

Abzyme Therapeutics LLC (Abzyme) Policy – Financial Conflict of Interest (FCOI) Policy (the “Policy”)

This Policy strives to ensure that the design, conduct and reporting of research meets the highest standard of integrity and is free from any bias and real or perceived financial conflicts of interest that could harm patients, the reputation of Abzyme, and any governmental agency providing funding.

Abzyme’s Policy is intended to comply with the requirements of federal regulations, including the conflict of interest regulations of the U.S. department of Health and Human Services Public Health Service (the “PHS FCOI Rules”) as found in [42 CFR Part 50 Subpart F](#) (titled Promoting Objectivity in Research) and [45 CFR Part 94](#) (titled Responsible Prospective Contractors).

The following are *key term definitions*, and Abzyme’s policy guidance for all its employees, sub recipients, consultants, or any covered organizations or persons involved in receiving governmental funding by means of a grant. A complete list of official definitions can be found at [42 CFR 50.603](#).

Institution - means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding.

Institutional responsibilities – means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator - means the project director or principal Investigator 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.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable. Financial Conflict of Interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the Regulations.

Training Requirement - Each Investigator is required to complete training relating to Financial Conflict of Interest (FCOI). If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less 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).

Significant Financial Interest (SFI) - 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:
 - o 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 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or 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 remuneration received 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 interest (e.g., stock, stock option, 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 (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, a medical center, or a 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 an FCOI with the PHS-funded research.
 3. The term *significant financial interest* does not include the following types of financial interests: salary, 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, 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.

A Financial Conflict of Interest (FCOI) exists when Abzyme reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of PHS funded research.

Management of a FCOI - means taking necessary 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.

Disclosures by Investigator - Each Investigator must disclose to Abzyme its SFI (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research and thereafter an updated SFI disclosure at least annually. If a new SFI is discovered or

acquired (e.g., through purchase, marriage, or inheritance) an updated disclosure is to be made within thirty days of discovering.

Abzyme's Reporting Process

Abzyme's designated official(s) will review all "disclosure" and evaluate whether they contain any FCOI. If no FCOI is found the "disclosure forms" will be filed in the SFI binder. If a FCOI is identified a FCOI Report will be put through the eRA Commons FCOI module prior to expending any funds. Any SFI identified subsequent to the initial FCOI Report will be reported to the PHS Awarding Component, within 60 days.

Records Management

The records of all financial disclosures and all actions taken by Abzyme will be maintained for at least three years from the date of submission of the final expenditures report.

Compliance and Penalties for Non-Performance

If an Investigator fails to comply with Abzyme's FCOI policy, within 120 days, Abzyme shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Abzyme shall submit a mitigation report to the NIH, in accordance with [42 CFR 50.605\(B\)\(iii\)](#), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. Abzyme will work with the Investigator to set up an FCOI management plan to mitigate the situation. Abzyme shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the Abzyme Institutional Officer, Dr. Hiep Tran (tran@abzymetx.com)



Abzyme Therapeutics LLC. – Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood Abzyme Therapeutics LLC., Financial Conflict of Interest Policy. If you have any questions regarding the Policy contact the Abzyme’s Institutional Officer prior to signing this document.

Investigator Name: _____

Title and Role with Respect to Research Project: _____

Research/Project Title: _____

Research/Project Sponsor: _____

Is this Disclosure: Initial Annual Update

1. Do you, your spouse, or dependent children have a Significant Financial Interest (as defined in the Policy) that would reasonably appear to be affected by this covered “Research”?

Yes No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

2. Do you, your spouse or dependent children have a Significant Financial Interest in any business or legal entity whose financial interests would reasonably appear to be affected by this covered “Research”?

Yes No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

I certify that:

- I have read Abzyme’s Policy on Financial Conflict of Interest.
- I have been trained on FCOI and Abzyme’s Employee Handbook Section– “Financial Conflict of Interest”.
- I have made all required financial disclosures.
- (If the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see Policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature _____ Date: _____