AIR Financial Conflict of Interest Management and Mitigation Program for NIH Grants

I. Introduction

This policy implements NIH FCOI requirements (42 CFR Part 50 Subpart F; 45 CFR Part 94) for all NIH-funded research at AIR. The regulations apply to all National Institutes of Health (NIH) applications and funded grants, cooperative agreements, and research contracts, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards. The policy establishes standards and practices that provide a reasonable expectation that the design, conduct and reporting of PHS/NIH-funded work will be protected from bias resulting from an Investigator's financial conflict of interest (FCOI). This policy also serves to protect the safety of animals and human research participants, the reputation of the recipient institution and of the "Investigator" who participates in PHS/NIH-funded research. These requirements also work together to preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

AIR is committed to maintaining a high standard of professional integrity as it carries out its mission to conduct and apply behavioral and social science research to improve people's lives and well-being. To uphold this commitment, AIR has established a comprehensive set of policies, practices, and standards, which form the foundation for our operations. These policies include AIR's Financial Conflict of Interest Management & Mitigation Program for NIH Grants (NIH FCOI Program), described herein. The NIH FCOI program implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. Each Investigator will be informed about AIR's NIH FCOI Program, trained and required to comply with the NIH FCOI Program.

II. Definitions

Designated Official: The individual designated by AIR to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring staff FCOI training requirements.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, Public Health Service or NIH funding.

Institutional Responsibilities: Professional activities an Investigator performs on behalf of AIR including research, development, engineering, publication, consulting, technical services, research services, and administration.

Investigator: The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an NIH award or proposed for NIH funding, which may include collaborators or consultants. AIR will consider the individual's role, rather than the title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the NIH-funded research.

NIH: The biomedical research agency of the PHS.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health

(NIH).

Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by AIR in the grant application, progress report or any other report submitted to NI by AIR.

Significant Financial Interest (SFI): An SFI is a domestic or foreign financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner, and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (such as research, development, engineering, publication, consulting, technical services, administration, committee memberships, etc.):

> **Publicly Traded Entity:** If the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
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> **Non-Publicly Traded Entity:** If the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or spouse/dependent children) holds any equity interest.
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> **Intellectual Property Rights and Interests:** Upon receipt of income greater than $5,000 received over the preceding twelve months related to such rights and interests (e.g., patents, copyrights).
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> **Reimbursed or Sponsored Travel:** Any reimbursed or sponsored travel related to institutional responsibilities that exceeds $5,000 in value, except for travel sponsored by certain U.S. government or academic entities.

Exclusions: Salary, royalties, or other remuneration paid by AIR to the Investigator, income from investment vehicles (such as mutual funds and retirement accounts) in which the Investigator does not directly control the investment decisions, income from seminars, lectures, or teaching engagements sponsored by a federal state or local government agency located in the US, a US institution of higher education, or a research institute affiliated with US institution of higher education, and income from service on advisory committees or review panels for a federal, state or local government agency located in the United States or a US. Institution of higher education. However, all foreign financial interests must be disclosed if they meet the threshold.

III. Disclosure of Significant Financial Interests

Investigators will disclose their SFIs that are related to the institutional responsibilities as defined in this policy.

The Investigator SFI Disclosures will be retained by the Institution as part of the record maintenance requirements.

Investigators will disclose their SFIs at the following times:

- **At the time of application:** The Principal Investigator and all other individuals who meet the definition of 'Investigator' must disclose their SFIs to AIR's Designated Official. Any new Investigator who, after applying for NIH funding or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official promptly and prior to participation in the project.

- **Annually:** Each Investigator participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. The annual disclosure must include any information not disclosed initially to AIR pursuant to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- **Ad Hoc Basis – New SFIs During the Award:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

IV. Review of SFI Disclosures

The Designated Official will review the SFI disclosures to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

The SFI disclosures will be reviewed as described below:

- **Prior to the expenditure of awarded funds (e.g., during the Just-in-Time stage):** The Designated Official(s) will review the Investigator's SFI(s) prior to the NIH issuing a new award. If an FCOI is identified, AIR will submit an FCOI report to the NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.
- **Annual Disclosure:** The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The Designated Official(s) will review the Investigator's annual disclosure and use the updated information to determine if any changes are needed to an existing management plan. Any changes to an existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.
- **Ad Hoc Basis – New SFIs During Award Period:** Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official(s) will, within 60 days: review the disclosure of SFI, determine whether the SFI is related to the NIH-funded research, determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. AIR will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

V. Determining relatedness of an SFI

The Designated Official will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

Relatedness Test: An Investigator's SFI is related to the research when the Designated Official reasonably determines the SFI:

1. Could be affected by the PHS/NIH-funded research; or
2. Is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

Investigator Involvement: The designated official(s) may involve the Investigator in determining whether an SFI is related to the NIH-funded research.

FCOI Determination: A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.

VI. Management of Significant Financial Interests that Pose Conflicts of Interest

If a financial conflict of interest exists, AIR's the Designated Official(s) will determine what management conditions and/or strategies will be put in place to address the conflict. These mitigation strategies may be employed on a temporary or continuing basis, until or unless further investigation shows that no SFI exists. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to AIR's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Severance of relationships that create financial conflicts;
- Divestiture of direct or indirect, problematic and/or financial arrangements and relationships
- Removal of the conflicted Investigator from all or certain aspects of the research.

If the Designated Official determines that a conflict exists, it will communicate its determination and the means developed for managing the FCOI in writing to the individual.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Designated Official(s) necessary to manage the Financial Conflict of Interest. The FCOI Designated Official(s) of AIR will submit the FCOI report to NIH via the eRA Commons FCOI Module.

VII. Monitoring Investigator Compliance

AIR will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring will include review of publications and presentations to confirm the FCOI has been disclosed as required. To facilitate monitoring, Investigators will be asked to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official.

VIII. Public Access to the AIR NIH FCOI Program and FCOI Information Held by Senior/Key Personnel

FCOI Policy:
A copy of the AIR NIH FCOI Program is posted on the institution's public website per the NIH requirements in the NIH Grants Policy Statement.

Identified FCOIs held by Senior/Key Personnel:

Prior to the expenditure of any funds under an NIH award, AIR will ensure public accessibility by providing a written response to any requestor within five (5) business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel
2. AIR has determined that the SFI is related to the research funded through an award; and
3. AIR has determined that the SFI is resulting in a financial conflict of interest.

The information made available in a written response will include, at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges:
    a. $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 interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of AIR's identification of a new FCOI which should be requested subsequently by the requestor.

IX. Reporting of Identified Financial Conflicts of Interest

AIR will assign an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI Reports to NIH. FCOI reports will be submitted to the NIH when a grant or cooperative agreement is active and an FCOI is identified. When there is no award or when there is no FCOI, no report will be submitted.

X. Training

Each Investigator will be informed about the AIR NIH FCOI Program and trained on their responsibility to disclose foreign and domestic SFIs. Training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years thereafter (if the individual remains an Investigator), and immediately when AIR finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the Designated Official(s)).

To ensure Investigators understand their responsibility to disclose SFIs per the policy, training will include the definition of "institutional responsibilities" and "significant financial interests" in addition to the information on when to disclose SFIs per Section 4.

To meet the training requirements of the FCOI regulation, AIR will utilize either the NIH's Financial Conflict of Interest tutorial or the "FCOI Presentation" located at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html and https://www.youtube.com/watch?v=D292YZ6BX24, respectively.

AIR will maintain documentation to ensure Investigator compliance with the training requirements. If the tutorial is used for training, the investigator will be required to provide a copy of the certificate to the

Designated Official. If the FCOI presentation is used, the investigator will be required to send an email to the Designated Official on the day the training was fulfilled.

XI. Failure to Comply with AIR's Financial Conflict of Interest Policy Applicable to Public Health Service Funded Award

Whenever AIR identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the Designated Official(s) will within 60 days: review the SFI, determine whether the SFI is related to research; determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward. AIR will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, AIR shall within 120 days of AIR's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

Such failures include:

- Failure by the Investigator to disclose a significant financial interest that is determined by AIR to result in a FCOI;
- Failure by AIR to review or manage such an FCOI;
- Failure by the Investigator to comply with a management plan;

If bias is found, AIR shall notify NIH promptly and submit a mitigation report per the regulation at 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52896 to NIH via the eRA Commons FCOI Module that shall address:

- Impact of the bias on the research project, and
- AIR's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, AIR will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart above. Depending on the nature of the Financial Conflict of Interest, AIR may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of AIR's independent retrospective review.

If bias is not found, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report information (e.g., increase in value of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

XII. Clinical Research Requirements

If NIH-funded clinical research is affected by an unmanaged or unreported financial conflict of interest, AIR will require the Investigator to disclose the conflict in all public presentations of research results and request addenda to previously published presentations.

XIII. Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through AIR to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to AIR for programmatic outcomes and compliance matters. Subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to AIR's terms and conditions. AIR will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

AIR will incorporate, as part of a written agreement with the subrecipient, terms that establish whether AIR's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written Agreement at https://grants.nih.gov/grants/policy/nihgps/html5/section 15/15.2 administrative and other requirements.htm.

- If the subrecipient's FCOI policy applies: The subrecipient institution will certify as part of the agreement with AIR that its policy is in compliance with the federal FCOI regulation. The agreement shall specify the time period for the subrecipient to report all identified FCOIs to AIR (e.g., within 55 days of identification to allow AIR to report within 60 days) to enable AIR to provide timely FCOI reports to the PHS/NIH as required by the regulation. AIR will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
- If the subrecipient cannot provide certification: The agreement shall state that the subrecipient Investigator is subject to AIR's FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for AIR. AIR will require the submission of all Investigator disclosures of SFIs to AIR. The agreement will include sufficient time period(s) to enable AIR to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, AIR will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module.

XIV. Records Maintenance

AIR will keep all records of all Investigator disclosures of financial interests and AIR's review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest), and all actions under this policy or retrospective review, if applicable. AIR will retain FCOI records for at least 3 years as required by 45 CFR 75.361.