

Responsibility of Applicants for Promoting Objectivity in Research 42 CFR Part 50 Subpart F

Novuson's Financial Conflict of Interest (FCOI) Policy

This policy addresses regulation 42 CFR, 50 Subpart. The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and report in research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigators financial conflicts of interest. This policy applies to investigators who are planning to participate in or who are participating in federally funded research. The company will assign a person, the Designated Official (DO) to solicit and review disclosure as is required by this policy.

Generally, "Significant Financial Interests" include all travel reimbursements of any amount, any equity interest in a privately-held entity other than Novuson Surgical Inc (NSI) and all other financial interests having a value in excess of \$5,000. Financial interests of a lesser amount do not require handling under this FCOI Policy. A more precise definition is given below.

Conflict of interest definition/Policy: 42 CFR 50.604(b)

Significant financial interest means:

1. **Policy:** A financial interest must be reported to the DO if it consists 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:
 - a. 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
 - b. With regard to any nonpublic 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
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. 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.

3. 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 20U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

FCOI Training: 42 CFR 50.604(b)

The DO shall ensure investigators understand this policy when they are engaged in a project funded by a federal grant and ensuring that each Investigator is informed about:

1. This FCOI Policy
2. The Investigator's responsibilities regarding disclosure of Significant Financial Interests relating to the Investigator's Company Responsibilities
3. The FCOI Regulations.

Training may consist of a group meeting, a one to one meeting, an online meeting, individual review of the policy or any method that will convey the information contained in 42 CFR Part 50 subpart F.

The DO shall require each Investigator to complete training regarding this policy prior to engaging in research related to any federal funded grant project, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies:

1. This FCOI Policy or the Disclosure Form are revised in any manner that affects the requirements of the Investigators
2. An Investigator is newly appointed at the Company
3. The Company finds that an Investigator is not in compliance with this FCOI Policy or management plan

Disclosure, Review and Monitoring Requirements: 42 CFR 50.604e(1-3)

1. **Disclosure:** A disclosure form will be distributed to investigators. The form will require the investigators to disclose SFI of the investigator, their spouse and dependent children that meet or exceed the regulatory definition of SFI:
 - a. No later than the time of application for federal funded research
 - b. At least annually during the period of the award
 - c. Within 30 days of discovering or acquiring a SFI

2. **Review:** This policy and the FCOI are guidelines are for the DO to use in determining if an investigator's SFI is related is a FCOI. A FCOI exists when the institution's DO reasonably determine that the significant financial interest could *directly and significantly affect the design, conduct, or reporting* of the federally funded research. 42 CHR 50.604(f)
 - a. Prior to Novuson's expenditure of federal grant funds Novuson's DO will: 42 CHR 50.605(a)(1)
 - i. Review all investigators SFI Disclosures
 - ii. Determine if the SFI's are related to the federally funded research
 - iii. Determine if an FCOI exists (*SFI that could directly and significantly affect the design, conduct or reporting of the funded research*)
 - iv. Development and implement management plans to address the FCOI
 - b. Item a.i-iv, will also apply when there is a new investigator on the federal grant. 42 CHR 50.605(a)(2)
 - c. Items a.i-iv, will apply within 60 days of discovering a SFI that was not previously known. 42 CHR 50.605(a)(3) and (i)-(iii)
3. **Monitoring Subrecipients:** Subrecipients will be reviewed for FCOI using the SFI Disclosure Form. If a FCOI exists, then subrecipients compliance with management plans will be monitored until completion of the project. See Subrecipient Requirements below.

Reporting Requirements to NIH 42CFR 50.604(h) and 42CFR 50.605(b)

1. Novuson's DO and investigators will work together to send accurate FCOI reports to NIH
 - a. Prior to the expenditure of funds
 - b. Within 60 days of the start of a new investigator participating on the project
 - c. Within 60 days of newly identified FCOI
 - d. At least annual and/or when the company is required to file progress reports.
 - e. Following a retrospective review to update a previous FCOI report if applicable.
2. When the company identifies a SFI that was not disclosed timely by an investigator or was not reviewed by the company during the federal award grant period, the DO within 60 days will review the SFI, determine if it is related to a federal award and if it is a FCOI. If appropriate, previous FCOI reports will be updated specifying the actions to be taken to manage the FCOI.
3. *If bias is found*, the company will immediately contact the awarding agency and submit a mitigation plan to include elements described in 42CFR50.605(a)(3)(iii).
4. If an investigator fails to comply with the FCOI policy or the management plan where it appears to have biased the design, conduct, or reporting of the federally funded research,

the company will immediately notify the awarding agency to discuss corrective action. The awarding agency may take action or require the company to act. Investigators who are noncompliant may be dismissed from the company. 42CFR 50.606(a)

Maintenance of Records 42CFR50.604(i)

The company is required to maintain disclosure forms and related actions taken by the company for all FCOI related incidences for at least 3 years from the date of the final expenditures report or from other dates specified in 45CFR74.361 where applicable.

Enforcement Mechanisms and Remedies and Noncompliance 45CFR50.604(j)

The DO is ultimately responsible to make sure disclosures are made in a timely manner. If a staff member is found not to have disclosed SFI, the DO will inform the grant's Primary Investigator and the awarding

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agency will be contacted. Corrective action will be decided by either the company or the awarding agency. The severity of the corrective action will be commensurate with the intent and severity of the nondisclosure action. Whenever a FCOI is not identified or managed in a timely manner including the investigator to disclose SFI that is determined by the company to be a FCOI, failure by the institution to review or manage such a FCOI, or failure by the investigator to comply with the FCOI management plan, the company will within 120 days of determining noncompliance, complete a retrospective review of the investigators activities and the awarded research project to determine if any funded research conducted during the time period of noncompliance was biased in the design, conduct or reporting.

42CFR50.605(a)(3)

If it is determined the federal grant funds used in a project whose purpose is to evaluate the safety or effectiveness of the company's medical device has been designed, conducted, or reported by an investigator with a FCOI that was not managed or reported by the company as required, the company will require the investigator to disclose the FCOI in each public presentation of the research results and append previous related publication. 42CFR50.606(c)

Subrecipient Requirements 42CFR50.604(c) and NIH Grants Policy Statement 15.2.1

A Financial Conflict of Interest Policy will be included in the written agreement between a subrecipient and the company. The FCOI policy must comply with 42 CFR Part 50 Subpart F: Responsibility of Applicants for Promoting Objectivity in Research. If applicable, the subrecipient must provide certification it is compliant with this regulation. If applicable, subrecipient must present disclosure forms that identify SFI to Novuson 60 days before expenditure of funds so the company can investigate the SFI for FCOI. The FCOI reports will be sent to the awarding agency prior to expenditure of funds and within 60 days of any subsequent identified FCOI.

Public Accessibility Requirements 42CFR50.604(a)

1. Novuson will make the company's FCOI policy available to the public through website access.
2. Novuson will post identified FCOI of investigators. The posted information will include:
42CFR50.605(a)(5)(i-iv)
 - a. Investigator's name, title and role on the funded project
 - b. Name of entity where the SFI is held
 - c. The nature of the SFI
 - d. The approximate dollar value or a statement that a dollar value cannot be determined through a dollar value or by other reasonable measures of fair market.
3. The information will be posted on the company's website, it will be updated annually, updated 60 days of newly identified FCOI and be available for 3 years from the date the information was most recently updated.