

<i>P&P 065</i>
FINANCIAL CONFLICT OF INTEREST (FCOI)
<i>04 April 2024</i>

Purpose

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have direct influence in the allocation and use of public funding in the conduct of research. The following FCOI policy applies to research and initiatives funded by US Public Health Service (PHS) grants wherein NeXolve or NeXolve subsidiaries are the recipient of public funding. The policy aligns to requirements within regulation 42 CFR Part 50 – Subpart F with the goal of promoting objectivity and transparency in research.

This FCOI policy defines the requirements and processes for investigators or individuals participating in PHS funded research to identify and properly disclose any FCOIs. In addition, it outlines activities related to management, enforcement, and reconciliation for all appropriate studies.

Definitions

Investigator(s) include the Principal Investigator (PI)/Project Director and any other individuals, regardless of title or position who is responsible for the design, conduct, or reporting of PHS/National Institutes of Health (NIH)-funded research, or proposed for such funding, and which may include for example, collaborators or consultants.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards for PHS funded research.

Financial interest means anything which has monetary value, and if the value is readily ascertainable.

Financial Conflicts of Interest (FCOI) in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research related to the PHS funded activity.

FCOI Manager - The grant recipient's designated official for managing the FCOI process related to a specific PHS grant.

Significant Financial Interest (SFI) - 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:

- (i) An SFI exists if the value of any remuneration received from an entity (other than the Company), in the twelve months preceding the disclosure and the value of any equity interest in an 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; and,
- (ii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

**Note: NeXolve includes the additional criteria related to the SFI definition and meets the NIH FCOI policy requirements.*

Subrecipient is a subcontractor or consortium participant who may indirectly receive grant funding via the Company that holds the prime contract with the US Government.

Training

In compliance with federal regulations, all NeXolve Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to review the NeXolve FCOI policy and complete the NIH's online FCOI Training module.

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years
- Immediately, if:
 - Company revises its FCOI policy that affects requirements of Investigators
 - An Investigator is new to the Company
 - An Investigator is not in compliance with the policy or management plan

Upon completion of the training, a certificate of completion must be sent to the FCOI Manager. Investigators should also retain a copy for their records

Disclosures, Review, and Monitoring Requirements

Disclosure

The Principal Investigator of a Research Project will identify all Investigators required to disclose SFIs (and those of the Investigator's spouse, partner, and dependent children) related to PHS funded activity, which meet the definition of SFI (see Attachment 1 - SFI Disclosure Form). The Principal Investigator and FCOI Manager will be responsible for ensuring disclosures of any new (e.g., marriage, purchase, or inheritance) or increased financial interests are completed:

- No later than at the time of application for PHS-funded research
- At least annually during the period of award, and
- Within 30 days of discovering or acquiring a new SFI.

Review and Monitoring

Prior to expenditure of funds, the FCOI Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists related to an investigator's institutional responsibilities.

If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce, or eliminate specific SFI to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct or reporting of research, the FCOI manager will introduce an FCOI management plan. The plan may outline terms, conditions, and restrictions, if any, to ensure compliance with this policy.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator. Compliance of the management plan will be monitored by the FCOI Manager.

Reporting Requirements

FCOI Manager is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the sponsor.

Initial Report

Prior to the Company's expenditure of any funds under a PHS/NIH-funded research project, the Company will provide to the sponsor an FCOI report regarding any Investigator SFI, if found by the Company to be a financial conflict of interest, in accordance with the regulation. In cases in which the Company identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, the Company shall not submit an FCOI report to the NIH.

During On-Going PHS/NIH-Funded Research Projects

Whenever, during the research project, a new Investigator discloses SFI or an existing Investigator discloses a new SFI, the company will:

- Review of disclosure of SFI
- Determine whether it is related to research
- Implement a management plan in interim
- Submit a report of FCOI within 60 days after its determination that a new FCOI exists.

Annual Report

For any FCOI previously reported to the sponsor, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. Further, NeXolve will notify the sponsor promptly:

- If bias is found the Company will notify and submit a mitigation report to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed above) and a description of the impact of the bias on the research project and the Company's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Company will submit FCOI reports annually.
- If an Investigator fails to comply with the Company's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research the company will take corrective action.

Records Maintenance

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential FCOI, shall be retained by the FCOI Manager for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

Whenever the Company identifies a SFI that was not disclosed timely to the sponsor, Company will complete a retrospective review within 120 days of discovery of noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research. Updated FCOI will be submitted to the sponsor. Required retrospective review elements are outlined in 42 CFR 50.605(a)(3)(iii).

Additionally, in any case in which the sponsor determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a vaccine, drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Company as required by this subpart, the Company will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the PHS funded research and to request an addendum to previously published presentations under PHS Funded research.

Subrecipient Requirements

When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Company shall establish a written agreement (e.g., subaward

contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is compliant with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

If an SFI is identified by the sub-award recipient, they are required to notify the PI and FCOI Manager of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

Public Accessibility Requirements

NeXolve will publish the institution's policy on its public website. NeXolve will respond to all written requests for information within five (5) calendar days and then release the required information about such SFI containing the minimum elements as provided by regulation.

Records of Investigator SFI Disclosure forms will be retained for a minimum of three years from the date the final expenditure report is submitted to the sponsor

References

COI Regulation 42 CFR Part 50 Subpart F

(<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>)

NIH Guide Notices Related to Financial Conflict of Interest

(<https://grants.nih.gov/grants/policy/coi/guide-notices.htm>)

FCOI Training module

<https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>



Authorized Signature

Jim Moore / CEO

Print Name and Title

3/25/2024

Date

Attachment 1

Significant Financial Interests (SFI) Disclosure Form

Investigator: _____

Type of disclosure: Initial/Annual report Change in SFI

Financial Conflict of Interest (FCOI) training : completed/current pending
(Training required upon award from PHS or other applicable sponsor, and renewed at least every 4 yrs.)

Significant Financial Interest (SFI): anything of monetary value received or held by an investigator or family member (spouse, domestic partner, parents, siblings or children), whether or not the value is readily ascertainable, that reasonably appears to be related to the investigator's institutional responsibilities. SFI includes:

- Salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received from a publicly traded entity during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- Salary or other payments for services, when the aggregated value received from a non-publicly traded entity during the 12 month period preceding the disclosure exceeds \$5,000; or
- Equity interests (e.g., stocks, stock options, or other ownership interests) in a non-publicly-traded company of any value during the 12 month period preceding or as of the date of disclosure; or
- Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through NDSU; and
- Reimbursed or sponsored travel that is related to investigator's institutional responsibilities. This includes travel that is paid on behalf of the investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

SFI does NOT include: 1) Salary, royalties, or other remuneration from NeXolve; 2) income from the authorship of academic or scholarly works; 3) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, or medical centers; or 4) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles.

Investigator certification: (mark one as applicable)

I certify **no SFI** related to my NeXolve responsibilities; or

I **disclose SFI** (as indicated above) which may be related to my NeXolve responsibilities. These interest(s) are described below, or provided as an attachment.

Describe the external entity, the type of business, the role/nature of financial interest that you or your family has in the entity, as well as any other relevant details:

By signing below, I certify that I have read and understand NeXolve P&P 065: FINANCIALCONFLICT OF INTEREST. I understand that, if awarded, disclosure is required annually, and upon any changes throughout the duration of the applicable sponsored project.

Investigator Signature _____ Date _____

Return completed form to:
brandon.farmer@nexolve.com

----- REVIEW SECTION -----

This section completed by the investigator's administrative head (CEO or Director) with primary authority for administering their unit.

Financial Conflict of Interest (FCOI): *a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of NeXolve research.*

CEO or Director response :
(mark one as applicable)

No SFI. I have reviewed this disclosure form, and agree and acknowledge that the investigator has no significant financial interests related to their NeXolve responsibilities.

Review pending. I acknowledge receipt of this disclosure form, and will review upon notice of funding award.

Review of SFI disclosure. I have reviewed the significant financial interest(s) described here, and in consultation with the investigator have determined:

No potential FCOI exists.

Actual or apparent FCOI exists that may directly and significantly affect the design, conduct or reporting of NeXolve research. Referred to CEO or Director for final review and management.

By signing below, I certify that I have read and understand NeXolve P&P 065: FINANCIALCONFLICT OF INTEREST.

CEO _____
Signature

Date

Comments: