Financial Conflict of Interest Policy

Sentient Research

Document control

Policy Owner	**Designated FCOI Officials:** Jorge A. Montoya (jorge@sentientresearch.net) Aaron Plant (aaron@sentientresearch.net) **Administrative Coordinator:** Deborah Neffa Creech (deborah@sentientresearch.net)
Approving Authority	Jorge A. Montoya President & CEO
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Review Cycle	At least annually and whenever applicable federal requirements change.
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1. Purpose

Sentient Research (the "Institution") is committed to maintaining objectivity in the design, conduct, and reporting of research. This policy establishes procedures to identify, disclose, review, manage, report, and retain records concerning financial conflicts of interest (FCOIs) in research funded by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), and in PHS-funded research contracts, as applicable.

2. Scope and applicable requirements

This policy applies to each Investigator who is planning to participate in, or is participating in, PHS-funded research conducted by or through Sentient Research. It applies to covered NIH grants and cooperative agreements under 42 CFR Part 50, Subpart F, and to applicable PHS research contracts under 45 CFR Part 94. The policy also applies to subrecipient Investigators when required by the applicable award or contract and the arrangements described in Section 12.

Phase I SBIR/STTR applications and awards are excluded from the NIH FCOI requirements in 42 CFR Part 50, Subpart F. Phase II SBIR/STTR awards are covered. This exclusion does not create a general exemption for Sentient Research as a for-profit small business, and it does not determine the coverage of a separate PHS research contract.

If an award, contract, solicitation, agency term, or applicable law imposes a more specific or more stringent requirement, Sentient Research will follow the controlling requirement. This policy is intended to implement federal requirements and does not replace award-specific terms.

3. Definitions

Institution: Sentient Research, a privately held, for-profit S corporation organized in California.

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 PHS-funded research. This may include employees, consultants, collaborators, and subrecipient personnel. The Designated FCOI Official determines Investigator status based on the person's actual research responsibilities.

Institutional responsibilities: An Investigator's professional responsibilities on behalf of Sentient Research, including research, research consultation, program evaluation, teaching, professional practice, institutional committee service, and other responsibilities assigned by Sentient Research.

Significant Financial Interest (SFI): A financial interest of the Investigator, and where required by the regulation, the Investigator's spouse and dependent children, that reasonably appears related to the Investigator's institutional responsibilities and meets the applicable regulatory thresholds or categories described in Section 5.

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

Designated FCOI Officials: The individuals appointed by Sentient Research to solicit and review disclosures, determine whether an SFI is related to PHS-funded research, determine whether an FCOI exists, and oversee required management, reporting, and records. Sentient Research designates Jorge Montoya and Aaron Plant to serve in this role for disclosures submitted by other Investigators, subject to the impartiality safeguards in this policy.

Management plan: A written plan specifying actions required to manage an identified FCOI, including monitoring and responsibilities.

4. Roles and responsibilities

President/CEO or authorized leadership: Approve this policy; provide resources for implementation; formally appoint the Designated FCOI Officials; authorize engagement of a qualified external reviewer when required; and ensure corrective action when necessary.

Designated FCOI Officials (Jorge Montoya and Aaron Plant): Review disclosures submitted by other Investigators, determine whether interests are related to research and constitute FCOIs, document decisions, establish or approve management plans, monitor compliance, make or oversee required reports and public disclosures, and maintain records. Neither may review or make the final determination on the other's disclosure if the disclosure concerns the other's financial interests or could reasonably impair impartiality. Neither may review or determine their own disclosure. Each must recuse from any matter in which they have a personal or financial interest or cannot act impartially.

Investigators: Complete training; disclose all required domestic and foreign SFIs related to institutional responsibilities, including interests of spouse and dependent children as required; update disclosures; comply with management plans; cooperate with reviews.

Designation and routing: Jorge Montoya and Aaron Plant are the two Designated FCOI Officials for disclosures by other Investigators. Deborah Neffa Creech is the Administrative Coordinator, not the routine decision-maker. A qualified external reviewer will be engaged for every disclosure submitted by either principal.

Administrative Coordinator (Deborah Neffa Creech): Coordinate distribution and collection of the policy and forms; track Investigator status and training; maintain secure administrative records; notify the Designated FCOI Officials of changes in project personnel or research responsibilities; and coordinate external review when needed. The Administrative Coordinator does not make FCOI determinations unless separately and formally designated.

External independent reviewer: A qualified person who is not subject to the relevant financial or other conflict and is engaged by Sentient Research to review disclosures submitted by either Jorge Montoya or Aaron Plant and make the institutional determination. The reviewer may also be engaged for any other matter in which neither Designated FCOI Official can act impartially or where specialized expertise is needed.

Because Sentient Research is closely held, the Institution adopts the following review arrangement: (a) Jorge Montoya and Aaron Plant are the Designated FCOI Officials for disclosures submitted by other Investigators; (b) neither may review or make a determination on their own disclosure; (c) every disclosure submitted by Jorge Montoya or Aaron Plant will be referred to a qualified external independent reviewer, who will be formally authorized by Sentient Research to conduct the review and make the institutional determination; and (d) either Designated FCOI Official must recuse from any other matter in which that person has a personal or financial interest or cannot act impartially. The external reviewer must be sufficiently independent and qualified to evaluate the disclosure, its relationship to the research, and whether an FCOI exists. Deborah Neffa Creech will coordinate the process but will not make determinations unless separately and formally appointed.

5. Investigator disclosure requirements and reportable interests

Before an Investigator participates in covered PHS-funded research, the Investigator must disclose to the Designated FCOI Official all domestic and foreign SFIs that are related to the Investigator's institutional responsibilities, including applicable interests of the Investigator's spouse and dependent children. Disclosures must be submitted no later than the time required by the applicable regulation, solicitation, award, or contract; for NIH/PHS grant applications, Sentient Research will obtain disclosures from proposed Investigators by the time the application is submitted.

Investigators must update disclosures at least annually during the period of the award or contract, and within 30 days after discovering or acquiring a new SFI. Sentient Research may require more frequent updates when appropriate. Investigators must use the Sentient Research Investigator Financial Disclosure Form to report required Significant Financial Interests. The Administrative Coordinator will distribute the form, collect completed disclosures, and route them to the appropriate Designated FCOI Official or authorized external reviewer (*see Appendix A: Investigator Financial Disclosure Form*).

The following categories generally require disclosure when the applicable regulatory conditions and thresholds are met:

- Remuneration from a publicly traded entity (including salary and other payments for services) and equity interests in that entity, when aggregated value exceeds $5,000 during the relevant 12-month period / as of the disclosure date.
- Remuneration from a non-publicly traded entity exceeding $5,000 in the preceding 12 months, or any equity interest in a non-publicly traded entity, subject to applicable regulatory exclusions.
- Intellectual property rights and interests (such as patents and copyrights) upon receipt of income related to those rights and interests.
- Reimbursed or sponsored travel related to institutional responsibilities, including the purpose, identity of the sponsor/organizer, destination, and duration; the Investigator must provide the information needed for the Institution to determine the value. Regulatory exceptions apply to specified government and academic entities.
- Any other interest or category that the applicable regulation, award, contract, or agency requirement directs the Institution to collect.

For purposes of the NIH regulation, an Investigator's ownership interest in Sentient Research itself is excluded from the definition of SFI because Sentient Research is a commercial or for-profit organization. This exclusion applies to the ownership interest as such; it does not exempt unrelated outside interests, interests in other entities, outside income, intellectual property income, sponsored travel, or other reportable interests. The Designated FCOI Official should obtain advice when the treatment of a particular payment or distribution is unclear.

Salary, royalties, or other remuneration paid by Sentient Research to its own Investigator for services or work for the Institution are generally excluded from SFI under the PHS definition, subject to the precise regulatory terms. Payments or interests from outside entities remain subject to disclosure when the regulatory criteria are met.

6. Training

Before engaging in PHS-funded research, each Investigator must complete training on the applicable FCOI regulation, this policy, and the Investigator's disclosure responsibilities. Training must be repeated at least every four years and immediately when: (a) this policy or related procedures are revised in a way that affects Investigator requirements; (b) an Investigator is new to Sentient Research; or (c) Sentient Research finds that an Investigator is not in compliance with this policy or a management plan.

Sentient Research will use the NIH self-paced FCOI training tutorial as a core resource, together with institution-specific orientation. The NIH tutorial is available at:

https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training

The NIH tutorial is designed to be used in conjunction with institutional training; it does not replace instruction on Sentient Research's own policy, forms, procedures, and Investigator responsibilities. The Institution will retain completion dates, training materials or course identifiers, and participant acknowledgments.

7. Review and determination process

1. The Administrative Coordinator will route each disclosure to an authorized reviewer. Jorge Montoya or Aaron Plant, acting as a Designated FCOI Official, will review disclosures submitted by other Investigators, provided the reviewer has no relevant conflict and can act impartially. Disclosures submitted by either Jorge Montoya or Aaron Plant will be referred to the qualified external independent reviewer. The reviewer will assess completeness and may request supporting information or clarification.
2. The authorized reviewer will determine whether each disclosed SFI is related to PHS-funded research. An SFI is related to research when the reviewer reasonably determines that the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.
3. If an SFI is related to research, the authorized reviewer will determine whether it constitutes an FCOI—that is, whether it could directly and significantly affect the design, conduct, or reporting of the research.
4. The review and determination will be completed before Sentient Research's expenditure of PHS funds, or within the timing required by the applicable contract or award. A new SFI or newly identified FCOI will be reviewed within the applicable regulatory deadline.
5. All determinations, supporting rationale, and management actions will be documented. If the assigned Designated FCOI Official has a personal interest or cannot act impartially, the matter will be referred to the external independent reviewer or another qualified, impartial person formally authorized by Sentient Research. The reviewer will document the review, determination, supporting rationale, and any required management actions using the Sentient Research FCOI Review and Determination Form. A written management plan will be attached when an FCOI is identified (*see Appendix B: FCOI Review and Determination Form*).

8. Management of identified FCOIs

When an FCOI is identified, Sentient Research will develop and implement a written management plan before the applicable research proceeds, consistent with the governing regulation and award/contract terms. The plan will identify the FCOI, the role of the Investigator, the conditions imposed, how the plan will safeguard objectivity, how compliance will be monitored, and the person responsible for monitoring.

Depending on the circumstances, management measures may include:

- Public disclosure of the FCOI when presenting or publishing research;
- Disclosure of the FCOI directly to human research participants, when applicable;
- Appointment of an independent monitor or reviewer;
- Modification of the research plan or methods;
- Change in personnel responsibilities or disqualification from all or part of the research;
- Reduction or elimination of the financial interest, where feasible; or
- Severance of the relationship that creates the conflict.

The assigned Designated FCOI Official or external independent reviewer, as appropriate, will oversee monitoring of each management plan throughout the PHS-funded project. The Administrative Coordinator may track monitoring dates and documentation. Investigators must promptly report any change that may affect the plan.

9. Reporting and public accessibility

For NIH grants and cooperative agreements, Sentient Research will submit required initial and ongoing FCOI reports through the eRA Commons FCOI Module, within the regulatory deadlines. Reports generally are required before expenditure of funds for an identified FCOI, within 60 days after identification of an FCOI involving a newly disclosed or newly identified SFI, and annually for an FCOI that continues. Sentient Research will follow current NIH instructions and award-specific requirements.

For PHS-funded research contracts, Sentient Research will report FCOIs to the contracting officer or other PHS awarding component contact identified in the contract, following 45 CFR Part 94 and the contract's reporting instructions. The eRA Commons grant FCOI reporting module should not be assumed to be the reporting route for a contract.

For NIH-funded research, Sentient Research will post this policy on a publicly accessible website and submit the policy PDF through the eRA Commons Institution Profile (IPF) Module. This is an institutional-level submission and ordinarily is not an attachment to each grant application.

When required by the regulation, Sentient Research will make specified information about an FCOI held by senior/key personnel publicly accessible on its website or provide it in writing within five business days of a request. The information will be limited to the required elements and will be updated as required. The assigned Designated FCOI Official or external independent reviewer, as appropriate, will verify the applicable criteria and required content before release.

10. Noncompliance and retrospective review

If an Investigator fails to disclose an SFI timely, fails to comply with a management plan, or Sentient Research otherwise identifies or manages an FCOI late, the Institution will take prompt corrective action. For NIH/PHS grant research, when required by 42 CFR 50.605, Sentient Research will complete a retrospective review within 120 days of its determination of noncompliance to determine whether the research conducted during the period of noncompliance was biased in its design, conduct, or reporting. Sentient Research will document the review and submit any required mitigation report. Additional corrective actions may include a revised management plan, additional training, removal from research responsibilities, or other administrative action.

11. Records and confidentiality

Sentient Research will maintain records of Investigator disclosures, the Institution's review and response, determinations, management plans, monitoring, training, and reports for at least three years from the date of submission of the final expenditure report, or for the longer period required by the applicable regulation, contract, award, or records schedule. For contracts, the retention period and trigger will be checked against 45 CFR Part 94 and the contract.

Financial disclosures and supporting information will be treated as confidential to the extent permitted by law. Access will be limited to individuals with a legitimate compliance, oversight, or legal need. This confidentiality provision does not limit required public disclosures, agency access, audits, or legally required production.

12. Subrecipients, consultants, and collaborators

When Sentient Research carries out PHS-funded research through a subrecipient, contractor, or collaborator, it will take reasonable steps to ensure that applicable Investigators comply with this policy or that the entity provides written assurances and information sufficient for Sentient Research to meet its regulatory responsibilities. The written agreement will identify which entity's FCOI policy applies, the required disclosure and reporting timelines, and the process for communicating identified FCOIs. A vendor or consultant is not automatically an Investigator; actual responsibility for design, conduct, or reporting of research controls.

13. Enforcement

Failure to comply with this policy or a management plan may result in corrective or administrative action, up to and including removal from the project or termination of engagement, consistent with applicable agreements and law. Sentient Research will apply this policy consistently and document enforcement actions.

14. Policy review and amendments

The Designated FCOI Officials, with administrative support from the Administrative Coordinator, will review this policy at least annually and whenever federal requirements, agency guidance, or Sentient Research's research operations materially change. Revisions affecting Investigator requirements will be communicated promptly, and affected Investigators will complete additional training as required.

15. Regulatory and guidance references

- 42 CFR Part 50, Subpart F, Promoting Objectivity in Research: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
- 45 CFR Part 94, Responsible Prospective Contractors: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94
- NIH FCOI policy and guidance: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- NIH FCOI training: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- NIH FCOI Policy Development Checklist: https://grants.nih.gov/grants/policy/coi/FCOI-Policy-Development-Checklist.pdf

Approval

Approved By	Jorge A. Montoya, PhD →
Title	President & CEO
Date	10/01/2026

Appendices

Appendix A. Investigator Financial Disclosure Form

Investigator Financial Disclosure Form

Sentient Research

Instructions: Complete this form before participating in covered PHS-funded research, annually thereafter, and within 30 days after discovering or acquiring a new reportable Significant Financial Interest (SFI). Include relevant domestic and foreign interests and, where required, interests of your spouse and dependent children. Ask the Designated FCOI Official if you are unsure whether an item is reportable.

A. Investigator and project information

Investigator Name	
Title / Role	
Project(s) / Grant or Contract Number	
Principal Investigator	
Disclosure Type	☐ Initial ☐ Annual ☐ New/Updated interest ☐ Other: _____
Date Completed	
Spouse/dependent child interests included?	☐ Yes ☐ Not applicable ☐ Need guidance

B. Reportable financial interests

Disclose interests related to your Sentient Research institutional responsibilities. Examples include remuneration from outside entities, equity in outside entities, intellectual property income, and reimbursed or sponsored travel. Use additional pages if needed. Do not list Sentient Research ownership interests solely because you are a shareholder; the NIH regulation excludes an Investigator's ownership interest in the for-profit Institution from SFI. This does not exclude other reportable interests.

1. Outside remuneration / payments

Identify entity, type of payment (consulting, honoraria, paid authorship, salary or other services), recipient, dates, and approximate amount in the preceding 12 months.

Entity / details / relationship / amount or value / dates:

2. Equity / ownership in outside entities

Identify entity, type and approximate value or percentage of equity, and whether publicly or non-publicly traded.

Entity / details / relationship / amount or value / dates:

3. Intellectual property

Identify patents, copyrights, licenses, or other IP interests and income received.

Entity / details / relationship / amount or value / dates:

4. Reimbursed or sponsored travel

Identify sponsor/organizer, destination, purpose, duration, dates, and estimated value, if known. Note any applicable government or academic exception.

Entity / details / relationship / amount or value / dates:

5. Other interests / explanation

Describe any other financial relationship that could reasonably appear related to your institutional responsibilities or the funded research.

Entity / details / relationship / amount or value / dates:

C. Investigator certification

I certify that the information provided is complete and accurate to the best of my knowledge. I understand that I must disclose applicable domestic and foreign SFIs related to my institutional responsibilities, including interests of my spouse and dependent children as required by the policy; update this disclosure at least annually and within 30 days after discovering or acquiring a new SFI; complete required training; and comply with any FCOI management plan.

Investigator signature: _____ Date: _____

Printed name: _____

D. For Designated FCOI Official / authorized reviewer use only

Date received	
Complete?	☐ Yes ☐ No – follow-up requested
SFI identified?	☐ Yes ☐ No
SFI related to PHS-funded research?	☐ Yes ☐ No ☐ Pending
FCOI determination	☐ FCOI ☐ No FCOI ☐ Pending
Independent review required?	☐ Yes ☐ No Reviewer: _____
Management plan required?	☐ Yes ☐ No
Agency report required / date	
Reviewer / date / rationale reference	

Administrative routing: Disclosures submitted by Jorge Montoya or Aaron Plant must be referred to a qualified external independent reviewer. Disclosures submitted by other Investigators may be reviewed by Jorge Montoya or Aaron Plant, provided the assigned reviewer has no relevant conflict and can act impartially. Attach a separate review and determination form and management plan, if applicable. Store this form securely with restricted access.

Appendix B. FCOI Review and Determination Form

FCOI Review and Determination Form

Sentient Research

Instructions: Complete one form for each disclosure requiring substantive review. Route disclosures submitted by Jorge Montoya or Aaron Plant to a qualified external independent reviewer. Disclosures submitted by other Investigators may be reviewed by either Designated FCOI Official, provided that reviewer has no relevant conflict and can act impartially. If an FCOI is identified, attach a written management plan and document agency reporting.

A. Case information

Assigned reviewer:

☐ Jorge Montoya

☐ Aaron Plant

☐ External independent reviewer

☐ Other: _____

Reason for external referral / recusal (if applicable):

_____

_____

Investigator	
Project / award or contract number	
External entity	
Date disclosure received	
Reviewer	
Review date	

B. Interest and relationship to research

Describe the SFI, including nature, approximate value/range, source, and relevant dates:

Describe the Investigator's role and institutional responsibilities:

Describe the PHS-funded research and how the SFI could be affected by the research or by an entity whose financial interests could be affected:

C. Determination

Is the interest an SFI under the applicable rule?	☐ Yes ☐ No ☐ Need more information
Is the SFI related to the PHS-funded research?	☐ Yes ☐ No ☐ Need more information
Could it directly and significantly affect design, conduct, or reporting?	☐ Yes – FCOI ☐ No – no FCOI ☐ Pending
Independent reviewer used?	☐ Yes ☐ No Name: _____
Applicable rule / agency	☐ 42 CFR Part 50, Subpart F ☐ 45 CFR Part 94 ☐ Both ☐ Other

Rationale and facts supporting the determination:

D. Management and reporting

Management plan required?	☐ Yes ☐ No
Management plan attached / date	
Monitoring official and frequency	
Research start / expenditure restriction cleared?	☐ Yes ☐ No ☐ Not applicable
Agency report required?	☐ Yes ☐ No
Agency / reporting route	☐ eRA Commons FCOI Module ☐ Contracting Officer ☐ Other
Report due date / submitted date	
Public disclosure required?	☐ Yes ☐ No ☐ Confirm criteria

E. Sign-off

Designated FCOI Official / authorized external reviewer: _____

Date: _____

External reviewer (if applicable; required for Jorge Montoya or Aaron Plant disclosures): _____

Date: _____

A person may not make the final determination on their own financial interest. Disclosures by Jorge Montoya or Aaron Plant must be reviewed by a qualified external independent reviewer. Either principal must also recuse from any other matter in which impartiality could reasonably be questioned. Refer to the policy for applicable timing, public-access, reporting, and retrospective-review requirements.