

## **Defined Bioscience Inc. Company Policy – Financial Conflict of Interest (FCOI) Policy, Updated May 4<sup>th</sup>, 2021**

Objective research is of paramount importance to Defined Bioscience and our subgrantees and defined vendors herein, 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 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 their final rules. Defined Bioscience believes we have fully addressed the requirements (including those of our defined sub-awardees) 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 May 4<sup>th</sup> 2021, Defined Bioscience’s policy requires that each investigator, subrecipients, subgrantees and collaborators affiliated with Defined Bioscience, by NIH or any other applicable grant or contract, be in compliance with [45 CFR Part 94](#). 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. Defined Bioscience 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 Defined Bioscience’s policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with Defined Bioscience. This policy and all FCOI Defined Bioscience guidance are also available on company-wide shared “Defined Bioscience Team Folder” under “Employee Information” (FCOI\_Policy\_V2021\_Defined Bioscience Inc) so that all interested parties, have access to this Company policy.

### **Investigator**

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by PHS.

### **Training Requirement**

Defined Bioscience 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. ([https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)).

## Significant Financial Interest (SFI)

Significant Financial Interest 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 reasonable appears to be related to the Investigators 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 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.

### **Financial Conflict of Interest (FCOI)**

A Financial conflict of interest exists when Defined Bioscience 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.

### **Disclosures/Reporting Process**

Defined Bioscience '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 it will 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 Defined Bioscience within 30 days. Defined Bioscience 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. If a PHS-funded project is conducted by an investigator or SO with a conflict that was not

disclosed or managed, Defined Bioscience is required to disclose the conflict in each public presentation related to the results of the research.

### **Records Management**

The records of all financial disclosures and all actions taken by Defined Bioscience 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 Defined Bioscience's FCOI policy, within 120 days, Defined Bioscience shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Defined Bioscience 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. Defined Bioscience will work with the Investigator to set up an FCOI management plan to mitigate the situation.

Companywide, Defined Bioscience 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.