Financial Conflict of Interest Policy: Objectivity in Research

Version 12/22/2020

Policy Statement

Objective research is of paramount importance to Molecular Targeting Technologies, Inc. (MTTI) and our subgrantees 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 their final rules. MTTI believes we have fully addressed the requirements of this ruling and we will continue to update this policy as needed, particularly related to any changes in personnel, FCOI issues, or upon further HHS guidance.

MTTI's policy requires that each investigator, and collaborators affiliated with MTTI by NIH or any other 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. MTTI intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly. These requirements do not apply to Phase I of the SBIR/STTR programs.

The following are key term definitions and MTTI's policy guidance for principal or program investigators and collaborators affiliated with MTTI. This policy and all FCOI guidance are also available at www.mtarget.com so that all interested parties, including the general public have access to this Company policy.

Definitions

As used in this Policy, the following terms shall have the following meanings:

CLINICAL RESEARCH: means any research or procedure involving human subjects in vivo or the use of human samples for the development and evaluation of patient therapies such as diagnostic tests, drug therapies, or medical devices. It includes early clinical studies, evaluative research, epidemiological studies and clinical trials. It excludes research using commercially obtained de-identified human cell lines as well as commercially obtained de-identified human tissue. It also excludes research that uses human tissue obtained from institutional tissue banks where the individual identifiers are unknown to the researcher. In general, the term includes all research required to be reviewed by an institution's Institutional Review Board.

INVESTIGATOR: means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PARTICIPATE: means to be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, study designer, research collaborator, provider of direct patient care, or author on a publication of the research study. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study's results or have privileged information as to the outcome.

PHS AWARDING COMPONENT: means the organizational unit of the PHS that funds the research that is subject to this subpart.

RESEARCH: means a systematic investigation designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

SIGNIFICANT FINANCIAL INTEREST: is defined as:

1. A Financial Interest consisting of one or more of the following interests of the Investigator (and those of its Immediate Family and Dependents) that reasonably appears to be related to Investigator's Institutional Responsibilities:

- Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure that, 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of a fair market value
- Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds $5,000 or any equity interest in such entity
- Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests

- Non-MTTI reimbursed or sponsored travel expenses

A Significant Financial Interest does **not** include any of the following:

- Salary or other remuneration from MTTI
- Any ownership interests in MTTI
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as Investigator does not directly control the investment decisions made in such 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
- Reimbursed or sponsored travel expenses 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

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 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, 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.

SMALL BUSINESS INNOVATION RESEARCH (SBIR): means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

MTTI responsibility regarding conflicting interests of investigators.

MTTI will:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. MTTI will take reasonable steps to ensure that Investigators working for subgrantees, contractors, or collaborators comply with this subpart, either by requiring those Investigators to comply with MTTI's policy or by requiring the entities to provide assurances to MTTI that will enable MTTI to comply with this subpart.

(b) Designate an MTTI official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c) (1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures will be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by MTTI with respect to each conflicting interest for at least three years from the

date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application for the funding to which this subpart applies, that:

(1) There is an effect at MTTI a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to expenditure of any funds under the award, MTTI will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by MTTI and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that MTTI identifies as conflicting subsequent to the initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) MTTI agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by MTTI and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) MTTI will otherwise comply with this subpart.

Management of conflict of interest.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by MTTI to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, MTTI may require the management of other conflicting financial interests, as MTTI deems appropriate.

Non-Compliance

(a) If the failure of an Investigator to comply with the conflict of interest policy of MTTI has biased the design, conduct, or reporting of the PHS-funded research, MTTI will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to MTTI for further action, which may include directions to MTTI on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into MTTI's procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that MTTI has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, MTTI will require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 74—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit

Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments

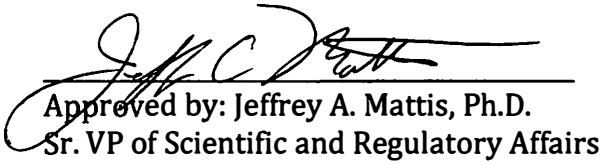
45 CFR part 76—Government-wide debarment and suspension (non-procurement)

45 CFR part 79--Program Fraud Civil Remedies

45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

ORIGINAL CREATION DATE: April 11, 2007
REVISION DATES: December 22, 2020

Responsibility for maintenance of policy: Jeffrey A. Mattis, Ph.D.



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