

Managing Financial Conflicts of Interest (FCOI) for Federally Funded Research Standard Operating Procedure (SOP)

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1. Purpose

To ensure transparency, objectivity, and integrity in research by identifying, managing, and when necessary, mitigating financial conflicts of interest (FCOI) in accordance with NIH regulations. This SOP aims to prevent any potential bias in research conducted by BioMimetix.

The policy aligns with U.S. Department of Health and Human Services requirements for institutions receiving Public Health Service (PHS) funds. It details types of financial conflicts of interest (FCOI), disclosure requirements, and enforcement measures.

2. Scope

This SOP applies to all BioMimetix employees, consultants, contractors and agents involved in National Institutes of Health (NIH) or PHS-funded research. Covered individuals, referred to as

"Investigators," or "Senior/Key Personnel" include any person responsible for the design, conduct, or reporting of such research, as well as their immediate family members [42 CFR Part 50 Subpart F].

3. Background

Under NIH and PHS, Investigators must disclose their significant financial interests (SFIs), including those of their spouse and dependent children, that may affect research integrity.

SFIs include personal and family financial interests that could appear to influence research activities. This SOP aligns with federal regulations to safeguard objectivity in NIH-funded research.

4. Significant Financial Interests (SFI)

An SFI includes the following types of financial interests held by an Investigator or their family that may relate to their institutional responsibilities (domestic and foreign):

- **Equity Interests:** Any stock, stock option, or other ownership interest in a publicly traded entity exceeding \$5000 in value (aggregated with remuneration) or any equity interest in a non-publicly traded entity
- **Remuneration:** Any compensation over \$5000 from a single entity in the prior 12 months.
- **Intellectual Property (IP) Income:** income from patents, copyrights, or other IP rights.
- **Travel Reimbursements:** Sponsored travel related to the institutional responsibilities (excluding those from government agencies or academic institutions). Disclosure should include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration will be provided. Upon review, BioMimetix will determine if further information is needed.

Exclusions: The following types of income and reimbursements are generally excluded from significant financial interest (SFI) disclosures:

- Salary or other compensation paid directly by BioMimetix.
- Income from seminars, lectures, or service on advisory committees or review panels for public or nonprofit organizations.
- Income from federal, state, or local government agencies, academic institutions, teaching hospitals, or public research institutions.
- Reimbursed or sponsored travel from federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education (as defined in 20 U.S.C. 1001(a)).

All subrecipients of an award will document that they follow the FCOI policy of BioMimetix or if they follow one of their institution. If following their institution FCOI policy it will need to be certified by the subrecipient that it complies with the regulations.

5. Disclosure and Review Process

BioMimetix will provide a form (see Appendix) for completion to review FCOI.

Timing of Disclosure: Investigators must disclose financial interests:

- Annually

- Within 30 days of discovering or acquiring a new financial interest
- Before engaging in research funded by NIH/PHS
- During dissemination of the results, At the beginning of any presentation of study results of a PHS funded study, through either oral presentation or publication, the covered person must disclose private sources of funding provided specifically for the study.

Review: BioMimetix’s designated FCOI Officer will review each Investigator SFI disclosure to determine if a SFI is related to NIH-funded research and, if so related, whether the SFI is a FCOI, and if so, develop a management plan.

- **Initial Review:** all disclosures will be reviewed to determine if any financial interest represents a significant financial conflict of interest related to federally funded research.
 - An Investigator’s SFI is related to NIH-funded research when the Institution’s designated official(s) determines the SFI:
 - could be affected by the research or
 - is in an entity whose financial interest could be affected by the research.
 - An Investigator’s SFI is a FCOI when the designated official(s) reasonably determines **the SFI could directly and significantly** (i.e., have a material effect on the research) **affect the design, conduct, or reporting of the NIH-funded research.**
- **Management Plan:** If an FCOI is identified, BioMimetix will develop a management plan which must be reported to the NIH. This may include:
 - Modifying the research plan.
 - Appointing an independent monitor/reviewer.
 - Requiring Investigator recusal from key project decisions.
 - Divestiture of financial interests.
 - Disclosures.
- **Annual and Updated Reporting to NIH:** BioMimetix will report identified FCOIs to NIH prior to the expenditure of any NIH funds and within 60 days of identifying any new FCOIs.

6. Training Requirements

Initial and Ongoing Training: All Investigators must complete NIH-compliant FCOI training:

- Prior to engaging in NIH-funded research.
- Every four years.
- Immediately if BioMimetix revises this policy in a way that affects Investigator requirements or if the Investigator is found to be in non-compliance.

BioMimetix will provide or ensure that subrecipients receive training.

7. Enforcement and Sanctions for Non-Compliance

BioMimetix will do everything possible to manage, eliminate, or reduce any potential conflicts of significant financial interests. BioMimetix requires covered persons to disclose any significant financial interest, including those of his/her family members, which would reasonably appear to be affected by the project. All financial conflict of interest disclosures will be reviewed by BioMimetix.

Sanctions: Violations of this policy may result in disciplinary actions, up to and including termination, in accordance with BioMimetix policies. BioMimetix will report any non-compliance and corrective actions to NIH within 120 days as required.

8. Publications

In cases where an FCOI was not managed or reported, the Investigator must disclose the FCOI in all public presentations or publications of the research findings. BioMimetix may also request addendums to previous publications.

9. Records Retention

All FCOI related records will be maintained for at least 3 years from the date the final expenditures report is submitted to the PHS as well as other dates as specified in 45 CFR 75.361, where applicable.

10. Public Accessibility

BioMimetix will make this FCOI policy available on its website.

Upon request, BioMimetix will provide information concerning FCOIs held by senior/key personnel in NIH-funded research, in accordance with NIH requirements, within five business days.

11. Abbreviations

Abbreviation	Term
FCOI	Financial Conflict of Interest
GCP	Good Clinical Practice
NIH	National Institutes of Health
PHS	Public Health Service
SFI	Significant financial interests
SOP	Standard Operating Procedure

12.References

- 41 CFR Part 50
- Objectivity in Research (Federal Register, July 11, 1995)
- 21 CFR §§ 312.53(c), 812.20(b)(5) and 812.43(c)
- <https://grants.nih.gov/grants/policy/coi/index.htm>
- 45 CFR 75.361
- U.S.C. Code 20. U.S.C. 1001

13.Revision History

Revision	Date	Description of Changes	Requested By
1.0	01 Aug 2019	Initial Release	BioMimetix JV, LLC
2.0	06 Mar 2020	Updates to Sponsor Master Template, update TMF filing structure tabs	BioMimetix JV, LLC
3.0	24 Apr 2020	Separated from Master SOP, Clarified policy, updated disclosures	BioMimetix JV, LLC
4.0	14 Jan 2021	Re-wrote policy, separate clinical center financial disclosure policy from this financial conflict of interest policy	BioMimetix JV, LLC
5.0	11 Nov 2024	Review and revisions for better alignment with NIH regulations	BioMimetix JV, LLV

Appendix: BioMimetix Financial Conflict of Interest Disclosure Form

Investigator Information

Date completed	
Name	
Title:	
Project Role	
Phone	
Email	

Disclosure of Significant Financial Interests (SFI)

Please provide details for each category below if applicable. All amounts should represent the value as of the date of disclosure. Report over the past 12 months. Attach additional sheets if needed.

Equity Interests	
Entity name and address:	
Type of Entity (Publicly traded/Non-publicly traded)	
Ownership Interest (e.g., stock, stock options)	
Value of equity interest	
Comments	

Income from Remunerative Activities	
Provide details of any remuneration received over \$5,000 in the last 12 months from any entity that reasonably appears to be related to your institutional responsibilities.	
Entity name and address:	
Type of Remuneration (e.g., consulting, honoraria):	
Annual income amount:	

Comments:	
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Intellectual Property Rights and Income	
Report income from intellectual property rights or interests that are reasonably related to your institutional responsibilities.	
Type of IP (e.g., patent, copyright):	
Income Source:	
Annual income amount:	
Comments:	

Reimbursed or Sponsored Travel	
List travel that was reimbursed or sponsored by an entity related to your institutional responsibilities (excluding travel sponsored by federal, state, or local government agencies, U.S. academic institutions, teaching hospitals, medical centers, or affiliated research institutions).	
Dates of travel:	
Purpose of travel:	
Travel destination:	
Sponsoring organization:	
Estimated value:	

I certify that the above information is true, complete, and accurate to the best of my knowledge. I understand that failure to disclose significant financial interests may result in disciplinary action and that it is my responsibility to comply with BioMimetix's FCOI policy and NIH requirements.

Signature	Date

For BioMimetix Use

Project Information

NIH Grant Number (s):	
Project Title(s):	

Reviewer's Findings

- I have reviewed these responses and find no reason for further action (no FCOI identified).
- I have reviewed these responses and find it necessary to proceed further (proceed to management plan).

Management Plan

(If FCOI is identified, provide details of the management plan here or attach as an appendix.)

Reporting

Initial Report to NIH (within 60 days of identification):	
Annual FCOI Report to NIH (as applicable):	

Signature of Reviewer	Date of Review
Reviewer Name	