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1. INTRODUCTION

The Federal Department of Health and Human Services has developed regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. The regulations were first developed in 1995, and in 2011, the regulations were revised. These regulations describe the actions an individual and an organization must take to promote objectivity in Public Health Service (PHS) funded research. The regulations apply to all PHS (e.g., National Institutes of Health [NIH]) funded grants, cooperative agreements, and research contracts. The regulations are not applicable to Phase 1 Small Business Innovation Research or Small Business Technology Transfer applications and/or awards.

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for NovoPedics, Inc. (hereinafter "NovoPedics").

The implementation of the regulation through the issuance of this policy ensures that the design, conduct and reporting of PHS/NIH-funded research will be protected from bias resulting from an Investigator's financial conflict of interest (FCOI). In addition, the policy serves to protect the safety of animals and human research participants, the reputation of the recipient institution and of the Investigator who participates in PHS/NIH-funded research. These requirements work together to preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

2. DEFINITIONS

For the purpose of these policies and procedures, the following definitions apply:

a. **Financial conflict of interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

b. **Financial Interest:** Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

c. **Institutional Responsibilities:** Institutional responsibilities are the professional activities an investigator performs on behalf of NovoPedics (e.g., research, clinical development, research publication, consulting, administration, or institutional committee memberships).

d. **Designated Official (DO):** The Designated Official(s) has been designated by NovoPedics as an Official to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, and identify FCOIs per the regulatory criteria provided in 42 CFR 50.604(f) and as stated within the policy below.

e. **Investigator:** 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 an award or proposed for funding, which may include, for example, collaborators or consultants. NovoPedics will consider the individual's role, rather than the title, of those involved in the research and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded research.

f. **Research:** Research implies a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and

applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or therapeutic drug).

g. **PHS-Funded Research:** The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

h. **PHS:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

i. **NIH:** The biomedical research agency of the PHS.

j. **Senior/key personnel:** Senior/key personnel means the PD/PI and any other person identified as Senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution. This term is defined only as it relates to the public accessibility requirements of identified FCOIs held by Senior/key personnel as described under the section 8.

k. Significant Financial Interest (SFI):

1. A **domestic or foreign 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 appear to be related to the Investigator's **institutional responsibilities** performed on behalf of NovoPedics:

    - **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,

- **With regard to intellectual property rights and interests (e.g., patents, copyrights)**, a significant financial interest exists upon receipt of income of greater than $5,000 related to such rights and interests.

2. Investigators must disclose the occurrence **of any reimbursed or sponsored travel that exceeds $5,000** (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 the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

   The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

   - a federal, state, or local government agency located in the United States,
   - a United States Institution of higher education,
   - an academic teaching hospital,
   - a medical center, or
   - a research institute affiliated with a United States Institution of Higher Education

3. The term **'significant financial interest' does <u>not</u> include**, and therefore, **investigators are not required to disclose**, the following types of financial interests:

   - **Salary, royalties, or other remuneration paid by NovoPedics** to the Investigator **if the Investigator is currently employed or otherwise appointed by NovoPedics**, including intellectual property rights assigned to NovoPedics and agreements to share in royalties related to such rights.
   - **Any ownership interest in NovoPedics**, held by the Investigator since NovoPedics is a non-publicly traded entity and such interest is excluded from the SFI definition per regulation. This exclusion only applies if the applicant or recipient (including a sub-recipient) is a for-profit or commercial institution.
   - 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 located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education or,
- Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Foreign Financial Interests: Investigators must disclose all foreign financial interests (which include income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

3. SIGNIFICANT FINANCIAL INTEREST DISCLOSURE REQUIREMENTS

a. **At the time of application**: The Principal Investigator and all other individuals who meet the definition of 'Investigator' must disclose their SFIs to the Designated Official(s). Any new Investigator who, after applying to NIH for funding from NIH or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official(s) promptly and prior to participation in the project.

b. **Annual Disclosure: Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually (<u>on or before May 01</u>)**, during the period of the award. Such disclosure must include any information that was not disclosed initially to NovoPedics pursuant to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH- funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

c. **New SFIs during the award**: Each Investigator participating in PHS/NIH-funded research must submit **an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI** (e.g., through purchase, marriage, or

inheritance). In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

4. REVIEW OF SFI DISCLOSURES BY NOVOPEDICS DESIGNATED OFFICIAL(S)

A Designated Officials Committee (consisting of: Dr. Kevin Weadock, Chief Operating Officer; Dr. Michael Dunn, Co-Founder; Claudia Campbell, Contract Program Manager) has been assigned at NovoPedics who will conduct reviews of SFI disclosures. The Designated Officials Committee will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award as explained in Section 5.

a. **Prior to the issuance of a new award:** The Designated Officials Committee will review the Investigator's SFI(s) prior to the NIH issuing a new award and if an FCOI is identified, the institution will submit an FCOI report to the NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.

b. **Annual SFI disclosure:** The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The Designated Officials Committee will review the Investigator's annual disclosure and will use the updated information to determine if any changes are needed to an existing management plan. Any changes to the existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.

c. **During award period:** Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Officials Committee will within 60 days: review the disclosure of SFI, determine whether the SFI is related to the NIH-funded research; determine whether an FCOI exists; and, if so, 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. The institution will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

5. GUIDELINES FOR DETERMINING 'RELATEDNESS' OF SFI TO PHS/NIH-FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST

The Designated Officials Committee will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

- **Relatedness Test:** An Investigator's SFI is "related" to the research when the designated Official(s) reasonably determines the SFI:
    - Could be affected by the PHS/NIH-funded research; or,
    - Is in an entity whose financial interest could be affected by the PHS/NIH-funded.

The Designated Officials Committee may involve the Investigator in determining whether an SFI is related to the research supported by the PHS/NIH-funded award.

- **FCOI determination:** A financial conflict of interest exists when the Designated Officials Committee reasonably determines that the SFI could **directly and significantly** affect the design, conduct, or reporting of the PHS/NIH-funded ('significantly" means that the financial interest would have a material effect on the research).

6. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT OF INTEREST

If a financial conflict of interest exists, the Designated Officials Committee will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
7. Severance of relationships that create financial conflicts.

If the Designated Officials Committee determines that a conflict exists, it will communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct supervisor.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated Official necessary to manage the Financial Conflict of Interest. The FCOI Designated Officials Committee of NovoPedics will submit the FCOI report to NIH via the eRA Commons FCOI Module.

7. MONITORING INVESTIGATOR COMPLIANCE

NovoPedics will monitor investigators' compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists during the period of an NIH-funded award. Monitoring public disclosure requirements will include reviewing publications and presentations to confirm that the investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Officials Committee.

8. PUBLIC ACCESSIBILITY OF FCOI POLICY AND INFORMATION RELATED TO A FCOI

a. FCOI Policy: A copy of the FCOI policy is posted on NovoPedics' public website per the NIH requirements in the NIH grants policy statement section 4.1.10 Financial Conflicts of Interest.

b. Identified FCOIs held by Senior/key Personnel: Prior to the expenditure of any funds under an NIH award, NovoPedics will ensure public accessibility by written response to any request within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the Senior/key personnel are the PD/PI and any other person identified as senior key personnel by NovoPedics in the award application, progress report, or any other report submitted to the NIH;
2. NovoPedics has determined that the SFI is related to the research funded through an award; and
3. NovoPedics has determined that the SFI is a financial conflict of

The information that NovoPedics will make available via a publicly accessible website or in a written response to any request within five days of request will include, at a minimum, the following:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000, 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.

Should NovoPedics choose to use a publicly accessible website to comply with the public disclosure requirements of the Regulation, the information posted will be updated at least annually and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the Senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of Senior/key personnel new to the NIH-funded research project, if it is determined by the Designated Officials Committee that the Significant Financial Interest is related to the research and is a financial conflict of interest.

Information concerning an individual's SFI, as limited by this Policy, will remain available for responses to written requests or for posting via NovoPedics' publicly accessible website for at least three years from the date that the information was most recently updated.

9. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any funds under an award funded by NIH, NovoPedics will provide to NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

NovoPedics will assign an institutional Official to serve as the FCOI SO (signing Official) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award – no FCOI and no FCOI – no FCOI report).

The FCOI Module User Guide is available at https://www.era.nih.gov/files/fcoi_user_guide.pdf to assist in submitting reports to the NIH.

Initial or original FCOI reports:

- **Prior to the Expenditure of Funds**: When an FCOI is identified upon the issuance of a new NIH award, the FCOI SO will submit a NIH "2011 FCOI" (Original) report prior to the expenditure of any funds under the award as required by the The Original FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888.
- **Within 60 days of Identifying a new FCOI During Award Period:** When an FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator who is participating in the NIH-funded research, upon the participation of an Investigator who is new to the research project,), the Institution will provide to NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the financial conflict of interest.

Annual FCOI reports: While the award is ongoing (including any extensions with or without funds), the Institution will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI (i.e., an indication whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

The Annual FCOI report will be submitted at the same time as when the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if applicable, per the NIH guidance (see NIH's FAQ H.2. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888).

Annual FCOI reports are not submitted as part of grant closeout.

REVISION (or Mitigation) FCOI REPORTS: Following the completion of a retrospective review, the Institution will provide NIH with a Revision if new information is discovered or a Mitigation Report if bias is found.

Types of FCOI Reports Summary Chart for NIH:

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	**CONTENT**	**REQUIRED WHEN?**
New FCOI Report (Initial submission	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	Prior to the expenditure of funds; Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to the originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings, and Conclusion.	When bias is found retrospective review.

10. TRAINING REQUIREMENTS

Each Investigator will be informed about NovoPedics' Financial Conflict of Interest Policy and be trained on the Investigator's responsibility to disclose foreign and domestic SFIs per this policy and of the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years and immediately (as defined below) when any of the following circumstances apply:

1. NovoPedics revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators;
2. An Investigator is new to NovoPedics research under an NIH award (training is to be completed prior to his/her participation in the research); or
3. NovoPedics finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the Designated Official(s)).

In fulfillment of the FCOI training requirement of the FCOI regulation, NovoPedics requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes. Additionally, NovoPedics also requires its investigators to acquaint themselves with the NIH Virtual Seminar presentation containing helpful information on developing or refining institutional FCOI policies to ensure compliance with the FCOI regulation – https://www.youtube.com/watch?v=D292YZ6BX24.

11. FAILURE TO COMPLY WITH NOVOPEDICS FINANCIAL CONFLICT OF INTEREST POLICY APPLICABLE TO NIH FUNDED AWARDS

Whenever NovoPedics identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the Designated Officials Committee will within 60 days: review the SFI, determine whether the SFI is related to research; determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward. NovoPedics will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI,

- failure by the Institution to review or manage such an FCOI; and
- failure by the Investigator to comply with a management plan;

NovoPedics will within 120 days of determining non-compliance:

1. Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
2. Document the retrospective review consistent with the regulation at 42 CFR 605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888.

If bias is found, NovoPedics shall notify NIH promptly and submit a mitigation report per the regulation at 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896 to NIH via the eRA Commons FCOI Module that shall address the following:

1. Impact of the bias on the research project, and
2. NovoPedics' plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, NovoPedics shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, NovoPedics may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of NovoPedics' independent retrospective review. If bias is not found, no further action is required.

12. CLINICAL RESEARCH REQUIREMENTS

If HHS determines that one of its funded clinical research projects 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 a Financial Conflict of Interest that was not managed or reported by NovoPedics shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

13. SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds flow down from or through NovoPedics to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to NovoPedics for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub- awardees, are subject to NovoPedics' terms and conditions, and as such, NovoPedics will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

NovoPedics will incorporate, as part of a written agreement with the subrecipient, terms that establish whether NovoPedics' FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written Agreement at:

https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm#Written.

If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with NovoPedics that its policy is in compliance with the federal FCOI regulation. In this situation, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to NovoPedics in sufficient time to enable NovoPedics to provide timely FCOI reports, as necessary, to the PHS/NIH as required by the regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement may establish a reporting requirement of FCOIs identified during the period of an award to be submitted to NovoPedics within 50 or 55 days of the subrecipient's identification of an FCOI to allow NovoPedics to report the FCOI within the 60-day period. The NovoPedics assigned FCOI DO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.

If the subrecipient cannot provide the certification of compliance with the FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to NovoPedics' FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for NovoPedics. Therefore, NovoPedics will require the submission of all Investigator disclosures of SFIs to NovoPedics. The agreement will include sufficient time period(s) to enable NovoPedics to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, NovoPedics will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

14. MAINTENANCE OF RECORDS

The Institution will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. NovoPedics will retain records for each competitive segment as provided in the regulation.

15. ENFORCEMENT ACTIONS: FAILURE TO COMPLY WITH THIS POLICY

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Therefore, such Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment or contract, and/or disqualification from further participation in any PHS/NIH-funded research, etc., as may be deemed appropriate.

16. USEFUL FCOI AND NIH RECORDS

- FCOI Regulation 42 CFR Part 50 Subpart F-Promoting Objectivity in Research: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
- Financial Conflict of Interest: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- FCOI Training: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- FCOI Frequently Asked Questions (FAQs): https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- Information for Foreign Grants: https://grants.nih.gov/new-to-nih/information-for/foreign-grants
- NIH's Welcome Wagon letter at NIH 'WELCOME WAGON' LETTER Information for New Recipient Organizations: https://grants.nih.gov/policy-and-compliance/welcome-wagon

17. POINT OF CONTACT

If you have a question related to the Financial Conflict of Interest Policy of NovoPedics or would like to disclose a financial interest, contact us using the information below.

Contact: NovoPedics, Inc., Dr. Kevin Weadock, tel. 908-656-4102; contact form: https://www.novopedics.com/contact.php

REVISION HISTORY RECORD

Rev #	Section/ Page	Reason for Change	Effective Date
000	N/A	Initial release	07-02-2025
001	Sec. 13, pg. 14	Subrecipient requirements – corrected for new link General – removed “confidential & proprietary” footer	07-07-2025