

Scanogen Inc.: Financial Conflict of Interest (FCOI) Policy

December 22, 2020

Purpose of This Policy

This Financial Conflict of Interest Policy (this “**Policy**”) describes certain legal obligations applicable to Investigators’ disclosure of potential Financial Conflicts of Interest (“**FCOI**”). The purpose of this policy is to comply with applicable law and to ensure the objectivity of the research conducted by Scanogen Inc. (“**Scanogen**”), its employees, contractors, and consultants.

Investigators applying for and working on Public Health Services (“**PHS**”), National Institutes of Health (“**NIH**”), or National Science Foundation (“**NSF**”) funded research must disclose significant financial interests that are related to the Investigator’s institutional responsibilities. Investigators are all persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, NIH, or NSF (the foregoing agencies, together with any other organizations providing funding through grant or contract to which the regulations contemplated herein apply, collectively, the “**Funding Agencies**”), including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

This policy requires that each Investigator, subrecipient, subgrantee and collaborator affiliated with Scanogen on a Funding Agency project be in compliance with 42 CFR Part 50, Subpart F for grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH’s commitment to preserving the public’s trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. Scanogen intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

Definitions

The following definitions apply to this policy:

An “**Awarding Component**” is the applicable sub-agency of a Funding Agency.

A “**Financial Conflict of Interest**” or “**FCOI**” exists when Scanogen reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of Funded Research.

“**Funded Research**” means any research funded by a Funding Agency.

“Investigator” means any person (including subrecipients, subgrantees, and collaborators) who is responsible for the design, conduct, or reporting of research funded by a Funding Agency.

“Management” of an FCOI means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of Funded Research will be free from bias.

“Significant Financial Interest” (SFI) means a financial interest consisting of one or more of the interests listed in Section 1-4 below of the Investigator (including those of the Investigator’s spouse and dependent children) that reasonable appears to be related to the Investigator’s institutional responsibilities.

An **“SFI Disclosure”** is a report that each Investigator shall submit: (a) annually to the Policy Coordinator; (b) in the event of certain sponsored travel, as set forth in the definition of “SFI” above; and (c) within thirty (30) days of an Investigator discovering or acquiring any SFI.

“Training Requirement” means training related to Financial Conflict of Interest (FCOI) and required under law. All Scanogen Investigators and all defined sub-level vendors are required to complete the Training Requirement. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no less frequently than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

What is an SFI and what is not

1. With regard to any publicly-traded entity, an SFI 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;
2. With regard to any privately held entity, a SFI 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
3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
4. With respect to Significant Financial Interest, Investigators also must disclose (and such disclosure shall constitute an SFI Disclosure, defined below) 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. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator 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 Funding Agency research.

The term SFI does **not** include the following types of financial interests: salaries, royalties, or other remuneration paid by Scanogen to the Investigator if the Investigator is currently employed or otherwise appointed by Scanogen, including intellectual property rights assigned to Scanogen and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator; income from investment vehicles, such as mutual funds and retirements 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.

Disclosures/Reporting Process

Each Investigator shall submit SFI Disclosures (using the Scanogen SFI Disclosure Form) to the Policy Coordinator as follows:

- (a) annually on or before the anniversary date of their initial disclosure;
- (b) promptly in the event of certain sponsored travel, as set forth in the definition of “SFI,” above; and
- (c) within thirty (30) days of an Investigator discovering or acquiring any SFI.

The Policy Coordinator will review each SFI Disclosure and evaluate whether any such SFI Disclosure has given rise to an FCOI. If no FCOI is found, the SFI Disclosure will be filed with the Policy Coordinator’s SFI Disclosure records. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module (or, where Scanogen is a subgrantee or subawardee, then Scanogen will report the FCOI as required under the applicable subgrant or subaward agreement) prior to expending any Funding Agency funds. Scanogen will then report any new FCOIs to the Awarding Component within 60 days. If an Investigator with an FCOI conducts a Funded Research, Scanogen shall disclose the FCOI in each public presentation related to the results of the Funded Research.

Records Management

Scanogen will maintain records of all SFI disclosures, and records of resulting Scanogen action, for at least three years from the date of submission of the final expenditures report for the applicable funding.

Funded Research Exclusions

Funded Research is any project governed by Funding Agency regulations, but excluding applications for *Phase I* support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Compliance and Penalties for Non-Performance

If an Investigator fails to comply with the Scanogen's FCOI policy, within 120 days, Scanogen shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Scanogen shall submit a mitigation report to the applicable Funding Agency, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. Scanogen will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, Scanogen is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Policy Coordinator

If you have a conflict of interest or if you have a question to discuss, contact the Scanogen FCOI Policy Coordinator, Alfredo Celedon, by email aceledon@scanogen.com.

[Downloadable Scanogen SFI Disclosure Form](#)

Glossary of Acronyms

CFR – Code of Federal Regulations

FCOI – Financial Conflict of Interest

NIH – National Institutes of Health

NSF – National Science Foundation

PHS – Public Health Services

SBIR – Small Business Innovation Research

SFI – Significant Financial Interest

STTR – Small Business Technology Transfer