

## ADASRI Conflict of Interest and Conflict of Commitment Policy

### Contents

<i>I. Purpose and Scope</i> .....	2
<i>II. Applicability</i> .....	3
<i>III. Definitions</i> .....	3
<i>IV. Required Conflict of Interest Training for all Covered Individuals</i> .....	6
<i>V. What Constitutes a Significant Financial Interest</i> .....	6
<i>VI. Conflicts of Commitment</i> .....	8
<i>VII. Submitting and Updating Annual Disclosure Forms</i> .....	8
<i>VIII. Annual Disclosure Form Review</i> .....	8
<i>IX. Managing, Reducing or Eliminating a Financial Conflict of Interest</i> .....	9
<i>X. Reporting the Financial Conflict of Interest to the Funding Agency</i> .....	10
<i>XI. What Financial Conflict of Interest Information is Submitted to the Funding Agency</i>	11
<i>XII. Public Accessibility of the Institute’s Investigator Conflict of Interest Policy and Identified Financial Conflict of Interests</i> .....	12
<i>XIV. What Happens After the Financial Conflict of Interest is Reported to the Federal Agency</i> .....	12
<i>XV. Non-Compliance and Enforcement</i> .....	13
<i>XVI. Project Specific Certification</i> .....	13
<i>XVII. Subrecipient Conflict of Interest Compliance</i> .....	14
<i>XVIII. Record Retention</i> .....	14
<i>XIX. Additional Resources</i> .....	15

## I. Purpose and Scope

The ADA Science and Research Institute LLC (ADASRI) is a recognized leader in the oral health sciences, basic and applied research, and technological innovation. A primary goal of the ADASRI is to be a “research center of excellence” that advances dentistry, improves oral health, and provides the evidence base for use by health care professionals, the public, policy makers and professional organizations. It is the policy of ADASRI that its staff conduct their responsibilities to ADASRI in accordance with the highest ethical and legal standards. To avoid a conflict between personal or professional interests and ADASRI interests, individuals must not be in a position to act on behalf of or make decisions for ADASRI if their personal economic gain or interest may directly or indirectly influence, or have the appearance of influencing, the performance of their ADASRI duties.

We are concerned with two broad kinds of conflict:

- (1) **Conflicts of interest**, which typically involve potential financial gain or personal benefit to an employee or related individuals; and
- (2) **Conflicts of commitment**, which typically arise when otherwise positive activities may compromise the fulfillment of an employee’s job responsibilities to ADASRI.

It is the ADASRI’s policy that Covered Individuals acting on the institution’s behalf have an obligation to report actual or potential ethical, legal, financial, or other conflicts of interest and commitment. The ADASRI policy requires that Covered Individuals disclose certain financial interests, which disclosure enables the ADASRI to determine if a financial interest creates a conflict of interest (COI) or the appearance of a conflict of interest. The existence of a conflict or the appearance of one does not imply wrongdoing on anyone’s part and does not necessarily mean that a Covered Individual (such as an Investigator, as defined below) may not retain the financial interest and undertake their institutional responsibilities or affected research. Some conflicts must be eliminated, but often the ADASRI can work with the Covered Individual to manage a conflict or the appearance of a conflict so that the individual’s duties (such as research) can continue in a way that minimizes the possibility of bias in the research and preserves the objectivity of the research, or otherwise ensures a Covered Individual’s activities are carried out in an objective manner, free from any undue external influence or the perception of such external influence. Proper management of a conflict depends on full and prompt disclosure.

This Conflicts Policy is intended to assist the ADASRI staff in applying and complying with the ADASRI’s requirements regarding the disclosure, review and reporting of conflicts of commitment and conflicts of interest in research and with the requirements of the ADASRI sponsors.

This Conflicts Policy also implements and ensures compliance with the specific federal requirements set forth in the United States Department of Health and Human Services’ Objectivity in Research Regulations (COI Regulations), 42 CFR part 50 subpart F (grants) and 45 CFR part 94 (contracts). The COI Regulations establish new standards and clarify previously established standards to be followed by institutions that apply for or receive Research funding

from the United States Public Health Service (PHS) Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts.

Interactions between research institutions, government, the private sector, and industry help ensure the rapid application of scientific discoveries and the efficient translation of Research findings. Although such interactions are encouraged in many forms, they have become increasingly complex and can lead to relationships involving a Significant Financial Interest (SFI). A Financial Conflict of Interest (FCOI) exists when the ADASRI, through procedures described in this Conflicts Policy, reasonably determines that a Covered Individual's SFI could affect the design, conduct or reporting of the Covered Individual's Institutional Responsibilities. An FCOI may arise even though no improper conduct or unethical behavior has occurred.

The ADASRI has the responsibility under the COI Regulations to manage Financial Conflicts of Interest between a Covered Individual's personal financial interests (and those of the Covered Individual's spouse and/or dependent children) and the Covered Individual's Institutional Responsibilities. The ADASRI and its Covered Individuals must identify, and then manage, reduce or eliminate, FCOIs to strengthen accountability and transparency, promote Research objectivity, maintain the integrity of Research findings, and ensure prudent stewardship of public funds.

Where more stringent requirements and regulations relating to conflict of interest of any funding agency or sponsor conflict with the ADASRI's Conflicts Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

## **II. Applicability**

This Conflicts Policy applies to all Covered Individuals, who have an obligation to become familiar with, and abide by the provisions of this Conflicts Policy.

Furthermore, the provisions of this Conflicts Policy with respect to Federally Funded Research apply to individuals who fit the definition of Investigator in Section III below, including, without limitation, professional research staff, post-doctoral fellows, and on-faculty staff scientists, as well as individuals identified by the ADASRI as senior/key personnel in a grant application, progress report or any other report submitted to a federal funding agency. Subrecipients, collaborators, visiting researchers, consortium members, consultants or subcontractors 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.

## **III. Definitions**

1. **Conflict Review Officer (CRO)** means the individual responsible for implementing this Conflicts Policy. That responsibility includes reviewing all disclosures of Significant Financial Interests (SFIs), Conflicts of Interest and Conflicts of Commitment, and

requiring any and all actions necessary to ensure that any Conflict of Interest or Commitment found will be managed, reduced or eliminated in accordance with this Conflicts Policy. The CRO shall be appointed by the Chief Executive Officer of the ADASRI.

2. **Conflict of Interest Committee (COI Committee)** is an administrative committee comprised of members of the administration that may advise and assist the CRO in reviewing Covered Individual disclosures of Significant Financial Interests (SFIs), determining whether a Financial Conflict of Interest (FCOI) exists, and, if so, developing a Management plan for the Covered Individual to manage, reduce or eliminate the FCOI
3. **Covered Individual** means any ADASRI employee, including but not limited to the ADASRI staff in research or administrative positions, including Investigators, pre-doctoral and post-doctoral researchers, research fellows, trainees, students, technicians, research support staff and any visitors, such as consultants and contractors using the ADASRI research facilities to conduct research.
4. A **Financial Conflict of Interest (FCOI)** will be deemed to exist when the ADASRI's COI Committee reasonably determines that a Significant Financial Interest disclosed by the Covered Individual could directly and significantly affect their Institutional Responsibilities. For an Investigator, this includes the design, conduct or reporting of Federally 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 I and are subject to this policy.
5. **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.
6. **Investigator** means the principal investigator or project director, co-principal investigator(s), co-investigators, project director(s), individuals identified by the ADASRI as senior/key personnel, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Research, including Federally Funded Research or Research that is proposed for federal funding, which may include Subrecipients, collaborators, visiting researchers, consultants or subcontractors.
7. **Institutional Responsibilities** means professional activities taking place on behalf of the ADASRI including, but not limited to, Research, Research consultation, teaching, purchasing, administration, institutional committee memberships and service on committees or panels such as Institutional Review Boards or other monitoring boards.

8. **Management of an FCOI** means taking action to address the FCOI, including by reducing or eliminating the conflict so that the ADASRI can reasonably expect that the Covered Individual's Institutional Responsibilities, which may include design, conduct and reporting of Research, will be free from bias.
9. **Management Plan** is a written document approved by the COI Committee under which a Covered Individual with an identified FCOI must take steps and follow guidelines, conditions and/or restrictions to reduce or eliminate the conflict.
10. **Outside Professional Activities** are any activity or activities outside of the ADASRI engaged in by a Covered Individual in a professional capacity. Outside Professional Activities include, for example, consulting services, teaching, service on public or private boards and advisory committees, and service to governmental, nonprofit and professional organizations. Outside Professional Activities may be compensated or uncompensated.
11. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, and encompasses basic and applied Research and product development. Research includes any activity for which research funding is available regardless of the source, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
12. **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 Covered Individual, the Covered Individual's spouse, and/or the Covered Individual's dependent children, alone or in combination, that reasonably appears to be related to the Covered Individual's Institutional Responsibilities.
13. **Small Business Innovation Research (SBIR)** is an award designed to support projects from small businesses having commercial viability.
14. **Small Business Technology Transfer (STTR)** is a program under the SBIR program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.
15. **Subrecipient** refers to an individual or entity that receives federal funds from or through the ADASRI, 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, e.g., programmatic outcomes and compliance matters.

#### **IV. Required Conflict of Interest Training for all Covered Individuals**

All Covered Individuals must be informed of ADASRI's COI Policy as well as their disclosure responsibilities and other requirements of the COI Regulations. The COI Regulations require all Covered Individuals to complete a COI training tutorial prior to engaging in Federally Funded Research and at least every four years thereafter. Additionally, training is required immediately under the following circumstances:

1. The ADASRI's COI Policy changes in a manner that affects Covered Individual requirements;
2. A Covered Individual is a new ADASRI employee;
3. A Covered Individual is non-compliant with ADASRI's COI Policy or management plan.

The ADASRI's training program will be provided through the Collaborative Institutional Training Initiative (CITI). More information may be found on the ADA Intranet Knowledge Center in the document "CITI Training" (<https://kc.ada.org/sites/sci/Administration/ADASRI%20Policies%20and%20Forms/Conflicts%20Policy/CITI%20Training.pdf>).

#### **V. What Constitutes a Significant Financial Interest**

An SFI is a financial interest consisting of one or more of the following interests of the Covered Individual (and those of the Covered Individual's spouse and dependent children) that reasonably appears to be related to the Covered Individual's Institutional Responsibilities:

1. With regard to any publicly traded entity, a SFI exists if the aggregated 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 disclosure, exceeds \$5,000.
  - a. Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria and paid authorship.
  - b. 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 aggregated value of any remuneration received from the entity in the twelve (12) months preceding the disclosure when aggregated, exceeds \$5,000, or when the Covered Individual or the Covered Individual's spouse or dependent children holds any equity interest.
  - a. Equity interests include stocks, stock options, or other ownership interests including any equity in a non-publically traded company.
  - b. Covered Individuals 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, not received from the ADASRI.
4. Travel. When the Covered Individual is an Investigator, the Investigator must disclose the occurrence of any reimbursed or sponsored travel (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 any entity other than the ADASRI or a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or another research institute that is affiliated with an institution of higher education. The disclosure must include the following details: the purpose of the trip, the destination of the trip, the identity of the sponsor/organizer and the time duration of the trip

The ADASRI 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.

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

1. Salary, royalties, or other remuneration received from the ADASRI if the Covered Individual is currently employed or appointed by the ADASRI.
2. Income from seminars, lectures, or teaching engagements sponsored by a United States federal, state or local government agency, a United States institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education in the United States.
3. Income from service on advisory committees or review panels for a United States federal, state or local government agency, a United States institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education in the United States.
4. Travel expenses that are reimbursed or sponsored by the ADASRI or a United States federal, state or local government agency, a United States Institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or another research institute that is affiliated with an institution of higher education in the United States.
5. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles.

## **VI. Conflicts of Commitment**

A Conflict of Commitment is a situation where a commitment to Outside Professional Activities of a Covered Individual adversely affects the capacity of the individual to meet the individual's responsibilities at the ADASRI. A Conflict of Commitment is perceptible because of a reduction of the Covered Individual's time and intellectual energies devoted to the ADASRI's activities. Furthermore, Outside Professional Activities should not conflict with a Covered Individual's Institutional Responsibilities, and should not be inconsistent with obligations under other ADASRI research policies, including the ADASRI Statement of Policy on Intellectual Property.

## **VII. Submitting and Updating Annual Disclosure Forms**

All Covered Individuals have the responsibility for disclosing Conflicts of Interest, Significant Financial Interests, and Conflicts of Commitment, including details of Outside Professional Activities. Furthermore, All Covered Individuals must submit an Annual Disclosure Form at the beginning of their time at the ADASRI and each subsequent year thereafter. The Annual Disclosure Form, available from Knowledge Center at <https://kc.ada.org/sites/sci/Administration/ADASRI%20Policies%20and%20Forms/Conflicts%20Policy/ADASRI-annual-conflict-form.docx?Web=1>, must be submitted to the CRO by the yearly October 1 deadline.

In addition, Covered Individuals have an ongoing obligation to promptly update their Annual Disclosure Forms to accurately reflect any significant change in their external activities, SFIs, and institutional responsibilities as follows:

1. No later than at the time of application for federally funded Research;
2. Within thirty (30) days of discovering or acquiring a new SFI (including through purchase, marriage, or inheritance); and
3. At least annually in accordance with the October 1 deadline.

*The ADASRI (i) may not submit any new grant applications to a federal 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.*

## **VIII. Annual Disclosure Form Review**

The ADASRI's CRO will initially review the Annual Disclosure Forms in a timely and objective manner to determine if a Conflict of Interest or Commitment appears to exist. The CRO may request further information or clarification about any SFI. Prior to the expenditure of any Federal Funds, the CRO will review all disclosures of SFIs and, when possible, make a determination (or recommendation) whether any SFI appears to relate to the Research. In complex cases, the CRO

may convene and consult with a COI Committee for review. The COI Committee will be comprised of approximately 3 or 4 ADASRI administrators. The ADASRI's General Counsel may serve on the COI Committee to provide legal advice to the Committee.

The CRO, in consultation with the COI Committee as may be necessary, reviews and analyzes the specific circumstances of an SFI by taking into account such factors as the nature of the Covered Individual'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 or the Covered Individual's Institutional Responsibilities. With respect to Covered Individuals, an FCOI will be deemed to exist when the CRO reasonably determines that an SFI disclosed by a Covered Individual could directly and significantly affect decisions made by the ADASRI with respect to contracts, sales, purchases, or other business decisions. With respect to Investigators, an FCOI will be deemed to exist when the CRO 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 Section VIII must be completed promptly following disclosure of an SFI in order to enable any FCOIs to be reported to the federal funding agency within the sixty (60) day deadline set forth in the COI Regulations and Section XI of this policy.

Any determination and/or recommendation made by the CRO with respect to a Covered Individual is subject to review by the ADASRI's Chief Executive Officer (CEO).

## **IX. Managing, Reducing or Eliminating a Financial Conflict of Interest**

If an SFI is identified by the CRO as an FCOI, the CRO will develop a Management Plan to manage, reduce or eliminate the conflict. The Management Plan may be developed in consultation with the COI Committee. The Management Plan will be set forth in a written document and may require the Covered Individual to take certain steps and follow guidelines approved by the CRO. Where the Covered Individual is an Investigator, 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 conflict

As appropriate, the CRO may meet with the Covered Individual and/or appoint an ADASRI official to meet with the Covered Individual during the design and development of a

Management Plan that will include mechanisms appropriate for the specific situation. The CRO 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 CRO to the Covered Individual and to the ADASRI's CEO, who will have final authority to determine whether an FCOI exists and the appropriate plan for managing the FCOI. The Covered Individual may appeal the proposed Management Plan, or the findings on which the plan is based, to the CEO within ten (10) calendar days of the date of the plan. After the Management Plan and its implementation schedule have been finalized, the CRO will forward the final version to the Covered Individual. The Covered Individual will then review and sign the plan to acknowledge the Covered Individual's commitment to compliance.

## **X. Reporting the Financial Conflict of Interest to the Funding Agency**

1. With regard to a new Federally Funded Research award, the CRO 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 ADASRI may be required to submit an FCOI report for FCOIs identified for subrecipient investigators, if applicable under Section XVII of this policy.
2. With regard to an ongoing Federally Funded Research award, the CRO will disclose through the eRA Commons FCOI Module information about the identified FCOI within sixty (60) days of the identification of the FCOI. For any SFI that is identified as an FCOI subsequent to the ADASRI's initial FCOI report during an ongoing Federally Funded Research project, the ADASRI 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 ADASRI 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 CRO 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 COI Coordinator will update the previously submitted FCOI report, specifying the actions that will be taken to reduce or eliminate the FCOI.
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 CRO 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 ADASRI 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 ADASRI's Grant Operations department submits the annual progress report or at the time of project extension.

## **XI. What Financial Conflict of Interest Information is Submitted to the Funding Agency**

Information submitted to a federal funding agency about the identified FCOI shall include the following:

- Grant/contract number
- Name of the principal investigator or project director
- Name of the Investigator with the FCOI
- The name of the entity with which the Investigator has a 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-\$19,000; amounts between \$20,000-\$100,00 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 the Institute's determination that a SFI conflicts with such Research

A description of the key elements of the Institute'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

## **XII. Public Accessibility of the Institute's Investigator Conflict of Interest Policy and Identified Financial Conflict of Interests**

The ADASRI's COI Policy will be publicly accessible on its web site at [https://www.ada.org/~media/ADA/Science%20and%20Research/SRI/Files/ADASRI\\_COI\\_Policy.pdf?la=en](https://www.ada.org/~media/ADA/Science%20and%20Research/SRI/Files/ADASRI_COI_Policy.pdf?la=en). In addition, in compliance with the COI Regulations, the ADASRI will make the following information about identified FCOIs available by written response within five (5) days of a request:

- The name of the Investigator
- The title and role of the Investigator with respect to the Research project
- Name of the entity in which the SFI is held
- The nature of the SFI
- Approximate value of the SFI as determined by dollar range from \$0--\$4,999;
- \$5,000-\$9,999; \$10,000-\$19,000; amounts between \$20,000-\$100,00, 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.

## **XIII. Continued Monitoring of the Financial Conflict of Interest and the Institute Compliance**

The Institute will monitor the FCOI and Covered Individual compliance with the FCOI Management Plan until the completion of the Research project, or other Institutional Responsibility. As necessary, the CRO may require and develop a project specific monitoring process, which may include appointing an ADASRI-designated official to assist with monitoring the FCOI and Covered Individual compliance. The CRO may modify a Covered Individual's Management Plan at any time.

## **XIV. What Happens After the Financial Conflict of Interest 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 ADASRI'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.

## **XV. Non-Compliance and Enforcement**

The ADASRI is required to establish adequate enforcement mechanisms and provide for employee sanctions and/or other administrative action, where appropriate, to address any failure by a Covered Individual to comply with the COI Policy or a Management Plan. Violations of this policy may result in progressive disciplinary action, including, without limitation, limiting the individual's research privileges and termination of employment.

A Covered Individual is non-compliant and in violation of the COI Policy if a Covered Individual fails to:

1. submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by the deadlines established for such submissions;
2. provide the CRO with written acknowledgement of a Management Plan; or
3. provide the CRO with requested documentation regarding compliance with a Management Plan.

For Federally Funded Research, if an Investigator fails to comply with the ADASRI's COI Policy or Management Plan, the ADASRI must complete within one-hundred twenty (120) days of determining non-compliance a retrospective review of the Investigator's activities and Research projects, document the Institute's determination as to whether the Federally 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.

The CRO will document the retrospective review. Such documentation shall include the following elements: (i) Project/Contract number and title; (ii) principal investigator/project director; (iii) name of the Investigator with the Conflict of Interest; (iv) name of entity in which the Investigator has a Significant Financial Interest that gives rise to the Financial Conflict of Interest; (v) reason for the retrospective review; (vi) detailed methodology used for the retrospective review; (vii) findings of the review; and (viii) conclusions of the review.

If bias is found, the ADASRI must 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 the Institute has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, the ADASRI 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 the ADASRI's retrospective review.

## **XVI. Project Specific Certification**

Each principal investigator or project director involved with a federal funding submission must certify to the ADASRI's Grant Operations department that all the Investigators on the federal grant application have updated their Conflicts of Interest and Commitment Disclosure Form they

have on file with the CRO and thus is complete and accurate as of the date the research funding application is sent to the outside entity.

## **XVII. Subrecipient Conflict of Interest Compliance**

If the ADASRI carries out Research through a subrecipient, the ADASRI, as the awardee institution, will take reasonable steps to ensure that any subrecipient Investigator complies with the federal FCOI regulations. The ADASRI will incorporate as part of a written agreement with the subrecipient, terms that establish whether the FCOI policy of the ADASRI or that of the subrecipient will apply to the subrecipient Investigators.

If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient will certify as part of the agreement that they are in compliance with federal regulations and that their portion of the project is in compliance with their institutional policies on conflict of interest. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigators are subject to the Institute's COI Policy for disclosing SFIs that are directly related to the subrecipient's work for the Institute. The ADASRI will, if applicable, submit an FCOI report through the eRA Commons FCOI Module for any FCOIs identified for subrecipient Investigators.

If the subrecipient's 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 ADASRI to provide timely FCOI reports, as necessary, through the eRA Commons FCOI Module.

If the ADASRI's FCOI policy applies to subrecipient Investigators, the agreement shall specify time periods for the subrecipient to submit all Investigator disclosures of SFIs to the ADASRI. Such time periods shall be sufficient to enable the Institute to comply with its review, Management, and reporting obligations under the COI Regulations. The ADASRI's Grant Operations department will submit any FCOI reports for subrecipient Investigators through the eRA Commons FCOI Module.

## **XVIII. Record Retention**

Records of the ADASRI's actions and of all disclosures under this Conflicts Policy will be maintained for at least three (3) years. For actions and disclosures related to Federally Funded Research, the three (3) year period begins after submission of the final award expenditure report or as otherwise required by the external agreement or applicable regulations. Upon authorized request of a sponsoring entity, the specific disclosure documents and related records will be made available to appropriate officials.

## **XIX. Additional Resources**

Additional training and information regarding NIH Conflict of Interest Policy and Guidance can be found at:

[NIH information on Financial Conflict of Interest](#)

[NIH Financial Conflict of Interest Tutorial](#)

[Title 42, Part 50, subpart F, Promoting Objectivity in Research](#)

[Title 45, Part 94, Responsible Prospective Contractors](#)