1. Purpose

This policy establishes Anivive's Financial Conflict of Interest (FCOI) program for research funded by the U.S. Public Health Service (PHS) via grants, cooperative agreements or contracts. It implements the PHS FCOI regulations at 42 CFR Part 50, Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors), as applicable. It sets out Anivive's institutional responsibilities to:

- collect and review Significant Financial Interest (SFI) disclosures;
- determine and manage financial conflicts of interest (FCOIs);
- ensure Investigator training;
- provide required public accessibility for senior/key personnel FCOIs;
- flow down or obtain certifications from subcontracts; and
- submit timely FCOI reports to the appropriate PHS Awarding Component or Contracting Officer identified in the applicable awards.

2. Scope

This policy applies when an Anivive PHS-funded award includes PHS financial conflict of interest requirements. This policy applies to each Investigator-- including the Program Director/Principal Investigator (PD/PI) and any person responsible for the design, conduct, or reporting of PHS-funded research -- whether employed by Anivive or engaged as a consultant or through a subcontract.

Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase I applications are exempt from PHS FCOI regulations. This policy applies to SBIR/STTR Phase II awards and to all other PHS-funded research that is subject to the PHS FCOI regulations.

When this policy applies, Anivive will ensure FCOI requirements are met for all covered work, including work performed by subcontractors, either by flowing down applicable FCOI obligations through subcontracts or by obtaining subcontractor certification of a compliant FCOI program, with timelines set so Anivive can meet applicable reporting deadlines.

3. Definitions and Abbreviations

Word or Abbreviations	Definition
Financial Conflict of Interest (FCOI)	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Public Health Service (PHS)	An operating division of the U.S. Department of Health and Human Services that includes NIH and other PHS agencies responsible for funding biomedical and behavioral research.

PHS Awarding Component	The organizational unit of the Public Health Service (PHS) that funds and administers a research award subject to the PHS FCOI regulations.
Code of Federal Regulations (CFR)	The codified regulations of U.S. federal agencies; this policy implements 45 CFR Part 94 and 42 CFR Part 50, Subpart F for Anivive.
Significant Financial Interest (SFI)	For the Investigator, spouse, and dependent children: • Publicly traded entity: aggregated remuneration in the past 12 months plus equity value > $5,000. • Non-public entity: remuneration in the past 12 months > $5,000 or any equity. • Intellectual property: disclose upon receipt of income (e.g., royalties). • Travel: disclose reimbursed or sponsored travel related to Institutional Responsibilities (except when 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). Include purpose, sponsor/organizer, destination, and duration. • Exclusions: salary/royalties from Anivive; Anivive ownership interests; income from mutual funds/retirement accounts not directed by the Investigator; and remuneration or sponsored travel from the excepted sources above.
Investigator	The PD/PI and any person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research (may include collaborators/consultants engaged under subcontracts).
Senior/key personnel	The PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution
Program Director/Principal Investigator (PD/PI)	The individual designated to direct the project; may be the prime point of contact with the PHS Awarding Component.

Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR)	U.S. SBIR/STTR programs; Phase I applications are exempt from this policy.
Subcontract/Subcontractor	As used in POL-9003 Procurement and Subcontracting Policy: a subcontract is a contract entered into by a prime contractor calling for supplies or services required for performance of a prime contract; a subcontractor is the performing party under a subcontract.
Institutional Responsibilities	An Investigator's professional responsibilities on behalf of Anivive (e.g., research consultation, teaching, professional or clinical practice, institutional committee memberships and service, IRB/DSMB service) as defined in 45 CFR 94.3 and 42 CFR 50.603)
Institutional Official (IO)	Anivive's designated official who receives SFI disclosures; determines relatedness and FCOIs; issues and monitors management plans; ensures public accessibility and PHS reporting; and maintains records.

4. References

4.1. POL-0002 *Record Retention Policy*

4.2. POL-9003 *Procurement and Subcontracting Policy*

4.3. 42 CFR Part 50, Subpart F *Promoting Objectivity in Research (current eCFR)*

4.4. 45 CFR Part 94 *Responsible Prospective Contractors (current eCFR)*

4.5. NIH FCOI Overview & Guidance (including public-accessibility and reporting elements)

4.6. Associated Anivive grant, cooperative agreement, or contract (as amended)

5. Roles and Responsibilities

Department/Role	**Key Responsibilities**
Institutional Official (IO)	Solicits and reviews SFI disclosures; determines relatedness and whether an FCOI exists; develops and implements management plans; ensures public accessibility; files FCOI reports to the PHS Awarding Component; monitors and

	documents compliance; conducts and documents retrospective reviews and mitigation where required; maintains records.
Investigators (including PD/PI)	Completes training; submits timely and accurate SFI disclosures (initial, annual, and within 30 days of new SFI); complies with management plans; provides information needed for public-accessibility requirements if designated as senior/key personnel.
Project Manager / Supervisor	Ensures FCOI obligations are included in project planning and schedules; coordinates with Procurement to incorporate FCOI requirements into subcontracts; tracks subcontractor FCOI deliverables/due dates; escalates issues to the IO.
Procurement Manager/ Buyers	Incorporates mandatory FCOI flowdowns or certification language in solicitations and subcontracts; verifies subcontractor acceptance; includes FCOI method and timing in consent-to-subcontract packages when required; maintains subcontract files with FCOI artifacts.
Business Development / Contracts	Ensures that proposals for PHS-funded efforts include the required certification regarding Anivive's FCOI program; coordinates with the IO to confirm policy is current and reporting practices are in place prior to submission.
Finance & Accounting	Maintains FCOI records consistent with this policy and POL-0002; ensures costs of FCOI compliance are recorded consistent with applicable accounting policy.
Human Resource (HR) / Ethics & Compliance Committee / Legal	Tracks training; maintains enforcement mechanisms and sanctions; supports investigation and corrective actions for non-compliance; aligns this policy with other corporate policies.

6. Materials/Equipment

N/A

7. Policy

7.1. Proposal Certifications

7.1.1. For each PHS-funded contract proposal subject to the PHS FCOI requirements, Anivive will include the certification required that it maintains an up-to-date, written, and enforced process to identify and manage financial conflicts of interest, promote objectivity in research, and will comply with all applicable requirements.

7.2. Training

7.2.1. Anivive will inform each Investigator of (a) this policy, (b) the Investigator's foreign and domestic SFI disclosure responsibilities consistent with the SFI definition in this policy, and (c) the applicable PHS FCOI regulations, including 42 CFR Part 50, Subpart F and/or 45 CFR Part 94, as applicable to the award.

7.2.2. Investigators must complete NIH's online FCOI training module (https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training) before engaging in PHS-funded research, at least every four (4) years, and immediately upon any of the following: policy revision affecting Investigator requirements, an Investigator joining the project, or a finding of non-compliance.

7.3. Disclosure Requirements and Timing

7.3.1. Each Investigator must disclose foreign and domestic SFIs related to their Institutional responsibilities:

7.3.1.1. No later than the time of application or proposal submission or prior to authorization to begin work, as directed by the IO.

7.3.1.2. At least annually for the duration of the PHS-funded project, including any extensions.

7.3.1.3. Within thirty (30) days of discovering/acquiring a new SFI (e.g., purchase, marriage, inheritance).

7.3.1.4. Disclose reimbursed or sponsored travel (non-exempt sources) with purpose, sponsor/organizer, destination, and duration.

7.4. Review, Determination, and Management

7.4.1. The IO determines whether disclosed SFIs are related to the PHS-funded research and, if so, whether they constitute an FCOI (i.e., could directly and significantly affect the project). If an FCOI exists, the IO will implement a management plan before expenditure of funds. For newly identified or late-disclosed SFIs during the project, the IO will complete review and implement a management plan within sixty (60) days. Management conditions may include public disclosure (e.g., publications, presentations), disclosure to human research participants (when applicable), independent monitoring, modification of roles/duties, divestiture or reduction of the financial interest, or severance of relationships.

7.4.2. Monitoring: Anivive will monitor Investigator compliance with management plans until project completion.

7.4.3. Retrospective Review: If non-compliance occurs (e.g., late disclosure or late review), the IO conducts and documents a retrospective review within 120 days of the determination of non-compliance to assess whether any PHS-funded research, or portion thereof, was biased in the design, conduct, or reporting.

Documentation of the retrospective review will, at a minimum, include:

7.4.3.1. project/contract number;

7.4.3.2. project title;

7.4.3.3. PD/PI or contact PD/PI (if a multiple-PD/PI model is used);

7.4.3.4. name of the Investigator with the FCOI;

7.4.3.5. name of the entity with which the Investigator has the financial conflict of interest;

7.4.3.6. reason(s) for the retrospective review;

7.4.3.7. detailed methodology used for the review (e.g., review process, composition of any review panel, documents reviewed);

7.4.3.8. findings of the review; and

7.4.3.9. conclusions of the review, consistent with 45 CFR 94.5(a)(3) and/or 42 CFR 50.605(a)(3), as applicable.

If bias is found, the IO will update any previously submitted FCOI report and prepare and submit a mitigation report to the appropriate PHS Awarding Component that includes the key elements of the retrospective review and a description of the impact of the bias on the research and the corrective actions taken or planned.

7.5. Public Accessibility (Senior/Key Personnel)

7.5.1. Policy posting. Anivive will post this FCOI policy on their publicly accessible website.

7.5.2. FCOI information. In addition, Anivive will either:

7.5.2.1. Post the required information on identified FCOIs of senior/key personnel on a publicly accessible website, or

7.5.2.2. Provide written responses within five (5) business days to any request for such information.

7.5.3. Required elements include:

7.5.3.1. Investigator's name;

7.5.3.2. title/role on the project;

7.5.3.3. entity name;

7.5.3.4. nature of the SFI; and

7.5.3.5. the value range of the financial interest (or a statement that the value cannot be readily determined).

7.5.4. Information will be updated at least annually and within sixty (60) days of identifying a new FCOI for senior/key personnel and remain available for at least three (3) years from the most recent update.

7.6. Reporting to the PHS Awarding Component

7.6.1. Anivive will report FCOIs to the appropriate PHS Awarding Component for the award as follows:

7.6.1.1. Initial: Before expenditure of funds when an FCOI is identified.

7.6.1.2. Subsequent: Within sixty (60) days for any FCOI identified after the initial report (e.g., when a new Investigator joins or a new SFI is disclosed).

7.6.1.3. Annual: For each previously reported FCOI, submit an annual update for the project period (including extensions), stating whether the FCOI persists and any changes to its management.

7.6.1.4. Post-review updates: Following a retrospective review, update any previously submitted FCOI report if new information is discovered as a result of the review. If bias is found with the design, conduct, or reporting of the research, Anivive will notify the PHS Awarding Component promptly and submit the required mitigation report

7.6.2. Report contents. Each FCOI report will include the elements listed in §7.5 (Investigator name; title/role; entity; nature of the SFI; and value range or a statement that value cannot be readily determined) plus:

7.6.2.1. a description of how the SFI relates to the PHS-funded project and the basis for Anivive's determination that the SFI is an FCOI; and

7.6.2.2. the key elements of the management plan (including principal conditions and actions to manage the FCOI).

7.6.3. When a retrospective review is required, the report will be updated to include the results of the review and, if bias is found, the required mitigation report.

7.6.4. Anivive will make FCOI and SFI information (including related institutional reviews and determinations) available to the PHS Awarding Component promptly upon request.

7.7. Subcontract Flowdown Compliance

7.7.1. Anivive shall incorporate FCOI requirements into every subcontract that supports PHS-funded research and shall ensure subcontractor compliance.

7.7.1.1. Policy selection (written). Each subcontract shall state whether the subcontractor will: (1) certify that its own FCOI policy complies with 42 CFR Part 50, Subpart F and/or 45 CFR Part 94, as applicable to the award, and provide timely FCOI information/reports for its Investigators, or (2) require its Investigators to comply with this policy and submit SFI disclosures to Anivive.

7.7.1.2. Timing. Each subcontract shall set deadlines sufficient for Anivive to meet required PHS reporting windows (initial before expenditure of funds, within sixty (60) days thereafter for newly identified FCOIs, and annual updates). Where the subcontractor follows this policy, its Investigators shall submit initial, annual, and within thirty (30) days disclosures to Anivive.

7.7.1.3. Clause management. Anivive shall treat FCOI terms as mandatory flowdowns, identify them in solicitations, and incorporate them into subcontracts by reference or full text. Subcontractors shall provide written acknowledgment of acceptance as a condition of award.

7.7.1.4. Monitoring. Project and Procurement shall monitor subcontractor FCOI deliverables and compliance with any management plan alongside technical performance for the duration of the subcontract.

7.7.1.5. Consent to subcontract (when required). When the prime contract requires consent to subcontract, Anivive shall include the selected policy approach, disclosure/reporting timelines, and any management-plan requirements in the consent package.

7.8. Records

7.8.1. Anivive will maintain all FCOI-related records (disclosures, reviews, determinations, management plans, retrospective reviews, and reports) for at least three (3) years after final payment, or longer if required by statute, regulation, POL-0002 *Record Retention Policy*, or the applicable PHS award terms.

7.9. Enforcement and Remedies

7.9.1. Anivive maintains enforcement mechanisms and may apply employee sanctions or other administrative actions for non-compliance (up to removal from a project or termination). If non-compliance appears to have biased the research, Anivive will promptly notify the appropriate PHS Awarding Component of corrective actions taken or to be taken. For clinical research evaluating the safety or effectiveness of a drug, device, or treatment, when required by regulation, the Investigator will disclose the FCOI in each public presentation of results and request addenda to prior publications.

7.10. SBIR/STTR Phase I Exemption

7.10.1. This policy does not apply to SBIR/STTR Phase I applications. However, it does apply to Phase II and to other PHS-funded research that are subject to the PHS FCOI regulations.

8. Associated Documents

8.1. FORM-9002-01 *Investigator SFI Disclosure Form (short form)*

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Trudy Yin	Vice President, Quality Assurance	16-Jan-2026 13:02
Review	Trudy Yin	Vice President, Quality Assurance	16-Jan-2026 13:03
Send for Approval	Trudy Yin	Vice President, Quality Assurance	16-Jan-2026 13:05
Approve	David Bruyette	Chief Medical Officer	16-Jan-2026 13:11
Approve	Chip Dorsey	Chief Financial Officer	23-Feb-2026 15:08
QA Approval	Trudy Yin	Vice President, Quality Assurance	23-Feb-2026 15:30
Sign Training Completion	Trudy Yin	Vice President, Quality Assurance	24-Feb-2026 10:13

* Dates are displayed according to the system time zone: (GMT-08:00) Pacific Standard Time (America/Los_Angeles)