



## COLD SPRING HARBOR LABORATORY Investigator Conflict of Interest Policy

### TABLE OF CONTENTS

Section	Description	Page
1	Key Definitions.....	1
2	Purpose of the Investigator Conflict of Interest Policy.....	3
3	Who Must Comply with the Investigator Conflict of Interest Policy.....	3
4	Mandated Conflict of Interest Training for All Investigators.....	4
5	What Constitutes a Significant Financial Interest.....	4
6	Who Must Submit an Annual Disclosure Form.....	6
7	Updating the Annual Disclosure Form and Significant Financial Interests.....	6
8	Annual Disclosure Form Review by the Conflict of Interest Committee.....	7
9	Managing, Reducing or Eliminating the Financial Conflict of Interest.....	7
10	Reporting the Financial Conflict of Interest to the Funding Agency.....	8
11	What Financial Conflict of Interest Information is Submitted to the Funding Agency....	9
12	Public Accessibility of CSHL’s Investigator Conflict of Interest Policy and Identified Financial Conflict of Interests.....	10
13	Continued Monitoring of the Financial Conflict of Interest and CSHL Compliance.....	10
14	What Happens After the Financial Conflict of Interest is Reported.....	10
15	Non-compliance and Enforcement.....	10
16	Project Specific Certification Form Submission.....	11
17	Human Subjects Research and Conflict of Interest.....	12
18	Subrecipient Conflict of Interest Compliance.....	13
19	Additional Resources.....	13

## 1. KEY DEFINITIONS

1. A **clinical trial** is a prospective or behavioral research study of human subjects that involves a researcher or researchers who directly observe a person or people, and/or who collect data to answer a scientific or medical question about the safety or potential benefit of an intervention such as medication, device, teaching concept, training method or behavioral change.
2. **Disclosure** refers to the investigator's disclosure of significant financial interests to Cold Spring Harbor Laboratory.
3. **Financial Conflict of Interest** (FCOI) will be deemed to exist when the Cold Spring Harbor Laboratory Conflict of Interest Committee reasonably determines that a significant financial interest disclosed by the investigator could directly and significantly affect the design, conduct or reporting of the investigator's research regardless of the funding source, with the exception of research funded through Phase I support under the Small Business Innovation Research and Small Business Technology Transfer programs. Phase II SBIR and STTR programs are not exempt like Phase I, and must comply with the regulation.
4. **Federally funded research** means any research funded by the U.S. Public Health Service (PHS), National Institute of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE) or other U.S. federal agency.
5. Research is considered to involve **human subjects** when the investigator(s) conducting research obtains data through intervention or interaction with a living individual, or identifiable private information about a living individual.
6. **Institution** refers to an entity like Cold Spring Harbor Laboratory that applies for and receives federally funded research support as well as other third party grant awards.
7. **Investigator** refers to the project director or principal investigator, and any other person regardless of title or position, who is responsible for the design, conduct or reporting of federally funded research, including subrecipients.
8. **Investigator's institutional responsibilities** means professional activities taking place on behalf of Cold Spring Harbor Laboratory including, but not limited to, research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
9. **Manage** means taking action to address the financial conflict of interest, which can include reducing or eliminating the financial conflict of interest so Cold Spring Harbor Laboratory, can ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

10. **Non-exempt human subjects research** is research that fails to meet the following criteria:
1. Research conducted in educational settings on educational practices.
  2. Educational tests, surveys, and interviews, but not if ID and information disclosure put the subject at risk; parts not applicable to research with children.
  3. Tests, surveys, and interviews with public officials, or if laws require confidentiality.
  4. The collection, study of existing data, and specimens if recorded by the investigator in which subjects cannot be identified.
  5. Research approved or conducted by federal agencies on public benefit programs.
  6. Evaluation of taste or food quality.
11. **Regulation or FCOI regulation** refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements.
12. **Report** refers to Cold Spring Harbor Laboratory's report of identified financial conflict of interests to the U.S. Public Health Service.
13. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health or agriculture, and encompasses basic and applied research. Research includes any activity for which research funding is available regardless of the source such as:
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| <ul style="list-style-type: none"> <li>• Research grant.</li> <li>• Career development award.</li> <li>• Center grant.</li> <li>• Individual fellowship award.</li> </ul> | <ul style="list-style-type: none"> <li>• Infrastructure award.</li> <li>• Institutional training grant.</li> <li>• Program project.</li> <li>• Research resources award.</li> </ul> |
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14. **Senior/Key Personnel** means the project director and principal investigator and any other person identified as senior/key personnel by Cold Spring Harbor Laboratory in the grant application, progress report or any other report submitted to the funding agency.
15. **Significant Financial Interest (SFI)** means anything of monetary value that was received from an entity in the 12 months preceding the disclosure, whether or not the value is readily ascertainable, belonging to the investigator, his or her spouse or domestic partner and dependent children, alone or in combination that reasonably appears to be related to the investigator's institutional responsibilities.
16. **Small Business Innovation Research (SBIR)** is an award designed to support projects from small businesses having commercial viability.

17. **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.
18. A **Subrecipient** is defined as all non-CSHL investigators who are receiving funding awarded to CSHL including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and subawardees.

## **2. PURPOSE OF THE INVESTIGATOR CONFLICT OF INTEREST POLICY**

Effective interactions between research institutions, government, the private sector, and industry is essential to bring about the rapid application of scientific discoveries to the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships, now encouraged in many forms, have become increasingly complex, and may involve financial linkages or a significant financial interest (SFI) that gives rise to a financial conflict of interest (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of the investigator's research in return for a financial benefit to the individual or his/her immediate family.

The FCOI exists when Cold Spring Harbor Laboratory (CSHL), through the procedures described in this policy, reasonably determines that the investigator's SFI could affect the design, conduct or reporting of research conducted at or by CSHL. The FCOI may arise even though no improper conduct or unethical behavior has occurred. CSHL and its investigators are responsible for identifying and then managing, reducing or eliminating such FCOIs to strengthen accountability and transparency, promote research objectivity, and maintain the integrity of research findings and prudent stewardship of public funds.

CSHL's Investigator Conflict of Interest policy (ICOI) has been developed to address and comply with the specific 2011 federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts). The U.S. Public Health Service oversees and monitors CSHL's compliance with the regulations. It may inquire at any time before, during or after an award about the investigator's SFI, and CSHL's review and response to such disclosure, regardless of whether the disclosure resulted in CSHL's determination of a FCOI.

All investigators will be notified about CSHL's conflict of interest (COI) requirements as well as their disclosure responsibilities under the ICOI policy. The Conflict of Interest Coordinator and the Conflict of Interest (COI) Committee administer this policy and emphasize compliance with its requirements, including the review of Annual Disclosure Forms, the training and management of investigators about COI policy, and the timely identification, reporting and management of the FCOI. Where more stringent requirements and regulations relating to conflict of interest of any funding agency or sponsor conflict with CSHL's policy, the requirements and regulations of that funding agency or sponsor will take precedence.

## **3. WHO MUST COMPLY WITH THE INVESTIGATOR CONFLICT OF INTEREST POLICY**

CSHL implemented specific procedures for annual disclosure and review of all SFIs so, that as an institution, the highest standards of integrity and objectivity could be applied to the design, the conduct and the reporting of research carried out at or by CSHL. Accordingly, this policy applies to all

CSHL faculty investigators including Ph.D.s, M.D.s, graduate students, collaborative and visiting researchers, as well as CSHL non-faculty staff, including and above the level of research associate, who contribute to the design, conduct or reporting of research, regardless of funding source.

#### **4. MANDATED CONFLICT OF INTEREST TRAINING FOR ALL INVESTIGATORS**

All CSHL investigators are mandated to complete the on-line, Investigator Conflict of Interest training tutorial prior to engaging in research and at least every four years thereafter, or immediately under the following circumstances:

1. CSHL's ICOI policy changes in a manner that affects investigator requirements.
2. An investigator is a new CSHL employee.
3. An investigator is non-compliant with CSHL's ICOI policy or management plan.

#### **5. WHAT CONSTITUTES A SIGNIFICANT FINANCIAL INTEREST**

A SFI is anything of monetary value received from an entity in the 12 months preceding the disclosure belonging to the investigator, his or her spouse or domestic partner and dependent children that reasonably appears to be related to the investigator's institutional responsibilities.

A SFI can consist of one or more of the following interests:

1. With regard to any **publicly traded entity**, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
  - Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria and paid authorship.
  - Equity interests include stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
2. With regard to any **non-publicly traded entity**, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure when aggregated, exceeds \$5,000, or when the investigator or his or her spouse or domestic partner or dependent children holds any equity interest.
  - Equity interests include stocks, stock options, or other ownership interests including any equity in a non-publically traded company.
  - The investigator must fully describe the nature of the equity interest including the number of shares owned, voting rights, etc. if at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity.
3. Remuneration from **intellectual property rights** such as patents, copyrights and royalties from such rights and agreements to share royalties related to intellectual

property rights and interests.

4. Investigators must disclose the occurrence of any **reimbursed or sponsored travel** related to their institutional responsibilities that is not stemming from a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The disclosure must include the following details:

<ul style="list-style-type: none"><li>• The purpose of the trip.</li><li>• The identity of the sponsor/organizer.</li></ul>	<ul style="list-style-type: none"><li>• The destination of the trip.</li><li>• The time duration of the trip.</li></ul>
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CSHL will then determine if any travel requires further investigation, including determination or disclosure of the monetary value in order to determine whether the travel constitutes a FCOI.

A SFI does not include the following types of financial interests:

1. Salary, royalties, or other remuneration received from CSHL if the investigator is currently employed or appointed by CSHL.
2. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
3. Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
4. Travel expenses that are reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
5. Salary, royalties or other payments that when aggregated for the investigator and the immediate family over the next 12 months are not expected to exceed \$5,000.
6. Intellectual property rights assigned to CSHL and unlicensed intellectual property that does not generate income.
7. Agreements with CSHL to share in royalties related to such rights.
8. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.

Many scientific journals have implemented policies that require 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 as to what information an investigator needs to disclose under CSHL's ICOI policy.

## **6. WHO MUST SUBMIT AN ANNUAL DISCLOSURE FORM**

All investigators, including Ph.D.s, M.D.s, graduate students, collaborative and visiting researchers as well as non-faculty scientific staff, including and above the level of research associate, are required at the beginning of their CSHL employment and each subsequent year thereafter to submit an Annual Disclosure Form and its associated Appendix Forms, which describes all external business activities and SFIs. Certain non-faculty administrators are also required to submit an Annual Disclosure Form.

## **7. UPDATING THE ANNUAL DISCLOSURE FORM AND SIGNIFICANT FINANCIAL INTERESTS**

All investigators and certain non-faculty administrators are required to simultaneously submit a current, accurate Annual Disclosure Form and all Appendix Forms, which identify and describe both existing and new SFIs into the CSHL financial conflict of interest portal located on CSHL's Intranet by the yearly November 15<sup>th</sup> deadline. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

In addition, investigators are required to promptly disclose new SFIs to accurately reflect any significant change in their external activities as follows:

1. No later than at the time of application for federally funded research.
2. Within 30 days of discovering or acquiring, through purchase, marriage, or inheritance, a new SFI.
3. At least annually in accordance with the November 15<sup>th</sup> deadline, during the period of the award.

## **8. ANNUAL DISCLOSURE FORM REVIEW BY THE CONFLICT OF INTEREST COMMITTEE**

The CSHL Conflict of Interest Coordinator will initially review the Annual Disclosure Form and may request further information or clarification about a SFI. Prior to the expenditure of any funds, the CSHL Conflict of Interest Coordinator will review all investigator disclosures of SFIs and determine if any SFIs appear to relate to the research. If necessary, the matter will be immediately referred to the CSHL Conflict of Interest Committee for further review. The CSHL Conflict of Interest Committee, which is comprised of 2-3 CSHL faculty members and 2-3 CSHL administrators, will thoroughly review all SFIs to identify whether any SFIs are related to the research and, if so related, whether the SFI is a FCOI. The CSHL Conflict of Interest Committee reviews and analyzes the specific circumstances of a SFI by taking into account such factors as the nature of the investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and the investigator's research. The CSHL Conflict of Interest Committee may, if warranted, involve the investigator in determining whether a SFI is related to the research in question. The FCOI will be deemed to exist when the CSHL Conflict of Interest Committee reasonably determines that a SFI disclosed by an investigator on the Annual Disclosure Form could directly and significantly affect the design, conduct or reporting of the investigator's research.

The Conflict of Interest Committee may decide to manage a documented SFI and institute guidelines for the investigator to follow as an interim measure and as a means of monitoring a SFI.

## **9. MANAGING, REDUCING OR ELIMINATING THE FINANCIAL CONFLICT OF INTEREST**

If a SFI is identified as a FCOI, the CSHL Conflict of Interest Committee will take action to robustly reduce or eliminate the conflict. The FCOI will be managed through a written plan that requires the investigator to take certain steps according to guidelines approved by the CSHL Conflict of Interest Committee. Conditions or restrictions that might be imposed to manage the FCOI include the following:

- Disclosure of the FCOI to lab personnel and collaborators.
- Disclosure of the FCOI in publications, journals, and posters, etc.
- Disclosure of the FCOI to audiences at conferences and seminars.
- Monitoring of research, proposals and data by independent peer reviewers.
- Modification of the research plan.
- Removal of an affected investigator from participation in all or the portion of the research, which is funded by the entity that would be affected by a SFI.
- Divestiture of a SFI by the affected investigator.
- Limiting the dollar value of fees received and/or stock ownership.
- Severance of the relationship creating the conflict.

As appropriate, the CSHL Conflict of Interest Committee may meet with the investigator or appoint a CSHL designated official to meet with the investigator to design a management plan or mechanism appropriate for the specific situation. The CSHL Conflict of Interest Committee may, as necessary, accept, modify or reject such plans and, in addition, query CSHL's Office of Sponsored Programs and/or the Internal Review Board to solicit alternate ideas. The investigator may appeal the findings to the CSHL Conflict of Interest Committee and CSHL's President by forwarding a request for reconsideration of these findings to the President's office within 30 days of the date of the letter. A copy of the letter sent to the investigator from the CSHL designated official will be forwarded to the



CSHL Conflict of Interest Committee and the President, who will determine whether the FCOI exists and the appropriate plan for managing the FCOI. The President and/or the CSHL Conflict of Interest Committee will consult with the Commercial Relations Committee of the CSHL Board of Trustees as needed. CSHL's President will have final review and authority regarding the management of all FCOI cases.

After the conditions or restrictions have been approved by the CSHL Conflict of Interest Committee, the CSHL Conflict of Interest Coordinator will forward a detailed letter to the investigator describing the management plan and its implementation schedule. The investigator will be asked to review and sign the letter as a sign of compliance.

## **10. REPORTING THE FINANCIAL CONFLICT OF INTEREST TO THE FUNDING AGENCY**

1. With regard to a **new federally funded research award**, CSHL will disclose through the eRA Commons FCOI Module information about the identified FCOI 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 for FCOIs identified for subrecipient investigators, if applicable. See Section 18, Subrecipient Conflict of Interest Compliance for more information regarding subrecipients.
2. With regard to an **ongoing federally funded research award**, CSHL will disclose through the eRA Commons FCOI Module information about the identified FCOI within 60 days of the FCOI's identification. For any SFI that is identified as a FCOI subsequent to CSHL's initial FCOI report during an ongoing federally funded research project, CSHL shall within 60 days, review the SFI disclosure, determine whether it is related to the research, and, if so, implement on at least an interim basis, a management plan that shall specify the actions that have been and will be, taken to manage the FCOI.
3. With regard to a **period of non-compliance during an ongoing federally funded research project**, CSHL will within 60 days of the investigator's delayed disclosure of a SFI, determine if a SFI constitutes a FCOI. If the FCOI exists, CSHL will implement, on at least an interim basis, a management plan that shall specify the actions that have been or will be taken to reduce or eliminate the FCOI going forward, as well as submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, CSHL will, within 120 days of its determination of non-compliance, complete a retrospective review of the investigator's activities, and the research project to determine whether all or part of the research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research. CSHL will, based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to reduce or eliminate the FCOI going forward.

Furthermore, if the federal agency 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 the institution, 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.

4. With regard to a **new, non-federal award entity**, CSHL may, if warranted, disclose through written notification, information about the identified FCOI to any corporation,

educational institution, nonprofit entity, private foundation, trust and individual donor before dispensing or spending any funds.

5. With regard to an **ongoing, non-federal award entity**, CSHL may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational institution, nonprofit entity, private foundation, trust and individual donor during the award's duration.
6. Annual FCOI follow-up reports will be provided to the funding agency for any FCOI previously reported by CSHL. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the management plan or explain why the FCOI no longer exists. CSHL will provide annual FCOI reports to the funding agency for the duration of the project period, including extensions with or without funds at the same time as when CSHL submits the annual progress report or at the time of project extension.

**11. WHAT INFORMATION ABOUT AN IDENTIFIED FINANCIAL CONFLICT OF INTEREST IS SUBMITTED TO THE FUNDING AGENCY**

Information submitted to the funding agency about the identified FCOI includes the following:

- Grant/contract number.
- Name of the project director or principal investigator.
- Name of the investigator with the FCOI.
- The name of the entity with which the investigator has the FCOI.
- Statement about whether the FCOI was managed, reduced or eliminated.
- The nature of the FCOI, i.e. equity, consulting fees, travel reimbursement, honoraria.
- 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 SFI conflicts with such research.

A description of the key elements of CSHL's management plan must also be submitted to the funding agency 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.

## **12. PUBLIC ACCESSIBILITY TO CSHL'S INVESTIGATOR CONFLICT OF INTEREST POLICY AND IDENTIFIED FINANCIAL CONFLICT OF INTERESTS**

CSHL's Investigator Conflict of Interest policy will be publically accessible on its website ([www.cshl.edu](http://www.cshl.edu)).

In compliance with the FCOI regulation, the following information concerning identified FCOIs will be made available to the public within 5 calendar days of a written request to CSHL:

- The name of the investigator.
- The title and role of the investigator with respect to the research project.
- Name of the entity with which the SFI is held.
- The nature of the SFI.
- Approximate value of the SFI as determined by dollar range \$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.

## **13. CONTINUED MONITORING OF THE FINANCIAL CONFLICT OF INTEREST AND CSHL COMPLIANCE**

CSHL will continually monitor the FCOI and investigator compliance with the FCOI management plan throughout the year and until the completion of the research project. As necessary, the CSHL Conflict of Interest Committee may require and develop a project specific monitoring process, which may include appointing a CSHL designated official to assist with monitoring the FCOI and investigator compliance.

## **14. WHAT HAPPENS AFTER THE FCOI IS REPORTED TO THE FEDERAL AGENCY**

The federal agency will evaluate the FCOI information received through the eRA Commons FCOI Module to determine if CSHL's actions are sufficient to reduce or eliminate the identified FCOI. The federal agency may request and review additional information before implementing, if needed, further corrective actions to ensure research objectivity.

If the federal agency 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 impose special award conditions, suspend funding or enforce other actions until the matter is sufficiently resolved.

## **15. NON-COMPLIANCE AND ENFORCEMENT**

CSHL will establish adequate enforcement mechanisms, provide for employee sanctions and other administrative action, where appropriate, in the event the investigator fails to comply with the CSHL Investigator Conflict of Interest policy or management plan. Violations of this policy may result in progressive disciplinary action including placing a hold on the processing of new grant applications

from a non-compliant investigator and/or withholding disbursement or distribution of project specific funding to the investigator's laboratory.

An investigator is non-compliant and in violation of the policy if an investigator fails:

1. To submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions by the CSHL Conflict of Interest Committee.
2. To provide the CSHL Conflict of Interest Committee with written acknowledgement of a management plan.
3. To provide the CSHL Conflict of Interest Committee with requested documentation regarding compliance with a management plan.

If an investigator fails to comply with CSHL's Investigator Conflict of Interest policy or management plan, CSHL will complete within 120 days of determining non-compliance a retrospective review of the investigator's activities and research projects, document CSHL's determination as to whether the funded research or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such research.

If bias is found, CSHL will submit a mitigation report addressing the impact of the bias on the research project including the extent of the harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions CSHL has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, CSHL may determine that additional interim measures are necessary with regard to the investigator's participation in the research project between the date the FCOI is identified and the completion of CSHL's retrospective review.

#### **16. PROJECT SPECIFIC CERTIFICATION FORM REQUIRED PRIOR TO ALL FUNDING SUBMISSION APPLICATIONS**

Each project director and principal investigator involved with a funding submission is required to enter a Project Specific Certification Form into the CSHL financial conflict of interest portal one week prior to submitting a sponsored research application that requests an amount greater than \$5,000 from a corporation, educational institution, federally funded agency, nonprofit entity, private foundation, trust, or individual donor. A Project Specific Certification Form certifies their compliance with the CSHL Investigator Conflict of Interest policy, lists all anticipated personnel and certifies that all who are responsible for the design, conduct, or reporting of the proposed research have submitted an Annual Disclosure Form.

Information needed to complete the Project Specific Certification Form is as follows:

- Name of the investigator.
- Application deadline.
- Funding opportunity announcement number.
- Funding agency or organization.
- Project title.
- Names of personnel who design, conduct or report on any of the proposed research, including non-CSHL investigators such as collaborators, sub-recipients, or subcontractors proposed for funding on a grant application.

The CSHL Conflict of Interest Coordinator monitors all grant submissions and contacts investigators who fail to submit Project Specific Certification Forms. Upon receipt of a \$5,000 or more award notice, the CSHL Conflict of Interest Official verifies that a Project Specific Certification Form has been entered into the CSHL financial conflict of interest portal, and if not, the investigator must complete the Project Specific Certification Form in order for the award to be processed by the Office of Sponsored Programs.

## **17. HUMAN SUBJECTS RESEARCH AND CONFLICT OF INTEREST**

Federal regulations aim to assure that research utilizing human subjects is ethical, and that the potential benefits outweigh the risks. The number of clinical trials has skyrocketed in recent years, and whereas trials used to be conducted mainly at academic institutions, the majority of clinical trials are now financed by for-profit pharmaceutical and biotechnology companies, which often use financial incentives and pay review boards to approve the trials. What if investigators testing a new drug are paid by the drug's manufacturer? What if the investigators are stockholders or even partners in that company? These types of arrangements raise concerns about financial conflict of interests between investigators, regulators, and pharmaceutical and biotechnology companies because such biases could produce unreliable and misleading research results.

CSHL must establish standards that provide a reasonable expectation that the integrity of research involving human subjects, whether it is funded by a corporation, educational institution, federally funded agency, nonprofit entity, private foundation, trust, or individual donor. Research involving human subjects must not be subordinate to, or compromised by a SFI. As such, CSHL has instituted under this CSHL Investigator Conflict of Interest policy a rebuttable presumption against SFIs in non-exempt human subject research. The rebuttable presumption against SFIs in non-exempt human subject research means that CSHL will presume, in order to assure that all potentially problematic circumstances are reviewed, that an investigator holding a SFI may not conduct the non-exempt human subjects research in question until the matter is thoroughly reviewed.

This rule is not intended to be absolute. A financially interested investigator may rebut the presumption by demonstrating facts that, in the opinion of the CSHL Conflict of Interest Committee, constitute compelling circumstances. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. If the CSHL Conflict of Interest Committee recommends that a financially interested individual be permitted to conduct the research, the investigator would be subject to the conditions specified by the CSHL Conflict of Interest Committee and approved by CSHL's Internal Review Board.

Monitoring and oversight by the CSHL Conflict of Interest Committee of the SFI will take place through updated reporting about any relevant change in financial circumstances. The CSHL Conflict of Interest Committee will, as needed, inform CSHL's Internal Review Board of any findings and determinations such as the nature and amount of the financial interest and CSHL Conflict of Interest Committee recommendation. It should be noted that this policy does not relieve investigators of any ethical obligations that may be imposed by CSHL's Internal Review Board. In fact, CSHL's Internal Review Board may require additional safeguards or demand the reduction or the elimination of the financial interest.

## **18. SUBRECIPIENT CONFLICT OF INTEREST COMPLIANCE**

Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to CSHL's terms and conditions, and as such, CSHL will take reasonable steps to ensure that any subrecipient investigator is in compliance with the federal FCOI regulation. CSHL will incorporate as part of a written agreement with the subrecipient, terms that establish whether CSHL's Investigator Conflict of Interest policy or that of the subrecipient will apply to the subrecipient investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient investigator, the subrecipient will certify as part of the agreement that he or she is in compliance with the federal financial conflict of interest regulation and that his or her portion of the project is in compliance with his or her institutional policy on conflict of interest. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient investigator is subject to CSHL's Investigator Conflict of Interest policy for disclosing SFIs that are directly related to the subrecipient's work for CSHL. CSHL will, if applicable, submit a FCOI report through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient investigator.

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 shall be sufficient to enable CSHL to provide timely FCOI reports, 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 SFIs 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 FCOI reports for a subrecipient investigator through the eRA Commons FCOI Module.

## **19. ADDITIONAL RESOURCES**

Please contact Cold Spring Harbor Laboratory by email at [FCOI@csih.edu](mailto:FCOI@csih.edu) to inquire about CSHL's Investigator Conflict of Interest policy or about CSHL's compliance with the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts).

NIH/HHS FCOI Policy and Guidance including the 2011 Revised Regulations  
<http://www.grants.nih.gov/grants/policy/coi/index.htm>