



Managing Financial Conflicts of Interest (FCOI) Standard Operating Procedure (SOP)

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1. Purpose

The research conducted by BioMimetix is facilitated and/or made possible through external funding from private as well as public sources. It is the Company's responsibility to assure the integrity of all aspects of such sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least managed equitably to the satisfaction of all concerned parties.

This policy is set forth to ensure that formal relationships of covered persons as defined in this document, involved in the design, conduct, and reporting of research sponsored by BioMimetix

and paid for by Public Health Service (PHS) - funds will not be biased by any conflicting financial interests. It is also written to ensure compliance with various government agency policies and regulations.

The U.S. Department of Health and Human Services requires that an institution receiving PHS research funds has a written financial conflict of interest (FCOI) policy.

This Policy describes types of FCOI, identifies when disclosure should be provided, and explains BioMimetix's administration and enforcement procedures. The policy is applicable to covered persons, which include Investigators, Senior/Key Personnel, and other persons and their immediate family members, regardless of title or position, who are responsible for the design, conduct, or reporting of research studies, who participate in PHS funded research. Participation includes having an active role in the development of protocols, the conduct of clinical trials, as well as the reporting of study results.

2. Scope

This policy is applicable to all PHS sponsored program activity carried out by covered participants. While this policy focuses upon avoiding, or at least managing, conflicts of significant financial interest, its primary purpose is to promote compliance with the standards of objectivity in research.

3. Background

Under the Public Health Service (PHS) and National Science Foundation (NSF) final rules on Objectivity in Research (Federal Register, July 11, 1995 and updated in 2011), each investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by the PHS or the NSF. An Investigator is defined by 42 CFR Part 50 Subpart F as *“the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, “Investigator” includes the Investigator's spouse and dependent children.”*

If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, BioMimetix will report the existence of such conflicting interests and act to protect the resulting research from bias owing to the conflict of interest. This policy is intended satisfy current Federal rules for disclosure with regard to projects funded by the PHS or the NSF.

4. Significant Financial Interests (SFI)

A “Significant Financial Interest” (SFI) is defined as follows:

- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the

entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, 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;

- With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term *significant financial interest* does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator,
- if the Institution is a commercial or for-profit organization; 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;
- income from seminars, lectures, or teaching engagements 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;

- or income from service on advisory committees or review panels for 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.

5. Procedure

A financial conflict of interest related to BioMimetix's PHS-funded study activities may occur when a covered participant has a significant financial interest that compromises, or appears to compromise, that individual's independence and objectivity in the discharge of responsibilities in the design, conduct, or reporting of research.

Investigators should avoid conflicts and the potential for conflicts resulting from financial arrangements with third parties that could have a special interest in a protocol. Entities that could have such a special interest include all organizations that are involved in the development, production and/or distribution of products used in medical research protocols conducted by BioMimetix. Following completion of a trial, covered persons providing leadership in the design or conduct of the study should refrain from activities primarily targeted at marketing of a product that was studied in that trial.

BioMimetix requires each covered person to disclose a listing of his/her significant conflict of financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research being conducted. This will be done annually or within thirty (30) days of any change leading to a significant financial interest.

A covered person must disclose any potential conflicts that develop during the design, conduct, or reporting of a clinical trial or during the dissemination of 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.

All subrecipients 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.

6. Enforcement

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. Financial conflicts of interest, if they arise will be reviewed and assessed by the Director of Operations and the CEO of BioMimetix. If one of these roles has a conflict of interest,

it will be reviewed by BioMimetix’s Business Advisory Board. The CEO or Business Advisory Board will determine if a conflict of interest exists and if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest.

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) Public disclosure of significant financial interests;
- (2) Monitoring of research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in all or a portion of the research funded by the PHS;
- (5) Divestiture of significant financial interests; or
- (6) Severance of relationships that create actual or potential conflicts.

If BioMimetix determines or is made aware that a covered person has not complied with the disclosure requirements for SFIs or that an FCOI was not identified and reported in a timely manner, BioMimetix will review the finding and if necessary report the finding to NIH within 120 days and document the review as required by federal regulation.

If it is determined that a covered person has an FCOI, the individual may not serve as study chair, lead investigator, study statistician, or as a member of the Data Monitoring Committee for any protocol involving the research product for which there is a conflict.

If an Investigator discloses a Significant Financial Interest that is above one of the following maximum thresholds, then the individual may be excluded from the development or management of a BioMimetix clinical trial.

- Payments from Sponsor in excess of \$25,000 per year during the research period and for one year after, not including research compensation;
- Any financial arrangement in which value of compensation could be influenced by outcome of the study;
- Equity interest in a publicly traded company sponsor exceeding \$50,000 a year during time of research and one year after; and any significant interest in a non-publicly traded company.

Summary of FCOI Noncompliance and FCOI Reporting https://grants.nih.gov/grants/policy/coi/index.htm	
FCOI Report (within 60 days of identification)	Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.
Retrospective Review (to determine bias)	If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a

	management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.
Update/Revise FCOI Report (following retrospective review)	If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.
Mitigation Report (promptly after retrospective review)	If bias is found, <ul style="list-style-type: none"> • Notify NIH promptly • Submit mitigation report through FCOI Module
Annual FCOI Report	Submit annual FCOI report thereafter through FCOI Module

7. Training

Annually, all person's subject to this policy Financial Conflict of Interest Policy, will be required to read and affirm their understanding of, and intent to comply with the FCOI policy. As required by 42 CFR Part 50, Subpart F, BioMimetix will file a report with the NIH providing information on every identified FCOI and the manner in which the FCOI is being or has been managed, reduced, or eliminated. Reports will include the elements required by these regulations. BioMimetix will notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research, and file a Mitigation Report in accordance with federal regulations.

8. Publications

If the DHHS determines that a PHS-funded study has an FCOI that was not managed or reported by BioMimetix, then BioMimetix will require the Investigator involved to disclose the FCOI in each public presentation of the research of the research and request an addendum to previously published presentations.

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

This policy will be posted to BioMimetix's publicly accessible website.

11. Abbreviations

Abbreviation	Term
FCOI	Financial Conflict of Interest
FDA	US Food and Drug Administration
GCP	Good Clinical Practice

IRB	Institutional Review Board
NIH	National Institutes of Health
NSF	National Science Foundation
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)

FDA Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators

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



BioMimetix Financial Conflict of Interest Disclosure Form

Date	
Name	
Address	
Phone	
Email	

1. Outside Interests

If, during the most recent 12 months, you or any member of your Immediate Family* owned an equity interest in an entity that reasonably appears to be related to your BioMimetix responsibilities, give details below.

Organization & Address	Nature of Business	Relationship of Family Member (or write "self")	Current Value of Equity Interest	Comments

2. Renumerative Activities

Please give details if, during the most recent 12 months and with respect to all financial interests that reasonably appear to be related to your BioMimetix responsibilities:

- you and/or members of your immediate family have received any sort of remuneration (cash or in kind) from a publicly traded entity that, in the aggregate and coupled with any equity interest you and your immediate family hold in that entity (valued as of today), exceeds \$10,000;
- the aggregated sum of any sort of remuneration (cash or in kind) received by you or a member of your immediate family from a non-publicly traded entity* exceeds \$10,000; or
- any receipt of income related to any intellectual property rights or interest (e.g., patents, copyrights) held by you or your immediate family members that are reasonably related to your BioMimetix responsibilities.

Organization & Address	Nature of Business	Relationship of Family	Current Value of	Comments

		Member (or write "self")	Equity Interest	

3. Other Transactions

During the most recent 12 months, did you or any member of your immediate family have an interest in any contract, sale or other transaction to which BioMimetix was a party, or are there other situations, not listed above, that you believe may create an actual or perceived conflict of interest? If so, describe:

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4. Travel

A covered person must disclose any Sponsored Travel provided (paid to or on behalf of) self or immediate family within the last (12) months to assess, in aggregate, if a CPs financial interest raises to the level of a SFI. Sponsored travel funding from BioMimetix, other Federal, state or local government agencies, US Institutes of higher education, US Research Institutes affiliated with institutions of higher education and US Academic teaching hospitals do not need to be disclosed. Covered persons need only disclose Sponsored Travel which could be reasonably linked to BioMimetix duties.

Dates of Travel	Purpose of Travel	Travel Destination	Identity of Travel Sponsor or Organizer	Value of Sponsored Travel

The above is an accurate and current statement of all my reportable outside interest and activities.

Signature	Date

For BioMimetix Use

Reviewer's Findings

- I have reviewed these responses and find no reason for further action.
- I have reviewed these responses and find it necessary to proceed further.

Signature of Reviewer	Date
Reviewer Name	