

Financial Conflicts of Interest (FCOI) Policy

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1 – General

It is BioTillion' (BioTillion) highest priority to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI). It is also BioTillion's responsibility to establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.

The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). BioTillion is determined to be an Institution subject to these regulations and must be in compliance.

It is BioTillion's responsibility to provide adequate guidelines consistent with the regulation to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. Therefore BioTillion has established standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.

This document contains BioTillion, LLC's Financial Conflict of Interest (FCOI) Policy that is a requirement of the Code of Federal Regulation (42 CFR Part 50, Subpart F). For more information please see the following sources:

<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

<https://grants.nih.gov/grants/policy/coi/index.htm>

2 – Glossary of Terms

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 BioTillion.

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. The term investigator includes the investigator's spouse and dependent children.

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:
 - (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 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;
 - (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 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
 - (c) 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.

3 – Training

Each Investigator, including sub recipient Investigator(s), will be informed of BioTillion's FCOI policy and must complete training prior to engaging in NIH-funded research and at least every 4 years, and immediately under these circumstances:

- (a) BioTillion's Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- (b) An Investigator is new BioTillion
- (c) BioTillion finds that an Investigator is not in compliance with this policy or management plan.

BioTillion will utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements.

However, BioTillion will provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and of BioTillion's specific policy on financial conflicts of interests.

This tutorial is related to the Financial Conflict of Interest (FCOI) regulation provided at [42 CFR Part 50 Subpart F on Promoting Objectivity in Research](#). The tutorial is also available in [PDF format](#) (PDF - 2.5 MB). The August 2, 2012 posting provides the capability to easily save and print the FCOI Certificate. <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

4 – Disclosure, Review and Monitoring

The BioTillion official(s) shall 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):

- (a) That would reasonably appear to be affected by the research for which PHS funding is sought and
- (b) In entities whose financial interests would reasonably appear to be affected by the research.

BioTillion will require that each Investigator who is planning to participate in the PHS-funded research disclose to BioTillion's 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.

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

BioTillion will require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Whenever BioTillion implements a management plan, BioTillion shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS- funded research project.

BioTillion shall inform each Investigator of its policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the regulations. Due to the serious nature of intentional FCOI violations, BioTillion’s enforcement mechanisms and employee sanctions to ensure Investigator compliance are also serious. BioTillion may have grounds to terminate any Investigator who willfully avoids, misreports or falsifies information related to FCOI and SFIs.

BioTillion will 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 BioTillion, during the period of the award. Such disclosure shall include any information that was not disclosed initially to BioTillion, 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).

In any case which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by BioTillion as required by regulation, BioTillion shall require the Investigator involved to: 1) Disclose the FOCI in each public presentation of the results of research, and 2) Request an addendum to previously published presentations.

Table 1: When to disclose and report

| Investigator Discloses known SFI(s) to BioTillion | BioTillion Reports identified FCOI(s) to NIH |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| At time of Application | Prior to the Expenditure of Funds |
| Within 30 days of acquiring or discovering SFI | Within 60 days of identification |
| Annually at the time period prescribed by the Institution during the award period | Annually: For any FCOI previously reported by BioTillion. At the same time as when the grantee submits the annual progress report or extends the project. Annual FCOI report is submitted through eRA Commons FCOI Module. |

The **Table 1** summarizes when disclosures of SFIs must occur.

At time of Funding Application: In order to ascertain the existence of any FCOI, any investigator or sub recipient associated with the project will be required to fill out an FCOI Disclosure Statement and submit it to Human Resources. If an FCOI exists, BioTillion will submit the FCOI report to NIH via the eRA Commons FCOI Module.

Post Award: An investigator or sub-recipient must file an FCOI Disclosure statement within 30 days of acquiring or discovering that an FCOI exists for an ongoing project.

Annual Disclosure: All investigators and sub-recipients working on NIH funded projects will be required to review BioTillion’s FCOI policy and fill out an annual FCOI Disclosure Statement.

BioTillion has designated the acting HR manager and the President as the 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. It is the official(s), responsibility to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

Upon receipt of any FCOI Disclosure Statement, BioTillion official(s), shall:

- (a) Review all Investigator disclosures of significant financial interests,
- (b) Determine whether any significant financial interests relate to PHS-funded research as defined in the glossary of terms above and
- (c) Determine whether a FCOI 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.

These requirements shall be conducted:

- (a) When required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI; or
- (b) Within 60 days whenever BioTillion identifies an SFI that was not disclosed in a timely manner by an Investigator or not previously reviewed by BioTillion.

An Investigator's significant financial interest is related to PHS-funded research when BioTillion's 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.

A financial conflict of interest exists when BioTillion's official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

BioTillion may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research.

BioTillion's official(s) shall have the authority to establish adequate enforcement mechanisms and provide for sanctions where appropriate.

The BioTillion official(s) must inform each Investigator of the:

- (a) PHS Regulation;
- (b) BioTillion's policy on FCOI; and
- (c) Investigator's responsibilities regarding disclosure of SFIs

BioTillion shall certify in each application for funding to which FCOI regulations apply, that BioTillion:

- (a) Has in effect 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;
- (b) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;
- (c) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart; and
- (d) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and BioTillion's review of, and response to, such disclosure, whether or not the disclosure resulted in BioTillion's determination of a financial conflict of interest.

FCOI Management Plans shall be monitored with their associated projects and include the following items:

- (a) The 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.

BioTillion's management plans may include reduction or elimination of the SFI.

5 – Reporting to NIH:

New Awards: Prior to the BioTillion’s expenditure of any funds under a PHS-funded research project, BioTillion shall provide to the PHS Awarding Component an FCOI report regarding any Investigator’s significant financial interest found by BioTillion to be conflicting and ensure that BioTillion has implemented a management plan in accordance with regulations. In cases in which BioTillion 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.

New Investigator: The Institution must submit an FCOI report within 60 days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to BioTillion during the period of award. Although the Institution has up to 60 days to report the identified FCOI to NIH, reports should be submitted during the ongoing project and not after the project period end date.

Newly Identified FCOI: Whenever an Investigator does not disclose in a timely manner a previously existing Significant Financial Interest or BioTillion fails to review a previously existing Significant Financial Interest during an ongoing NIH-funded project, the BioTillion’s designated official(s) shall, within 60 days: review the Significant Financial Interest; determine whether it is related to the NIH-funded research; determine whether a Financial Conflict of Interest exists. If so, BioTillion will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the NIH.

Annual FCOI Report to NIH: For any Financial Conflict of Interest previously reported by BioTillion to NIH, BioTillion shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.

FICO Submission Period: These Annual FCOI Reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as BioTillion is required to submit the annual progress report (i.e., 2 months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.)

Bias Found: If bias is found, NIH will promptly be notified and BioTillion will submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and BioTillion’s plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter BioTillion will submit FCOI reports annually.

No Report Necessary: In the following cases no annual FCOI report is necessary:

- (a) Cases in which BioTillion identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds
- (b) Negative FCOI reports to NIH and
- (c) Annual FCOI reports are not required as part of the grant closeout requirements. The last submitted Annual Report will be required prior to the issuance of the last year noncompeting award within the project’s competitive segment unless the grant is extended via the Commons or through the issuance of a revised Notice of Award.

Content of Reports: Reports 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 BioTillion’s management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (a) Project number;
- (b) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (c) Name of the Investigator with the financial conflict of interest;
- (d) Name of the entity with which the Investigator has a financial conflict of interest;

- (e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (f) 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

Table 2: Summary of required reports to the NIH

| Report | Content | Required When? |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Initial FCOI Report | Grant Number, PI, Name of Entity with FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan | 1) Prior to expenditure of funds 2) Within 60 days of any subsequently identified FCOI |
| Annual FCOI Report | Status of FCOI and Changes to Management Plan | For any Financial Conflict of Interest previously reported by the Institution - Due at same time as when submitting annual progress report or at time of extension |
| Revised FCOI Report | If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward. | After completion of retrospective review, if needed. |
| Mitigation Report | Project Number, Project Title, Contract PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion | When bias is found as a result of a retrospective review |

one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

- (i) A description of how the financial interest relates to the PHS-funded research and the basis for BioTillion’s determination that the financial interest conflicts with such research; and
- (j) A description of the key elements of BioTillion’s management plan, including:
 - (1) Role and principal duties of the conflicted Investigator in the research project
 - (2) Conditions of the management plan;
 - (3) How the management plan is designed to safeguard objectivity in the research project;
 - (4) Confirmation of the Investigator's agreement to the management plan;
 - (5) How the management plan will be monitored to ensure Investigator compliance and
 - (6) Other information as needed.

Electronic Report Submission: The FCOI Module in the eRA Commons portal will be the primary reporting mechanism for reports to the NIH. More information on the FCOI Module can be found at:

http://era.nih.gov/services_for_applicants/other/fcoi.cfm

6 – Records:

BioTillion shall maintain records of all financial disclosures and all actions taken by BioTillion with respect to each conflicting interest for three years from the date the final expenditures report is submitted to the PHS

(NIH), or, where applicable, for the other time periods specified in 48 CFR parts 4, subpart 4.7.

7 – Enforcement Mechanisms, Remedies and Non-compliance

In the case when BioTillion identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by BioTillion during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a sub recipient), the designated official(s) shall, within 120 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:

- (a) 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;
- (b) 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 BioTillion to constitute a financial conflict of interest; failure by BioTillion 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, BioTillion shall, within 120 days of BioTillion'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.
- (c) BioTillion will 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.

Retrospective Review: In addition to the FCOI report, BioTillion will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

Revised FCOI: Based on the results of the retrospective review, if appropriate, BioTillion shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. When bias is not found following the completion of a Retrospective Review, the Institution should not submit a "Revised" FCOI report.

New Reports: The Institution must submit a new FCOI report if any of the following elements of a previously submitted FCOI report changes:

- (a) Project Number
- (b) Name of Investigator with the FCOI
- (c) Name of the entity
- (d) Nature of the Significant Financial Interest

If the value of a reported SFI changes during the year, the Investigator should disclose the change to the Institution in his/her annual disclosure. Changes in the value of an SFI do not constitute a "new" FCOI report. The annual FCOI report will provide the status of the existing FCOI and any changes to the

management plan that may result due to the increase in value.

Mitigation Report: If bias is found, BioTillion will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will 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 BioTillion'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).

Possible Sanctions Resulting from Non Compliance: If the failure of an Investigator to comply with BioTillion'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, BioTillion shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

BioTillion may use the following examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- (a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (c) 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;
- (d) Modification of the research plan;
- (e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (g) Severance of relationships that create financial conflicts.

8 – Sub-recipients:

BioTillion is responsible for ensuring any sub-recipient's compliance with the regulation required by 42 CFR Part 50 Subpart F and reporting identified financial conflicts of interests for sub-recipient Investigators to the NIH.

BioTillion shall incorporate, as part of a written agreement with sub-recipient terms, which establish whether the Financial Conflict of Interest policy of BioTillion or that of the sub-recipient will apply to sub-recipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

If using the sub-recipient's FCOI policy, the official(s) shall obtain a certification in the form of a formal letter from the sub-recipient stating that its FCOI policy complies with the regulation.

Sub-recipient Agreement: The written sub-recipient agreement shall either a) require the sub-recipient to report identified FCOIs for its Investigators in a time frame that allows BioTillion to report identified FCOIs to the NIH or b) require BioTillion to solicit and review sub-recipient Investigator disclosures that enable BioTillion to identify, manage and report identified FCOIs to the NIH. The method chosen to be incorporated into the sub-recipient agreement shall be determined by official(s) based upon the sub-recipient's sophistication and needs.

Monitoring compliance: BioTillion's official(s) is responsible for monitoring sub-recipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

9 – Public Information:

BioTillion will maintain a publicly accessible website that shows this FCOI policy.

Prior to BioTillion's expenditure of any funds under a PHS-funded research project, BioTillion shall ensure

public accessibility, via a publicly accessible web site information concerning any significant financial interest disclosed to BioTillion that meets the following three criteria:

- (a) The significant financial interest was disclosed and is still held by the senior/key personnel,
- (b) BioTillion determines that the significant financial interest is related to the PHS-funded research,
- (c) BioTillion determines that the significant financial interest is a financial conflict of interest.

The information that BioTillion makes available via a publicly accessible Web site shall include:

- (a) the Investigator's name,
- (b) the Investigator's title and role with respect to the research project,
- (c) the name of the entity in which the significant financial interest is held,
- (d) the nature of the significant financial interest,
- (e) 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.

Annual Update to Public Information: The information that BioTillion posts shall be updated at least annually on BioTillion's publicly accessible web site. In addition, BioTillion shall update the Web site within 60 days of BioTillion'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 BioTillion determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest.

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

10 – Point of Contact

If you have a financial conflict of interest (FCOI), or if you have an issue to discuss please contact our Company Policy Coordinator: J. Salcedo at fcoi@biotillion.com.