Guidelines; and (2) ensures these agents are used in accordance with any requirements and are used safely and, as necessary, are biosecure.
- The *Institutional Biosafety Committee (IBC)* reviews and approves research and teaching that (1) involves the use of recombinant or synthetic nucleic acids; and (2) are subject to NIH Guidelines. If a protocol includes research that falls under both IBC & BOC, the IBC can conduct a review that will suffice for both.
- The *Institute Review Entity (IRE)* oversees the identification risk assessment, and implementation of biosecurity measures to address (1) Dual Use Research of Concern (DURC); and (2) Dangerous Gain of Function (DGOF).

(2) **Executive Order: Improving the Safety and Security of Biological Research:** On May 5, 2025, the White House issued an Executive Order (EO) on *Improving the Safety and Security of Biological Research* and an accompanying Factsheet regarding dangerous gain-of-function (DGOF) research. The EO rescinded the recently implemented 2024 US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Pandemic Potential (USG Policy). Subsequently, NIH released Notice NOT-OD-25-112, directing awardees to pause any NIH-funded research that meets the definition of DGOF until a new updated

federal policy is issued. This notice was followed by NOT-OD-25-127 which provided notice that all NIH funding for DGOF research conducted by foreign entities in countries of concern was to be terminated This latest notice also asked that all researchers review ongoing research activities to identify NIH funding and other support for projects, including unfunded collaborations/projects, meeting the definition of dangerous gain-of-function research that has not been identified as such by NIH and immediately notify the funding NIH Institute, Center, or Office. Review was to be completed by June 30, 2025 (12 days after the notice).

- **What Caltech Researchers Must Do:**
  Consider whether any of your research could be "dangerous gain-of-function (DGOF)" Research. DGOF research means scientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility. Covered research activities are those that could result in significant societal consequences and that seek or achieve one or more of the following outcomes:

  (a) enhancing the harmful consequences of the agent or toxin;
  (b) disrupting beneficial immunological response or the effectiveness of an immunization against the agent or toxin;
  (c) conferring to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitating their ability to evade detection methodologies;
  (d) increasing the stability, transmissibility, or the ability to disseminate the agent or toxin;
  (e) altering the host range or tropism of the agent or toxin;
  (f) enhancing the susceptibility of a human host population to the agent or toxin; or
  (g) generating or reconstituting an eradicated or extinct agent or toxin.

  If you believe your research meets the definition of DGOF research or are unsure, pause the research immediately, and contact the Biosafety Officer (BiosafetyOfficer@caltech.edu). At the time your protocol is up for review, the IRE will ask you to complete a DURC/DGOF questionnaire and provide rationale for why the work is or is not DGOF research. The IRE will consider this before making a determination about whether the work meets the definition. The IRE has already conducted a first-pass review of all the active protocols. If you have any questions, please contact the Biosafety Officer.
- **Impact on Grants:**
  - As a reminder, per NOT-OD-25-112, NIH is not accepting competitive applications for grants and cooperative agreements submitted for due dates after May 7, 2025 and/or R&D contract proposals submitted to solicitations issued after May 7, 2025 for dangerous gain-of-function research, as defined in Section 8 of the Executive Order.
  - NIH will terminate funding and other support for projects, including unfunded collaborations/projects, meeting the definition of dangerous gain-of-function research conducted by foreign entities in countries of concern or foreign countries where there is not adequate oversight.
  - NIH will suspend all other funding and other support for projects, including unfunded collaborations/projects, meeting the definition of dangerous gain-of-function research until implementation of the new policy described in Section 4(a) of the Executive Order. ***We have been receiving requests from federal sponsors for Caltech and/or individual researchers to explain why certain research is or is not DGOF. If you receive such a request from your sponsor, please contact us immediately.***

(3) **Training Reminder:** An important aspect of laboratory safety is proper training in laboratory techniques. The Caltech ACB requires all laboratories to ensure their personnel are properly trained regarding the hazards of the biological agents used in the lab in accordance with all Caltech policies and local, state and federal

requirements. 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.

IRB Updates

(1) **Protocol Closures.** PIs have the responsibility of responding to IRB correspondence in a timely manner. Failure to respond to any IRB action, memorandum, or request for information or modification within the timeframes below may result in closure of a pending application or active protocol.
- Active Protocols (Renewals): Protocols will be closed 30 days after the expiration date if no communication is received from the PI or lab regarding renewal status.
- Pending Applications (New): If an application is submitted but there is no response from the PI or lab within 2 weeks of the IRB's review and request for modifications, the protocol will be closed 30 days after the initial 2-week period.
- Pending Applications (Amendments): If an amendment is submitted but there is no response from the PI or lab within 2 weeks of the IRB's review and request for modifications, the amendment will be determined as Not Approved 30 days after the initial 2-week period. The protocol will revert to its previous version.
- Official Correspondence from the IRB: Protocols may be suspended or closed within 30 days if no communication is received from the PI or lab in response to the correspondence.

(2) **Pilot Study Timeframes.** Pilot studies require a reasonable endpoint and cannot continue for multiple years without transitioning into a full study or closing. Pilot studies will be approved annually for a maximum length of two years. If a study requires additional time, the PI must provide sufficient justification to the IRB for continued approval of a pilot study.

(3) **NIH Genomic Sharing.** Updated requirements to the NIH Genomic Data Sharing policy went into effect on January 25, 2025. These updates made two major changes to requirements for accessing Covered Data: 1) Stricter cybersecurity standards and 2) Terms of access requirements for developers. Investigators should work with the IRB office to execute any necessary Institutional Certifications, and work with IMSS to confirm all cybersecurity requirements have been met.

(4) **Department of Justice Bulk Data Transfers.** Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons: The U.S. Department of Justice (DOJ) issued a Final Rule, effective April 8, 2025, to implement Executive Order 14117 *Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons*, which was issued on February 28, 2024. It covers transfer of personal information, genetic/genomic/'nomic data and biospecimens to countries of concern. More information can be found in DOJ's Frequently Asked Questions. Caltech has a webpage providing guidance for researchers.

(5) **IRB SOPs.** Investigators and staff involved in human subjects research at Caltech should familiarize themselves with the IRB Policy found on the IRB website and the IRB SOPs found through the SOP Repository in the IRB Protocol Application System (PAS) or the IRB website. The three most recently created or updated SOPs are as follows: 1) Protocol Closures 2) Pilot Studies; and 3) NIH Genomic Data Sharing

IACUC and OLAR Updates

(1) **Grant Updates:**

- **Important Updated Requirements for NIH Grant Proposals Involving Vertebrate Animals.** In April 2025, the NIH announced it will no longer develop new funding opportunities focused exclusively on animal models of human disease. NIH is expected to continue to support the use of animals in research only when the proposed models are clearly scientifically appropriate and well-justified. It will be critical for proposals using traditional animal models to include justification of model selection and animal use numbers, with an explanation of how animal numbers are limited to only what is

necessary. Consideration of new approach methodologies (NAMs) and alternatives to laboratory animal use, including human and in vitro/in silico models such as microphysiological systems and organoids and/or computational and AI approaches, should be addressed in the proposal narrative.

Additional information is available at: How Does the NIH Initiative to Prioritize Human-Based Research Affect Research Proposing the Use of Laboratory Animals? | Grants & Funding

- **Vertebrate Animal Section of Proposal.** The NIH Vertebrate Animal Section (VAS) has also been recently updated, and the required information has changed. A helpful overview and tutorial is available at: Vertebrate Animals Section | OLAW. The OLAR veterinary staff is available to assist in confirming that your grant language is congruent with your approved animal use protocol and Caltech IACUC procedures. Please email olar@caltech.edu for assistance or questions about grant submissions involving vertebrate animals.

(2) **FDA Plan to Phase Out Animal Testing for Monoclonal Antibodies and Other Drugs.** The new FDA roadmap was released in April 2025, outlining steps that the FDA will be taking to ensure reduction, refinement, or replacement of required animal testing in drug development. Implementation of these principles began immediately for all new Investigational Drug Applications (IND). Animal testing will decrease through the use of pre-existing safety data and NAMs such as AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting.

(3) **Information for Animal Use Collaborations.** Animal-based projects frequently include collaborations with other institutions. In 2025, the NIH Office of Laboratory Animal Welfare updated its Frequently Asked Questions on institutional responsibilities during a collaboration on animal research with an outside entity. The collaborating institutions are required to have a formal written agreement that covers animal ownership and care, IACUC review of the activities, and IACUC oversight (to include inspections, reporting of concerns, etc.).

It is important to work with the IACUC closely to ensure that oversight requirements are met, including having Memorandums of Understanding in place to clarify responsibilities for each organization. In the IACUC Protocol Application System, there is now a section to outline the collaborative efforts. Please make sure to outline all 'Partner Organizations' involved in the collaborative project and contact the IACUC (iacuc@caltech.edu) to ensure all requirements are met prior to initiating work.

From our Library

The Library can assist with questions about public access to articles and research data, as required by many federal funding agencies. On July 1, 2025, the NIH requirement for immediate public access to articles resulting from research funded by NIH became effective. This requirement will become effective for all other federal funding agencies on January 1, 2026. To help researchers navigate this new requirement, the Library developed guidance on the NIH Public Access Policy (updated 09/25) and has a short list of publisher policies around immediate public access (in progress). For questions about specific public access requirements, please email library@caltech.edu.

Additionally, the following services are provided by the library and open to the Caltech research community: General Grant Support: ORCID, collaborator reports, data management, SciENcv, etc.; Support managing ORCID accounts for identity management and grant compliance; Open Access Publishing Support: Publish manuscripts Open Access (OA) for free or at a discount through the Caltech Library's agreements with several publishers; Consultations with Subject Librarians to help determine appropriate manuscript version to submit and submission process - email library@caltech.edu; CaltechAUTHORS can track open access status, personal and document identifiers, and other needed metadata; CaltechDATA can provide storage, manage public access, assign DOIs, and other services; Research Data Support: Consultations with Librarians for guidance on general data management and preservation, Data Management & Sharing Plans (DMSP's), and more.

Our Team

In the past several months, the Office of Research Policy has welcomed several new staff, including Rachel Smith, our new Director of Research Security, Teresa Recinos our new Export Compliance Manager, Galia Bar-Sever an interim Research Compliance Administrator, and Marlene Lopez, our office's new Administrative Assistant. Welcome all!

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