VOLERE MEDICAL, INC.

Policy on Financial Conflicts of Interest in Public Health Service-Funded Research

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Effective date	November 4, 2026
Approved by	Thomas Nyikos, Chief Executive Officer
Designated Official	Thomas Nyikos, Chief Executive Officer – fcoi@voleremedical.com
Regulatory basis	42 CFR Part 50, Subpart F (Promoting Objectivity in Research); NIH Grants Policy Statement, Section 4.1.10
Public posting	www.voleremedical.com/fcoi-policy

1. Purpose

Volere Medical, Inc. ("Volere" or the "Institution") is committed to ensuring that the design, conduct and reporting of research funded by the Public Health Service ("PHS"), including the National Institutes of Health ("NIH"), is free from bias resulting from Investigator financial conflicts of interest. This Policy implements the requirements of 42 CFR Part 50, Subpart F (the "Regulation"). Where this Policy and the Regulation differ, the Regulation controls.

2. Scope and Applicability

This Policy applies to every Investigator who is planning to participate in, or is participating in, research funded by PHS through a grant or cooperative agreement awarded to Volere, or through a subaward under which Volere is a subrecipient, including Investigators who are employees, consultants, contractors, collaborators or subrecipient personnel. It does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications or awards.

Volere informs each Investigator of this Policy, of the Investigator's responsibilities to disclose Significant Financial Interests, and of the Regulation. This Policy is posted on Volere's publicly accessible website identified above.

3. Definitions

Designated Official means the Volere official responsible for soliciting and reviewing disclosures of Significant Financial Interests, determining whether a Financial Conflict of Interest exists, managing Financial Conflicts of Interest and reporting to the PHS Awarding Component. The Designated Official is identified at the top of this Policy.

Financial Conflict of Interest ("FCOI") means a Significant Financial Interest that the Designated Official reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Volere, including research, research consultation, administration, regulatory and clinical activities, and service on Volere committees or review boards.

Investigator means 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 research funded by PHS, or proposed for such funding, which may include collaborators or consultants.

PHS Awarding Component means the organizational unit of PHS, such as an NIH Institute or Center, that funds the research.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research and product development.

Senior/Key Personnel means the project director or principal investigator and any other person identified as senior/key personnel by Volere in the grant application, progress report or any other report submitted to PHS.

Significant Financial Interest ("SFI") means a financial interest held by the Investigator, or the Investigator's spouse and dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities and consists of one or more of the following:

a. With regard to any publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure, plus the value of any equity interest in the entity as of the date of disclosure, exceeds $5,000 in the aggregate. Remuneration includes salary and any payment for services not otherwise identified as salary (for example, consulting fees, honoraria and 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;
b. With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds $5,000, or the Investigator (or spouse or dependent children) holds any equity interest in the entity;
c. Intellectual property rights and interests (for example, patents and copyrights) upon receipt of income related to those rights and interests; and
d. Reimbursed or sponsored travel (travel paid on behalf of the Investigator and not reimbursed to the Investigator, so that the exact monetary value may not be readily available) related to the Investigator's Institutional Responsibilities, except travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The term SFI does **not** include: (i) salary, royalties or other remuneration paid by Volere to the Investigator if the Investigator is currently employed or otherwise appointed by Volere, including intellectual property rights assigned to Volere and agreements to share in royalties related to such rights; (ii) any ownership interest in Volere held by the Investigator, Volere being a commercial, for-profit organization; (iii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; (iv) income from seminars, lectures or teaching engagements sponsored by, or from service on advisory committees or review panels for, a

federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

4. Responsibilities of the Designated Official

The Designated Official: (a) distributes this Policy and ensures that Investigators complete required training; (b) solicits, receives and reviews SFI disclosures; (c) determines whether an SFI is related to PHS-funded research and whether it is an FCOI; (d) develops, implements and monitors management plans; (e) submits FCOI reports to the PHS Awarding Component; (f) responds to public requests for FCOI information; and (g) maintains records required by this Policy.

If the Designated Official is an Investigator on the research under review, or has a personal interest in the matter, the disclosure and any related determination will instead be reviewed and decided by a member of Volere's Board of Directors who is not an Investigator on the research, or by outside counsel appointed by the Board for that purpose.

5. Investigator Training

Each Investigator must complete training on this Policy, the Investigator's responsibilities regarding disclosure of SFIs, and the Regulation (for example, the NIH FCOI online tutorial) **before** engaging in research related to any PHS-funded grant, and at least every four years thereafter. In addition, an Investigator must complete training immediately when: (a) Volere revises this Policy in a manner that affects the requirements of Investigators; (b) the Investigator is new to Volere; or (c) Volere finds that the Investigator is not in compliance with this Policy or a management plan. The Designated Official keeps a record of each completed training.

6. Disclosure of Significant Financial Interests

Each Investigator must disclose to the Designated Official, using the form in Appendix A or an equivalent written statement, all SFIs of the Investigator and of the Investigator's spouse and dependent children:

a. no later than the time of application for PHS-funded research;

b. at least annually during the period of the award, no later than the date Volere submits the annual progress report, and including any information not previously disclosed and updated information regarding any previously disclosed SFI (for example, an updated value of a previously disclosed equity interest);

c. within thirty (30) days of discovering or acquiring (for example, through purchase, marriage or inheritance) a new SFI; and

d. for an Investigator who is new to Volere or newly participating in PHS-funded research, no later than the date of joining the research.

Travel. Investigators must disclose the occurrence of any reimbursed or sponsored travel that is an SFI within thirty (30) days of the travel, including its purpose, the identity of the sponsor or organizer, the destination and the duration. The Designated Official will determine whether further information, including monetary value, is needed to determine whether the travel constitutes an FCOI.

7. Review of Disclosures and Determination of FCOI

Before Volere spends any funds under a new PHS award, and within sixty (60) days of receiving any new or updated disclosure during an ongoing award, the Designated Official will review each SFI disclosure and will:

a. determine whether the SFI is related to PHS-funded research. An SFI is related to the research when the Designated Official 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. The Designated Official may involve the Investigator in this determination; and

b. determine whether the related SFI is an FCOI, that is, whether it could directly and significantly affect the design, conduct or reporting of the research.

The Designated Official documents each determination and its basis.

8. Management of Financial Conflicts of Interest

When an FCOI is identified, the Designated Official will, before any related funds are spent (or within sixty (60) days for an FCOI identified during an ongoing award), develop and implement a written management plan specifying the actions that have been, and will be, taken to manage the FCOI. Conditions or restrictions that may be imposed include:

a. public disclosure of the FCOI (for example, when presenting or publishing the research);

b. for research projects involving human subjects, disclosure of the FCOI directly to participants;

c. appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI;

d. modification of the research plan;

e. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

f. reduction or elimination of the financial interest (for example, sale of an equity interest); and

g. severance of relationships that create the FCOI.

Each management plan identifies the role and principal duties of the conflicted Investigator in the research; the conditions of the plan; how the plan is designed to safeguard objectivity in the research; confirmation of the Investigator's written agreement to the plan; and how the plan will be monitored to ensure Investigator compliance. The Designated Official monitors Investigator compliance with each management plan on an ongoing basis until completion of the PHS-funded research project.

9. Reporting to the PHS Awarding Component

Volere will submit FCOI reports to the PHS Awarding Component through the eRA Commons FCOI Module:

a. prior to the expenditure of funds under a PHS award, for any FCOI identified at that time;

b. within sixty (60) days of identifying any FCOI for an Investigator who is newly participating in the project, or for a new or newly identified FCOI of an existing Investigator; and

c. annually, for any previously reported FCOI, at the same time as the annual progress report or at the time of any extension of the project period, describing the status of the FCOI (whether it is still being managed or explaining why it no longer exists) and any changes to the management plan, until completion of the project.

Each initial FCOI report will include: the project number; the project director or principal investigator; 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 (for example, equity, consulting fee, travel reimbursement, honorarium); the value of the financial interest within the dollar ranges set out in Section 10, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; a description of how the financial interest relates to the PHS-funded research and the basis for determining that it conflicts with that research; and the key elements of the management plan. An FCOI report is not required if the conflicting interest is eliminated before the expenditure of PHS funds.

Volere will make information about all disclosures, determinations and management actions available to HHS promptly upon request.

10. Public Accessibility

Before spending funds under a PHS award, Volere will ensure public accessibility of information on any FCOI held by Senior/Key Personnel that was disclosed and that Volere determined to be related to the PHS-funded research and to be an FCOI. Volere will respond to any written request for such information within five (5) business days of receipt. Requests may be sent to the Designated Official at fcoi@voleremedical.com. The information provided will include, at minimum: the Investigator's name; the Investigator's title and role in the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the 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; and amounts above $100,000 by increments of $50,000 (or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value). The information will be updated at least annually and within sixty (60) days of Volere's receipt or identification of information concerning any additional FCOI of Senior/Key Personnel, and will remain available for at least three years from the date of its most recent update.

11. Failure to Disclose and Retrospective Review

If Volere learns of an SFI that was not disclosed in a timely manner, or was not previously reviewed by the Designated Official during an ongoing award, the Designated Official will, within sixty (60) days, review the SFI, determine whether it is related to PHS-funded research and whether an FCOI exists, and, if so, implement on at least an interim basis a management plan specifying the actions that have been, and will be, taken to manage the FCOI going forward.

Whenever an FCOI is not identified or managed in a timely manner (including through an Investigator's failure to disclose, Volere's failure to review or manage, or an Investigator's failure to comply with a management plan), Volere will, within one hundred twenty (120) days of its determination of noncompliance, complete and document a retrospective review of the Investigator's activities and the

PHS-funded research to determine whether any research conducted during the period of noncompliance was biased in its design, conduct or reporting. The documentation will include: the project number; the project title; the project director or principal investigator; the name of the Investigator with the FCOI; the name of the entity with which the Investigator has the FCOI; the reason(s) for the retrospective review; the detailed methodology used for the review (for example, methodology of the review process, composition of any review panel, and documents reviewed); and the findings and conclusions of the review.

Volere will update any previously submitted FCOI report as necessary. If bias is found, Volere will promptly notify the PHS Awarding Component and submit a mitigation report that includes the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and Volere's plan of action to eliminate or mitigate the effect of the bias.

12. Noncompliance and Enforcement

Investigators who fail to comply with this Policy or with a management plan may be subject to corrective action, which may include required retraining, removal from the research project, suspension of research activities, and termination of employment, consulting or other engagement with Volere. In any case in which HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by Volere as required by the Regulation, Volere will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

If the failure of an Investigator to comply with this Policy or a management plan appears to have biased the design, conduct or reporting of PHS-funded research, Volere will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

13. Subrecipients

When Volere carries out PHS-funded research through a subrecipient (for example, a subcontractor or consortium member), Volere will incorporate, as part of a written agreement, terms that establish whether Volere's FCOI policy or the subrecipient's FCOI policy will apply to the subrecipient's Investigators.

a. If the subrecipient's policy applies, the subrecipient must certify that its policy complies with the Regulation, and the agreement will specify time periods for the subrecipient to report all identified FCOIs to Volere sufficient to enable Volere to provide timely FCOI reports to the PHS Awarding Component as required by the Regulation.
b. If the subrecipient cannot provide that certification, or Volere's policy is otherwise to apply, the agreement will state that the subrecipient's Investigators are subject to this Policy for disclosing SFIs directly related to the subrecipient's work for Volere, and will specify time periods for the subrecipient to submit all Investigator disclosures of SFIs to Volere sufficient to enable Volere to comply with the review, management and reporting obligations of the Regulation.

Volere will provide FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators consistent with the Regulation.

14. Records

Volere will maintain records relating to all Investigator disclosures of financial interests, the Designated Official's review of and response to those disclosures (whether or not a disclosure resulted in a determination of an FCOI), all actions under this Policy and any retrospective review, for at least three (3) years from the date of submission of the final expenditures report or, where applicable, for the other time periods specified in the HHS record-retention regulations applicable to the award.

15. Questions and Review of this Policy

Questions about this Policy should be directed to the Designated Official at fcoi@voleremedical.com. Volere will review this Policy at least every four years and whenever the Regulation or NIH policy changes, and will notify Investigators of any revisions affecting their obligations.

Appendix A – Investigator Disclosure of Significant Financial Interests

Complete for yourself, your spouse and your dependent children. Return to the Designated Official (fcoi@voleremedical.com). See Section 3 of the Policy for the definition of a Significant Financial Interest and its exclusions; ownership interests in Volere Medical, Inc. and remuneration paid by Volere do not need to be disclosed.

Investigator name	
Title / role on the project	
PHS/NIH project(s) (number and title)	
Type of disclosure	☐ Application ☐ Annual ☐ New SFI (within 30 days) ☐ New Investigator ☐ Travel

1. Do you, your spouse or dependent children have any Significant Financial Interest that reasonably appears related to your Institutional Responsibilities at Volere? ☐ No ☐ Yes – complete the table below.

Entity	**Type of interest (remuneration, equity, IP income, other)**	**Held by (self / spouse / child)**	**Approximate value**	**Relationship to your Volere work**

2. Reimbursed or sponsored travel in the past 12 months (excluding travel paid by government, universities, academic teaching hospitals, medical centers or university-affiliated research institutes):

Sponsor / organizer	**Purpose**	**Destination**	**Dates / duration**

3. I have completed FCOI training (e.g., the NIH FCOI tutorial) within the past four years. ☐ Yes, on (date): _____ ☐ No

Certification. I certify that this disclosure is complete and accurate, that I have read the Volere FCOI Policy, and that I will update this disclosure within 30 days of discovering or acquiring any new Significant Financial Interest.

Signature: _____ Date: _____

For Designated Official use

Date received / reviewed	
SFI related to PHS-funded research?	☐ No ☐ Yes
FCOI determined?	☐ No ☐ Yes – management plan dated: _____; reported to NIH on: _____
Reviewer signature	