

Financial Conflict of Interest Policy for Federally Funded Research

FCOI-Policy-01 Effective Date: May 12, 2023

Policy Statement:

AimMax Therapeutics, Inc. (AimMax) is committed to protecting the objectivity and integrity of its research and development activities to ensure public trust and to meet scientific and ethical standards of AimMax's National Institutes of Health (NIH) grants or Public Health Services (PHS)-funded research efforts. AimMax has implemented this Financial Conflict of Interest (FCOI) Policy for Federally Funded Research ("Policy") to require its employees, contractors and collaborators who are Investigators to be compliant with 42 CFR part 50, Subpart F ("Regulations") when participating in research activities at AimMax that are supported or sponsored by NIH grants or PHS funding except for Phase I SBIR and Phase I STTR grants ("covered research"). This Policy is to be updated periodically as needed to comply with changes in the Regulations.

Definitions:

<u>Investigator</u>: An Investigator is any person who is responsible for the design, conduct or reporting of the covered research funded by NIH or PHS at AimMax. The principal investigator of a funded project shall determine which individual is responsible for the design, conduct, or reporting of the covered research.

Administrator: The Chief Executive Officer of AimMax shall designate an FCOI Policy Administrator who is not an Investigator to administer this Policy according to the Regulations. The FCOI Policy Administrator shall oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests. This Administrator is also the Point of Contact for the discussion and resolution of any emergent issues relating to the FCOI Policy.

Significant Financial Interest (SFI): Significant Financial Interest means a financial interest (anything of monetary value) consisting of one or more of the following interests of the Investigator and his/her immediate family (spouse or dependent children) that reasonably appear to be related to the Investigator's project or research responsibility at AimMax, including:

- 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;
- 2) 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



3) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of >\$5,000 income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that is paid on behalf of the Investigator and not directly reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their 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 details of such disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The AimMax FCOI Policy Administrator 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.

The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by AimMax to the Investigator if the Investigator is currently employed or contracted by AimMax, including intellectual property rights assigned to AimMax and agreements to share in royalties related to such rights; any ownership interest in AimMax held by the Investigator; income from investment vehicles, such as mutual funds, brokerage accounts 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, medical center, or 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.

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

<u>Financial Conflict of Interest</u>: A financial conflict of interest exists when AimMax FCOI Policy Administrator reasonably determines that a disclosed Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH- or PHS-covered research as defined in the Policy Statement above.

Processes:

<u>Training Requirements</u>: Investigators must be trained on the FCOI regulation on disclosure of Significant Financial Interest and the AimMax FCOI Policy. AimMax shall require each Investigator to complete training of this Policy prior to engaging in the covered research defined in the Policy Statement and thereafter at least every four years, and immediately when any of the following circumstances apply: (i) AimMax revises this Policy or any procedures in a manner that affects the requirements of Investigators; (ii) an Investigator is



new to AimMax; or (iii) AimMax finds that an Investigator is not in compliance with this Policy or a management plan (see below) instituted by AimMax. The training of Investigators and scientific personnel at AimMax will use information and resources developed by NIH at https://grants.nih.gov/grants/policy/coi/index.htm
http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

<u>Disclosure and Reporting</u>: If any financial conflict of interest is found or known, it must be disclosed and reported. All Investigators at AimMax must submit to the AimMax FCOI Policy Administrator a disclosure form ("SFI Disclosure Form") under this Policy that discloses all Significant Financial Interests in the covered research at the following times: (i) for employees, contractors and collaborators who have not previously disclosed their SFIs and who are proposed Investigators in an application or Investigators in a funded grant or support, disclosure is to be made prior to applying for an NIH or PHS grant and prior to engaging in the covered research defined in the Policy Statement; (ii) annually if participating in the covered research defined in the Policy Statement, on or about May 31 each year; or (iii) as soon as possible, but not later than 30 days, after discovering previously unreported Significant Financial Interest or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. All completed SFI Disclosure Forms will be filed in an AimMax SFI file.

Prior to beginning performance of a NIH or PHS grant funded project, the AimMax FCOI Policy Administrator will solicit from Investigators SFI Disclosure Form and determine whether an Investigator's SFI is related to the covered research defined in the Policy Statement, and if so related, whether the SFI is an FCOI that could directly or significantly affect the design, conduct or reporting of the NIH funded research. If the Investigator eliminates the FCOI and revises and resubmits the report to the Administrator, then no further action is needed. Any existing FCOIs will be handled based on the management plan of this Policy (see below).

AimMax shall report any FCOI identified as promptly as practical and within 60 days through the PHS eRA Commons FCOI module and prior to expending any grant funds involving the specific Investigator with an FCOI who is newly participating in the covered research. For existing Investigators on a covered research project, if a previously unreported FCOI of the Investigator is discovered, it must be reported as promptly as practical, and within 60 days, to the PHS awarding component that issued the award. Reporting is also required at the time when AimMax is to submit the annual progress report or multi-year progress report, if applicable, or at time of extension for covered research defined in the Policy Statement, the status of the FCOI and any changes to the management plan (see below), or until the completion of the funded project. If a bias is found with the design, conduct or reporting of the covered research under this Policy, a mitigation report will also be included in the reporting process.

Management Plan of FCOI: AimMax FCOI Policy Administrator will implement a plan by taking 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 company of small business, this process must be adaptable, but in the event of any identified FCOI, must include actions that either reduce or eliminate the FCOI, must include monitoring each Investigator to ensure compliance with the management plan requirements, must include reporting promptly to NIH discovery of a bias with the design, conduct or reporting of the



funded research, or noncompliance of the Investigator with an FCOI and any corrective action taken.

In addition, for any FCOI previously reported by AimMax with regard to ongoing covered research, AimMax shall provide to the appropriate PHS agency an annual FCOI report that addresses the status of the FCOI resolution and any changes to the management plan for the duration of the covered research. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Maintenance of Records: The records of all AimMax SFI Disclosure Forms and actions taken by AimMax will be maintained in a secured SFI folder for at least 3 years from the date of submission of the final expenditures report for each NIH/PHS funded grant project, and throughout the completion of any litigation, claim negotiation, audit or other action involving the records, whichever date is later. The AimMax FCOI Policy Administrator is responsible to ensure that records are placed and maintained during the required time period.

Enforcement Mechanisms and Remedies for Noncompliance: If AimMax discovers that an Investigator fails to comply with the AimMax FCOI Policy, within 120 days, AimMax shall remedy such noncompliance and complete and document a retrospective review of the Investigator's activities to determine if any bias exists. If a bias is found, AimMax shall provide a mitigation report to the NIH/PHS as described under the Reporting process above. AimMax will work with the Investigator to set up a management plan to mitigate the situation companywide, and mandate the Investigator to disclose the FCOI in each public presentation or publication of the results of the affected research if it was not reported to NIH at the outset. AimMax shall also disclose the Investigator FCOI in each public presentation related to the results of the affected research, and request an addendum to each previously published presentation. Any research that is affected by the FCOI shall not be allowed to proceed; if FCOIs are avoided or eliminated, such public disclosure requirement will not be triggered.

Extreme cases of bias or noncompliance with this Policy by an Investigator will result in disciplinary action by AimMax up to and including termination of employment, contracting or collaborating relationship with AimMax.

<u>Subaward or Subrecipient Requirements</u>: If any covered research at AimMax involves subawards to subrecipients, AimMax must take reasonable steps to ensure that any Investigators in the subawards (subrecipients) comply with this Policy and the federal Regulations by incorporating as part of a written agreement with the subrecipient terms that establish (i) that this Policy will apply to Investigators of the subawards; (ii) time periods for the subrecipient to submit disclosures of SFI, which time periods shall allow sufficient time for AimMax to comply with its requirements under this Policy; and (iii) that the subrecipient will accept any determination by the AimMax FCOI Policy Administrator that an FCOI exists and shall enforce on its Investigators any management plan established by the AimMax FCOI Policy Administrator.

<u>Public Accessibility</u>: AimMax shall publicly disclose this Policy on its company's website. The SFI disclosures and FCOI records on file shall be available for audit by the PHS awarding component. Any identified and existing FCOIs with a direct and significant impact on the design, conduct or reporting of NIH- or PHS-funded research will be publicly disclosed.