

Financial Conflict of Interest (FCOI) Policy

Objective research is of paramount importance to ZabBio and our sub-grantees and defined vendors herein, to ensure public trust and meet scientific, program and ethical goals of our Department of Health and Human Services (DHHS), National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Services (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published their final rule¹. ZabBio believes we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling, although we will continue to update this policy as needed, particularly related to any changes in personnel FCOI issues or upon further DHHS guidance.

Effective December 1, 2018, ZabBio's policy requires that each investigator, collaborator, sub-grantee, contractor, fee-for-services provider and/or consultant affiliated with ZabBio, by DHHS or any applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS 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. ZabBio 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 ZabBio's policy guidance for principal or program investigators, collaborators, sub-grantees, contractors, fee-for-service providers and/or consultants affiliated with ZabBio.

Investigator

An Investigator is any person (including collaborators, sub-grantees, contractors, fee-for-services providers and/or consultants) who is responsible for the design, conduct or reporting of research funded by PHS.

Training Requirement

ZabBio and all defined sub-level vendors are required to complete training related 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 (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

Financial Conflict of Interest (FCOI) or Significant Financial Interest (SFI)

An SFI is defined as financial interest greater than \$5,000 or that may unduly influence professional judgments about the primary interests or goals of medicine. If the investigator (or an immediate family member) has a Significant Financial Interest (SFI) in any entity that has a business or scientific relationship

with ZabBio, it must be reported as a FCOI. Mutual funds or other investments that an investigator doesn't have the capability of influencing management decisions don't have to be disclosed.

Disclosures/Reporting Process

Any Significant Financial Interests (SFI) that might create a conflict of interest must be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. If any interests are identified as conflicting subsequent to the initial report, they must be reported to ZabBio within 30 days. ZabBio 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 no less than annually. If a PHS-funded project is conducted by an investigator or SO with a conflict that was not disclosed or managed, ZabBio is required to disclose the conflict in each public presentation related to the results of the research.

Management of a FCOI

ZabBio reserves the right to take 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.

Records Management

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

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.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with ZabBio's FCOI policy or a FCOI management plan, ZabBio shall complete within 120 days of determining non-compliance a retrospective review of the Investigator's activities and the NIH-funded research project. If bias is found, ZabBio 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. ZabBio will attempt to work with the investigator to set up a FCOI management plan to mitigate any bias in the design, conduct or reporting of the NIH-funded research. ZabBio is required to mandate the investigator disclose the FCOI in each public presentation of the results of the research 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.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the ZabBio Signing Officials and Principal Investigators, Kevin, J. Whaley, Ph.D., at kevin.whaley@zabbio.com and Larry Zeitlin, Ph.D., at larry.zeitlin@zabbio.com.

¹ Part IV, Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Final Rule. <https://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>