

FINANCIAL CONFLICT OF INTEREST POLICY

Policy Statement

It is the policy of Novilytic, LLC to ensure that personnel avoid situations in which personal interests may affect, or have the appearance of affecting, their professional judgment in exercising their duties or responsibilities, or in conducting or reporting research. This policy provides guidance to help personnel manage situations in their personal affairs, employment outside Novilytic, LLC, and financial activities that may appear to conflict with their responsibilities. Novilytic, LLC personnel should promptly disclose the circumstances of any situation that might be covered by this policy. This policy applies to any Novilytic, LLC member acting as Investigator or as a Senior/Key personnel on any Public Health Service (PHS) research project and any Sub-recipient of that project.

Procedure Statement(s)

This procedure is designed to comply with PHS regulations (42 CFR Part 50 Subpart F, Promoting Objectivity in Research, 45 CFR Part 94, Responsible Prospective Contractors). These standards and procedures are intended to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator FCOIs. Novilytic, LLC Conflict of Interest Policy implements the requirements of these federal regulations.

Disclosure Requirements

By the time a proposal is submitted to PHS, all investigators, senior or key personnel requesting PHS funding—whether grant, cooperative agreement, or contract—are required to have submitted to the Company Official (CO) a Financial Interest Disclosure Form. These completed forms either indicate that the investigators, senior or key personnel has no significant financial interests (SFI) or includes a listing of known SFIs (and those of the spouse and dependent children) in entities whose financial interests would reasonably appear to be affected by the research for which PHS funding is sought. Financial disclosures must be updated by all investigators, senior or key personnel on an annual basis during the award period or as new reportable SFIs are obtained, whichever occurs first.

Responsibilities

PHS-Funded Investigators/Senior/Key Personnel:

- Must complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Must complete and submit to the CO a Financial Interest Disclosure Form prior to working on PHS-funded projects.
- Must update the Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.

Sub-Recipient:

- Must complete and submit to the CO a Sub-Recipient FCOI disclosure form prior to working on PHS funded projects.
- Sub-recipient organization will certify that it has a PHS FCOI compliant policy in place or that it intends to have one in place at the time of the award or that it will abide by Novilytic, LLC policy.

- Sub-recipient organization will certify that the investigators, senior and/or key personnel will complete required training.

Company Official (CO):

- Must record and review all Financial Interest Disclosure forms from PHS-funded researchers to determine whether a FCOI exists.
- Must provide required information concerning FCOIs to the expenditure of PHS funds, and must update such information at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first.
- Must prepare the Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
 - Project/Contract number
 - Investigator's name
 - Investigator's title and role with respect to the research project
 - Name of the entity in which the relevant significant financial interest (SFI) is held
 - Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
 - Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.)
- For reported FCOIs, must develop a FCOI management plan to include: role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the PHS research project; confirmation that Investigator agrees with the FCOI Management Plan; and how the FCOI Management Plan will be monitored.
- Must maintain for three years records of all Statement of Financial Interest Disclosure form records and FCOI Management Plans.
- Maintains the FCOI Policy and Procedure on the Novilytic, LLC external website.

CEO Ensures compliance with FCOI policy and procedures.

- In cases where a potential FCOI exists, assists in the development and implementation of FCOI Management Plan in consultation with the CO. The FCOI Management Plan must be completed in advance of Novilytic, LLC expending PHS funds and a summary of the management plan must be included in the FCOI Report.

Definitions:

For the purposes of this procedure, the following definitions apply:

- Company Official means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's Company Responsibilities.
- Company Responsibilities means the Investigator's responsibilities associated with his or her Company appointment or position, such as research, teaching, administration, and internal and external professional committee service.
- Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees,

paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

- Investigator means the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.
- Sub-recipient means any party that has entered into an Agreement with Novilytic, LLC as a sub-grantee, subcontractor, collaborator, contractor, or consultant.
- Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Company Responsibilities, and is:
 - a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received 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
 - b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
 - c) if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
 - d) income related to intellectual property rights and interests not reimbursed through the Company.

The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Company 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.