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CATENA BIOSCIENCES, INC.
FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

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

Effective: 9/21/2026

Doc Number:	CB-POL-001	Version:	1.0
Doc Title:	FCOI Policy	Owner:	Designated FCOI Official
Effective Date:	9/21/2026	Supersedes:	None - initial issue

Institution	Catena Biosciences, Inc. (d/b/a CatenaBio)
Address	Bakar Labs, 2625 Durant Avenue, Berkeley, CA 94720-2251
Designated FCOI Official	Chief Financial Officer – Zachary McNealy, fcoi@catenabio.com,
Applies to	All PHS/NIH grants and cooperative agreements, including NIH SBIR Phase II and Direct Phase II awards; applied to PHS contracts and, as a matter of institutional practice, to Phase I SBIR/STTR activity
Current award	[1R44CA314761-01] - National Cancer Institute (NCI), NIH
Approved by	Catena Biosciences' Board of Directors 9/19/2026
Review cycle	Annually, and upon any change to 42 CFR Part 50 Subpart F, the NIH Grants Policy Statement, or applicable NIH Guide Notices
Public posting	https://catenabio.com/fcoi-policy
NIH submission	eRA Commons Institution Profile (IPF) Module - upload and submit (two separate steps)

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1) Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). The 2011 revised regulations are 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research," and 45 CFR Part 94, "Responsible Prospective Contractors," which set requirements for promoting objectivity in Public Health Service (PHS)-funded research for grants, cooperative agreements, and research contracts, respectively.

This policy is intended to implement the regulatory requirements for PHS/NIH grants and cooperative agreements per the regulation at 42 CFR Part 50 Subpart F and NIH's guidance, including Section 4.1.10 of the NIH Grants Policy Statement. To the extent CatenaBio holds or seeks a PHS contract, this policy is also applied to satisfy the parallel requirements of 45 CFR Part 94.

Catena Biosciences, Inc. ("CatenaBio," "the Company," "the Institution") adopts this policy for all Investigators (as defined below) engaged in PHS/NIH-funded research. It establishes the processes by which CatenaBio identifies, discloses, reviews, manages, reports and, where necessary, eliminates Investigator financial conflicts of interest, in order to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NIH-supported research.

1.1 Policy Administration, Review, and Revision

The Designated Official administers this policy, maintains the forms at Appendices A and B, and reviews this policy at least annually and whenever 42 CFR Part 50 Subpart F, the NIH Grants Policy Statement, or an applicable NIH Guide Notice is amended. Material revisions are approved by the Chief Executive Officer and, where required, by the Board of Directors; are posted to the Company's public website; are resubmitted to NIH through the eRA Commons Institution Profile (IPF) Module; and trigger the retraining requirement in Section 11.

2) Applicability

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. This policy applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in, or who participate in, PHS/NIH-funded research. It applies regardless of the individual's title, position, or employment status, and therefore reaches employees, officers, consultants, contractors, collaborators, and subrecipient personnel who are responsible for the design, conduct, or reporting of the research, except where a subrecipient's own compliant FCOI policy governs its Investigators under a written agreement made pursuant to Section 14.

This policy applies to all PHS/NIH grants and cooperative agreements held or sought by CatenaBio, including NIH Small Business Innovation Research (SBIR) Phase II and Direct Phase II awards, and is applied by CatenaBio to PHS contracts as described in Section 1.

Regulatory exemption and CatenaBio practice. Under 42 CFR 50.602, Subpart F does not apply to SBIR Program Phase I applications and awards; the STTR Program is included within the definition of the SBIR Program at 42 CFR 50.603, so Phase I STTR is likewise excluded.

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CatenaBio nevertheless applies this policy to Phase I SBIR/STTR activity as a matter of institutional practice, so that a single, consistent disclosure and review process governs all federally funded research at the Company.

This policy does not replace CatenaBio's general employee conflict-of-interest, confidentiality, intellectual-property, or code-of-conduct obligations, which continue to apply in addition to this policy.

2.1 Institutional Certification

As required by 42 CFR 50.604(k), CatenaBio certifies in each application for PHS funding to which 42 CFR Part 50 Subpart F applies that CatenaBio:

- has in effect at the Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which PHS funding is sought or received;
- shall promote and enforce Investigator compliance with the requirements of 42 CFR Part 50 Subpart F regarding the disclosure of Significant Financial Interests and the identification and management of financial conflicts of interest;
- shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS consistent with 42 CFR Part 50 Subpart F;
- agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and CatenaBio's review of, and response to, such disclosure, whether or not the disclosure resulted in CatenaBio's determination of a financial conflict of interest; and
- shall fully comply with the requirements of 42 CFR Part 50 Subpart F.

The Authorized Organization Representative makes this certification through eRA Commons at the time of application. The Designated Official is responsible for confirming, before each certification is made, that the statements above remain accurate.

3) Definitions

For the purpose of these policies and procedures, the following definitions apply.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that the Institution's Designated Official determines is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research, or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

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

Institutional Responsibilities: The professional responsibilities that an Investigator performs on behalf of CatenaBio. CatenaBio is a small, privately held biotechnology company whose personnel hold broad and overlapping roles; accordingly, an Investigator's Institutional Responsibilities at CatenaBio comprise the following activities, to the extent the Investigator performs them for the Company:

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- design, conduct, oversight, analysis, and reporting of research, whether federally funded, internally funded, or collaborative;
- research consultation and scientific collaboration with academic, clinical, and commercial partners;
- preclinical development activity, including protein and conjugate engineering, assay development, and in vitro and in vivo studies, whether performed in-house or through a contract research organization;
- process development, manufacturing and CMC oversight, product testing, and validation;
- clinical development activity and interactions with clinical sites and clinical investigators;
- preparation and submission of regulatory filings and interactions with the U.S. Food and Drug Administration or other regulatory authorities;
- invention disclosure, patent prosecution, and management or licensing of the Company's intellectual property;
- publication, presentation, and other public communication of Company research results;
- preparation and submission of grant applications, progress reports, and other submissions to NIH or other funding agencies;
- selection, oversight, and management of vendors, contract research organizations, consultants, and subrecipients;
- business development, licensing, partnering, and fundraising conducted on behalf of the Company, including scientific diligence presented to investors or prospective partners;
- service on CatenaBio internal committees; and
- service, on behalf of CatenaBio, on external panels, including Institutional Review Boards, Data Safety Monitoring Boards, and scientific or clinical advisory boards.

This definition is specific to CatenaBio and is broader than the Investigator's responsibilities on any single research project. Where an Investigator is uncertain whether a given activity is an Institutional Responsibility, the Investigator should consult the Designated Official before concluding that a financial interest need not be disclosed.

Designated Official (DO): The individual appointed by CatenaBio to solicit and review disclosures of Significant Financial Interests, determine whether a disclosed SFI is related to the PHS/NIH-funded research, determine whether an FCOI exists in accordance with 42 CFR 50.604(f) and this policy, develop and implement management plans for identified FCOIs, submit FCOI reports to NIH through the eRA Commons FCOI Module, and maintain the records required by this policy. The Designated Official and the alternate are named in Section 5.

Institution: Any public or private organization, domestic or foreign (excluding a federal agency), that is applying for or receives PHS/NIH research funding. For purposes of this policy, the Institution is Catena Biosciences, Inc.

Investigator: The Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants. CatenaBio determines who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, considering the individual's role rather than the individual's title and the degree of independence with which the individual carries out the work. A spouse or dependent child is not an Investigator by reason of that relationship; rather, the

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financial interests of an Investigator's spouse, domestic partner, and dependent children are attributed to the Investigator and must be disclosed by the Investigator under Section 4.

Manage: Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Research: 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 the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

PHS-Funded Research: Any activity supported by a PHS Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

PHS Awarding Component: The organizational unit of the PHS that funds the research subject to this policy. For CatenaBio's current award, the PHS Awarding Component is the National Cancer Institute (NCI), NIH.

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).

NIH: The biomedical research agency within the Public Health Service that funds and conducts research to improve health and advance scientific knowledge.

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by CatenaBio in a grant application, progress report, or other submission to PHS/NIH. For this policy, the term applies specifically to the public accessibility requirement in Section 9, which mandates disclosure only of financial conflicts of interest held by these senior/key personnel.

Significant Financial Interest (SFI)

1.) A domestic or foreign (non-United States) 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 appears to be related to the *Investigator's Institutional Responsibilities* (see definition above) performed on behalf of the Institution *(i.e., the applicant or recipient)*:

i. **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. For purposes of this definition, 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.

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ii. **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, domestic partner, or dependent children) holds any equity interest of any value (e.g., stock, stock option, warrant, convertible instrument, partnership interest, or other ownership interest); or

iii. **Intellectual property (IP) rights and interests (e.g., patents, copyrights):** An SFI exists upon receipt of income greater than $5,000 in the twelve months preceding the disclosure that is related to such rights and interests, received from an entity other than CatenaBio. This includes royalties from such rights and agreements to share in royalties related to licensed IP rights. The regulation at 42 CFR 50.603 requires disclosure upon receipt of any such income; CatenaBio applies the $5,000 de minimis threshold expressly permitted for this category, consistent with the preamble to the 2011 Final Rule (76 FR 53265) and NIH's FCOI Policy Development Checklist.

2.) Investigators must disclose any **reimbursed or sponsored travel** related to their Institutional Responsibilities where the aggregate value received from a single entity exceeds $5,000 in the twelve months preceding the disclosure. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly to the Investigator, where the exact cost may not be known. The regulation at 42 CFR 50.604(e)(3) requires disclosure of the occurrence of any such travel; CatenaBio applies the $5,000 de minimis threshold, aggregated per entity, as expressly permitted by NIH Guide Notice NOT-OD-13-004. The disclosure must cover the previous 12 months and include, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of each trip. The Designated Official will determine whether further information, including the monetary value of the travel, is needed to determine whether the travel constitutes an FCOI.

The travel disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- 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 affiliated with a United States institution of higher education.

3.) The term "Significant Financial Interest" does not include, and therefore Investigators are not required to disclose, the following types of financial interests:

- Salary, royalties, or other remuneration paid by CatenaBio to the Investigator if the Investigator is currently employed or otherwise appointed by CatenaBio, including intellectual property rights assigned to CatenaBio and any agreements to share in royalties related to those rights.
- Any equity interest in CatenaBio itself, since CatenaBio is a commercial, for-profit organization. Founder equity, employee stock, and option grants in CatenaBio are therefore not Significant Financial Interests under this policy. Equity and remuneration from **any other** entity remain fully disclosable under the thresholds above.
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.

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- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
- Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Exclusions Related to Foreign Financial Interests: Investigators must disclose all foreign financial interests - which include income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel - received from any foreign entity, including foreign institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country), when such income meets the threshold for disclosure (e.g., income in excess of $5,000). The exclusions listed in paragraph 3.) above reach **only** United States government agencies and United States institutions of higher education and their affiliated entities; they do not exclude any foreign sponsor. Consistent with NIH Guide Notice NOT-OD-22-210, Investigators must disclose foreign as well as domestic Significant Financial Interests, including remuneration, equity, foreign appointments, and travel supported by foreign entities, foreign institutions, or foreign governments.

4) Significant Financial Interest (SFI) Disclosure Requirements

Investigators will disclose their SFIs that are related to their *Institutional Responsibilities* as defined in this policy, using the SFI Disclosure Form at Appendix A or a successor electronic form maintained by the Designated Official.

The disclosure will not be limited to an Investigator's research responsibilities or their funded research, as this is too narrow in scope and not consistent with the 2011 regulation.

Relatedness is not the Investigator's determination to make. Disclosure of an SFI is not based on whether the Investigator believes the interest is related to the NIH-funded or to-be-funded research. The determination of relatedness to the research is an institutional responsibility carried out by the Designated Official under Section 6. An Investigator who is uncertain whether an interest must be disclosed must disclose it and allow the Designated Official to make the determination.

Investigators must disclose the SFIs of their spouse, domestic partner, and dependent children on the same basis as their own. An Investigator with no SFIs to disclose must nevertheless submit a negative disclosure ("None") at the time of application and at each annual disclosure.

The Investigator SFI disclosures will be retained by the Institution as part of the record maintenance requirements in Section 15.

Investigators are required to disclose SFIs at the following times:

A. At the time of application: The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the Designated Official no later than the time of application for PHS/NIH-funded research. Any new Investigator who joins the project

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after the NIH application has been submitted, or during the course of the research, must also disclose their SFI(s) to the Designated Official promptly and before participating in the project, using the SFI Disclosure Form.

B. Annual disclosure during the award: Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually as prescribed by CatenaBio, on a schedule set by the Designated Official and aligned with the Research Performance Progress Report (RPPR). The annual disclosure must include: (1) any new information that was not previously disclosed to the Designated Official under this policy, including SFIs associated with NIH-funded projects transferred from another institution; and (2) updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

C. Ad hoc basis during the award: Each Investigator participating in PHS/NIH-funded research must submit an updated SFI disclosure within **thirty (30) days** of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel that meets the threshold in Section 3 must also be submitted within thirty (30) days of each occurrence.

5) Review of SFI Disclosures

Designated Official. Pursuant to 42 CFR 50.604(d), CatenaBio appoints the **Chief Financial Officer** as the Designated Official responsible for soliciting and reviewing all SFI disclosures and making determinations of FCOI. A fractional or part-time officer may serve in this role provided the individual is formally appointed, has the authority described in this policy, and is available to meet the review and reporting deadlines in Sections 6, 7, and 10.

Designated FCOI Official	CHIEF FINANCIAL OFFICER
Independent reviewer	Board of Directors

Recusal and independent review. No individual may review, evaluate, or determine the disposition of his or her own SFI, or that of a spouse, domestic partner, or dependent child. Because the Chief Executive Officer serves as Contact Principal Investigator on CatenaBio PHS awards, the following applies without exception:

- The Chief Executive Officer discloses his SFIs to the Designated Official on the same schedule and in the same form as every other Investigator.
- The Designated Official reviews those disclosures. The Chief Executive Officer takes no part in the relatedness determination, the FCOI determination, the design of any management plan applicable to him, or the decision to report.
- Where a disclosure by the Chief Executive Officer, by the Designated Official, or by any other officer of the Company results in a determination that an FCOI exists, the determination and the management plan are reviewed and approved by the independent reviewer named above, who is not subject to the plan, before funds are expended or, where the FCOI is first identified after expenditure has begun, within the applicable sixty (60) day window described below.
- Where the Designated Official is the disclosing party, the alternate official named above performs the review, subject to the same independent approval.

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- Each recusal and each independent review is documented in the disclosure file.

Enforcement authority. The Designated Official has authority to require an Investigator to complete training, to withhold approval for expenditure of PHS/NIH funds pending review, to impose conditions on participation in a project, and to recommend the sanctions described in Section 16.

Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

The SFI disclosures will be reviewed as described below:

A. **Prior to the issuance of a new award or before any expenditure of any awarded funds (e.g., during the Just-in-Time stage):** The Designated Official will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.

B. **Annual SFI disclosure:** As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The Designated Official will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.

C. **Ad hoc basis during award period:** If a new Investigator joins a project, or an existing Investigator acquires or discloses a new SFI during the project, the Designated Official will, **within 60 days**:

1. review the disclosure;
2. determine whether the SFI is related to the PHS/NIH-funded research;
3. determine whether an FCOI exists; and, if so,
4. implement, on at least an interim basis, a management plan.

The same sixty (60) day review applies where CatenaBio identifies an SFI that was not disclosed in a timely manner by an Investigator, or that was not previously reviewed during an ongoing PHS/NIH-funded project. An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

6) Relatedness of SFIs to PHS/NIH-Funded Research and FCOI

The Designated Official is responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute an FCOI. This determination is an institutional responsibility and is never delegated to the disclosing Investigator.

Relatedness Test: The Designated Official determines whether an Investigator's SFI is related to research under an NIH award. An SFI is considered "related" when the Designated Official reasonably determines that:

- The SFI could be affected by the PHS/NIH-funded research, **or**

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- The SFI is in an entity whose financial interests could be affected by the PHS/NIH-funded research.

INVESTIGATOR INVOLVEMENT: The Designated Official may consult with the Investigator when assessing whether an SFI is related to the research. Consultation does not transfer the determination to the Investigator.

FCOI Determination: An FCOI 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" in this statement means that the financial interest would have a **material effect** on the research.

Factors considered in making this determination include the nature and value of the interest; the Investigator's role on the project; whether the entity holding the interest makes, licenses, supplies, or competes with the technology under study; whether the Investigator could influence data generation, analysis, or interpretation; and whether the research could reasonably increase or decrease the value of the interest.

The Designated Official documents the basis for each relatedness and FCOI determination, including determinations that an SFI is not related or does not constitute an FCOI, in the Investigator's disclosure file.

7) Management of SFIs that Pose an FCOI

When an FCOI is identified, the Designated Official will determine and implement management strategies to ensure the research is conducted objectively. A written management plan is developed and implemented before the expenditure of funds, or within the sixty (60) day window described in Section 5, and specifies the actions that have been taken and will be taken to manage the FCOI. Examples of management conditions include, but are not limited to:

1. Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board).
2. For human subjects research, disclosure of the FCOI to participants in the informed consent document.
3. Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research.
4. Modification of the research plan.
5. Change of personnel roles or removal from portions of the research, including disqualification from participation in all or a portion of the research.
6. Reduction or elimination of the financial interest (e.g., divesting equity).
7. Severance of relationships that create financial conflicts.

The Designated Official will communicate the determination and the management plan in writing to the Investigator, to the PD/PI for the affected project, and to the Investigator's direct supervisor, and will require the Investigator to certify in writing agreement to and compliance with the management plan.

No expenditures on an NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. The Designated

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Official will submit an FCOI report to NIH via the eRA Commons FCOI Module before any funds are expended.

Each management plan is documented in writing, is signed by the Investigator to acknowledge agreement, states how compliance will be monitored, and is retained under Section 15. The Designated Official reviews each active management plan at least annually and revises it as circumstances change. Copies of management plans are retained as part of the record maintenance requirements and are not submitted to NIH, consistent with NIH FAQ guidance; the key elements of the plan are reported in the FCOI report.

8) Monitoring Investigator Compliance

CatenaBio will monitor Investigator compliance with the management plan for the duration of the NIH award, until completion of the project.

When this policy applies to subrecipient Investigators, CatenaBio will monitor subrecipient Investigator compliance with the management plan.

As part of this monitoring process, the Designated Official may request and review documentation demonstrating compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters, and written communications to study personnel. Investigators must provide copies of such materials, including relevant emails or other written disclosures, to the Designated Official for recordkeeping. These records will be maintained to document compliance with the management plan and to support institutional review and audit activities.

9) Public Accessibility of the FCOI Policy and FCOIs Held by Senior/Key Personnel

9.1 FCOI Policy

Since CatenaBio receives NIH funding to further its research, CatenaBio is required to make this Financial Conflict of Interest policy publicly available. A copy of this FCOI policy is available on CatenaBio's public website at https://catenabio.com/fcoi-policy as required by Section 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement. A copy is also submitted to NIH through the eRA Commons Institution Profile (IPF) Module as required by NIH Guide Notice NOT-OD-21-002.

The five (5) business day written-response alternative permitted by 42 CFR 50.604(a) applies only where CatenaBio has no current presence on a publicly accessible website; in that case, and only in that case, CatenaBio will make this policy available to any requestor within five (5) business days of a written request. If CatenaBio acquires a presence on a publicly accessible website during a period of award, it will post this policy on that website within thirty (30) calendar days.

9.2 Identified FCOIs held by Senior/Key Personnel

Before any funds are spent under an NIH award, CatenaBio will ensure public accessibility, by providing a written response within **five business days** to requests for information about any SFI that meets all three of the following criteria:

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- The SFI was disclosed and is still held by Senior/Key Personnel (the PD/PI and any other individual identified by CatenaBio as senior/key personnel in the application, progress report, or other NIH submission).
- CatenaBio has determined that the SFI is related to the NIH-funded research.
- CatenaBio has determined that the SFI constitutes an FCOI.

When applicable, CatenaBio will make available at least the following information:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI in the following ranges: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures

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 the Institution's identification of a new FCOI, which should be requested subsequently by the requestor.

If CatenaBio uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the Designated Official to be related and an FCOI.

Information on SFIs subject to public accessibility will remain available for at least three years from the most recent update.

10) Reporting Identified Financial Conflicts of Interest

Prior to spending any funds under an NIH-funded award, CatenaBio will submit an identified FCOI report to NIH, in accordance with the FCOI regulations, for any Investigator's SFI determined to be an FCOI. CatenaBio will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

CatenaBio will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH and is ordinarily the Designated Official named in Section 5. FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report). No report is required if the FCOI is eliminated before any expenditure of funds.

The NIH eRA Commons FCOI Module User Guide, available at the following location, provides instructions for preparing and submitting FCOI reports.

https://www.era.nih.gov/files/fcoi_user_guide.pdf

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The Institution will submit the following types of reports as explained below:

A. **Initial (Original) FCOI Reports:** The report must include all information required under 42 CFR 50.605(b)(3) or as outlined in NIH's FAQ currently numbered H.5. When an FCOI is identified, the Original Report will be submitted as described below:

- **Prior to the expenditure of funds:** If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent.
- **Within 60 days of identifying a new FCOI during the award:** If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), the Institution must submit an Original FCOI report within 60 days of identifying the FCOI.

B. **Annual FCOI Reports:** For the duration of an award, including any extensions with or without funds, the Institution must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable.

- The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance. NIH creates the opportunity for the FCOI SO to submit the Annual report 75 days prior to the next budget period start date for continuation awards. NIH will notify the Institution by email when an annual report is due.
- Annual FCOI reports are not required at grant closeout.

C. **Revision (or Mitigation) FCOI Reports:** After completing a retrospective review, the Institution will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

Each FCOI report includes, at a minimum: the grant or contract number; the PD/PI name (or contact PD/PI); the name of the Investigator with the FCOI; the name of the entity with which the Investigator has the FCOI; the nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); the approximate dollar value of the financial interest in the ranges set out in Section 9.2, or a statement that the value cannot be readily determined; a description of how the financial interest relates to the PHS/NIH-funded research and the basis for CatenaBio's determination that the financial interest conflicts with such research; and a description of the key elements of the management plan, including the role and principal duties of the conflicted Investigator, the conditions of the plan, how the plan is designed to safeguard objectivity, confirmation of the Investigator's agreement to the plan, how the plan will be monitored, and any other relevant information.

Types of FCOI Reports Summary Chart for NIH:

Required FCOI Reports to NIH via eRA Commons FCOI Module		
REPORT	**CONTENT**	**REQUIRED WHEN**
New FCOI Report (Initial Submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan	1) Prior to the expenditure of funds on a new award; or 2) Within 60 days of identifying any new FCOI during the award period

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Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.	Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension.
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report.	Following a retrospective review when noncompliance with the regulation is identified, if applicable.
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions.	After a retrospective review when bias is found.

11) Training Requirements for Investigators

Each Investigator will be informed of CatenaBio's FCOI policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

- CatenaBio revises this policy or related procedures in a way that affects Investigator requirements.
- An Investigator is new to CatenaBio research under an NIH award (training must be completed before participating in the research).
- CatenaBio determines that an Investigator has not complied with this policy or with a management plan issued under it (training must be completed within 30 days as directed by the Designated Official).

To supplement the regulatory training requirements, CatenaBio will utilize NIH's training programs to train Investigators on the FCOI regulation. CatenaBio requires Investigators to complete either:

- The NIH FCOI Training module at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training and print and retain the Completion Certificate for audit purposes. The certificate should be shared with the Designated Official; **OR**
- Review the NIH Virtual Seminar presentation on FCOI compliance and send the Designated Official the date of completion through email for audit purposes.

In addition, and separately from the NIH module, the Designated Official provides training on this policy itself - including the CatenaBio-specific definition of Institutional Responsibilities in Section 3 - and on the Investigator disclosure requirements in Section 4. Each Investigator certifies completion of training using the attestation at Appendix B. The Designated Official maintains training records for the retention period stated in Section 15.

12) Noncompliance With FCOI Policy and Corrective Actions

If CatenaBio identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the Designated Official will, within 60 days: review the SFI; determine whether it is related to NIH-funded research; determine whether it constitutes an FCOI; and, if so, implement an interim

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management plan describing actions that have been and will be taken to manage the FCOI going forward. CatenaBio will also submit an FCOI report to NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI
- Failure by the Institution to review or manage an FCOI
- Failure by the Investigator to comply with an established management plan

CatenaBio will, within 120 days of identifying noncompliance:

1. Complete a retrospective review of the Investigator's activities and the NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.
2. Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

The retrospective review is documented in the Investigator's file and records at least the following: project number and project title; name of the PD/PI or contact PD/PI if a multiple-PD/PI model is used; name of the Investigator with the FCOI; name of the entity with which the Investigator has the FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review (for example, a description of the process, documents reviewed, and personnel interviewed); findings of the review; and conclusions of the review.

If bias is found, CatenaBio will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. to NIH via the FCOI Module.

The report will include:

- The key elements documented in the retrospective review,
- The impact of the bias on the research project,
- The extent of the harm done, including any qualitative and quantitative data to support any actual or future harm,
- An analysis of whether the research project is salvageable, and
- The plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

CatenaBio will thereafter submit FCOI reports annually to NIH as required by the regulations and the terms and conditions of the award. Depending on the circumstances, CatenaBio may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete.

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

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If the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, CatenaBio shall promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken, as required by 42 CFR 50.606(a). The PHS/NIH Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS/NIH-funded research project. PHS may, for example, require institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS/NIH award or when the transfer of a PHS/NIH grant involves such an Investigator.

13) Clinical Research Requirements

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, CatenaBio will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations, as required by 42 CFR 50.606(c).

14) Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through CatenaBio to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to CatenaBio for programmatic outcomes and compliance.

Subrecipients (e.g., collaborators or consortium members) are subject to CatenaBio's terms and conditions. CatenaBio will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. CatenaBio will include in each written agreement with a subrecipient terms specifying whether CatenaBio's FCOI policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators (see NIH Grants Policy Statement Section 15.2.1, Written Agreement).

If the subrecipient's FCOI policy applies:

The subrecipient institution must certify in the agreement that its policy complies with the federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to CatenaBio in time for CatenaBio to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). CatenaBio ordinarily requires subrecipients to report identified FCOIs within thirty (30) days of identification, and in every case prior to the expenditure of funds under the subaward, so that CatenaBio retains sufficient time to review and submit its own report to NIH within the sixty (60) day deadline. CatenaBio's Designated Official will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

If the subrecipient cannot certify compliance, or has no FCOI policy:

The agreement will specify that CatenaBio's FCOI policy applies. In this case, subrecipient Investigators must disclose their SFIs to CatenaBio. The SFI disclosure must include SFIs that are **related to the subrecipient's work performed for CatenaBio**. The agreement will allow sufficient time for CatenaBio to review, manage, and report any resulting FCOIs. When an FCOI is identified, CatenaBio will implement a management plan, monitor compliance by the

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subrecipient Investigator, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

Consultants and collaborators

Consultants, contractors, and collaborators who are responsible for the design, conduct, or reporting of PHS/NIH-funded research meet the definition of "Investigator" and are subject to the regulation. Where the consultant or subrecipient institution does not have an FCOI policy that implements the regulation, the consultant or subrecipient institution must follow this policy, and disclosure of SFIs is made to CatenaBio for review and determination of an FCOI under the criteria in Section 6. CatenaBio obtains these disclosures directly through the process in Section 4 unless a subrecipient agreement provides otherwise.

Individuals who serve in a purely ad hoc advisory capacity and who are not responsible for the design, conduct, or reporting of the research are not Investigators for purposes of this policy; the Designated Official documents that determination in the project file.

Status for grant [1R44CA314761-01]. The budget for this award includes no subawards, consortium costs, or contractual costs. Contract research organization engagements are budgeted as facility/user fees and technical assistance rather than as subawards. The Designated Official will nevertheless assess each CRO, consultant, and collaborator engagement against the Investigator definition in Section 3 and obtain disclosures where the definition is met.

15) Maintenance of Records

CatenaBio will maintain records of all Investigator financial interest disclosures, CatenaBio's review of and response to those disclosures (whether or not they resulted in a determination of an FCOI), all management plans and monitoring documentation, all retrospective reviews and mitigation reports, all FCOI reports submitted to NIH, all training completions, and any actions taken under this policy.

These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 2 CFR 200.334 for different situations. CatenaBio will retain these records for each competitive segment as required by regulation. Records are retained longer where required by litigation, audit, or other proceedings.

Copies of management plans will be retained as part of the record maintenance requirements and not submitted to the NIH per NIH's FAQ guidance.

Disclosures are treated as confidential and are made available only to those with a need to know for purposes of administering this policy, to NIH and HHS upon request, and as otherwise required by law or by the public accessibility requirements of Section 9.

16) Enforcement Actions for Investigator Noncompliance and Remedies for Noncompliance

As required by 42 CFR 50.604(j), CatenaBio maintains adequate enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance with this policy. Compliance with this policy is a condition of employment and/or

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participation for all applicable Investigators. Failure to comply with this policy, including failure to disclose a Significant Financial Interest, failure to disclose in a timely manner, submission of an incomplete or inaccurate disclosure, failure to comply with a conflict management plan, or failure to complete required training, may result in appropriate corrective or disciplinary actions.

Such actions may include, but are not limited to:

- Written warning or letter of reprimand placed in the personnel file;
- Mandatory retraining;
- Imposition of, or modification to, a management plan, including additional monitoring;
- Removal from the PHS/NIH-funded project in whole or in part, or removal from Senior/Key Personnel designation;
- Suspension of authority to expend or approve expenditure of PHS/NIH funds;
- Ineligibility to serve as an Investigator on future PHS/NIH-funded applications;
- Suspension or termination of employment or of the consulting or contractor relationship; and
- Any other action available to CatenaBio under law or contract, including disqualification from participation in government award-funded research, as appropriate.

The Designated Official recommends sanctions; the Chief Executive Officer imposes them, except where the Chief Executive Officer is the subject of the matter, in which case the independent reviewer identified in Section 5 imposes them.

In addition, CatenaBio will take all actions required under applicable federal regulations and sponsor requirements, including conducting retrospective review, implementing mitigation measures where necessary, and notifying the sponsor when required.

HHS review authority. The PHS/NIH Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of an FCOI. The Institution will submit, or permit on-site review of, all records pertinent to compliance with the regulation and this policy. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS/NIH Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS/NIH-funded research to such an extent that further corrective action is needed, or that the Institution has not managed the FCOI in accordance with the regulation or this policy. The PHS/NIH Awarding Component may determine that imposition of specific award conditions under 2 CFR 200.208, or suspension of funding or other enforcement action under 2 CFR 200.339, is necessary until the matter is resolved.

17) Useful FCOI and NIH Resources

- NIH e-mail addresses for FCOI-related and policy inquiries: FCOICompliance@mail.nih.gov; GrantsPolicy@mail.nih.gov; GrantsCompliance@mail.nih.gov
- FCOI Regulation, 42 CFR Part 50 Subpart F - Promoting Objectivity in Research: https://www.ecfr.gov/current/title-42/part-50/subpart-F
- 45 CFR Part 94 - Responsible Prospective Contractors (PHS contracts)
- Financial Conflict of Interest: https://grants.nih.gov/grants/policy/coi/index.htm
- FCOI Training: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training

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- NIH FCOI Frequently Asked Questions: https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm
- NIH Grants Policy Statement, Section 4.1.10 - Financial Conflict of Interest: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm
- NIH Grants Policy Statement, Section 15.2.1 - Written Agreement (subawards)
- FCOI Policy Development Checklist: https://grants.nih.gov/grants/policy/coi/FCOI-Policy-Development-Checklist.pdf
- Instructions for Submitting an FCOI Policy into the eRA Commons IPF Module: https://grants.nih.gov/grants/Instructions-Submitting-FCOI-PolicyIPFModul.pdf
- eRA Commons FCOI Module User Guide: https://www.era.nih.gov/files/fcoi_user_guide.pdf
- Elements of an FCOI report: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi#elements-of-an-fcoi-report
- NOT-OD-21-002 - Required Submission of FCOI Policy into the eRA Commons IPF Module
- NOT-OD-22-210 - Financial Conflict of Interest (FCOI) and Other Support: Reminders
- 2 CFR Part 200 - Uniform Administrative Requirements, including 2 CFR 200.334 (record retention), 200.208 and 200.339: https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200
- NIH Grants Process: https://grants.nih.gov/grants-process
- NIH Grants Policy Statement: https://grants.nih.gov/policy/nihgps/index.htm
- NIH SEED / SBIR-STTR resources: https://seed.nih.gov/ and https://seed.nih.gov/faqs
- NIH Guide for Grants and Contracts: https://grants.nih.gov/grants/guide/index.html
- Notices of NIH Policy Changes: https://grants.nih.gov/policy-and-compliance/notice-of-policy-changes
- NIH Extramural Nexus subscription: https://public.govdelivery.com/accounts/USNIHOER/subscriber/new?qsp=CODE_RED
- Calendar of Events: https://grants.nih.gov/news-events/calendar-of-events

Grant-specific questions should be directed to the assigned Institute or Center Grants Management Specialist, Grants Management Officer, and/or Program Officer.

18) Point of Contact

If you have a question related to the FCOI Policy of CatenaBio, or would like to disclose a financial interest, contact us using the information below:

Contact:
Zachary McNealy
Chief Financial Officer / Designated FCOI Official
Catena Biosciences, Inc. (CatenaBio)
Bakar Labs, 2625 Durant Avenue
Berkeley, CA 94720-2251
Phone: +1 415-562-6496
Email: fcoi@catenabio.com

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Appendix A - Investigator Significant Financial Interest Disclosure Form

Complete and return this form to the Designated FCOI Official (i) at the time of application for PHS/NIH-funded research, (ii) at least annually during the period of the award, (iii) within 30 days of discovering or acquiring a new Significant Financial Interest, and (iv) within 30 days of each occurrence of reimbursed or sponsored travel that meets the threshold in Part 2, Category 4.

Disclose all domestic and foreign (non-United States) Significant Financial Interests, including those of your spouse, domestic partner, and dependent children, that reasonably appear to be related to your Institutional Responsibilities. SFI disclosure is **not** limited to your research responsibilities, nor to your NIH-funded research. Do not attempt to decide whether an interest is related to the funded research - that determination is made by the Designated FCOI Official under Section 6 of the Policy. Interests held in CatenaBio itself are excluded and need not be disclosed.

Definitions used on this form

Institutional Responsibilities	Your professional responsibilities on behalf of CatenaBio, as defined in Section 3 of the Policy: research and its design, conduct and reporting; research consultation and scientific collaboration; preclinical development; process development, manufacturing and CMC oversight, product testing and validation; clinical development; regulatory filings; invention disclosure, patent prosecution and IP licensing; publication and presentation of Company research; grant applications and progress reports; oversight of vendors, CROs, consultants and subrecipients; business development, licensing, partnering and fundraising; internal committee service; and service on external panels (IRBs, DSMBs, scientific or clinical advisory boards) on behalf of CatenaBio.
Remuneration	Salary and any payment for services not otherwise identified as salary - for example consulting fees, honoraria, paid authorship, or payment for services.
Equity interest	Any stock, stock option, warrant, convertible instrument, partnership interest or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
Intellectual property rights and interests	Patents, copyrights and similar rights, upon receipt of related income (e.g., royalties, licensing fees).
Reimbursed or sponsored travel	Travel paid on your behalf and not reimbursed directly to you, so that the exact monetary value may not be readily available.

Part 1 - Investigator and project information

Disclosing Investigator's name	
Principal Investigator's name (if different)	
Role on the project(s)	
eRA Commons ID	

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Grant application or funded NIH grant number(s)	
Project title(s)	
Project dates	
Name of funder	National Institutes of Health (National Cancer Institute) / other:
Type of disclosure	☐ Initial disclosure ☐ Annual disclosure ☐ New SFI (within 30 days) ☐ Travel (within 30 days)
Reporting period	Remuneration, IP income and travel: the twelve (12) months preceding this disclosure. Equity: value as of the date of this disclosure.

Part 2 - Significant Financial Interests

Answer every category below. If you have nothing to disclose in a category, check the "No SFI exists under this category" box for that category. Give each entity name as it appears on the entity's public website, and state whether the entity is domestic or foreign.

Category 1 - SFI related to a publicly traded entity

Have you, your spouse, domestic partner, or dependent children received any remuneration from a publicly traded entity over the preceding 12 months, and/or do you hold any equity interest in such an entity as of the date of this disclosure, that when aggregated **exceeds $5,000**?

☐ **No SFI exists under this category** ☐ Yes - complete the table below

Entity name (as on its public website)	Domestic / foreign	Nature of the SFI	Value (range) or "cannot be readily determined"	Held by	Date acquired

Category 2 - SFI related to a non-publicly traded entity

Have you, your spouse, domestic partner, or dependent children received remuneration from a non-publicly traded entity over the preceding 12 months that **exceeds $5,000**, **or** do you hold **any equity interest of any value** in such an entity as of the date of this disclosure? Note that for a non-publicly traded entity there is **no minimum value for equity** - any ownership interest, including stock options, warrants and convertible instruments, must be disclosed.

☐ **No SFI exists under this category** ☐ Yes - complete the table below

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Entity name (as on its public website)	Domestic / foreign	Nature of the SFI	Value (range) or "cannot be readily determined"	Held by	Date acquired

Category 3 - SFI related to intellectual property rights and interests

Have you, your spouse, domestic partner, or dependent children received income **greater than $5,000** over the preceding 12 months related to intellectual property rights and interests (e.g., patents, copyrights) from an entity **other than CatenaBio**?

☐ **No SFI exists under this category** ☐ Yes - complete the table below

Entity name (as on its public website)	Domestic / foreign	Nature of the SFI (e.g., royalties, licensing fees)	Value (range) or "cannot be readily determined"	Held by	Date received

Category 4 - SFI related to reimbursed or sponsored travel

Have you, your spouse, domestic partner, or dependent children received reimbursed or sponsored travel related to your Institutional Responsibilities that **exceeds $5,000 in aggregate from a single entity** over the preceding 12 months?

You need **not** disclose travel 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 affiliated with a United States institution of higher education. **Travel supported by a foreign university, foreign institute, foreign government, or any other foreign entity IS disclosable.**

☐ **No SFI exists under this category** ☐ Yes - complete the table below

Sponsor / organizer	Domestic / foreign	Purpose of the trip	Destination	Dates and duration	Value

Value ranges to use above: $0-$4,999 · $5,000-$9,999 · $10,000-$19,999 · $20,000-$100,000 in $20,000 increments · above $100,000 in $50,000 increments · or "value cannot

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be readily determined through reference to public prices or other reasonable measures of fair market value."

Part 3 - Relatedness to NIH-funded research (your view)

Although this is an institutional determination, in your opinion are any of the Significant Financial Interests disclosed above related to a CatenaBio NIH application expected to be awarded, or to an already funded NIH research project, under the criteria below?

1. Could the SFI be affected by the NIH-funded research?	☐ Yes ☐ No
2. Is the SFI in an entity whose financial interest could be affected by the NIH-funded research?	☐ Yes ☐ No

If yes to either question, identify which SFI(s) you believe meet the criteria:

The Designated FCOI Official will consider this information when making determinations of relatedness and FCOI. Your answer here does not limit your obligation to disclose, and a "no" answer does not remove an interest from review.

Part 4 - Certification

I certify that this is a complete disclosure of all my domestic and foreign Significant Financial Interests that are related to my Institutional Responsibilities - including research, research consultation, publication, preclinical and clinical development, regulatory submissions, intellectual property, business development and fundraising - and that this disclosure is not limited to my PHS/NIH research. I have used all reasonable diligence in preparing this disclosure and, to the best of my knowledge, it is true and complete. I acknowledge that it is my responsibility to disclose my Significant Financial Interests on an annual basis, within thirty (30) days of discovering or acquiring a new Significant Financial Interest, and within thirty (30) days of each disclosable travel occurrence during the period of performance of an NIH-funded project. I also certify that I have received FCOI training prior to engaging in PHS/NIH-funded research and/or within the past four years.

Investigator signature	**Printed name and title**	**Date**

For institutional use - Designated FCOI Official

Date received	
Related to PHS/NIH research?	☐ Yes ☐ No - basis:
FCOI determination	☐ FCOI exists ☐ No FCOI - basis:
Management plan required?	☐ Yes (attach) ☐ No
Reported to NIH	☐ Prior to expenditure ☐ Within 60 days ☐ Annual ☐ Revised ☐ Not applicable
Recusal applied?	☐ Yes - independent reviewer: ☐ Not applicable
Reviewer signature / date	

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Appendix B - FCOI Training Certification and Attestation

Each Investigator must complete FCOI training prior to engaging in research related to any PHS/NIH-funded grant, cooperative agreement, or contract; at least every four (4) years thereafter; and immediately upon a policy revision affecting Investigator requirements, upon becoming new to CatenaBio, or upon a finding of noncompliance (see Section 11 of the Policy).

Part 1 - Training completed

Training component	Provider	Date completed
NIH FCOI Training Module (regulatory requirements under 42 CFR Part 50 Subpart F)	NIH Office of Extramural Research	
CatenaBio FCOI Policy and Investigator disclosure requirements, including the CatenaBio definition of Institutional Responsibilities	Designated FCOI Official	

Part 2 - Trigger for this training

☐ Prior to engaging in PHS/NIH-funded research (initial)

☐ Four-year refresher

☐ Policy revision affecting Investigator requirements

☐ New to CatenaBio

☐ Following a finding of noncompliance with the Policy or a management plan

Part 3 - Attestation

I certify that I have completed the training identified above; that I have read and understand the CatenaBio Financial Conflict of Interest Policy; that I understand my responsibility to disclose foreign and domestic Significant Financial Interests, including those of my spouse, domestic partner, and dependent children, at the times required by the Policy; that I understand the consequences of noncompliance; and that I will comply with any management plan applicable to me.

Investigator signature	Printed name / title	Date

Designated FCOI Official	Printed name / title	Date

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Appendix C - Regulatory Citations and NIH Resources

This appendix maps each requirement of this Policy to its source in 42 CFR Part 50 Subpart F. It is provided for reference and does not create obligations beyond those in the body of the Policy.

C.1 Regulatory citations

Requirement	Citation	Where addressed in this Policy
Written, enforced, publicly available policy	42 CFR 50.604(a)	Sections 1, 1.1, 9.1
Investigator training	42 CFR 50.604(b)	Section 11; Appendix B
Subrecipient requirements	42 CFR 50.604(c)	Section 14
Designation of institutional official	42 CFR 50.604(d)	Section 5
Disclosure timing - application, annual, 30 days	42 CFR 50.604(e)(1)-(3)	Section 4; Appendix A
Definition of SFI, travel, and exclusions	42 CFR 50.603; 50.604(e)(3)	Section 3
Institution-specific Institutional Responsibilities	42 CFR 50.603	Section 3
Guidelines for determining relatedness and FCOI	42 CFR 50.604(f)	Section 6
Management of FCOIs; compliance actions	42 CFR 50.604(g); 50.605(a)(4)	Sections 7, 8
Review of disclosures; examples of restrictions	42 CFR 50.605(a)(1)-(2)	Sections 5, 7
SFIs not disclosed or reviewed in a timely manner	42 CFR 50.605(a)(3)(i)-(iii)	Sections 5, 12
Public accessibility of senior/key personnel FCOIs	42 CFR 50.605(a)(5)	Section 9.2
Initial, annual, and revised FCOI reports	42 CFR 50.604(h); 50.605(b)	Section 10
Retrospective review; mitigation report	42 CFR 50.605(a)(3)(ii)-(iii)	Section 12
Maintenance of records	42 CFR 50.604(i); 2 CFR 200.334	Section 15
Enforcement mechanisms and sanctions	42 CFR 50.604(j)	Section 16
Institutional certification	42 CFR 50.604(k)	Section 2.1
Notification of Investigator noncompliance	42 CFR 50.606(a)	Sections 12, 16
HHS review and enforcement authority	42 CFR 50.606(b); 2 CFR 200.208, 200.339	Section 16
Disclosure in clinical research presentations	42 CFR 50.606(c)	Section 13
Applicability; Phase I SBIR/STTR exclusion	42 CFR 50.602; 50.603	Section 2

C.2 NIH policy and guidance relied upon

- NIH Grants Policy Statement, Section 4.1.10 - Financial Conflict of Interest.
- NIH Grants Policy Statement, Section 15.2.1 - Written Agreement (subawards).
- NOT-OD-21-002 - Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module.
- NOT-OD-22-210 - Financial Conflict of Interest (FCOI) and Other Support: Reminders.
- NIH FCOI Policy Development Checklist.

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- NIH FCOI Frequently Asked Questions, including D.5 (Investigator), D.8 (SFI), F.1 (management), H.5 (report content), I.2 and I.3 (retrospective review and mitigation), and K.1 (subrecipients).
- 45 CFR Part 94 - Responsible Prospective Contractors (applies to PHS contracts).
- 2 CFR 200.334 - Retention requirements for records.