

Financial Conflict of Interest Policy and Procedures

PHS/NIH-Supported Research

Policy No.	FCOI-001
Institution	CellsBin, Inc.
Effective Date	09/17/2026
Public URL	www.cellsbin.com/FCOI
Policy Owner	Designated Institutional Official
Current DIO	Nima Sarshar, CTO
Review Cycle	At least annually and when requirements change

1. Purpose

CellsBin, Inc. (“CellsBin” or the “Institution”) is committed to promoting objectivity in research and ensuring that the design, conduct, and reporting of research funded by the U.S. Public Health Service (“PHS”), including the National Institutes of Health (“NIH”), are free from bias resulting from Investigator financial conflicts of interest. This policy establishes CellsBin’s process to identify, review, manage, report, and monitor Significant Financial Interests (“SFIs”) and Financial Conflicts of Interest (“FCOIs”) in accordance with 42 CFR Part 50, Subpart F and applicable NIH requirements.

2. Scope

This policy applies to each Investigator who is planning to participate in, or is participating in, PHS/NIH-funded research for which the FCOI regulation applies. “Investigator” is determined by responsibility for the design, conduct, or reporting of the research, regardless of title or employment status. It may include the PD/PI, senior/key personnel, employees, consultants, collaborators, and subrecipient Investigators. The federal FCOI regulation excludes Phase I SBIR/STTR applications and awards; this policy applies to applicable Phase II and later PHS/NIH-funded research, including CellsBin Award 1R44CA314758-01.

3. Regulatory basis

- 42 CFR Part 50, Subpart F.
- NIH Grants Policy Statement, Section 4.1.10.
- Applicable NIH FCOI guidance, notices, and award-specific terms and conditions.

4. Definitions

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

Institutional Responsibilities: an Investigator’s professional responsibilities performed on behalf of CellsBin, including research, development, product development, scientific or clinical activities, consulting for the Institution, grant activities, supervision, regulatory work, and other assigned professional duties.

Investigator: the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS/NIH-funded research or research proposed for such funding.

Manage: taking action to address an FCOI, including reducing or eliminating it, so that the design, conduct, and reporting of the research are protected from bias to the extent possible.

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

Significant Financial Interest (SFI): a financial interest consisting of one or more interests of the Investigator, the Investigator's spouse, or dependent children that reasonably appears related to the Investigator's Institutional Responsibilities and meets the applicable thresholds below.

5. Financial interests requiring disclosure

5.1 Publicly traded entities

An SFI exists when the aggregate value of remuneration received from a publicly traded entity in the 12 months preceding the disclosure plus the value of any equity interest in that entity as of the disclosure date exceeds \$5,000. Remuneration includes salary and payments for services such as consulting fees, honoraria, and paid authorship. Equity includes stock, stock options, and other ownership interests.

5.2 Non-publicly traded entities

An SFI exists when remuneration received from a non-publicly traded entity in the preceding 12 months exceeds \$5,000, or when the Investigator, spouse, or dependent child holds any equity interest in that entity, regardless of value.

5.3 Intellectual property

Investigators must disclose intellectual property rights and interests, including patents and copyrights, upon receipt of income related to those rights or interests.

5.4 Reimbursed or sponsored travel

Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities when the travel is paid by an outside entity, subject to the exclusions below. The disclosure must include at least the purpose of the trip, sponsor/organizer, destination, and duration. CellsBin may request additional information, including estimated value.

6. Foreign financial interests

Applicable foreign financial interests must be disclosed. Foreign governments and foreign institutions of higher education do not receive the same categorical exclusions that apply to certain U.S. governmental or academic entities. Investigators must therefore disclose applicable foreign remuneration, equity, advisory activity, teaching/speaking income, sponsored or reimbursed travel, and other financial interests when they meet CellsBin's disclosure requirements.

7. Interests generally excluded from the federal SFI definition

- Salary, royalties, or other remuneration paid by CellsBin to an Investigator employed or appointed by CellsBin.
- Intellectual property rights assigned to CellsBin and agreements to share royalties related to those rights.
- Ownership interest in CellsBin held by an Investigator, because CellsBin is a commercial/for-profit organization.
- Income from diversified investment vehicles, such as mutual funds or retirement accounts, where the Investigator does not directly control investment decisions.
- Income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education as defined in 20 U.S.C. 1001(a); a U.S. academic teaching hospital; a U.S. medical center; or a research institute affiliated with a U.S. institution of higher education.
- Reimbursed or sponsored travel paid by the same qualifying U.S. governmental or academic entities listed above.

When uncertain, the Investigator must disclose the interest to the DIO rather than make a unilateral determination that disclosure is unnecessary.

8. Investigator disclosure requirements

Each Investigator must submit an SFI disclosure to the DIO:

- No later than the time an application for applicable PHS/NIH funding is submitted;
- Before beginning participation if the person becomes an Investigator after application or award;
- At least annually during the period of the award, on the schedule established by CellsBin; and
- Within 30 calendar days after discovering or acquiring a new SFI.

Annual disclosures must include newly acquired interests, interests not previously disclosed, updated values or information concerning previously disclosed interests, and any additional information requested by CellsBin.

9. Investigator training

CellsBin will inform each Investigator of this policy, the Investigator's disclosure responsibilities, and the federal FCOI regulation. Each Investigator must complete CellsBin-approved FCOI training before engaging in applicable NIH/PHS-funded research, at least every four years thereafter, and immediately when: (a) CellsBin materially revises this policy in a manner that affects Investigator requirements; (b) the Investigator is new to CellsBin; or (c) CellsBin determines the Investigator is not in compliance with this policy or an FCOI management plan.

CellsBin may use its own internal training, NIH training resources, or a combination. Completion of a particular NIH online tutorial is not required by this policy unless CellsBin separately designates it as required.

10. Designated Institutional Official

CellsBin designates Nima Sarshar, CTO, as the Designated Institutional Official ("DIO") for administration of this policy, unless superseded by a later written appointment. The DIO is responsible for collecting disclosures, reviewing SFIs, determining relatedness to NIH/PHS-funded research, determining whether an FCOI exists, developing and monitoring management plans, coordinating required reporting, ensuring training, maintaining records, and administering public-access requirements.

No individual may make the final institutional determination on his or her own disclosure. For any matter involving the DIO's own disclosure or another conflict affecting the DIO's impartiality, CellsBin will use a written alternate-reviewer designation. For the current award, Ali Kabiri is designated as alternate institutional reviewer for Nima Sarshar, subject to replacement by an independent reviewer if Ali has a conflict concerning the matter.

11. Institutional review and determination

Before expenditure of applicable NIH/PHS funds, CellsBin will review all required disclosures and determine whether any SFI is related to the funded research and, if related, whether it constitutes an FCOI. An SFI is related when it could be affected by the research or is held in an entity whose financial interests could be affected by the research. An FCOI exists when CellsBin reasonably determines the SFI could directly and significantly affect the design, conduct, or reporting of the funded research.

For a new Investigator or a newly disclosed/acquired SFI during an ongoing award, CellsBin will complete the required institutional review within 60 days.

12. Management of identified FCOIs

When an FCOI exists, CellsBin will implement a written management plan appropriate to the circumstances. Measures may include public disclosure; disclosure in publications/presentations or to human research participants when appropriate; independent monitoring; modification of the research plan; independent data review; modification of responsibilities; removal from specified research activities; reduction or elimination of the financial interest; severance of the outside relationship; or other measures sufficient to protect research objectivity. CellsBin will monitor compliance with the management plan throughout the project.

13. Reporting to NIH/PHS

When CellsBin determines that an FCOI exists, CellsBin will submit the required FCOI report to the applicable PHS Awarding Component, including NIH through the eRA Commons FCOI Module for NIH grants/cooperative agreements, before expenditure of funds or within 60 days of a subsequently identified FCOI, as applicable. Annual FCOI reports will be submitted for continuing FCOIs for the duration of the project period, including extensions. If no FCOI is identified, CellsBin will retain its disclosures and determinations internally and will not submit a "none" FCOI report unless NIH specifically requires one.

14. Public accessibility

CellsBin will make this FCOI policy publicly accessible on its website and submit the institutional policy to NIH through the eRA Commons Institution Profile (IPF) Module in accordance with NIH requirements.

For an identified FCOI held by senior/key personnel that is subject to the federal public-access requirement, CellsBin will make the required information publicly accessible by website posting or by written response to a requestor within five business days. Public information will be updated and retained for the periods required by the regulation.

15. Subrecipients

If CellsBin carries out applicable PHS/NIH-funded research through a subrecipient, the written agreement will establish whether subrecipient Investigators comply with the subrecipient’s compliant FCOI policy or CellsBin’s policy. A subrecipient relying on its own policy must certify in the agreement that its policy complies with 42 CFR Part 50, Subpart F and must report identified FCOIs to CellsBin in sufficient time for CellsBin to meet NIH reporting deadlines. If CellsBin’s policy applies, the agreement will require timely submission of SFI disclosures to CellsBin.

16. Noncompliance, retrospective review, and mitigation

If an FCOI was not identified or managed in a timely manner, including because an Investigator failed to disclose an SFI or failed to comply with a management plan, CellsBin will complete a retrospective review within 120 days of determining the noncompliance to assess whether the research was biased in its design, conduct, or reporting. If bias is found, CellsBin will promptly notify the applicable PHS Awarding Component and submit the required mitigation report. Interim protective measures may be imposed while the review is pending.

17. Enforcement

Failure to comply with this policy may result in corrective or disciplinary action appropriate to the circumstances, including additional training, monitoring, modification of research responsibilities, removal from specified activities, suspension from applicable research, corrective action concerning a subrecipient, or employment/contractual discipline. CellsBin will make required reports to NIH/PHS or other authorities when applicable.

18. Records and confidentiality

CellsBin will maintain records of Investigator disclosures, institutional reviews and determinations, management plans, reports, training, retrospective reviews, mitigation reports, subrecipient documentation, and related actions for at least three years from the date the final expenditures report is submitted, or longer when required by 2 CFR 200.334, another applicable retention rule, litigation hold, audit, investigation, or award-specific term. CellsBin will protect disclosure information as confidentially as reasonably possible, subject to federal reporting, public-access, audit, and oversight requirements.

19. Institutional certification

By submitting applications for PHS/NIH funding subject to the regulation, CellsBin certifies that it maintains an up-to-date written and enforced FCOI policy and administrative process; promotes and enforces Investigator compliance; manages and reports identified FCOIs; makes required information available to NIH/HHS; and otherwise complies with 42 CFR Part 50, Subpart F.

20. Questions and disclosures

Designated Institutional Official	Nima Sarshar, CTO
Institution	CellsBin, Inc.
Address	293 Durham Road, Guilford, CT 06437
Email	info@cellsbin.com