

of Interest Committee. Collaborative and visiting researchers and subrecipient Investigators who are receiving federal funding awarded through CSHL may also be deemed Investigators and be required to comply with this CSHL Investigator Conflict of Interest Policy.

11. ***Institutional responsibilities*** mean an Investigator's professional activities on behalf of CSHL including, but not limited to, research, research consultation, teaching, professional practice,

20. ***Small business technology transfer*** (SBTT) is a program under the SBIR program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.
21. ***Sponsored/Reimbursed Travel*** is any travel expense related to an Investigator's institutional responsibilities that are either paid directly by a third party on behalf of Investigator so that the exact monetary value may not be readily available or for which the Investigator is

7. **Sponsored/Reimbursed Travel** that meets the following criteria:

- travel **within the United States** received from a U.S. entity that when aggregated exceeds \$5,000.

Note: Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- travel **outside the United States** received from a U.S. or foreign entity* regardless of dollar amount.

*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

Information needed for the disclosure of Sponsored/Reimbursed Travel:

- Identity of the sponsor/organizer.
- Month and year of the travel.
- Financial value by range of the travel.
- Value of any associated honorarium.
- Purpose of the travel.
- Destination of the travel.
- Time duration of the travel.

Most scientific journals have implemented policies requiring authors to declare competing financial interests in relation to work published in those journals. Such requirements, including how financial interests are defined under those policies, are distinct from federal requirements relating to federally funded research and should not be used as a guide to what information an Investigator needs to disclose under CSHL's Investigator Conflict of Interest Policy.

6. WHO MUST SUBMIT AN ANNUAL DISCLOSURE FORM?

At time of appointment/employment, all Investigators, including by way of example PhDs, MDs, graduate students, non-faculty scientific staff at and above the level of research associate and any others deemed appropriate, are required to enter an initial Annual Disclosure Form and associated Appendix Forms that describe all Significant Financial Interests and Outside Activities and Interests related to their Institutional Responsibilities and then submit a new Annual Disclosure Form each subsequent year thereafter. Refer to **Section 7, *Updating the Annual Disclosure Form*** for additional information. Submitted Annual Disclosure Forms are retained in the FCOI portal. Collaborative and visiting researchers and subrecipient Investigators who are subject to CSHL's Investigator Conflict of Interest Policy and participating in PHS-funded research are also required to submit an Annual Disclosure Form, which will be provided as an electronic copy instead of through access to the FCOI portal.

7. UPDATING THE ANNUAL DISCLOSURE FORM

All Investigators are required to simultaneously submit a current, accurate Annual Disclosure Form and associated Appendix Forms that identify and describe both existing and new Significant Financial Interests and Outside Activities and Interests related to their Institutional Responsibilities into the FCOI portal by the yearly November 15th deadline. Subrecipient Investigators will complete an electronic Annual Disclosure Form based on their particular funding cycle. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

Investigators are required to promptly disclose Significant Financial Interests and Outside Activities and Interests to accurately reflect their external activities as follows:

1. Disclose Significant Financial Interests and Outside Activities and Interests no later than at the time of application for PHS-funded research.
2. Within 30 days of acquiring and/or discovering a new Significant Financial Interest or Outside Activity or Interest, including through purchase, marriage, or inheritance.
3. Within 30 days of a material change to a previously disclosed Significant Financial Interest or Outside Activity or Interest.
4. At least annually in accordance with the November 15th deadline, during the period of an award.

8. ANNUAL DISCLOSURE FORM REVIEWED BY THE CONFLICT OF INTEREST COMMITTEE

CSHL's Conflict of Interest Coordinator will review the Annual Disclosure Form and any new or modified Significant Financial Interests or Outside Activities or Interests disclosed throughout the year, and as such, may request further information or clarification from the Investigator. CSHL's Conflict of Interest Coordinator will review each of the Investigator's disclosures and determine whether a Significant Financial Interest or Outside Activity or Interest is related to PHS funded research.

If there are Significant Financial Interests or Outside Activities or Interests related to the Investigator's funded research, these relationships must be examined and dealt with according to CSHL and funding agency policies on conflict of interest. A personal financial interest with an entity would be reasonably considered related to an Investigator's research in circumstances such as the following:

1. Entity sponsors

10. REPORTING A FINANCIAL CONFLICT OF INTEREST TO THE FUNDING AGENCY

CSHL will promptly notify the appropriate funding agency about any corrective action taken or to be taken in a situation of noncompliance.

1. With regard to a **new NIH - sponsored research award**, CSHL will report the identified FCOI to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. CSHL will submit the FCOI report before dispensing or spending any funds. If the FCOI is eliminated prior to dispensing or spending any funds, then no FCOI report is required. In addition, CSHL is required to submit a FCOI report fo

- The value of the financial interest; \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.
- A description about how the FCOI relates to the research and the basis for CSHL's determination that a Significant Financial Interest conflicts with such research.

A description of the key elements of CSHL's management plan must also be submitted to the NIH including the following information:

- Role and principal duties of the conflicted Investigator in the research project.
- Conditions of the management plan.
- How the management plan is designed to safeguard objectivity in the research project.
- Confirmation of the Investigator's agreement to the management plan.
- How the management plan will be monitored to facilitate Investigator compliance.
- Other information as needed.

Other funding agencies outside the NIH may require that different information to be submitted, and CSHL

information before implementing, if needed, further corrective actions to ensure research objectivity. If the NIH decides that the particular FCOI will bias the objectivity of the funded research to such an extent that further corrective action is needed or that CSHL has not managed the FCOI in accordance with the regulation, it may

participation in the research project between the date the FCOI is identified and the completion of CSHL's retrospective review. Thereafter, CSHL will submit FCOI reports as prescribed by the regulation.

Furthermore, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by CSHL, CSHL shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

The following key elements apply to both the retrospective review and mitigation report:

- Project number.
- Project title.
- The PI or contact PI/PD if a multiple PI model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has a FCOI.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review including the methodology of the process, composition of the review panel, documents reviewed etc.
- Findings of the review.
- Conclusions of the review.

16. PROJECT SPECIFIC CERTIFICATION FORM SUBMISSION

The Principal Investigator or Project Director involved with a funding submission is required to enter a Project Specific Certification Form into the FCOI portal one week prior to submitting a sponsored research application requesting an amount greater than \$5,000 from a corporation, educational institution, federally funded agency, non-profit entity, private foundation or trust in order to confirm the PI/PD's continued compliance with the Investigator Conflict of Interest policy.

The basic information needed to complete the Project Specific Certification Form is as follows:

- Name of the Principal Investigator or Project Director.
- Name of the funding organization.
- The funding opportunity announcement.
- Submission deadline.
- Project title.
- Names of personnel who are responsible for the design, conduct or reporting on any of the proposed research, including non-CSHL Investigators (domestic and foreign) such as collaborators, sub-recipients, or subcontractors proposed for funding.

The Project Specific Certification Form then confirms the following:

- That the Principal Investigator or Project Director has read the Investigator Conflict of Interest Policy and submitted an Annual Disclosure Form in the last 12 months.
- That the Principal Investigator or Project Director does not have any new or changed Significant Financial Interest information to disclose.
- Whether any Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.
- The project's involvement in a clinical trial.
- The involvement of any foreign component.

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If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to CSHL. Such time period must be sufficient to enable CSHL to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to CSHL's Investigator Conflict of Interest Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to CSHL. Such time period shall be sufficient to enable CSHL to comply with its review, management, and reporting obligations under the regulation. CSHL will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

Other funding agencies