

California Institute for Biomedical Research <i>Financial Conflict of Interest (FCOI) Policy</i>	Effective Date: January 1, 2014
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1. Purpose

This Financial Conflict of Interest Policy (hereafter “Policy”) implements Federal disclosure regulations and requirements pertaining to the objectivity in research issued by the Public Health Service (PHS) in in 42 CFR Part 50 (grants) and 45 CFR Part 94 (contracts). The Conflict of Interest (COI) Regulation establish new standards and clarify previously established standards to be followed by institutions that apply or receive research funding from PHS awarding components, including National Institute of Health, for all grants, cooperative agreements, and research grants.

As such, California Institute for Biomedical Research (hereafter “Calibr”) has a responsibility to effectively manage Financial Conflict of Interest as outlined by said Regulations. Calibr has adopted this Policy to promote research integrity and ensure responsible use of public funds.

This policy applies to each Investigator, as defined in Section 2, and Calibr certifies with the adoption of this Policy that it:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI;
- Shall promote and enforce Investigator compliance with the regulation;
- Shall manage FCOI and provide initial and ongoing FCOI reports;
- Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request; and,
- Shall fully comply with the requirements of this policy.

2. Applicability

The Conflict of Interest Policy (COI Policy) applies to all individuals who fit the definition of Investigator as described in Section 3 below, including, without limitation, principal investigators, investigators, post-doctoral fellows, as well as individuals identified by the Institute as senior/key personnel in a grant application, progress report or any other report submitted to a PHS funding agency. Subrecipients, collaborators, visiting researchers consortium members, consultants may also be subject to this policy if they are responsible for the design, conduct or reporting of federally funded research or research that is proposed for federal funding.

3. Definitions

1. **Conflict Review Officer** shall be appointed by the Institute Director. The CRO will be review COI disclosures to determine whether a FCOI exists, and, if so, develop a Management plan for the Investigator to manage, reduce or eliminate the FCOI.
2. **Federally Funded Research** means any Research funded by a Public Health Service (PHS) awarding component, such as the National Institute of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE) or other U.S. federal agency.
3. **Financial Conflict of Interest** will be deemed to exist when Calibr's Conflict Review Office (CRO) reasonably determines that a Significant Financial Interest disclosed by the Investigator could directly or significantly affect the design, conduct, or reporting of PHS or other Federal funded research with the exception of Research funded through Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Note: Phase II SBIR and STTR programs are not exempt like Phase 1, and are subject to this policy.
4. **Investigator** refers to the Principal Investigator or Project Director (PI/PD), and any other person, regardless of title or position, who is eligible to submit a grant application on behalf of the Calibr or who will be responsible for the design, conduct, or reporting of research by the PHS or other Federal agencies, or proposed for such funding. Investigators include individuals identified by the Institute as senior/key personnel in a grant application, progress report, or any other report submitted to the federal funding agency.
5. **Investigators' Institutional Responsibilities** on behalf of Calibr include, but are not limited to, research, purchasing research, research consultation, administration, professional practice, institutional committee memberships and service on committees or panels such as Institutional Review Boards or other monitoring boards.

6. **Management Plan** is a written document created by the CRO that will specify the actions, guidelines, conditions and/or restrictions that have been taken or will be taken to reduce or eliminate an identified FCOI.
7. **Significant Financial Interest (SFI)** means anything of monetary value that was received from an entity in the twelve (12) months preceding the disclosure, whether or not the value is readily ascertainable, belonging to the Investigator, the Investigator's spouse or dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities.
8. **Small Business Innovation Research (SBIR)** is an award designed to support projects from small businesses having commercial viability.
9. **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.
10. **Subrecipient** refers to an individual or entity that receives federal funds from or through Calibr, as an awardee institution, where the subrecipient will be conducting a substantive portion of the Federally Funded Research and who will be accountable to the awardee institution for programmatic outcomes and compliance matters.

4. What Constitutes a Significant Financial Conflict of Interest

A SFI is a financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities.

1. **Publicly Traded Entity:** A SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. **Non-Publicly Traded Entity:** A SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds equity interest (e.g., stock, stock option, or other ownership interest); or other ownership interests including equity in a non-publicly traded company. The Investigator must fully describe the nature of the equity interests (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:** Payment directly to the Investigator from intellectual property rights such as patents, copyrights and royalties not owned by Calibr.

4. **Travel:** Investigators must disclose the occurrence of any reimbursed or sponsored travel if in aggregate the travel exceeds \$5,000.00 per entity (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be readily ascertainable) that is related to their Institutional Responsibilities and reimbursed or sponsored by an entity other than the Institute or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or another research institute that is affiliated with an institution of higher education including the Institute. The disclosure must include the following details:

- Purpose of travel
- Destination of travel
- Identify of sponsor/organization
- Time duration of travel

Calibr will determine if any travel requires further investigation, including determination or disclosure of the monetary value 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 Calibr if the Investigator is currently employed or appointed by Calibr.
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 intuition of higher education.
3. Income from service on advisory committees or review panels for a Institute or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or another research institute that is affiliated with an institution of higher education including the Institute.
4. Travel expenses that are reimbursed or sponsored by Calibr or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or another research institute that is affiliated with an institution of higher education.
5. An equity interest that when aggregated for the Investigator and the immediate family, meets both of the following tests:
 - Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value.
 - Does not represent more than five (5) percent ownership interest in any single entity.
6. Salary, royalties or other payments that when aggregated for the Investigator and the immediate family over the next twelve (12) months are not expected to exceed \$5,000.
7. Intellectual property rights assigned to Calibr and unlicensed intellectual property that does not generate income.
8. Agreements with Calibr to share in royalties related to such rights.
9. 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 of third parties, including how financial interests are defined, are distinct from the requirements in this Policy relating to Federally Funded Research and should not be used as guidance for the information an Investigator must disclose under this policy.

5. Annual Disclosure: Submission and Updates

All individuals who meet the definition of Investigator in Section 2 must submit an Annual Disclosure Form at time of hire and each subsequent year thereafter. All Investigators are required to complete a current, accurate Annual Disclosure Form that identifies, describes, and updates both existing and new SFIs. Annual Disclosure Forms must be submitted to the CRO by the annual deadline. In addition, Investigators have an ongoing obligation to promptly update their Annual Disclosure Form to accurately reflect any significant change in their external activities and SFIs as follows:

- At the time of application for federally funded research
- Within 30 days of determining or acquiring a new SFI
- On an annual basis, on a deadline to be determined by the CRO

Calibr may not submit any new grant applications to a Federal agency for research projects, and may not spend any Federal funds in connection with award notices for new or continuing Federally funded research projects, until all Investigators identified to work on such projects have completed training and submitted their disclosures required by this Policy. 42CFR50.604(2)

6. Annual Disclosure: CRO Review

Calibr's CRO will review the Annual Disclosure forms and may request further information or clarification about an SFI. Prior to the expenditure of any Federal Funds, the CRO will review all disclosures of SFIs and make a determination whether any SFI appears to relate to the Research. The CRO will determine whether any are related to the Investigator's Research and, if so, whether the SFI may be an FCOI. The CRO 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 degree and nature of any overlap between that relationship and the Investigator's research. The CRO, if warranted, involve the Investigator and/or other employees or advisors in determining whether a SFI is related to the research in question. An FCOI will be deemed to exist when the CRO and advisors (as needed) reasonably determines that an SFI disclosed by an Investigator could directly and significantly affect the design, conduct, or reporting of the Investigator's research.

The steps set forth in Section 7 must be completed promptly following the disclosure of an SFI in order to enable any FCOIs to be reported to the federal funding agency within sixty (60) day deadline set forth in the COI Regulation. Where a SFI is deemed not to be FCOI, the CRO nevertheless may decide to manage the SFI and may institute guidelines for the Investigator to follow as an internal measure. 42CFR 50.604(d)

7. Managing, Reducing or Eliminating a Financial Conflict of Interest

If an FCOI is identified by the CRO, the CRO will develop a Management plan to manage, reduce or eliminate the conflict. The Management plan will be set forth in a written document and may require the Investigator to take certain steps and follow guidelines approved by the CRO.

The Management Plan shall specify the actions that have been or will be taken to manage, reduce or eliminate the FCOI. Conditions or restrictions that might be imposed include, but are not limited to, the following:

- Disclosure of the FCOI to lab personnel and collaborators
- Disclosure of the FCOI in publications, journals, and posters
- 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 Investigator from participating in all or a portion of the project funded by the entity
- Divestiture of an SFI by the affected Investigator
- Severance of relationship(s) that created the conflict

As appropriate, the CRO may meet with the Investigator during the design and development of the Management Plan that will include mechanism appropriate for the specific situation. A copy of the Management Plan will be sent by the CRO to the Investigator and to Calibr's Institute Director, who will have final authority to determine whether an FCOI exists and the appropriate plan for managing the FCOI. The Investigator may appeal the CRO's proposed Management Plan, or the findings on which the plan is based, to the Institute Director within ten (1) calendar days of the receipt of the Management Plan. After the Management Plan and its implementation schedule have been finalized, the CRO will forward the final version to the Investigator. The Investigator will then review and sign the Management Plan to acknowledge his or her commitment to compliance.

The Institute's Management Plan will contain all elements required by the COI Regulations, which may include: role and principle duties of the conflicted Investigator in the research project; terms and conditions; how the Management Plan is designed to safeguard objectivity in the research; confirmation of the Investigators agreement to the Management Plan; how the Management Plan will be monitored; and other information as needed. 42CFR50.605(b)(1)

8. Reporting Financial Conflict of Interest to PHS

Calibr will report any significant financial interest disclosed that meet the following three criteria: (1) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this Policy; (2) Calibr determines that the significant financial interest is related to the PHS-funded research; and (3) Calibr determines that the significant financial interest is a financial conflict of interest.

1. **New PHS Funded Research:** Prior to Calibr's expenditure of any funds on a PHS funded research project, the CRO, within sixty (60) days, will provide to the PHS a FCOI report. All FCOI reports will be submitted through the eRA Commons FCOI Module. If a FCOI is able to be reduced or eliminated prior to expenditure of funds, a report to the PHS is not required. 42CFR50.605(b)(1)

The report will contain all elements required by the COI Regulations, which may include: Project number; project title; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; nature of the financial interest; value of the financial interest, or a statement that the interest is one whose value cannot be readily

determined through reference to public prices or other reasonable measures of fair market value; a description of how the financial interest relates to the PHS-funded research and the basis for the Institute's determination that the financial interest conflicts with such research; a description of the key elements of the Institute's Management Plan, including; role and principle duties of the conflicted Investigator in the research project; terms and conditions; 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 ensure Investigator compliance; other information as needed.

2. **Ongoing PHS Research Projects:** Whenever a new or existing Investigator discloses a new SFI, the Institute will review the disclosure, determine whether it is related to PHS-funded research, and determine if a FCOI exists. If a FCOI exists, the Institute will within sixty (60) days complete required reporting through the eRA Commons FCOI Module. 42CFR50.605(a)(2)

For any FCOI identified subsequent to the Institute's initial report during an ongoing funded research project, the Institute shall implement, within sixty (60) days, on at least an interim basis, a Management Plan that will specify the actions that have been and/or will be taken to manage the FCOI. If the FCOI is able to be reduced or eliminated, a report to the PHS is not required. 42CFR50.605(b)(2)

3. **Period of Non-Compliance during an Ongoing PHS Funded Project:** Calibr will within sixty (60) days of the Investigator's delayed disclosure of an SFI, determine if the SFI constitutes an FCOI. If the FCOI exists, Calibr will implement, on at least an interim basis, a Management Plan that shall specify the actions that have been and/or will be taken to reduce or eliminate the FCOI, and the CRO will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, Calibr will, within one-hundred twenty (120) days of its determination of non-compliance, complete a retrospective review of the Investigator's activities, and the Research project to determine whether part or all of the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of such Research. Based on the results of the retrospective review, if appropriate, the CRO will update the previously submitted FCOI report, specifying the actions that will be taken to reduce or eliminate the FCOI. 42CFR50.605(a)(3)

The Institute will document the retrospective review, including all of the following key elements: project number; project title; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review. 42CFR50.605(a)(3)

In any case in which the HHS determines that a PHS-funded research project of clinical research 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 a financial conflict of interest that was not managed or reported by the Institution as required by the COI Regulations, Calibr will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations. 42CFR50.606(c)

4. **Annual Reports:** Annual follow-up reports will be provided by the CRO to the funding agency for any previously reported FCOIs. 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. The Institute 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 Calibr's Grants Administration department submits the annual progress report or at the time of project extension. 42CFR50.605(b)(4)

9. Public Accessibility

Calibr's FCOI policy will be accessible through its public web site (www.calibr.org). In addition, in compliance with the COI Regulation, Calibr will make the following information about identified FCOIS available by written respond within five (5) days of a request:

- Investigator's name
- Investigator's title and role with rest to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI as determined by dollar range from \$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 the value cannot be readily determined through referenced to public prices or other reasonable measures of fair market value.

42CFR50.605(a)(5)(ii)

10. Financial Conflict of Interest Monitoring

The Institute will monitor the FCOI and Investigator compliance with the FCOI Management Plan until the completion of the research project. As necessary, the COI Committee may require and develop a project specific monitoring process, which may include appointing an Institute designated official to assist with monitoring the FCOI and Investigator compliance. The COI Committee may modify an Investigator's Management Plan at any time. 42CFR50.605(a)(4)

11. 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 the Institute'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 the Institute 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.

12. Subrecipient Conflict of Interest Compliance

If Calibr carries out research through a Subrecipient, Calibr, as the awardee institution, will take reasonable steps to ensure any Subrecipient Investigator complies with the COI Regulations. Calibr will incorporate as part of its written consortium agreement with the Subrecipient, terms that establish

whether the FCOI policy of the Institute or that of the subrecipient will apply to the subrecipient Investigator(s).

If the Subrecipient can provide certification of an established FCOI policy, the written agreement will specify time periods for the Subrecipient to report all identified Financial Conflicts of Interest to the Institute. Such time periods will provide SBMRI with sufficient time to review the reports and make timely reports to PHS, as necessary. 42CFR50.604(c)(1)(ii)

If the Subrecipient cannot provide certification of an established FCOI Policy, the written agreement issued by Calibr will state that subrecipient Investigators are subject to Calibr's FCOI Policy for disclosing SFIs that are directly related to the performance of work. The Subrecipient agreement will also specify time periods for the Subrecipient to submit Investigator disclosures to Calibr to allow sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy. 42CFR50.604(c)(1)(iii)

Calibr's Grants Administration department will submit any FCOI reports for subrecipient Investigators through the eRA Commons FCOI Module.

13. Enforcement and Non-Compliance

Calibr is required to establish adequate enforcement mechanisms and provide for employee sanctions and/or other administrative action, where appropriate, to address any failure by an Investigator to comply with the COI Policy or a Management Plan. Violations of this policy may result in disciplinary actions as deemed appropriate by Calibr.

- Submit an Annual Disclosure form or provide an update to the Annual Disclosure form by the deadlines established for such submissions
- Provide the CRO with written acknowledgement of a Management Plan
- Provide the CRO with requested documentation regarding compliance with a Management Plan
- Complete required FCOI training

If an Investigator fails to comply with the Calibr FCOI Policy and/or Management Plan, Calibr must complete within one-hundred twenty (120) days of determining non-compliance a retrospective review of the Investigator's activities and research projects, document Calibr's determination as to whether the federal funded research or any 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, Calibr must submit a mitigation report addressing the impact of the bias on the research project including the extent of 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 the Institute has taken, or will take to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, Calibr may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date of the FCOI is identified and the completion of Calibr's retrospective review. 42CFR50.604(j)

14. Project Specific Certification

Investigators have an ongoing obligation to promptly update their Annual Disclosure form should their situation change prior to the issuance of an award. The Grants Department will query all Investigators associated with the research to confirm there are no changes, to their Annual Financial Conflict of Interest Disclosure on file. If there are reportable changes the Grants Department will collect an updated Disclosure form for review and processing by the COI Committee.

15. Mandatory Conflict of Interest Training for all Investigators

Calibr requires all Investigators to complete COI training prior to engaging in federally funded research and at least every 4 years thereafter, or as directed by Calibr. Training is required immediately when any of the following circumstances apply:

- The Institute revises its FCOI policies and procedures in a manner that affects the requirements of Investigators
- Investigator is new to the Institute
- Investigator is not in compliance with the Institute's FCOI Policy or Management Plan

The Institute's training program will be available on-line, on the Institute intranet. Each Investigator must certify his/her completion after each training session. 42CFR50.604(b)

16. Record Maintenance

Records relating to all Investigator disclosures of FCOIs and Calibr's review of, or response to, such disclosures, and all actions under Calibr's Policy or retrospective review, if applicable, will be maintained for at least three (3) years from the date the final expenditure report is submitted to the PHS. 42CFR50.604(i)