



INVESTIGATOR CONFLICTS OF INTEREST, FINANCIAL CONFLICTS OF INTEREST, AND CONFLICTS OF COMMITMENT POLICY

POLICY STATEMENT AND PURPOSE

The Salk Institute (the “Institute”) is committed to maintaining the highest standards of integrity and transparency in its research and academic activities. Institute Investigators are obligated to carry out their duties in a transparent, lawful, and ethical manner. The purpose of this policy is to protect the reputation and integrity of both the Institute and its Investigators by providing a system for identifying, reporting, and managing actual, apparent, and potential conflicts. This policy (“Policy”) and associated procedures outline the requirements for disclosing and managing Conflicts of Interest (COI), Financial Conflicts of Interest (FCOI), and Conflicts of Commitment (COC), both foreign and domestic, and are intended to comply with federal laws and regulations, including but not limited to those from the Department of Energy (DoE), National Institutes of Health (NIH)¹, National Science Foundation (NSF), and National Aeronautics and Space Administration (NASA). This policy will be understood to incorporate any requirements stipulated by those regulations and laws, even if they are not expressly outlined in this Policy document or its related procedures.

SCOPE

This policy applies to all full-time and part-time faculty, postdoctoral fellows, graduate students, staff scientists, and other personnel of the Institute who are responsible for the design, conduct, or reporting of research activities (collectively “Investigators”). Subrecipients, collaborators, visiting researchers, consortium members, consultants, subcontractors, and others may also be subject to this policy if they are responsible for the design, conduct, or reporting of research. In such instances, these personnel are also considered “Investigators” for the purposes of this policy and associated procedures. Program Directors/Principal Investigators (PD/PI) listed on all PHS funding are always considered Investigators and thus subject to this policy. When DoE funding is involved, Investigators also include what DoE refers to as “Covered Individuals,” which means any person, regardless of title or position, who contributes in a substantive, meaningful way to development or execution of the project scope of work and is designated by DoE. This includes all people listed above as “Investigators” plus any additional persons designated by the NOFO or award terms; project managers and functional equivalents; and any person for whom a current and pending support disclosure and/or biosketch/resume is submitted to DoE.

DEFINITIONS

¹ Health and Human Services (HHS) regulation 42 CFR Part 50 Subpart F (the “COI Regulations”).

Conflict of Interest (COI): When an Investigator's personal, financial, professional, or other interests, or those of their Family Member(s), could directly or indirectly compromise or appear to compromise their judgment, decisions, or actions in executing their professional responsibilities, including the design, conduct, and/or reporting of research.

Conflict of Commitment (COC): When an Investigator engages in external activities or assumes external commitments, either paid or unpaid, that have the possibility (either in actuality or in appearance) of interfering or competing with their ability to fulfill their professional obligations to the Institute. Examples may include current or pending employment; paid or unpaid positions, appointments, or affiliations; participation in or applications to foreign government-sponsored talent recruitment or similar programs; and obligations to improperly share information with, or withhold information from, the Institute or a federal funding agency (e.g., DoE, NIH, NSF, etc.).

Conflict of Interest (COI) Committee: Institutional committee that oversees the implementation of this policy and associated procedures; reviews and approves disclosures and Management Plans; approves training materials; and provides guidance and direction to Investigators and other personnel in fulfilling their responsibilities or addressing noncompliance. The COI Committee is comprised of the following (or their designees): (1) Senior Director, Research Compliance and Integrity (Chair), (2) SVP & Chief Science Officer, (3) VP & Chief Operating Officer, (4) General Counsel, (5) Chief Financial Officer, (6) Senior Director, Office of Technology Development, and (7) any other Institute official designated by the COI Committee and/or President.

Designated Official: The person that the Institute designates to direct and manage all activities related to COI, FCOI, COC, and MFTRP. The Designated official will be the Senior Director, Research Compliance and Integrity. The Designated Official is responsible for the following:

- updating policies and procedures
- soliciting and reviewing Investigator disclosures for Outside Interests and Significant Financial Interests
- determining if any Outside Interests relate to the Investigator's research
- determining if a COI, FCOI, or COC exists
- developing and implementing Management Plans to manage COIs/FCOIs/COCs
- monitoring Investigator compliance with Management Plans
- reporting COIs, FCOIs, COCs, and participation in Foreign Talent Recruitment Programs to relevant federal agencies, as required by applicable regulations
- promptly notifying federal agencies if an Investigator fails to comply with this policy or if failure to comply with a Management Plan appears to have biased the design, conduct, or reporting of research funded by the applicable federal agency; AND
- maintaining all records relating to all Investigator disclosures of Outside Interests and the Institution's review of, and response to, such disclosures.²

Family Member: An Investigator's spouse or domestic partner, and dependent children.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that is related to the research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research.

² See section on Record Retention for additional information.

Investigator's Institutional Responsibilities: Professional activities taking place on behalf of the Institute including, but not limited to, Research, Research consultation, teaching, institutional committee memberships and service on committees or panels such as Institutional Review Boards or other monitoring boards.

Outside Interests: Any activity, relationship, financial interest, or resource external to an Investigator's primary institutional obligations that could potentially influence, or appear to influence, their professional judgement or responsibilities. This includes but is not limited to: conflicts of commitment; significant financial interests³; sponsored or reimbursed travel; participation in foreign talent recruitment programs; foreign scholarly activities; external positions or appointments (paid or unpaid); and any other external resources or support for research activities that have not been processed through the Institute. All Outside Interests must be disclosed on the Annual Disclosure and Research Based Disclosure.⁴

Other Support: Per National Institutes of Health (NIH) policy, Other Support includes "all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant." Other support does *not* include training awards, prizes, or gifts⁵. Also referred to as "Current and Pending Support" by the National Science Foundation (NSF), National Aeronautics and Space Administration (NASA), and Department of Energy (DOE), or "Previous, Current and Pending Support" by the Department of Defense (DOD).

Malign Foreign Talent Recruitment Program (MFTRP)⁶: (A) Any program position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to the targeted individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue, in exchange for the individual:

1. Engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States entity or developed with Federal research and development award to the government of a foreign country or an entity based in, funded by, or affiliated with a foreign country regardless of whether that government or entity provided support for the development of the intellectual property, materials, or data products;

³ See Significant Financial Interest (SFI) under Definitions for further details on what constitutes an SFI. Refer to the Salk Investigator COI SOP for details on what is not considered an SFI.

⁴ Outside Interests, as defined by this policy and associated procedures, may overlap with activities, interests, relationships, or resources that require disclosure under other Institute policies (e.g., consulting activities). Disclosure under other policies or procedures does not exempt Investigators from the obligation to disclose Outside Interests as required by this policy and its associated procedures.

⁵ Gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return.

⁶ As defined in 42 USC § 19237(4)

2. Being required to recruit trainees or researchers to enroll in such program, position, or activity;
3. Establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment in a foreign country or with an entity based in, funded by, or affiliated with a foreign country if such activities are in violation of the standard terms and conditions of a Federal research and development award;
4. Being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;
5. Through funding or effort related to the foreign talent recruitment program, being limited in the capacity to carry out a research and development award or required to engage in work that would result in substantial overlap or duplication with a Federal research and development award;
6. Being required to apply for and successfully receive funding from the sponsoring foreign government's funding agencies with the sponsoring foreign organization as the recipient;
7. Being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the Federal research agency sponsoring the research and development award, contrary to the institutional policies or standard terms and conditions of the Federal research and development award;
8. Being required to not disclose to the Federal research agency or employing institution the participation of such individual in such program, position, or activity; or
9. Having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of the Federal research and development award; AND

(B) a program that is sponsored by:

1. A foreign country of concern or an entity based in a foreign country of concern, whether or not directly sponsored by the foreign country of concern;
2. An academic institution on the most recent list developed under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 2358 note; public Law 115-232) or such other list developed by the Federal Government to replace this list; or
3. A foreign talent recruitment program on the most recent list developed under section 1286(c)(9) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 2358 note; 1 Public Law 115-232) or such other list as may be developed by the Federal Government to replace this list.

Management Plan: A formal document that outlines responsibilities and specific actions that must be taken to eliminate, reduce, or mitigate a COI, FCOI, or COC.

Senior/Key Personnel: The Program Director/Principal Investigator (PD/PI) and any other individual who contributes to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive a salary.

Significant Financial Interest (SFI): A financial interest that is held by the Investigator or their Family Member(s) that reasonably appears to be related to the Investigator's Institutional Responsibilities. Each of the following are considered an SFI:

- Publicly traded entities: Total value of any remuneration (including salary, consulting fees, honoraria, paid authorship, and other payments not otherwise identified as salary) received from the entity in the 12 months preceding the disclosure, plus the value of any equity interest in the entity as of date of disclosure, exceeds \$5,000 when aggregated for the Investigator and their Family Member(s);

- Non-publicly traded entities: The aggregate value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000, or the Investigator and/or their Family Member(s) holds any equity interest in the entity;
- Intellectual property rights and interests (e.g., patents and copyrights), upon receipt of income related to such rights and interests; and
- Travel: Any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities that, when aggregated by sponsoring entity over the preceding 12 months, equals or exceeds \$5,000. Travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education does **NOT** need to be disclosed. For DOE-funded research, Covered Individuals must disclose all sponsored or reimbursed travel related to their Institutional Responsibilities as required by DOE, regardless of value, except travel that is excluded from disclosure under applicable DOE requirements. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

The term SFI does not include salary, royalties, or other remuneration paid by the Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Institute; income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with an Institution of higher education; or income from service on advisory committees or review panels for such entities. Additional exclusions from SFI and sponsored or reimbursed travel disclosure requirements are described in the associated Procedures and will be applied consistent with applicable sponsor requirements.

Subrecipient: An individual or entity that receives federal funds from or through the Institute, as an awardee institution, where the subrecipient will be conducting a substantive portion of the research and who will be accountable to the awardee institution for, e.g., programmatic outcomes and compliance matters.

FOREIGN TALENT PROGRAMS

Participation in foreign talent programs may create an actual or perceived conflict of interest and/or commitment. Any individual involved with such programs must disclose their participation as outlined in this policy and associated procedures.

This policy prohibits Institute Investigators and other individuals involved in the design, conduct, or reporting of research from taking part in any program that falls under the definition of Malign Foreign Talent Recruitment Programs (MFTRP) as specified in this policy.

DISCLOSURE REQUIREMENTS – OUTSIDE INTERESTS

1. Annual Disclosure: All Investigators must complete an Annual Disclosure to disclose all Outside Interests as required on the form, including but not limited to new and existing Significant Financial Interests (SFI), sponsored and reimbursed travel relating to the institutional responsibilities, participation in foreign talent programs, and other Outside Interests as requested in the disclosure form. All Investigators must also provide additional relevant information regarding disclosed or undisclosed Outside Interests at the request of the Conflict of

Interest Committee, their supervisor, or the Designated Official. Newly employed Investigators, or those newly identified as an Investigator, must complete an Annual Disclosure at time of hire or within 15 days of being identified as an Investigator and each year thereafter. For DOE-funded research, each disclosure and update submitted by a Covered Individual must be signed and dated and include the certification statement required by Appendix A to 2 CFR Part 910, Subpart C. In addition, Investigators have an ongoing obligation to promptly update their Annual Disclosure to accurately reflect any significant change in their external activities, SFIs, and internal responsibilities as follows:

- a) No later than at the time of application for Federally Funded Research;
- b) Within fifteen (15) days of discovering or acquiring a new SFI (including through purchase, marriage, or inheritance);
- c) Within fifteen (15) days of sponsored or reimbursed travel that causes the aggregate value from a sponsoring entity to reach or exceed \$5,000 during the preceding 12 months, or, for DOE Covered Individuals, any sponsored or reimbursed travel required to be disclosed under applicable DOE requirements; and
- d) At least annually.

The Institute (i) may not submit any new grant applications to a funding agency for Research projects, and (ii) may not spend any federal funds in connection with Notices of Award for new or continuing Federally Funded Research projects, until all Investigators identified to work on such projects have completed the training and submitted their disclosures as required by the COI Regulations and this policy.

2. Ad Hoc Disclosure: Investigators must disclose any new Outside Interests within fifteen (15) days of becoming aware of or initiating the related activity, relationship, financial interest, or resource. Updates to the Annual Disclosure may also be required for Institutional changes (e.g., new policy, procedures, or disclosure management system).

3. Research Based Disclosure (RBD)⁷: If an Investigator discloses any Outside Interests on their Annual Disclosure form or has a new or upcoming Outside Interest related to the proposed/awarded project, they will be required to complete a Research Based Disclosure attesting to whether the Outside Interest is related to the proposed/awarded project. The RBD must be complete prior to the expenditure of federal funds.

4. Review Process: Disclosures will be reviewed by the Designated Official and the Conflict of Interest Committee (as needed) to determine if a conflict exists and to develop a Management Plan, if necessary.

DISCLOSURE REQUIREMENTS – OTHER SUPPORT

Senior/Key Personnel on NIH-funded projects must disclose their Other Support at time of application, Just-in-Time (JIT) stage and in Research Performance Progress Reports (RPPRs) when there are changes in active support⁸. All Senior/Key Personnel are subject to this policy except Program Directors or training faculty on training grants and those designated as Other

⁷ Previously referred to as Project-Specific Certification or PSC. The federal requirement to disclose the relationship between Outside Interests and specific projects remains the same.

⁸ Investigators must likewise ensure compliance with similar requirements from other federal sponsors (e.g., Current and Pending Support for NSF, NASA, and DOE)

Significant Contributors. Each Investigator is personally responsible for ensuring that their Other Support disclosure is complete and accurate.

For DoE purposes, Other Support includes all resources made available in support of or related to a covered individual's professional research, development, demonstration, or deployment efforts, whether monetary or in-kind and whether provided through Salk or directly to the covered individual, including gifts with or without terms or conditions.

SFI DISCLOSURE REVIEW BY THE CONFLICT OF INTEREST COMMITTEE

The Institute's Designated Official will initially review the FCOI Annual Disclosure Forms and may request further information or clarification about an SFI. Prior to the expenditure of any Federal Funds, the Designated will review all disclosures of SFIs and make a preliminary determination whether any SFI appears to relate to the Investigator's PHS/NIH-funded research. If so, the matter will be immediately referred to the COI Committee for further review.

The administrative members of the COI Committee will initially review all disclosed SFIs to determine whether any are related to the Investigator's research by determining if the SFI could be affected by the research or the SFI is an entity whose financial interest could be affected by the research. If so, the Committee will also determine whether the SFI may be an FCOI. The Committee reviews and analyzes the specific circumstances of an 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 administrative members of the COI Committee may, if warranted, involve the faculty chair, the Investigator, and/or other faculty members or advisors in determining whether an SFI is related to the research in question. An FCOI will be deemed to exist when the full COI Committee 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 this Policy must be completed promptly following disclosure of an SFI in order to enable any FCOIs to be reported to the federal funding agency prior to the expenditure of funds under a newly issued award and within the sixty (60) days of identifying an FCOI during the period of an award.

Where a documented SFI is deemed by the COI Committee not to constitute an actual FCOI, the COI Committee nevertheless may decide to manage the SFI and may institute guidelines for the Investigator to follow as an interim measure.

MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

If an SFI is identified by the COI Committee as an FCOI, the COI Committee 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 COI Committee. Conditions or restrictions that might be imposed to manage the FCOI 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, 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 an SFI by the affected Investigator
- Limiting the dollar value of fees received and/or stock ownership
- Severing of the relationship(s) that created the FCOI

As appropriate, the COI Committee may meet with the Investigator and/or appoint an Institute official to meet with the Investigator during the design and development of a Management Plan that will include mechanisms appropriate for the specific situation. The COI Committee may, as necessary, query other Institute committees and/or personnel to solicit alternate ideas for management of the conflict.

A copy of the Management Plan will be sent by the Designated Official to the Investigator and to the Institute's President, who will have final authority to determine whether an FCOI exists and the appropriate plan for managing the FCOI. The Investigator may appeal the COI Committee's proposed Management Plan, or the findings on which the plan is based, to the President within ten (10) calendar days of the date of the plan. The President and/or the COI Committee may consult with members of the Institute Board of Trustees as needed regarding the FCOI and its Management. After the Management Plan and its implementation schedule have been finalized, the Designated Official will forward the final version to the Investigator. The Investigator will then review and sign the plan to acknowledge his or her commitment to compliance.

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 a Management Plan at any time.

MANAGEMENT OF CONFLICTS OF INTERESTS OR CONFLICT OF COMMITMENT

1. Conflict Management Plans: If an Outside Interest is identified as a COI or COC, a Management Plan will be developed by the Designated Official and/or COI Committee to manage, reduce, or eliminate the conflict. Management plans must be maintained and complied with until the identified conflict no longer exists. If a situation, activity, relationship, or transaction is deemed to be unmanageable or prohibited by applicable state and federal law, or other Institute policies, the Designated Official and COI Committee will notify the President and Chief Science Officer.

2. Monitoring: Investigators are responsible for implementing and complying with their Management Plan and training or educating others as necessary about how they should comply with the plan. The Designated Official will regularly monitor compliance with Management Plans and update them as necessary for the duration of the conflict. The COI Committee may require and develop a project-specific monitoring process, which may include appointing an Institute official or subcommittee to assist with monitoring the conflict and Investigator compliance.

3. The Investigator may appeal the proposed Management Plan, or the findings on which the plan is based, to the COI Committee within ten (10) calendar days of the date of the plan being issued.

TRAINING

Investigators will be informed of this Policy, their disclosure responsibilities, and the COI Regulations and are required to complete COI/FCOI/COC training as described in the Procedures document associated with this policy before engaging in federally funded research and at least every four years thereafter. DoE covered individuals must complete COI/COC training before engaging in a DoE-funded project and refresher training at least every two (2) years. In addition, training is required immediately for all personnel subject to this policy under the following circumstances:

1. The Institute's Policy changes in a manner that affects Investigator requirements;
2. An Investigator is a new Institute employee; and
3. An Investigator is noncompliant with the Institute's Policy or a Management Plan.

Additionally, beginning October 1, 2025, all Senior/Key Personnel on NIH-funded projects must complete training on the disclosure of Other Support prior to participating in NIH-funded research. This training will be implemented and managed by the Senior Director for Research Compliance and Integrity.

REPORTING FINANCIAL CONFLICTS OF INTEREST TO THE FUNDING AGENCY

1. With regard to a **new PHS/NIH-funded research award**, the Designated Official will disclose through the eRA Commons FCOI Module required information about the identified FCOI **before the Institute spends any awarded funds**. If the FCOI is eliminated prior to spending any funds, then no FCOI report is required. In addition, the Institute may be required to submit an FCOI report for FCOIs identified for subrecipient investigators, if applicable under this Policy.
2. With regard to an **ongoing PHS/NIH-funded research award**, the Designated Official will disclose through the eRA Commons FCOI Module information about the identified FCOI (including from subrecipient Investigators) within sixty (60) days of the identification of the FCOI. For any SFI that is identified as an FCOI subsequent to the Institute's initial FCOI report during an ongoing Federally Funded Research project, the Institute shall implement, within sixty (60) days, 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**, the Institute 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, the Institute 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 Designated Official will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, the Institute 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 Designated Official will update the previously submitted FCOI report with any new information found following the retrospective review through a revised report. If bias is found, and the Designated Official will submit a mitigation report to provide the actions taken or to be taken to mitigate the effects of the bias.

4. With regard to a **new, non-federal award entity**, the Institute may, if warranted, disclose to such entity (e.g., corporation, educational institution, nonprofit entity, private foundation, trust or individual donor) information about an identified FCOI before dispersing or spending any funds and/or during the duration of the award.
5. Annual FCOI follow-up reports will be provided by the Designated Official to the funding agency for any FCOI previously reported by the Institute. 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 the Institute's Grants Administration department submits the annual progress report or at the time of project extension.
6. If an Investigator (or subrecipient Investigator) fails to comply with the Institute's FCOI Policy or if noncompliance with an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, the Institute shall promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken.

REPORTING OTHER CONFLICTS TO THE FUNDING AGENCY

When DoE funding is involved, the following written disclosures to DoE are required: (a) actual/apparent/potential COI/COC that cannot be eliminated or appropriately managed/reduced; (b) any such conflict involving a foreign government, instrumentality, or entity owned, funded, or controlled by a foreign government, together with mitigation measures; and (c) any additional conflicts required by the NOFO/award terms. All reportable conflicts must be clearly and explicitly disclosed in the DoE application. For a covered individual added later, any reportable conflict must be disclosed to DoE before the individual participates. For every COI/COC previously reported to DoE, the Institute will submit an annual report for the full project period, including extensions with or without funds, and state whether the conflict is still managed, unmanaged/unmanageable, or no longer exists, and will describe any management plan changes.

RETROSPECTIVE REVIEW

If the Institute discovers an Outside Interest that an Investigator failed to disclose promptly, or that wasn't reviewed during an ongoing federally-funded project for any reason (including delayed review or reporting by a subrecipient), the DO must determine within sixty (60) days whether an FCOI exists. If an FCOI is found, the Institute will implement a Management Plan to address it moving forward. (See section on "management Plans" for more details.)

In addition, if an FCOI is not identified or managed promptly, including: (1) an Investigator's failure to disclose an Outside Interest, (2) the Institute's failure to review or manage a conflict, or (3) an Investigator's non-compliance with a Management Plan, the Institute must, within one-hundred twenty (120) days of discovering the noncompliance, conduct a retrospective review of the Investigator's activities and the federally-funded research project. This review will cover the

period of non-compliance and aim to determine if any part of the federally funded research was biased in its design, conduct, or reporting of the research.

The DO will document the retrospective review, which will include the following:

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

Based on the results of the retrospective review, if appropriate, the Institute shall update any previously submitted reports to federal agencies, specifying the actions that will be taken to manage the conflict going forward. If bias is found, the Institution is required to notify the funding agency promptly. If PHS/NIH funding is involved, the Institute must also submit a mitigation report to the PHS/NIH Awarding Component, which must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

In any case in which the United States Department of Health and Human Services determines that an NIH-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 an FCOI that was not managed or reported by the Institute as required by the regulation, the Investigator shall:

1. Disclose the FCOI in each public presentation of the result of the research; and
2. Request an addendum to previously published presentations.

SUBRECIPIENT COMPLIANCE

Subrecipient agreements on federal awards, where the Institute is the primary awardee, will certify either 1) the subrecipient has a FCOI/COI policy that is compliant with the sponsor's requirements, including the COI Regulations; OR 2) the subrecipient(s) will follow this Policy and associated policies and procedures. For instances in which a subrecipient institution does *not* have its own compliant FCOI/COI policy, the COI Committee will determine if the subrecipient will be allowed to follow this Institute policy, or if they must implement their own compliant FCOI/COI policy, before the sub-agreement is signed by the Institute.

When the subrecipient's FCOI/COI policy applies to subrecipient Investigators, the agreement shall specify the time period(s) for the subrecipient to report all identified FCOIs to the Institute. Such time period(s) must be sufficient to enable the Institute to provide timely FCOI reports, as necessary, through the eRA Commons FCOI Module.

When the Institute's FCOI/COI/COC Policy applies to subrecipient Investigators, the agreement shall specify time periods for the subrecipient to submit all Investigator disclosures of SFIs to the Institute. Such time periods shall be sufficient to enable the Institute to comply with its review, management, and reporting obligations under the COI Regulations. The Institute's Grants Administration department will submit any FCOI reports for subrecipient Investigators through the eRA Commons FCOI Module.

RECORD RETENTION

The Institute will maintain all records related to COI, FCOI, and COC, including those that meet or exceed the regulatory requirements under 42 CFR 50.604(i) relating to Investigator disclosures of FCOIs. The following records will be retained for the duration of an Investigator's employment or engagement with the Institute and for a minimum of six (6) years following: (1) termination of Investigator's employment or engagement with the Institute, (2) expiration of a Management Plan, or (3) conclusion of a federally funded project associated with a conflict:

- Outside Interest disclosures;
- Institutional reviews of and response to Outside Interest Disclosures;
- Management Plans;
- All documentation associated with retrospective reviews;
- All documentation associated with foreign entity screening; and
- All documentation associated with noncompliance.

The DO is responsible for maintaining a records repository. All members of the COI Committee will have access to the repository. Additional access to specific documents will be granted to others as necessary for compliance with Institutional policy and state and federal laws and regulations. All additional considerations related to document retention fall under the Institute's Document Retention Policy, including but not limited to destruction of documents and lawsuits or government investigations.

NON-COMPLIANCE AND ENFORCEMENT

An Investigator's failure to comply with this Policy and/or Management Plan established under the purview of this policy, may result in modification of awards, disclosures to awarding entities, exclusion from the performance of research, removal or reassignment of job responsibilities, corrective and/or disciplinary action up to and including termination, criminal or civil prosecution under applicable state or federal law, and/or other appropriate action warranted under an associated research contract, law, regulation, and/or policy.

An Investigator is noncompliant and in violation of the Policy if an Investigator fails to:

1. disclose an SFI that is determined by the Institute to be an FCOI;
2. submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions;
3. provide the Designated Official with written acknowledgement of a Management Plan; or
4. provide the Designated Official and/or COI Committee with requested documentation regarding compliance with a Management Plan.

PUBLIC ACCESSIBILITY

This Policy will be publicly accessible on the Institute's website (www.salk.edu).

The Institute will also make available within five business days of a request the following information about SFIs if the following criteria are met:

1. The SFI was disclosed and is still held by the Senior/Key Personnel;
2. The Institute determines the SFI is related to the PHS/NIH-funded research; and
3. The Institute determines the SFI is an FCOI.

The information provided shall include:

- The Investigator's name, title, and role with respect to the project;
- The name of the entity in which the SFI is held;
- The nature of the SFI;
- The approximate dollar value of the SFI (using dollar ranges from \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999, and increments of \$20,000 for amounts between \$20,000 and \$100,000, and increments of \$50,000 for amounts over \$100,000), 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.

This information shall remain available for at least three (3) years from the date the information was most recently updated, or for a longer period if otherwise required by this Policy or applicable law or regulation.

If DoE requests a copy of this policy, disclosures, or supporting documents related to COI/COC, the Designated Official will ensure that they are made available within five (5) business days following any DoE request.

ADDITIONAL RESOURCES

- [HHS Promoting Objectivity in Research](#) (42 CFR Part 50 Subpart F)
- [DoE COI and COC Policy Requirements \(2 CFR Part 910\)](#)
- [DoE Interim Conflict of Interest Policy](#)
- [NSF Conflict of Interest Policies \(PAPPG IX-1\)](#)
- [NASA Conflict of Interest Policy](#)

RELATED INSTITUTE POLICIES AND PROCEDURES

- SOP – Investigator Conflicts of Interest and Conflicts of Commitment
- Policy on Outside Consulting Activities
- Conflict of Interest Policy – Administrative Staff
- Conflict of Interest Policy – Senior Management
- Organizational Conflict of Interest Policy
- Export Compliance Policy

CONTACTS

- Senior Director, Research Compliance and Integrity
- Conflict of Interest Committee

----- Page intentionally left blank -----