

FINANCIAL CONFLICT OF INTEREST POLICY

PZA Innovation LLC

Effective Date: December 01, 2023

PURPOSE

PZA Innovation LLC is committed to maintaining the integrity and objectivity of its research activities. This commitment involves ensuring that the design, conduct, and reporting of research are not biased by personal financial conflicts of interest (FCOI). PZA Innovation LLC has established this policy aimed at identifying, managing, reducing, or eliminating FCOI. This policy serves to guarantee that our research activities remain free from the influence of personal financial conflicts.

The guidelines outlined in this policy are primarily formulated to align with the regulatory requirements of U.S. Public Health Service/National Institutes of Health (PHS/NIH)-sponsored research. Additionally, they are designed to establish a fundamental framework and set standards for the identification, evaluation, and management of potential FCOI in PZA Innovation LLC's various research activities. While the specific procedures, timelines, decisions, records, and communications for non-PHS research may be customized as needed, the overarching goal remains consistent: upholding PZA Innovation LLC's commitment to the highest standards of research integrity and the effective management or resolution of any real or potential FCOI.

The intention of this FCOI policy is to identify and manage any potential threats to the integrity of the research conducted by PZA Innovation LLC. It also provides education to PZA Innovation LLC employees and collaborators about disclosure requirements and information on how FCOIs are assessed. PZA Innovation LLC requires all its investigators and collaborators to adhere to [42 CFR Part 50, Subpart F](#), for PHS/NIH-funded grants and cooperative agreements, and 45 CFR Part 94 for government contracts. This compliance ensures that all PHS/NIH-funded research is free from bias and upholds the highest scientific and ethical standards. PZA Innovation LLC also intends to apply these stringent FCOI standards to grants and contracts from other federal agencies, with necessary adaptations or amendments.

SCOPE

This Policy governing FCOI is universally applicable within PZA Innovation LLC. It applies to all Founder/Investigator/Support Personnel including Subrecipients engaged in PHS/NIH-

funded research or other related activities. PZA Innovation LLC is responsible for ensuring implementation of this FCOI policy. Every Investigator is obligated to report their external financial interests to PZA Innovation LLC both annually and on an as-needed (ad hoc) basis. It is the responsibility of the designated PZA Innovation LLC's Official or their appointee to oversee the dissemination, collection, processing, evaluation, and preservation of these disclosure forms. Violation of the policy will be identified, reported and recorded accordingly.

Regulation Applicability: This procedure is mandated by 42 CFR Part 50 Subpart F available at [eCFR :: 42 CFR Part 50 Subpart F — Promoting Objectivity in Research](#). For purposes of this policy, the following definitions shall apply:

- 1) **Investigator** means 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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- 2) **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS/NIH Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- 3) **Disclosure means** Founder/Investigator/Support Personnel's statement to the Company of any Significant Financial Interests. Equity interest: Any stock, stock option, Intellectual property (IP) right or other ownership interest.
- 4) **Family member** indicates Founder/Investigator/Support Personnel's spouse or dependent children.
- 5) **Financial Interest** refers to any monetary value that is received or held by an Investigator and family member. This definition encompasses a wide range of financial benefits, regardless of whether their value is easily determined. Examples include, but are not

limited to: (1) Salaries or any other form of payment for services, such as consulting fees, honoraria, or payments for authored works (excluding scholarly works). (2) Equity interests of various kinds, including stocks, stock options, or other forms of ownership interests. (3) Intellectual property rights and interests, like patents, trademarks, service marks, and copyrights. This also includes any royalties or income derived from these intellectual property rights and interests.

6) Significant Financial Interest (SFI) means

- a) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's company responsibilities:
 - i. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests in excess of \$5,000.
- b) Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of \$5,000 received in the preceding 12 months (initial disclosure) related to their company responsibilities; provided, however, that this

disclosure requirement does not apply to 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. Note: Reimbursed or sponsored travel from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income is more than \$5,000. The details of the disclosure will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

- c) The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by the company to the Investigator if the Investigator is currently employed or otherwise appointed by the company, including intellectual property rights assigned to the company and agreements to share in royalties related to such rights; any interest in the company held by the Investigator, if the company is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements 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; or income from any service on advisory committees or review panels for 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. **Note:** Income from seminars, lectures, or teaching engagements and from service on advisory committees or review panels received from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed

when such income meets the threshold for disclosure (e.g., income more than \$5,000). See NIH's FAQs E.36. and E.37. for more information.

Exclusions from SFI: Salaries or Royalties from PZA Innovation LLC, Ownership in PZA Innovation LLC if it's a for-profit entity, income from certain investment vehicles, payments for seminars or lectures by the United States government or educational institution.

- 7) **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- 8) **Sponsored Travel** means travel expenses paid for directly or reimbursed to you for travel by you or your family when the travel or the sponsoring Organization could be related to your company Responsibilities.

PROCEDURE

The Chief Executive Officer (CEO) or Chief Financial Officer (CFO) of PZA Innovation LLC will be appointed as a dedicated Administrator, to oversee the enforcement of this Policy, thereby fulfilling the role of the company Official as defined in the Regulations. The detail procedure include

1. Training Requirements.

- 1.1. All Investigators who plan to participate in or are participating in PHS/NIH-funded research must be taken PZA Innovation LLC's FCOI policy, the Federal regulation 42 CFR Part 50 Subpart F, and the Investigator's responsibility training to disclose significant financial interests.
- 1.2. Investigators must be trained:
 - 1.2.1. Prior to engaging in PHS/NIH-funded research.
 - 1.2.2. Every four years, thereafter.
 - 1.2.3. Immediately, if:
 - PZA Innovation LLC's FCOI policy is revised.
 - An Investigator is new to PZA Innovation LLC; and
 - An Investigator does not comply with the FCOI policy or management plan.

1.3. Training constitutes Investigators certifying they have read and reviewed:

1.3.1. PZA Innovation LLC Financial Conflict of Interest Policy

1.3.2. NIH's "FCOI Training" on Regulation 42 CFR Part 50 Subpart F at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>.

1.4. The FCOI Policy has been implemented in the following ways:

1.4.1. Each Investigator has been provided a written copy;

1.4.2. The FCOI Policy has been added to PZA Innovation LLC's website at <https://pzainnovation.com/wp-content/uploads/2023/12/FCOI-12-18-2023.pdf>.

2. Disclosure, Review, and Monitoring Requirements. All Investigators are obligated to disclose their foreign and domestic significant financial interests to PZA Innovation LLC both annually and on an ad hoc basis, as detailed below.

2.1. Each Investigator has a responsibility to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities that meet or exceed the definition of SFI as provided in this policy using PZA Innovation LLC's Significant Financial Interest Form.

2.1.1. No later than at the time of application for PHS/NIH-funded research

2.1.2. At least annually during the period of the award

2.1.3. Within 30 days of discovering or acquiring a new SFI

2.2. PZA Innovation LLC's Chief Executive Officer (CEO) or Chief Financial Officer (CFO), as the company's designated institutional official, will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities for determination of FCOI.

2.2.1. An SFI is related to PHS/NIH-funded research if the CEO or CFO reasonably determines that the SFI is related to the PHS/NIH-funded research and is an FCOI.

An SFI is related to the research if the SFI:

2.2.1.1. Could be affected by the PHS/NIH-funded research; or

2.2.1.2. Is in an entity whose financial interest could be affected by the research.

2.2.2. An Investigator may be involved in making the determination of whether the SFI is related to PHS/NIH-funded research.

4.1.2. Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

5. Enforcement Mechanisms and Remedies and Noncompliance.

- 5.1. In the case an Investigator fails to comply with PZA Innovation LLC's FCOI policy or an FCOI management plan, employee sanctions or other administrative actions will be implemented. These may include a letter of reprimand, restriction on the use of funds, loss of wages, or termination from the company.
- 5.2. PZA Innovation LLC will perform a retrospective review within 120 days of a determination of noncompliance when either an SFI is not disclosed timely or not previously reviewed or when an FCOI is not identified or managed in a timely manner, including:
- 5.2.1. Failure by the Investigator to disclose a significant financial interest that is determined by the company to constitute an FCOI.
 - 5.2.2. Failure by the company to review or manage an FCOI.
 - 5.2.3. Failure by the Investigator to comply with the FCOI management plan.
- 5.3. The retrospective review will be documented and will include, at minimum, the following:
- 5.3.1. Project number
 - 5.3.2. Project title
 - 5.3.3. PD/PI and contact information
 - 5.3.4. Name of Investigator with the FCOI
 - 5.3.5. Name of the entity with which the Investigator has an FCOI
 - 5.3.6. Reasons for the retrospective review
 - 5.3.7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
 - 5.3.8. Findings of the review
 - 5.3.9. Conclusions of the review
- 5.4. In the case where a PHS/NIH-funded project includes clinical research with the purpose to evaluate the safety or effectiveness of PZA Innovation LLC's medical device or treatment and said PHS/NIH-funded project was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the company as required by [42 CFR 50.606\(c\)](#), PZA Innovation LLC will require the Investigator involved to:

- 5.4.1. Disclose the FCOI in each public presentation of the results of the research, and
- 5.4.2. Request an addendum to previously published presentations.

6. Subrecipient Requirements.

- 6.1. When applicable, PZA Innovation LLC will comply with all subrecipient requirements according to [42 CFR 50.604\(c\)](#) and [NIH Grants Policy Statement 15.2.1](#).
- 6.2. PZA Innovation LLC will establish, via a written agreement, whether the subrecipient will follow PZA Innovation LLC's FCOI policy or the FCOI policy of the subrecipient. In the case of the latter:
 - 6.2.1. PZA Innovation LLC will obtain a certification from the subrecipient that its FCOI policy complies with [42 CFR Part 50 Subpart F](#).
 - 6.2.2. PZA Innovation LLC will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the company to report identified FCOIs to the NIH as required by 42 CFR Part 50.605(b)(1) and (2) (i.e., prior to the expenditure of subrecipient funds under a new award or within a certain period of time of identifying an FCOI during the period of award (e.g., 50 days) to allow the institution to report the FCOI to the NIH prior to the 60-day reporting period.
 - 6.2.3. Alternatively, PZA Innovation LLC will include in the written subrecipient agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the company to identify, manage, and report identified FCOIs to the NIH.

7. Public Accessibility Requirements.

- 7.1. PZA Innovation LLC's FCOI policy will be made publicly accessible on PZA Innovation LLC's website.
- 7.2. Information concerning identified FCOIs held by senior/key personnel, as defined by 42 CFR Part 50.603, will be made publicly accessible prior to the expenditure of funds. The publicly accessible information will:
 - 7.2.1. Include the minimum elements as provided in 42 CFR Part 50.605(a)(5)(ii).
 - 7.2.2. Be made available within 5 business days of a written request.
 - 7.2.3. Be updated at least annually, but a response to a written request must be current.
 - 7.2.4. Be updated within 60 days of a newly identified FCOI, but a response to a written request must be current.

7.2.5. Remain available for 3 years from the date the information was most recently updated.

7.3. Financial and other disclosures made in compliance with this policy will be treated with confidentiality and disclosed only when necessary for appropriate review and evaluation. The only exception to this confidentiality is the public accessibility requirement for identified financial conflicts of interest held by senior/key personnel.

Approval and Effectiveness:

This Policy is hereby approved and made effective as of December 01, 2023, and will be subject to periodic review and amendment in accordance with regulatory changes and organizational requirements.

PZA Innovation LLC

Date: December 01, 2023