Turing Medical Technologies Inc. (formerly NOUS Imaging Inc.) Financial Conflict of Interest (FCOI) Policy

Effective June 1st, 2020, revised June 12th, 2023

Overview and purpose

Objective research is of paramount importance to Turing Medical to ensure public trust and meet scientific, program 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) has published 42 CFR Part 50.

Turing Medical has developed this policy to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the regulation is found at:

http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf.

Each Investigator, subrecipient, subgrantee and collaborator affiliated with Turing Medical, by NIH or any other applicable grant or contract, is required to be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts).

The following includes key definitions and a summary of Turing Medical's FCOI policy and process.

DEFINITIONS

Investigator

An Investigator is defined as the 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 NIH, or proposed for such funding. Individuals with the role PI or Co-Investigator (Co-I) on a grant are considered Investigators by this definition. It is the responsibility of the Principal Investigator to determine if any other individual's beyond the PIs and Co-Is have the ability to make independent decisions related to the design, conduct, or reporting of the NIH research, who would therefore be considered an Investigator and required to submit disclosures.

Institution

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding. Turing Medical is an institution that applies for and receives NIH funding.

Significant Financial Interest (SFI)

A Significant Financial Interest includes any one or more of the following from any single entity OUTSIDE THE COMPANY for activity that is related to the Investigator's professional qualifications:

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:

• 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;

• 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

• 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, 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 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 institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, an academic teaching hospital, a medical center, research 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 Institute that is affiliated wit

For simplicity and clarity, a Significant Financial Interest of Conflict would exist in the following (non-exclusive) examples:

(i) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that sponsors their research project;

(ii) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that produces products (equipment, software, compounds, drugs, devices, etc.) or services used in their research project;

(iii) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that develops product or services their research project intends to evaluate or develop; or

(iv) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity with whom they are consulting in an area that overlaps with or is the main subject of his/her research.

Financial Conflict of Interest (FCOI)

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

Management of a FCOI

Means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

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 regulations but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

POLICY REQUIREMENTS

Training Requirement

Turing Medical Investigators are required to complete training related to Financial Conflict of Interest (FCOI). The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide educational training on what constitutes a financial conflict of interest. The training must be completed by each Investigator prior to engaging in the NIH funded research, at least every 4 years, and immediately if an investigator is new to the institution or not in compliance with the policy or management plan.

The course is available at (<u>http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm</u>).

Investigator's Disclosure Responsibilities

Turing Medical requires that Investigators (defined above) disclose all SFIs on the Significant Financial Interest Disclosure Form (SFIDF). This form provides a mechanism for all Investigators to submit an itemized disclosure statement regarding SFI categories. It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in accordance with the federal policy. The SFIDF shall be completed prior to engaging in the NIH funded research, whenever a new SFI arises during research, and no less than annually (regardless of whether a SFI exists). Specifically, it is required at the following timepoints:

- No later than at the time of application for PHS-funded research
- At least annually during the period of the award
- Within 30 days of discovering or acquiring a new SFI

Investigators shall return complete and signed SFIDFs and any supporting materials to the designated Institutional Official (noted below) via email.

Disclosure review and reporting process

Turing Medical's designated Institutional Official(s) will review all SFIDFs and determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. If no FCOI is found, the disclosures will be filed for record keeping. If an FCOI is identified, the designated Institutional Official will develop and implement management plans as needed. Management of an FCOI will be monitored by the Institutional Officials. All identified FCOIs will be reported to NIH through the eRA Commons FCOI module in accordance with the regulation requirements and at the time points defined by the regulation. If any interests are identified as conflicting subsequent to the initial report they must be reported to Turing Medical within 30 days. Turing Medical will then report it to the PHS awarding component that has issued the award within 60 days. Each Investigator must submit an updated disclosure of an SFI not less than annually.

Compliance and Penalties for Non-Performance

Investigators are expected to comply fully and promptly with this policy. If an Investigator fails to comply with Turing Medical's FCOI policy, within 120 days, Turing Medical shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Turing Medical shall submit a mitigation report to the NIH, 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. Turing Medical will work with the Investigator to set up an FCOI management plan to mitigate the situation. If a PHS-funded project is conducted by an Investigator with a conflict that was not disclosed or managed, Turing Medical is required to disclose the conflict in each public presentation related to the results of the research. Companywide, Turing Medical 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.

Subrecipient Requirements

Turing Medical requires that all subrecipients on their NIH funded awards follow the subrecipient Institution's FCOI policy. Written and signed subaward agreements are in place for existing awards, and will be put into place on any future awards, that certify that the subrecipient will follow its own FCOI policy and that their policy complies with the federal regulation. Subrecipients must report any FCOIs to Turing Medical's Institutional Official. Such reports will subsequently be reported to NIH.

Records Management

All FCOI-related records will be maintained for at minimum, the time period specified in the federal regulations. The records of all financial disclosures and all actions taken by Turing Medical will be maintained for at least three years from the date of submission of the final expenditures report.

Public Accessibility Requirements

This FCOI policy is publicly accessible on our website at <u>www.turingmedical.com</u>. Any future updates to this policy will be posted publicly upon implementation. Any information concerning identified FCOIs held by Investigators will be made available within 5 calendar days of a written request in compliance with the regulation.

Point of Contact

If you have a conflict of interest or if you have questions, please contact Turing Medical's Institutional Officials:

Primary Institutional Official: Laura Young (<u>laura.young@turingmedical.com</u>). Secondary Institutional Official: Carl Eschbach (<u>carl.eschbach@turingmedical.com</u>).