

EMULATE, INC.

SUMMARY OF FINANCIAL CONFLICT OF INTEREST POLICY FOR PROMOTING OBJECTIVITY IN RESEARCH

Attached are the policies and procedures (“**Policy**”) of Emulate, Inc. (“**Company**”) for identifying and managing financial conflicts of interests relating to research that is funded by the Public Health Service (“**PHS**”) under grants or cooperative agreements. Below is a high-level summary of the contents of the Policy.

1. **Purpose:** The purpose of the Policy is to help the Company identify and manage, through a process of disclosure and review (as described more fully below), any financial conflicts of interest that might affect the objectivity of PHS-funded research that is conducted, designed and reported by or on behalf of the Company.
2. **Applicability:** The Policy applies to all Investigators (as that term is defined below) who participate in, or who are applying to participate in, PHS-funded research on behalf of the Company. For purposes of the Policy, “Investigator” means (a) any principal investigator, project manager or senior/key personnel identified in a PHS grant application or any report furnished to PHS and (b) any other person, regardless of title or position, who has independent decision-making authority with respect to the conduct, design or reporting of the PHS-funded research, including employees, consultants, graduate students, visiting scientists and collaborators. In addition, this Policy applies to the Company’s subcontractors, sub-grantees and sub-awardees who are involved in PHS-funded research.
3. **Disclosure:** There are two main sets of disclosure requirements under the Policy. Those disclosure requirements are as follows:
 - a. Thirty (30) days prior to submitting an application for PHS funds for a research project, the principal investigator/project manager for such research project must submit a written description of the proposed research project to Company’s Policy Administrator, who is the person responsible for managing and administering this Policy. The Policy Administrator will initially be the Company’s Executive Project Manager (or his or her designee).
 - b. The Policy Administrator shall promptly notify all Investigators who are planning to participate in the PHS-funded Research project of this Policy. Each Investigator must disclose to the Policy Administrator any Significant Financial Interests (as that term is specifically defined in the Policy) he or she might have at the following times: (i) when the application for PHS funds for the research project is submitted, (ii) on an annual basis and (iii) within thirty (30) days of becoming a new Investigator on the project or discovering a new Significant Financial Interest. Significant Financial Interests must be disclosed on a special form known as the “Significant Financial Interest Disclosure Form” (“**SFI Disclosure Form**”), which is attached to the Policy as Exhibit B.
4. **Review:** Prior to the Company’s expenditure of any PHS funds for a particular research project, all SFI Disclosure Forms submitted in connection with that research project must

be reviewed as follows:

- a. The Policy Administrator must review all SFI Disclosure Forms and determine if any disclosed Significant Financial Interests are related to the PHS-funded research project. In general, a Significant Financial Interest is related to PHS-funded research if the Policy Administrator reasonably determines that such Significant Financial Interest could be affected by the PHS-funded research.
 - b. If the Policy Administrator determines that any Significant Financial Interests relate to the PHS-funded research project, the Policy Administrator must then forward the applicable SFI Disclosure Forms to the Company's FCOI Officer, who is the person responsible for reviewing and providing recommendations for managing financial conflicts of interests. The FCOI Officer will initially be the Company's Chief Commercial Officer (or his or her designee).
 - c. The FCOI Officer is responsible for investigating Significant Financial Interests it receives from the Policy Administrator to determine whether a financial conflict of interest exists. A financial conflict of interest exists if the FCOI Officer determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research at issue.
- 5. Management:** If the FCOI Officer determines that a financial conflict of interests exists, he or she will decide, prior to the Company's expenditure of any PHS funds for the research project at issue, on the appropriate action to manage, reduce or eliminate such financial conflict of interest and, with support from the Policy Administrator, will develop a plan to mitigate or eliminate the financial conflict of interest ("**FCOI Management Plan**") if necessary to ensure the objectivity of the design, conduct and reporting of the research project. The affected Investigator must agree in writing to the FCOI Management Plan before the research project goes forward.
- 6. Reporting:** (a) Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company must provide to PHS a report regarding any financial conflicts of interests related to the research project, unless such financial conflicts of interests were eliminated. (b) Upon written request by a member of the public, the Policy Administrator must provide written information about any then-existing financial conflicts of interests reported to the Company related to ongoing PHS-funded research projects. (c) Upon inquiry by PHS or the U.S. Department of Health and Human Services at any time before, during or after receipt of PHS funds, the Company must provide information regarding any Investigator disclosure of Significant Financial Interests.
- 7. Training:** All Investigators must complete training regarding the purpose of, and their obligations under, this Policy, at the following times: (a) prior to engaging in a PHS-funded research project, (b) at least once every four (4) years thereafter and (c) immediately when (i) the Company revises this Policy in a manner that affects Investigator requirements, (ii) an Investigator is new to the Company or is new to the PHS-funded research project at issue and (iii) the Company finds that an Investigator is not in compliance with this Policy or a FCOI Management Plan.
- 8. Record Retention:** Records of disclosures of Significant Financial Interests, the Company's review of, and response to, such disclosures and all actions taken by the Company shall be maintained for at least three (3) years as described more fully in the Policy.

EMULATE, INC.

**FINANCIAL CONFLICT OF INTEREST
POLICY FOR PROMOTING
OBJECTIVITY IN RESEARCH**

Effective as of May 2018

EMULATE, INC.

FINANCIAL CONFLICT OF INTEREST POLICY FOR PROMOTING OBJECTIVITY IN RESEARCH

I. INTRODUCTION

The purpose of this Financial Conflict of Interest Policy for Promoting Objectivity in Research (this “**Policy**”) is to ensure that Research (as defined below) funded under Public Health Service (“**PHS**”) grants or cooperative agreements is conducted, designed and reported by or on behalf of Emulate, Inc. (the “**Company**”) in an objective manner by identifying and managing, through a process of disclosure and review, any Financial Conflicts of Interests held by the Investigators (as each term is defined below) who are involved in the Research.

This Policy is written to conform to the PHS regulations regarding Financial Conflicts of Interest, 42 CFR Part 50, Subpart F (the “**Regulation**”), a copy of which is attached hereto as Exhibit A.

II. APPLICABILITY

This Policy is applicable to all Investigators participating in, or applying to participate in, Research funded or to be funded under PHS grants or cooperative agreements for or on behalf of the Company. Every Investigator has an obligation to review and abide by the provisions of this Policy and must undergo training to familiarize themselves with their obligations under this Policy as described more fully herein. Any Investigator with questions regarding Financial Conflicts of Interest or this Policy should contact the Policy Administrator (as defined below) for assistance.

This Policy also extends to any subcontractors, sub-grantees or sub-awardees (collectively, “**Sub-Recipients**”) at other institutions who are conducting Research for or on behalf of the Company, as further described below. The Policy Administrator, on behalf of the Company, will take reasonable steps to ensure that all Investigators or Sub-Recipients comply with this Policy.

III. DEFINITIONS

“**Financial Conflict of Interest**” or “**FCOI**” means a Significant Financial Interest (as defined below) that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

“**Financial Conflict of Interest Management Plan**” or “**FCOI Management Plan**” means a plan developed in accordance with this Policy that specifies the actions that have been, and should be, taken for the management, reduction, or elimination of an identified Financial Conflict of Interest to ensure, to the extent possible, that the design, conduct, and reporting of the Research at issue will be free from bias.

“**Financial Conflict of Interest Officer**” or “**FCOI Officer**” means a representative of the Company who is responsible for reviewing and providing recommendations to manage Financial Conflicts of Interest in accordance with this Policy. The FCOI Officer will be initially

be the Company's Chief Commercial Officer (or his or her designee).

"Financial Conflict of Interest Report" or "FCOI Report" means the Company's report of a Financial Conflict of Interest to the applicable awarding agency of PHS.

"Institutional Responsibilities" means an Investigator's professional activities on behalf of the Company, including as may be described in his or her offer letter, employment agreement, consultancy agreement, visiting scientist agreement or any similar agreement.

"Investigator" means (a) any principal investigator, project manager or senior/key personnel identified by the Company in a PHS grant application, progress report or any other report submitted to PHS by the Company and (b) any other individual, regardless of title or position, who the principal investigator/project manager identifies as having responsibility for independent decision-making for or on behalf of the Company with respect to the design, conduct, or reporting of PHS-funded Research (or proposed for such funding), including employees (full- and part- time), consultants, graduate students, visiting scientists and collaborators.

"Policy Administrator" means the individual within the Company who is responsible for managing and administering this Policy, including the solicitation and review of disclosures of Significant Financial Interests, training of Investigators, record retention, and reporting to funding agencies, sponsors and the public as detailed herein. The initial Policy Administrator shall be the Company's Executive Project Manager (or his or her designee).

"Research" means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., research and development devices and instruments, diagnostic tests or drugs).

"Significant Financial Interest" or "SFI" means:

1. A financial interest consisting of one or more of the following interests of the Investigator (aggregated together with those of the Investigator's spouse, same-sex domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - a. 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 (12) 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**. 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;
 - b. 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 (12) months preceding the disclosure, when aggregated, **exceeds \$5,000**, or if any equity interests are held (e.g., stock, stock option, or other ownership interest);

- c. With regard to any **intellectual property rights and interests** (e.g., patents, copyrights), a *significant financial interest* exists upon receipt of income of related to such rights and interests; or
- d. With regard to any **third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse, same-sex domestic partner and dependent children), a *significant financial interest* exists if it is related to the Investigator's Institutional Responsibilities; provided, however, travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, an institution of higher education as defined in 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 shall not be deemed to be a *significant financial interest*.

2. The term *significant financial interest* does not include the following:

- a. Salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
- b. Any ownership interest in the Company held by the Investigator;
- c. 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;
- d. Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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
- e. Income from service on advisory committees or review panels for an U.S. 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.

IV. DISCLOSURE PROCEDURES

Thirty (30) days prior to submitting an application for PHS funds for a Research project, the principal investigator and/or project manager for such project (or their designees) is responsible for accurately completing and submitting to the Policy Administrator a written description of the Research project at issue, which description shall include a list of the internal and external Investigators and Sub-Recipients who will participate in the Research project.

The Policy Administrator shall promptly notify all Investigators who are planning to participate in the PHS-funded Research project at issue of this Policy. Each Investigator must disclose to the Policy Administrator any Significant Financial Interest he or she might have on the Significant Financial Interest Disclosure Form attached hereto as **Exhibit B** (the

“**SFI Disclosure Form**”) at the following times:

1. At the time of submitting the application for PHS funds for the Research project (“**Initial Disclosure**”);
2. On an annual basis on (a) the date the Company submits its annual progress report to PHS for the applicable Research project or (b) twelve (12) months after the notice of award for the Research project, whichever is earlier (“**Annual Disclosure**”); and
3. Within thirty (30) days of (a) becoming a new Investigator of the Company and (b) discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest (“**Ad Hoc Disclosure**”).

The Annual Disclosure must include any information that was not disclosed to the Policy Administrator in the Initial Disclosure or in an Ad Hoc Disclosure, and shall include updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest).

To the extent any Significant Financial Interests relate to third party reimbursed or sponsored travel, the Investigator must disclose the following information regarding the travel at issue: (a) the purpose, (b) the identity of the sponsor/organizer, (c) the destination and (d) the duration.

In addition, any individual involved with Research at the Company may report suspected Financial Conflicts of Interest or alleged violations of this Policy to the Policy Administrator.

V. REVIEW, MANAGEMENT AND REPORTING PROCEDURES

A. Policy Administrator Review and Responsibilities

Prior to the Company’s expenditure of any funds under a PHS-funded Research project, the Policy Administrator (or his or her designee) shall, consistent with the guidelines set forth below, (a) review all SFI Disclosure Forms and (b) determine whether any disclosed Significant Financial Interests are related to the PHS-funded Research at issue.

An Investigator’s Significant Financial Interest is related to PHS-funded Research if the Policy Administrator reasonably determines that such Significant Financial Interest could be affected by the PHS-funded Research or is in an entity whose financial interests could be affected by such Research. The Policy Administrator may involve the applicable Investigator in the determination of whether his or her Significant Financial Interests are related to the PHS-funded Research; provided, however, prior to doing so, the Policy Administrator shall consult with and follow directions from the Company’s internal and/or external legal counsel regarding appropriate procedures to afford the maximum confidentiality and privilege protection.

The Policy Administrator will forward all SFI Disclosure Forms revealing a Significant Financial Interest that is related to PHS-funded Research to the FCOI Officer for review, along with the Policy Administrator’s recommendations as to which Significant Financial Interests may warrant further investigation to determine whether a Financial Conflict of Interest exists.

It is also the responsibility of the Policy Administrator to perform the following tasks, as more fully described in this Policy:

1. Review all other SFI Disclosure Forms submitted under this Policy and other reports of Significant Financial Interests to determine whether such forms or reports reveal a Significant Financial Interest that is related to PHS-funded Research and, if so, forward such forms and reports to the FCOI Officer along with a recommendation as to which Significant Financial Interests may warrant further investigation to determine whether a Financial Conflict of Interest exists;
2. Request and review any additional materials needed to fully evaluate the relationship of the Significant Financial Interest to the Research;
3. Implement and manage the training of Investigators in accordance with this Policy;
4. Maintain an up-to-date version of this Policy on the Company's publicly available website;
5. Oversee initial and ongoing reporting to PHS;
6. Respond to requests from the public regarding Financial Conflicts of Interest;
7. Implement and monitor compliance with FCOI Management Plans;
8. Coordinate with the FCOI Officer and the Company's human resources department to impose disciplinary sanctions for violations of this Policy or any FCOI Management Policy;
9. Oversee the retrospective review and related procedures if a Financial Conflict of Interest is not identified or managed in a timely manner; and
10. Maintain records relating to training, disclosures, review and response under this Policy.

B. Financial Conflict of Interest Officer

The FCOI Officer is responsible for investigating Significant Financial Interests that the Policy Administrator determines are related to PHS-funded Research to determine whether a Financial Conflict of Interest exists. A Financial Conflict of Interest exists if the FCOI Officer determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research at issue. If the FCOI Officer determines that a Financial Conflict of Interest exists, the FCOI Officer will decide on the appropriate action to manage, reduce or eliminate such Financial Conflict of Interest and, with support from the Policy Administrator, will develop a FCOI Management Plan if needed, as more fully described below.

It is also the responsibility of the FCOI Officer to perform the following tasks, as more fully described in this Policy:

1. Review any SFI Disclosure Forms or other reports made regarding Significant Financial Interests that the Policy Administrator determines are related to PHS-funded Research;
2. Recommend whether the Significant Financial Interest requires a FCOI

Management Plan to manage, reduce, or eliminate the Financial Conflict of Interest and to develop such a plan with support from the Policy Administrator;

3. Determine whether the Significant Financial Interest is a Financial Conflict of Interest that must be reported to PHS; and
4. Investigate allegations of noncompliance with this Policy or any FCOI Management Plan and work with the Company's human resources department, to determine corrective actions, disciplinary sanctions, and PHS reporting, as appropriate.

C. FCOI Management Plans

If the FCOI Officer determines that a Financial Conflict of Interests exists with respect to a particular PHS-funded Research project, the FCOI Officer, with support from the Policy Administrator, will develop a FCOI Management Plan prior to the Company's expenditure of any funds under a PHS-funded Research project. A FCOI Management Plan will focus on the steps to manage such Financial Conflict of Interest and ensure the objectivity of the design, conduct, and reporting of the Research, which may include, but not be limited to:

1. Public disclosure of an Investigator's Significant Financial Interest (e.g., when presenting or publishing the Research);
2. Appointment of an independent reviewer of data, manuscripts, and/or presentations capable of taking measures to protect the design, conduct, and report of the Research against bias resulting from the Financial Conflict of Interest;
3. Modification of any Research proposal or plan;
4. Change in personnel or personnel responsibilities, or disqualification of an Investigator from participating in all or a portion of any Research;
5. Reduction or elimination by an Investigator of the Financial Conflict of Interest (e.g., sale of any equity interest); or
6. Severance of relationships that create the Financial Conflicts of Interest.

For any FCOI Management Plan, the affected Investigator must agree in writing to the FCOI Management Plan before the Research goes forward. The Policy Administrator shall monitor the affected Investigator's compliance with the FCOI Management Plan on an ongoing basis until the completion of the PHS-funded Research project.

D. FCOI Reporting to PHS

Prior to the Company's expenditure of any funds under a PHS-funded Research project, the Company shall provide to PHS a FCOI Report regarding any Financial Conflicts of Interest related to such Research; provided, however, the Company shall not be required to submit a FCOI Report to PHS if it eliminates the Financial Conflict of Interest prior to expenditure of PHS-awarded funds. The FCOI Report shall contain sufficient information to enable PHS to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the Company's FCOI Management Plan related thereto, which information shall include at a minimum:

1. Project number;
2. Project manager or principal investigator or, if there are multiple project managers and/or principal investigators, the project manager or principal investigator who serves as the primary contact for the Research project;
3. Name of the Investigator with the Financial Conflict of Interest;
4. Name of the entity with which the Investigator has a Financial Conflict of Interest;
5. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest in ranges (e.g., \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
7. A description of how the financial interest relates to the PHS-funded Research and the basis for the Company's determination that the financial interest conflicts with such Research; and
8. A description of key elements of the Institution's FCOI Management Plan including:
 - (a) role and principal duties of the conflicted Investigator in the Research project;
 - (b) conditions of the FCOI Management Plan;
 - (c) how the FCOI Management Plan is designed to safeguard objectivity in the Research project;
 - (d) confirmation of the Investigator's agreement to the FCOI Management Plan;
 - (e) how the FCOI Management Plan will be monitored to ensure Investigator compliance; and
 - (f) other information as needed or requested by PHS.

For any Significant Financial Interest that is identified after the funding for the Research is awarded, including Significant Financial Interests identified by Investigators new to the project, the Company will determine whether a Financial Conflict of Interest exists and whether a FCOI Management Plan is required at least on an interim basis, and shall provide a FCOI Report with the information above to the PHS funding agency within sixty (60) days of identification of the Significant Financial Interest.

Where such FCOI Report involves a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Company, the Company shall also complete a retrospective review as described in Section VIII.D. below to determine whether the PHS-funded Research, or portion thereof, conducted prior to the identification and management of the Financial Conflict of Interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, the Company shall promptly notify and submit to PHS a mitigation report as described herein.

Additionally, for any Financial Conflict of Interest previously reported by the Company with regard to an ongoing PHS-funded Research project, the Company shall provide to PHS an annual FCOI Report that addresses the status of the Financial Conflict of Interest and any changes to the FCOI Management Plan for the duration of the project period (including extensions with or without funding). The annual FCOI Report shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. The Company must report to the PHS-funding agency the annual FCOI Report at the time of it submits an annual progress report to PHS for the affected

Research project or such other time as requested by PHS.

E. Reports to the Public for PHS-Supported Research

As required by the Regulation, upon written request by a member of the public (a “**Requestor**”), the Policy Administrator shall provide to such Requestor written information about any then-existing Financial Conflicts of Interest reported to the Company related to ongoing PHS-funded Research projects within five (5) business days of such request. Requests must be in writing and received through the U.S. mail. The request must identify the specific PHS Research project number and the name of Investigator for whom information is being requested. The request must include a named recipient and return address with a physical street address (P.O. boxes are not acceptable). The Company will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually and within sixty (60) days of the Company’s identification of a new Financial Conflict of Interest, which must be requested under separate cover by the Requestor.

The following information will be provided to the Requestor:

1. Project number;
2. Name of the Investigator with a Financial Conflict of Interest;
3. Investigator’s title and role with respect to the Research project;
4. Name of the entity in which the Significant Financial Interest is held;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); and
6. Value of the financial interest in ranges (e.g., \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

VI. SUB-RECIPIENT MONITORING

For Research covered by this Policy that involves Sub-Recipients, the Company must take reasonable steps to ensure that any Sub-Recipient Investigator complies with the Regulation by:

1. Incorporating as part of a written agreement with the Sub-Recipient (the “**Sub-Agreement**”) terms that establish whether this Policy or the Sub-Recipient’s financial conflicts of interest policy (the “**Sub-Recipient Policy**”) will apply to the Sub-Recipient’s Investigators.
 - a. If the Sub-Recipient Policy is to be used, the Sub-Recipient must certify as part of the Sub-Agreement that the Sub-Recipient Policy complies with the Regulation and will be responsible for ensuring that the Sub-Recipient and its Investigators comply with the Regulation. Sub-Recipients must report to the Company any identified Financial Conflict of Interest no later than forty (45) days after identification of the Financial Conflict of Interest by the Sub-

Recipient. The details of the Financial Conflict of Interest will be reported to PHS by the Sub-Recipient as required under the Regulation.

- b. If the Sub-Recipient cannot provide the certification described above, the Sub-Agreement shall state that the Sub-Recipient Investigators are subject to the Company's Policy for disclosing Significant Financial Interests that are directly related to the Sub-Recipients work for the Company.
 - c. If the Company's Policy is used, the Sub-Recipient must ensure that its Investigators submit the SFI Disclosure Form to the Company at the time of application by the Company or at the time the Sub-Recipient signs an institutional letter of support if during an on-going award grant or contract. Notwithstanding the use of the Company's Policy, the Sub-Recipient shall have a duty to monitor its Investigator's compliance with the Policy and any FCOI Management Plan. Sub-Recipients must report to the Company any identified Financial Conflict of Interest no later than forty (45) days after identification of the Financial Conflict of Interest by the Sub-Recipient.
2. Reporting to PHS any Sub-Recipient Financial Conflicts of Interest prior to the execution of the Sub-Agreement or within sixty (60) days of identification of a new Financial Conflict of Interest by the Sub-Recipient or the Company that arises during the term of the Sub-Agreement.

VII. TRAINING

Each Investigator must complete training, as administered by the Policy Administrator, regarding the purpose of, and their obligations under, this Policy, at the following times: (a) prior to engaging in PHS-funded Research, (b) at least every four (4) years thereafter, and (c) immediately when:

1. The Company revises this Policy in any manner that affects Investigator requirements;
2. An Investigator is new to the Company or to an ongoing PHS-funded Research project; or
3. The Company finds that an Investigator is not in compliance with this Policy or a FCOI Management Plan.

Each Investigator is ultimately responsible for ensuring that he/she makes any necessary disclosures to the Company required by this Policy and follows any prescribed plan for the management, reduction, or elimination of an identified Financial Conflict of Interest. Failure to do so shall be deemed a violation of this Policy and may result in sanctions on the Investigator.

VIII. COMPLIANCE

A. Oversight

The Policy Administrator will maintain an up-to-date version of this Policy on the Company's publicly available website and is responsible for training on and ensuring compliance with this Policy and the procedures contained herein. In cases where a FCOI Management Plan has been developed, it is the task of the Policy Administrator to implement and oversee

compliance with such FCOI Management Plan on an ongoing basis.

B. Policy or FCOI Management Plan Violations

The FCOI Officer shall be responsible for investigating any alleged violations of this Policy or of a FCOI Management Plan by an Investigator. The FCOI Officer will follow directions from the Company's internal and/or external legal counsel regarding appropriate procedures to afford the maximum confidentiality and privilege protection for all such investigations. In investigating any violation of this Policy or a FCOI Management Plan, the FCOI Officer shall determine if the violation has biased the design, conduct, or reporting of any PHS-funded Research. The FCOI Officer will promptly report the results of such investigations to the Policy Administrator along with any appropriate corrective actions to maintain the objectivity of the Research, including suspension of the Research project, if necessary. The Policy Administrator shall implement such corrective actions.

The Policy Administrator, in consultation with the FCOI Officer and the company's human resources department will decide on appropriate sanctions or disciplinary actions to be taken, if any. Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination. The Policy Administrator will promptly notify the affected Investigator in writing of the results of the investigation and plans for disciplinary action against the Investigator, if applicable.

The Policy Administrator will promptly notify PHS of any violation of this Policy or a FCOI Management Plan and the corrective action taken or to be taken by the Company. PHS will consider the situation and, as necessary, take appropriate action, or refer the matter to the Company for further action, which may include directions to the Company on how to maintain appropriate objectivity in the applicable Research project.

C. PHS Inquiries

PHS or the U.S. Department of Health and Human Services ("HHS") may inquire at any time before, during, or after award of PHS funds into any Investigator disclosure of Significant Financial Interests and the Company's review (including any retrospective review as described below) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Company's determination of a Financial Conflict of Interest. The Company is required to submit, or permit on site review of, all records pertinent to compliance with this Section and the Regulation. To the extent permitted by law, PHS and/or HHS will maintain the confidentiality of all records of Significant Financial Interests. On the basis of its review of records or other information that may be available, PHS may decide that a particular Financial Conflict of Interest will bias the objectivity of the PHS-funded Research to such an extent that further corrective action is needed or that the Company has not managed the Financial Conflict of Interest in accordance with this Section and/or the Regulation. PHS may determine that imposition of special award conditions, or suspension of funding or other enforcement action, is necessary until the matter is resolved.

D. Retrospective Review Procedures

Investigators are subject to the following retrospective review procedures when a Financial Conflict of Interest is not identified or managed in a timely manner. In the event that the Company identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed and/or managed by the Company during an ongoing PHS-funded research project, the Company shall within (60) days, utilizing the procedures set forth in Section VI herein (a) review the Significant

Financial Interest at issue, (b) determine whether such Significant Financial Interest is related to the PHS-funded Research, (c) determine whether a Financial Conflict of Interest exists, and (d) if so, implement, on at least an interim basis, a FCOI Management Plan that shall specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest going forward.

In addition, in the event that the Company identifies a Significant Financial Interest that was not disclosed timely by an Investigator, was not previously reviewed and/or managed by the Company during an ongoing PHS-funded research project or the Company discovers that an Investigator failed to comply with a FCOI Management plan, the Company shall, within one hundred twenty (120) days of the Company's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether all or a portion of such Research conducted during the time period of the noncompliance was biased with respect to its design, conduct, or reporting.

The Company must document the retrospective review and include in such documentation, at minimum, the following information:

1. Project number;
2. Project title;
3. Project manager or principal investigator or, if there are multiple project managers and/or principal investigators, the project manager or principal investigator who serves as the primary contact for the Research project;
4. Name of the Investigator with the Financial Conflict of Interest;
5. Name of the entity with which the Investigator has a Financial Conflict of Interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the retrospective review; and
9. Conclusion of the retrospective review.

Based on the results of the retrospective review, if appropriate, the Company shall update the previously submitted FCOI Report related to the PHS-funded Research at issue, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If the results of the retrospective review indicate bias, the Company shall promptly notify and submit a mitigation report to PHS. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and the Company's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Depending on the nature of the Financial Conflict of Interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in

the PHS-funded Research project between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of the Company's retrospective review.

In any case that a clinical Research project, 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 reported or managed as required by this Policy or the applicable regulations, then the Company shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will also be subject to sanctions under this Policy.

IX. GENERAL PRINCIPLES

A. Confidentiality

To the extent permitted by law, all SFI Disclosure Forms, FCOI Management Plans, and related information will be treated as confidential and privileged. However, the Company may be required to make such information available to PHS and/or other federal agencies, to a Requestor of information concerning Financial Conflict of Interests related to PHS funding or to the primary entity who made the funding available to the Company, if requested or required. If the Company is requested to provide SFI Disclosure Forms, FCOI Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

The Policy Administrator, the FCOI Officer and any other parties involved in reviews or investigations under this Policy will follow directions from the Company's internal and/or external legal counsel regarding appropriate procedures to afford the maximum confidentiality and privilege protection for any such reviews or investigations.

B. Record Retention

The Policy Administrator shall be responsible for maintaining records of (a) Investigator disclosures of Significant Financial Interest (including on SFI Disclosure Forms), (b) the Institution's review of, and response to, such disclosures (whether or not such disclosures resulted in the Company's determination of a Financial Conflict of Interest), and (c) all actions taken by the Company under the Policy for at three (3) years from: (i) the date of submission to PHS of the Company's final expenditures report relating to the PHS award, (ii) for any PHS award that renews annually, the date of submission to PHS of the Company's annual expenditures report for the federal fiscal year and (iii) for any PHS award that renews quarterly, the date of submission to PHS of the Company's final quarterly expenditures report for the applicable federal fiscal year.

History/Revision Dates

Revision Date	History
May 2018	Original Policy Adopted

Exhibit A

Regulation

[Subpart F—Promoting Objectivity in Research](#)

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Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-4; Sec. 219, Tit. II, Div. D, Pub. L. 111-117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

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§50.601 Purpose.

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

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§50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

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§50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

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 PHS by the Institution under this subpart.

Significant financial interest means:

(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:

(i) 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;

(ii) 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

(iii) 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, 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.

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

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§50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

Each Institution shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this subpart (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this subpart.

(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the

subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to §50.605(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

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

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this subpart.

[76 FR 53283, August 25, 2011, as amended at 81 FR 3006, Jan. 20, 2016]

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§50.605 Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with §50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii)(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the

Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this subpart that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

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§50.606 Remedies.

(a) If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall 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 the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

(b) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or

permit on site review of, 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 or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, 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 financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution 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

[76 FR 53283, August 25, 2011, as amended at 81 FR 3006, Jan. 20, 2016]

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§50.607 Other HHS regulations that apply.

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

2 CFR part 376—Nonprocurement debarment and suspension (HHS)

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 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

45 CFR part 79—Program fraud civil remedies

[76 FR 53283, August 25, 2011, as amended at 81 FR 3006, Jan. 20, 2016]

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Exhibit B

SFI Disclosure Form

Investigator Name (Last, first, middle):	Work Phone:	Date of Disclosure:	Date FCOI Training Received:
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Emulate Employees continue to Parts 1, 2 and 3 of this form

Only non-Emulate Investigators complete this section

Employer's Name: _____

Choose one of the following two options and follow the instructions indicated for that option

I am employed by an institution with a Financial Conflict of Interest Policy that complies with PHS regulations. Choose one of the following two options.

I have disclosed my significant financial interests and the work scope for this project to the FCOI Designated Official at my institution and he/she has determined that I have no financial conflict with working on this project

STOP AND SUBMIT THIS FORM TO SFIDisclosures@emulatebio.com

I have disclosed my significant financial interests and the work scope for this project to the FCOI Designated Official at my institution and he/she has determined that I may have a financial conflict with working on this project. The FCOI management plan prepared by this Official will be submitted separately.

STOP AND SUBMIT THIS FORM TO SFIDisclosures@emulatebio.com

I am not employed by an institution with a compliant FCOI Policy and therefore agree to comply with Emulate's Financial Conflict of Interest Policy, including completing the FCOI training identified by Emulate and disclosing my significant financial interests to Emulate.

CONTINUE TO COMPLETE PARTS 1, 2 AND 3 OF THIS FORM.

Part 1. ASSETS

For you, your spouse and your dependent children, identify assets with a fair market value of \$5,000 as of the date of disclosure. Assets include stocks, bonds, tax shelters, pensions, annuities, real estate, commodity futures, trades and business and partnership interests. Refer to the definitions below Part 3 for additional information

I do not have any assets requiring disclosure. **CONTINUE TO PART 2 OF THIS FORM.**

I disclose the following assets. **After completing this section, CONTINUE TO PART 2 OF THIS FORM.**

Name of asset	Asset belongs to (Employee, Spouse, Dependent Child, or combination)	(X) if no longer held	Asset Type (pension, stock, dividends, interest, real estate, capital gains)	Approximate value of the financial interest		
				\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

Part 2. SOURCES OF EARNED INCOME AND TRAVEL

For you, your spouse and your dependent children, identify sources of earned income which generated over \$5,000 in income as of the date of the disclosure. Sources of Earned Income include salaries received from other than your current employer, fees, honoraria and travel. Refer to the definitions below Part 3 for additional information.

I do not have any sources of earned income or travel requiring disclosure. **CONTINUE TO PART 3 OF THIS FORM.**

I disclose the following sources of earned income or travel. **After completing this section, CONTINUE TO PART 3 OF THIS FORM.**

Name of Earned Income Source(s)	Income Recipient (Employee, Spouse, Dependent Child, or combination)	Income Type (salary, consulting fees, honoraria, etc.)	Approximate value of the financial interest		
			\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

For travel disclosures, please provide the following additional detail

Travel Sponsor	Destination	Duration	Purpose

Part 3

UPON COMPLETION OF THIS DISCLOSURE FORM, PLEASE EMAIL IT AS AN ATTACHMENT TO: SFIDisclosures@emulatebio.com
Submission of this form confirms your belief that all information provided is true, complete and accurate to the best of your knowledge.

SFI Disclosure Form Definitions as provided by the Office of Extramural Research of the National Institutes of Health

Significant Financial Interest (SFI) is defined by the regulation as:

- I. 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:
 - a. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- II. Investigators also must disclose the occurrence of any reimburse 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, a medical center, or a research institute that is affiliated with an institution of higher education. The Investigator's disclosure will include the identity of the sponsor/organizer, the destination, and the duration. The FCOI Officer can request additional information from the Investigator in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- III. The term SFI does not include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by the Institution (i.e., Investigator's employer) to the Investigator if the Investigator is currently employed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - b. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

- c. 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;
- d. 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;
- e. 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.