SANO Healthcare Consultants, LLC (SANO Healthcare™)

Financial Conflict of Interest (FCOI) Disclosure & Reporting Form

Required under 42 CFR Part 50 Subpart F — Promoting Objectivity in Research

INSTRUCTIONS FOR COMPLETION

Who must complete this form: All Investigators (PD/PI and any person responsible for the design, conduct, or reporting of NIH-funded research, including collaborators and consultants).

When to submit: (1) At the time of application; (2) At least annually during the award period; (3) Within 30 days of acquiring or discovering a new SFI; (4) Within 30 days of each reimbursed or sponsored travel occurrence.

What to disclose: All domestic and foreign Significant Financial Interests (SFIs) of the Investigator and the Investigator's spouse and dependent children that reasonably appear related to institutional responsibilities (research, teaching, consulting, professional practice, etc.).

Submit completed form to: SANO Healthcare Designated Official(s) — retain a copy for your records.

** Required fields. ☐ = Check all that apply.*

SECTION 1 SUBMISSION TYPE & REASON FOR DISCLOSURE

Select all that apply. If submitting for multiple reasons, complete a separate entry for each NIH-funded project.

☐ Initial Disclosure — at time of application	☐ Annual Update — during award period
☐ New / Amended SFI — within 30 days of discovery or acquisition	☐ Sponsored / Reimbursed Travel — within 30 days of occurrence
☐ Policy Revision / New to Institution — training triggered	☐ Other (describe below)

If "Other," describe reason:

SECTION 2 INVESTIGATOR INFORMATION

Last Name *	**First Name / Middle Initial ***
Title / Position *	**Department / Business Unit**
SANO Healthcare Email Address *	**Phone Number**
Mailing Address (Street, City, State, ZIP)	
eRA Commons User ID *	**Date of This Submission *** *(MM/DD/YYYY)*

SECTION 3 NIH-FUNDED PROJECT INFORMATION

Complete one row per applicable NIH project. Attach additional sheets if needed.

Project No.	Project Title	PD/PI Name	Funding Period	Investigator's Role on Project

SECTION 4 SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURE

4A. No Reportable SFI

☐ I certify that I have NO Significant Financial Interests to disclose that are related to my institutional responsibilities or to any NIH-funded project listed in Section 3.

If this box is checked, proceed directly to Section 7 (Certification & Signature). Do not complete Sections 4B–6.

4B. Remuneration & Equity Interests (Domestic & Foreign)

Disclose remuneration (salary, consulting fees, honoraria, paid authorship, etc.) and equity interests from any entity exceeding $5,000 in the prior 12 months, or any equity interest in a non-publicly traded entity regardless of value. Include interests of your spouse and dependent children.

Entity Name	Nature of Interest	Approx. Value (USD)	Publicly Traded?	Related to NIH Project? (Y/N + Explanation)

Add additional rows on a separate sheet if needed. For non-publicly traded entities, describe equity interest type (e.g., stock, stock option, ownership interest).

4C. Intellectual Property (IP) Rights & Interests

Disclose any patents, copyrights, or other IP rights from which income has been received during the disclosure period.

IP Type (Patent, Copyright, etc.)	Entity / Licensee Name	Income Received (USD)	Related to NIH Project? (Y/N + Explanation)

4D. Reimbursed or Sponsored Travel

Disclose each occurrence of reimbursed or sponsored travel (i.e., travel paid on your behalf, not directly reimbursed to you) related to institutional responsibilities within the past 12 months. Exclude travel sponsored by federal, state, or local government agencies or U.S. institutions of higher education, or research or teaching hospitals.

Sponsor / Organizer	Purpose of Travel	Destination (City, Country)	Travel Dates	Approx. Value (USD)	Related to NIH Project? (Y/N)

4E. Foreign Financial Interests

Disclose all financial interests received from foreign institutions of higher education or the government of another country when such income meets the applicable SFI threshold. Note: 20 U.S.C. § 1001(a) references institutions of higher education located within the United States; foreign entities do not qualify for the SFI exclusion applicable to U.S. institutions of higher education.

Foreign Entity Name & Country	Nature of Interest	Role/Relationship	Value (USD or Est.)	Related to NIH Project? (Y/N + Explanation)

SECTION 5 ADDITIONAL CONTEXT & EXPLANATION

Use this section to provide any additional information that may assist the Designated Official(s) in evaluating the disclosed SFIs, including whether and how any SFI could affect NIH-funded research. Attach supporting documentation if relevant (e.g., agreements, equity certificates).

Additional explanation or context:

Have you previously disclosed an FCOI on this project? ☐ *Yes* ☐ *No*

If yes, date of most recent prior disclosure: *(MM/DD/YYYY)*

If yes, describe any changes from prior disclosure:

SECTION 6 FCOI TRAINING ATTESTATION

All Investigators must complete FCOI training before engaging in NIH-funded research, at least every four (4) years, and immediately upon certain triggering events (new to institution, policy revision affecting investigators, noncompliance determination).

☐ I confirm that I have completed FCOI training that satisfies the requirements of 42 CFR § 50.604(b), including training on SANO Healthcare's FCOI policy and the applicable federal regulations.

Training Format / Provider	Training Completion Date *	Certificate / Record No. (if available)

☐ Training is pending. I understand I must complete training *before* engaging in NIH-funded research activities.

SECTION 7 INVESTIGATOR CERTIFICATION & SIGNATURE

By signing below, I certify that:

1. The information provided on this form is true, complete, and accurate to the best of my knowledge.
2. I have disclosed all Significant Financial Interests (domestic and foreign) of myself and my spouse and dependent children that reasonably appear related to my institutional responsibilities, as required by SANO Healthcare's FCOI Policy and 42 CFR Part 50 Subpart F.
3. I understand that failure to disclose required SFIs, or to comply with any FCOI management plan, may result in corrective or disciplinary action by SANO Healthcare and/or notification to NIH.
4. I agree to promptly update this disclosure within 30 days of acquiring or identifying any new SFI, or within 30 days of each reimbursed or sponsored travel occurrence.
5. I agree to cooperate fully with SANO Healthcare's review and, if applicable, comply with any FCOI management plan established by the Designated Official(s).

Investigator Signature	Date (MM/DD/YYYY)
Printed Name	Title / Position

SECTION 8 FOR OFFICE USE ONLY — DESIGNATED OFFICIAL REVIEW

This section is to be completed by the SANO Healthcare Designated Official(s). Do not complete this section as the submitting Investigator.

Form Received By (Designated Official Name) * | **Date Received *** *(MM/DD/YYYY)*

Review Determination

1. Is the disclosed SFI related to the Investigator's NIH-funded research?

☐ Yes — SFI is related to NIH-funded research (proceed to item 2 & referenced in SANO Healthcare FCOI)

☐ No — SFI is not related; no further action required

☐ Not applicable — No SFI disclosed

2. Does the SFI constitute a Financial Conflict of Interest (FCOI)?

An FCOI exists when the Institution reasonably determines the SFI could directly and significantly (i.e., materially) affect the design, conduct, or reporting of the NIH-funded research. -referenced in SANO Healthcare FCOI

☐ Yes — FCOI identified; management plan required (complete items 3–5)

☐ No — SFI related but does not rise to the level of an FCOI

3. If FCOI identified: Management Plan Status

☐ Management plan developed and implemented prior to expenditure of funds

☐ Interim management plan implemented (within 60 days) — new investigator or new SFI

☐ Interim management plan implemented (within 60 days) — untimely or previously unreviewed disclosure

☐ Management plan pending — explain below

Management plan reference number / summary:

4. NIH Reporting Required?

☐ Yes — initial FCOI report submitted (or to be submitted) via eRA Commons FCOI Module

☐ Yes — within 60-day reporting window for new investigator or new FCOI

☐ Yes — annual FCOI report update required

☐ No — no reportable FCOI

NIH FCOI Report Submitted? ☐ *Yes* ☐ *No* ☐ *Pending* | **Date of NIH Report Submission** *(MM/DD/YYYY)*

5. Retrospective Review Required (only if done after-the-fact)?

☐ No — disclosure made timely; no retrospective review required

☐ Yes — retrospective review required within 120 days (late disclosure / noncompliance)

☐ Retrospective review completed — attach documentation

☐ Bias found — mitigation report submitted to NIH

Additional notes / actions taken:

Designated Official Signature	Date of Determination (MM/DD/YYYY)
Printed Name	Title

RECORDS RETENTION NOTICE: This form and all related documentation must be retained for at least three (3) years from the date the Final Federal Financial Report is submitted to NIH, or from other dates specified in 2 CFR § 200.334, whichever is later. Records must be made available to NIH promptly upon request. (42 CFR § 50.604(i))