ZWICOAT MATERIALS INNOVATIONS, LLC
Financial Conflict of Interest (FCOI) Policy

Pursuant to 42 CFR Part 50, Subpart F

Effective Date: May 1, 2026

1. Purpose

This Financial Conflict of Interest (FCOI) Policy of ZwiCoat Materials Innovations, LLC ("the Company" or "ZCMI") is established to comply with the requirements of the 2011 revised regulation, 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research," as applicable to National Institutes of Health (NIH) grants and cooperative agreements. This Policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the Public Health Service (PHS), including NIH, will be free from bias resulting from Investigator financial conflicts of interest.

This Policy applies to all NIH-funded grants and cooperative agreements, excluding Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications and awards.

2. Scope and Applicability

This Policy applies to all Investigators, as defined in Section 3, who are planning to participate in or are participating in PHS-funded research conducted by or through the Company. This includes, but is not limited to, the Principal Investigator (PI), Co-Principal Investigators (Co-PIs), and any other person regardless of title or position who is responsible for the design, conduct, or reporting of PHS-funded research, which may include collaborators, consultants, and subrecipient investigators subject to this Policy.

3. Definitions

Financial Conflict of Interest (FCOI): A Significant Financial Interest (SFI) that the Company reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

Institutional Official: The President and Chief Technology Officer of ZwiCoat Materials Innovations, LLC, or his/her designee, who is responsible for the implementation and oversight of this Policy.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Company, including but not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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 the PHS, or proposed for such funding. This may include, for example, collaborators or consultants.

PHS-Funded Research: Research funded by the Public Health Service (e.g., NIH) by means of a grant or cooperative agreement, excluding Phase I SBIR/STTR applications and awards.

Significant Financial Interest (SFI): 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 institutional responsibilities:

> (i) With regard to any publicly traded entity, an SFI exists 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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> (ii) With regard to any non-publicly traded entity, an SFI exists 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 the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
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> (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
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> (iv) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value is not readily available) related to the Investigator's institutional responsibilities, excluding travel reimbursed or sponsored by a federal, state, or local government agency, an 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.

SFI does not include:

> (a) Salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company;
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> (b) Intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
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> (c) Any ownership interest in the Company held by the Investigator, if the Company is an applicant under the SBIR/STTR programs;
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> (d) 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;
>
> (e) Income from seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

4. Institutional Official

The President and Chief Technology Officer of ZwiCoat Materials Innovations, LLC serves as the Institutional Official and is responsible for the implementation, oversight, and enforcement of this Policy. The Institutional Official's responsibilities include, but are not limited to:

- Informing each Investigator of this Policy, the Investigator's disclosure obligations, and the federal regulation (42 CFR Part 50, Subpart F);

- Soliciting and reviewing Investigator SFI disclosures;
- Determining whether disclosed SFIs are related to PHS-funded research and whether they constitute FCOIs;
- Developing and implementing management plans for identified FCOIs;
- Reporting identified FCOIs to the NIH through the eRA Commons FCOI Module;
- Ensuring Investigator compliance with this Policy and applicable management plans;
- Maintaining records of all disclosures and actions taken; and
- Ensuring that training requirements are met.

5. Investigator Training

Each Investigator must complete FCOI training before engaging in PHS-funded research and at least every four years thereafter. Training must also be completed:

- When the Company revises this FCOI Policy in any manner that affects the requirements of Investigators;
- When an Investigator is new to the Company; and
- When the Company finds that an Investigator is not in compliance with this Policy or a management plan.

Training shall cover the federal FCOI regulation (42 CFR Part 50, Subpart F), this Policy, and the Investigator's responsibilities regarding disclosure of SFIs. The NIH FCOI Training Module, available at https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm, may be used to satisfy the regulatory training requirement. Upon completion, certificates of completion must be provided to the Institutional Official. The Company will also provide training on this Policy and the Investigator's disclosure requirements.

6. Disclosure of Significant Financial Interests

Each Investigator must disclose to the Institutional Official all Significant Financial Interests (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities. Disclosures must be made using the Company's SFI Disclosure Form and are required at the following times:

- No later than at the time of application for PHS-funded research;
- At least annually during the period of an award (within 30 days of the anniversary of the initial disclosure); and
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities (as defined in Section 3), including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

7. Review and Determination of FCOI

The Institutional Official will review each Investigator's SFI disclosure to determine:

- Whether an Investigator's SFI is related to PHS-funded research (i.e., whether the SFI could be affected by the research, or is in an entity whose financial interest could be affected by the research); and
- If so related, whether the SFI constitutes a Financial Conflict of Interest (i.e., whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

The Institutional Official will complete this review and any resulting determination prior to the expenditure of any PHS funds for the applicable research project. For any SFI that the Investigator did not disclose timely or that the Company did not review timely, the Institutional Official will review the SFI within 60 days and implement, on at least an interim basis, a management plan.

8. Management of Financial Conflicts of Interest

If the Institutional Official determines that a Financial Conflict of Interest exists, the Institutional Official will develop and implement a management plan that specifies the actions to be taken to manage the FCOI. Examples of management plan conditions may include, but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of Investigators from participation in all or a portion of the research;
- Reduction or elimination of the financial interest; and/or
- Severance of relationships that create the conflict.

The affected Investigator must formally agree to the management plan in writing before participating or continuing to participate in the related PHS-funded research. The Institutional Official will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the project.

9. Reporting to NIH

9.1. Initial FCOI Report

Prior to the expenditure of any funds under a PHS-funded research project, the Company will submit an FCOI report to the NIH through the eRA Commons FCOI Module for each identified FCOI. The report will include:

- Grant number and project title;

- PD/PI name;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fees, intellectual property);
- Value of the financial interest or a statement that the value cannot be readily determined;
- A description of how the financial interest relates to the PHS-funded research and the basis for the Company's determination that the interest is an FCOI; and
- Key elements of the management plan.

9.2. Annual FCOI Report

The Company will submit an annual FCOI report to the NIH for the duration of the project period regarding any previously reported FCOI and the status of the management plan. The annual report will specify whether the FCOI is still being managed, explain any changes to the management plan, and confirm Investigator compliance.

9.3. Revised FCOI Report

For any newly identified FCOI during an ongoing project, the Company will submit an FCOI report to the NIH within 60 days of identification.

10. Retrospective Review

If the Company identifies an SFI that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by the Company, the Institutional Official will, within 60 days, review the SFI, determine whether it constitutes an FCOI, and if so, implement an interim management plan. In addition, whenever an FCOI is not identified or managed in a timely manner (including failure by an Investigator to disclose an SFI that is determined to be an FCOI, failure to review or manage an FCOI, or failure by an Investigator to comply with an FCOI management plan), the Company will complete a retrospective review of the Investigator's activities and the PHS-funded research project within 120 days to determine whether any PHS-funded research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

If the retrospective review determines that the PHS-funded research was biased, the Company will notify the NIH promptly and submit a mitigation report that includes:

- The grant number and project title;
- The PD/PI and Investigator name;
- The entity with which the Investigator has an FCOI;
- The reason(s) for the retrospective review;
- Detailed methodology used in the review;
- Findings and conclusions;

- Impact of the bias on the research project; and
- Actions taken or planned to eliminate or mitigate the bias.

11. Subrecipient Requirements

When the Company enters into a subaward agreement with a subrecipient for PHS-funded research, the written agreement will specify whether the subrecipient's Investigators will comply with this Policy or the subrecipient's own FCOI policy.

If the subrecipient's Investigators will follow the subrecipient's own policy, the subrecipient must certify that its policy complies with 42 CFR Part 50, Subpart F. The subaward agreement will specify time periods for the subrecipient to report identified FCOIs to the Company, which must be sufficient to enable the Company to report to NIH in a timely manner.

If the subrecipient cannot make such a certification, the agreement will state that the subrecipient's Investigators are subject to this Policy for disclosing SFIs that are directly related to the subrecipient's work for the Company.

12. Public Accessibility

This Policy is publicly accessible on the Company's website. If requested, the Company will make this Policy available to any individual within five business days of the request. In addition, information concerning any Investigator's SFI determined to be an FCOI held by senior/key personnel will be made available, upon written request, within five business days. The information made available will include, at a minimum:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the SFI is held;
- The nature of the SFI; and
- The approximate dollar value of the SFI, 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.

13. Enforcement and Sanctions

The Company has established enforcement mechanisms to ensure Investigator compliance with this Policy. Failure to comply with any aspect of this Policy, including but not limited to failure to disclose SFIs timely, failure to complete required training, or failure to comply with a management plan, may result in sanctions or administrative actions including, but not limited to:

- Written warning;
- Required retraining;
- Suspension or termination of participation in PHS-funded research;

- Reduction or elimination of the financial interest causing the conflict; and/or
- Other administrative action, up to and including termination of employment or consulting arrangement.

14. Record Retention

The Company will maintain records of all Investigator SFI disclosures, the Company's review of and response to such disclosures (whether or not a disclosure resulted in a determination of an FCOI), all actions taken under this Policy, and any retrospective reviews, for a period of at least three years from the date the final expenditure report is submitted to the PHS, or as otherwise required by 2 CFR 200.334.

15. Policy Review and Updates

This Policy will be reviewed at least annually by the Institutional Official and updated as necessary to ensure continued compliance with 42 CFR Part 50, Subpart F, and NIH requirements. Any revisions to this Policy will be communicated to all Investigators, and retraining will be required as applicable.

16. Regulatory References

42 CFR Part 50, Subpart F – Promoting Objectivity in Research

45 CFR Part 94 – Responsible Prospective Contractors

NIH Grants Policy Statement, Section 4.1.10 – Financial Conflict of Interest

NIH Guide Notice NOT-OD-21-002 – Required Submission of FCOI Policy into eRA Commons IPF Module

17. Contact Information

For questions regarding this Policy, please contact:

Institutional Official:
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