 NOVOBIOTIC PHARMACEUTICALS	Policy		
	NovoBiotic Pharmaceuticals Financial Conflict of Interest Policy		
FCOI_Policy_001		Effective Date: 30 November 2020	

NovoBiotic Pharmaceutical. Company Policy - Financial Conflict of Interest (FCOI) Policy

Objective research is of paramount importance to NovoBiotic Pharmaceuticals to ensure public trust and meet scientific, programmatic and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) have published final rules. NovoBiotic Pharmaceuticals believes we have fully addressed the requirements of this ruling and we will continue to update this policy as needed, particularly related to any changes in personnel, FCOI issues, or upon further HHS guidance.

NovoBiotic Pharmaceuticals' policy requires that its investigators and collaborators be in compliance with 42 CFR Part 50, Subpart F, for PHS grants and cooperative agreements and 45 CFR Part 94 for contracts. These enforce NIH's commitment that the research it funds is conducted without bias and with the highest scientific and ethical standards. NovoBiotic Pharmaceutical intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

The following are key term definitions and NovoBiotic Pharmaceuticals' policy guidance for principal or program investigators, as well as collaborators affiliated with NovoBiotic Pharmaceuticals.

Definitions

Investigator

An Investigator is any person who is responsible for the **design, conduct or reporting** of research funded by PHS.

Significant Financial Interest (SFI)


Significant Financial Interest is defined by the regulations as:

1. 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) 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

 NOVOBIOTIC PHARMACEUTICALS	Policy		
	NovoBiotic Pharmaceuticals Financial Conflict of Interest Policy		
FCOI_Policy_001		Effective Date: 30 November 2020	

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, medical center, or 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 a FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, 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, 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.

Financial Conflict of Interest (FCOI)

A financial conflict of interest exists when NovoBiotic Pharmaceuticals reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research.

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Research


PHS research is any project governed by PHS regulation, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Processes

PHS regulations and guidance require specific processes for compliance, not simple recitation of requirements.

Training Requirement

NovoBiotic Pharmaceuticals is required to complete training of its Investigators related to FCOI: the regulations, our Policy, and the Investigator's disclosure responsibilities. The training must be given to each NovoBiotic Pharmaceuticals Investigator (i) upon the effective date of this Policy, (ii) for each new Investigator upon hire, (iii) each time we change requirements for Investigators in this Policy (to the extent required to train the investigators on the new material implemented), (iv) whenever an Investigator has been found not to be following this policy,

	Policy		
	NovoBiotic Pharmaceuticals Financial Conflict of Interest Policy		
FCOI_Policy_001		Effective Date: 30 November 2020	

and (v) no less than every four years or as designated based on grant or role circumstances. NovoBiotic Pharmaceuticals training will use information and other resources developed by NIH, presently at <https://grants.nih.gov/grants/policy/coi/index.htm>

Reporting and Disclosures Process

If any financial conflicts of interest (FCOIs) are found or known, they must be disclosed.

Prior to application for a PHS grant, and not less than annually during grant performance, all NovoBiotic Pharmaceuticals Investigators will review their financial interests and disclose all Significant Financial Interests to the NovoBiotic Pharmaceuticals Head of Grants or their designee. Any Investigator who is new to participating in a research project will review the financial interests policy and disclose all Significant Financial Interests to the NovoBiotic Pharmaceuticals Head of Grants or their designee, prior to beginning effort on the grant. The NovoBiotic Pharmaceuticals Head of Grants, or their designee, will solicit a disclosure from any grant Investigator from whom a required disclosure has not been received.

Prior to beginning performance of a grant project, NovoBiotic Pharmaceuticals' Head of Grants and President, or their designees, will review all disclosures, and determine whether they contain any FCOI as defined above and in PHS regulations. All disclosure forms will be filed in a NovoBiotic Pharmaceuticals SFI file. If a FCOI is identified it will be put on the FCOI report through PHS's eRA Commons FCOI module as promptly as practicable, and prior to expending any grant funds. See *also* Management, below.

If, subsequent to the initial report through PHS's eRA Commons FCOI module, a previously unreported SFI is disclosed or discovered by a NovoBiotic Pharmaceuticals Investigator, or any other employee, office, agent, or subawardee of NovoBiotic Pharmaceuticals, such FCOI must be reported to NovoBiotic Pharmaceuticals within 30 days. NovoBiotic Pharmaceuticals' Head of Grants and President, or their designees, will review and then report any actual FCOI as promptly as practical, and within 60 days, to the PHS awarding component that issued the award. See *also* Management, below.


Designees may be necessary where, for example, the Head of Grants or the President will have some role in reporting research results, and thus is an "investigator" under the regulations and must submit a disclosure of SFIs.

Records Management

The records of all financial disclosures and all actions taken by NovoBiotic Pharmaceuticals will be maintained in an SFI binder or binders, for at least three years from the date of submission of the final expenditures report for each PHS research grant, and throughout the completion of any litigation, claim, negotiation, audit or other action involving the records, whichever date is later. The Head of Grants is responsible to ensuring that records are placed in SFI binders and maintained the required time. SFI files may state a disposition date (the latest date) when they are full; such legends must be updated if a litigation, claim, negotiation, audit or other action involving the records require a later disposition date.

Management of a FCOI

NovoBiotic Pharmaceuticals' designated official(s) will take case-by-case action to address each FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Being a small company, this process must be adaptable, but in the event of any identified FCOI, must include either reducing or eliminating the FCOI, must include monitoring each Investigator to ensure compliance with management plan requirements, must include reporting promptly to NIH any discovery of noncompliance or other bias related to an enacted management plan, and must include reporting on the FCOI as described above and at least annually thereafter (during the grant performance) in time for the funding PHS Institution's annual report.

	Policy		
	NovoBiotic Pharmaceuticals Financial Conflict of Interest Policy		
FCOI_Policy_001		Effective Date: 30 November 2020	

Publication of PHS Research Performed by an Investigator with an FCOI

If a PHS-funded project is conducted by an Investigator with a conflict that was not disclosed or managed, NovoBiotic Pharmaceuticals will disclose the conflict in each public presentation related to the results of the research, and request an addendum to each previously published presentation. Any research that is performed despite an FCOI causes a requirement to publish details of the FCOI on the NovoBiotic Pharmaceuticals web page, and to update the details annually on the web page, within 60 days of newly discovered FCOI, and remaining for at least three years from the most recent update. Note that it is NovoBiotic Pharmaceuticals policy not to permit research to proceed with an FCOI; if FCOIs are avoided, such a publication requirement will not be triggered.

Compliance, Enforcement Mechanisms, and Penalties for Non-Performance

If an investigator fails to comply with NovoBiotic Pharmaceuticals' FCOI policy, within 120 days, NovoBiotic Pharmaceuticals shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, NovoBiotic Pharmaceuticals shall report a mitigation plan to the NIH, as described in Processes, above. NovoBiotic Pharmaceuticals will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, NovoBiotic Pharmaceuticals is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported to NIH at the outset. In extreme cases of bias or noncompliance, the Investigator may lose the right to work on the project or receive any future NIH funding, and/or be terminated by NovoBiotic Pharmaceuticals.

Subawards for PHS Research Effort

NovoBiotic Pharmaceuticals' *Policies & Procedures For Federal Grant Subrecipients* apply to all subrecipient awards ("subawards") by NovoBiotic Pharmaceuticals. In addition, subawards for research funded by a PHS Institution will establish in that written agreement that the subrecipient will have and follow its own FCOI policy, compliant with PHS regulations, and will require the subrecipient to report FCOIs it has discovered for its Investigators (or those of its own subrecipients) to NovoBiotic Pharmaceuticals, in a time frame that allows NovoBiotic Pharmaceuticals to timely report to NIH; each reporting time period above will therefore be shortened by at least 5 days in the written subrecipient agreement.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact NovoBiotic Pharmaceuticals' Head of Grants. The Head of Grants is NovoBiotic Pharmaceuticals' designated official to solicit and review disclosures of SFIs; this responsibility may be further delegated by the Head of Grants on a case-by-case basis.