



Policy on Disclosure and Management of Financial Conflicts of Interest related to Public Health Service Research

Responsible Officer:	Director of Operations
Effective Date:	01/02/2019
Scope:	This policy for disclosure and management of financial conflicts of interest related to PHS Research (“ Policy ”) applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, FDA, etc.) and other non-federal sponsors that require compliance with PHS policies for research

Notice Address: 6 Davis Drive, PO Box 12317, Research Triangle Park, NC 27709; info@simulations-plus.com

I. PURPOSE, SCOPE AND APPLICATION

The federal Department of Health and Human Services (DHHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS)-sponsored Investigators (as defined below) shall be subject to specific requirements regarding the disclosure and management of Financial Conflicts of Interest with regard to Research (as defined below) in order to provide a reasonable expectation that PHS-sponsored Research will be conducted free of bias resulting from Investigator Financial Conflicts of Interest.

These regulations require the Company to maintain a written policy on disclosure of a Financial Conflict of Interest as a condition for receiving PHS Research awards. Therefore, the Company has established this Policy consistent with these regulations to require disclosure, and identification and management of Financial Conflicts of Interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) Research awards and other non-federal sponsors that require such policies for sponsored research.

This Policy applies to all grants and cooperative agreements contracts awarded after August 24, 2012 that are for PHS-awarded Research, and are applicable to all proposals for extramural Research awards submitted to PHS by Company for Research funding.

Consistent with PHS regulations, this Policy will be made available via a publicly-accessible website. All Company Investigators (as defined below) shall be informed where this Policy and relevant reporting requirements may be accessed via the web.

II. DEFINITIONS

Designated Official means the Director of Operations, or designee, who solicits and reviews Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.

Financial Conflict of Interest means a Significant Financial Interest that is related to the PHS-funded Research activity in which the Investigator is engaged in his/her Company Responsibilities and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded Research activity.

Independent Review Committee (IRC) means a committee which may be appointed (in lieu of or in addition to a designated individual) by the Director of Operations (or designee) to review Investigators' Significant Financial Interests related to PHS funded Research and Company Responsibilities, and to serve as the Designated Official(s) who determines whether any of the such Significant Financial Interests constitute a Financial Conflict of Interest.

Company Responsibilities means research, consulting service, and administrative services on behalf of the Company which are in the course and scope of the Investigator's employment.

Investigator means any individual responsible for the design, conduct, or reporting of the results of Research performed or to be performed under the PHS-sponsored Research project. This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of Research funded by PHS or proposed for such funding.

Principal Investigator means an Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a PHS-sponsored Research project.

Key Personnel means a PHS Research: Project Director, Principal Investigator and any other personnel considered essential to performance of Research and identified as Key Personnel in the contract proposal, grant, or contract for Research.

Research

As used in this Policy, any activity for which research funding is available from a PHS-awarding agency, including but not limited to Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards; *but excluded from this Policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.*

Significant Financial Interest means, as consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or state-recognized domestic partner and dependent children for the following categories, except in the case of travel:

- a. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph 5, below), consulting fees, honoraria, and the equity interest value at the date of

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disclosure as determined by public prices or other reasonable measure of fair market value.

- b. With regard to any non-publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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, state-recognized domestic partner, or dependent children) holds any equity interest.
- c. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do not include royalties received from the Company.
- d. In the case of travel, sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Company Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

The term "Significant Financial Interest" does not include the following types of financial interests:

- i. Salary, royalties, or other payments made by the Company to a Company Investigator who is currently employed or otherwise appointed by the Company;
- ii. income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education; or
- iii. Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

III. POLICY TERMS

A. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

Investigators seeking PHS Research funding or receiving PHS Research support are required to disclose Significant Financial Interests related to their Company

Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests related to their Company Responsibilities in accordance with Company's procedures for disclosure.

The requirement that an Investigator disclose a Significant Financial Interest related to their Company Responsibilities under the terms of this Policy does not in and of itself imply the existence of an actual or potential Financial Conflict of Interest. The existence of a Financial Conflict of Interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigator's Company Responsibilities, is determined by a Designated Official or an IRC with input from the Investigator. If a Financial Conflict of Interest is identified, the Designated Official or the IRC shall recommend additional steps to manage or eliminate the conflict, to the Company management team to act on that recommendation.

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Investigators as defined by this Policy, shall disclose all Significant Financial Interests related to their Company Responsibilities to the Designated Official, no later than at the time of application for PHS funding for Research.

This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS Research award to disclose to the Designated Official his or her Significant Financial Interests, and those of his or her spouse or state-recognized domestic partner, and dependent children), related to the Investigator's Company Responsibilities:

- Within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
- At least annually throughout the period of the PHS Research award.

Before joining an ongoing PHS-funded Research project new Investigators must submit a disclosure of Significant Financial Interests related to their Company Responsibilities to the Designated Official.

Under the terms of this Policy, a Principal Investigator must identify all Investigators on the Research award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the Research to be funded by PHS) are required to disclose Significant Financial Interests related to their Company Responsibilities. Sponsored or reimbursed travel related to their Company Responsibilities may be disclosed.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of Research results, and who will be conducting Research under a sub-grant or subcontract from the Company are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interest at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with the DHHS regulations, they must comply with the Company's Policy and procedures for disclosure and review of a Significant Financial Interests related to PHS-sponsored Research awards. Subawards for PHS-sponsored Research issued by the Company will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending the Company notification of such conflict and of the subrecipient institution's plan to manage, reduce or eliminate such identified conflicts, in accordance with PHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of Research results and who will participate in Research under an independent consulting agreement issued by the Company should be identified as Investigators by the Principal Investigator and should complete the Company disclosure forms. If, upon review, the Company determines that identified Financial Conflict of Interests could directly and significantly affect the design, conduct, or reporting of the Research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce or manage such identified conflicts of interest.

B. REVIEW OF DISCLOSURES; MANAGEMENT PLAN

With each PHS Research proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official to determine whether there are any Significant Financial Interests that reasonably appear to be related to Investigator's Company Responsibilities and the PHS-funded Research activity in which the

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Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) related to their Company Responsibilities that they reported are related to their PHS-funded Research activities.

In the event that the Designated Official(s) conclude that an Investigator's Significant Financial Interest related to the Investigator's Company Responsibilities reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded Research; or is in an entity whose financial interest could be affected by the Research, the Disclosure and appropriate documentation shall be forwarded to the IRC for consideration and recommendation about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted. The Company Management Team (Company President, Chief Science Officer, and Director of Operations, or designee) shall then make the decision about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest through a management plan before the support can be accepted.

Should management plan be the course of action, the management plan is to be implemented prior to the Company's expenditure of PHS funds awarded for the Research, and shall specify the actions that are required to manage the Financial Conflict of Interest, including:

- The role and principal duties of the conflicted Investigator with respect to the Research;
- Terms and conditions of the management plan;
- How the management plan will safeguard objectivity in the Research activity;
- How the management plan will confirm the Investigator's compliance; and
- How and who will monitor the plan's implementation.

The same review process takes place when an Investigator reports a new Significant Financial Interest related to the Investigator's Company Responsibilities.

C. REPORTING TO PHS

Prior to the Company's expenditure of any funds provided under a PHS Research award, the Company must provide to the PHS funding agency an initial report regarding an Investigator's Financial Conflict of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, the Company is not required to submit a report to the PHS funding agency.

During the period of the PHS Research award, the Company shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest related to the Investigator's Company Responsibilities, review the disclosure, determine whether it is related to PHS-funded Research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the Company reports to a PHS awarding agency, the Company shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the PHS Research project. The annual report shall specify whether the Financial Conflict of Interest is still being managed or explain why it no longer exists. The Company must provide annual reports to the PHS awarding agency for the duration of the Research project period ((including extensions with or without funds).

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Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded Research activity, the Company must implement a management plan and submit a report to the PHS funding agency regarding the same.

D. MONITORING OF MANAGEMENT PLAN

A management plan put in place by the Company shall specify the way in which the Investigator's compliance with the management plan will be monitored on an ongoing basis until completion of the PHS-funded Research project.

E. RETROSPECTIVE REVIEWS AND MITIGATION REPORTS

When during the course on ongoing PHS-funded Research project, the Company identifies a Significant Financial Interest related to the Investigator's Company Responsibilities that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review such Significant Financial Interest to determine whether it is related to PHS-funded Research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an Significant Financial Interest that was later determined to be a Financial Conflict of Interest, or the Company did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, the Company must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research. The purpose of this retrospective review is to determine if the ongoing PHS-funded Research was biased in its design, conduct or reporting. The Company will document the retrospective review; such documentation will include the Research project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; and review findings and conclusions. Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the Company will take to manage the identified Financial Conflict of Interest going forward.

If bias was found during the retrospective review, the Company will promptly notify the PHS funding agency for the PHS-funded Research and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Company's plans to eliminate or mitigate the effect of the bias.

F. RECORD RETENTION

Records of financial disclosures and the Company's review of, or response to such disclosures, whether or not a disclosure resulted in the Company's determination of a Financial Conflict of Interest, and all substantive actions under this Policy or retrospective review shall be maintained for at least 3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. for the PHS-funded Research award or as otherwise required under 45 CFR 74.53(b) and 92.42(b)(pertaining to pending litigation and audits, or where real property and equipment purchased under the Research award are retained beyond 3 years, when records are transferred to or maintained by the DHHS Research awarding agency, or indirect cost proposals and cost allocation plans. Records relating to unfunded Research awards need not be retained.

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G. TRAINING

Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training about the PHS rules on financial conflicts of interest and this Policy prior to engaging in Research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS Research funding, and at other times as may be required by the Company in accordance with DHHS regulations. For PHS-funded Investigators who are new to the Company or who are joining an ongoing PHS Research activity, the Company should establish a reasonable, timeframe for such Investigators to complete such training.

H. PUBLIC ACCESS TO INFORMATION

The Designated Official shall identify one Company e-mail address and one office address as the addresses to receive public requests for information under the PHS regulations and this Policy, and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on the Company web site.

The Company must respond within 5 business days to any legitimate request for information about Significant Financial Interests related to Company Responsibilities held by Key Personnel when the Company has determined that the disclosed Significant Financial Interests are related to the PHS-funded Research, and constitute Financial Conflicts of Interest. The 5-day response time shall be measured from the date that the request for information is received at the Company-designated address until the date a response is sent to the requestor.

To the extent required under federal and/or state law, Financial Conflict of Interest disclosure forms, determinations of Financial Conflicts of Interest under this Policy, and related management plans may constitute public records open to public inspection.

I. SANCTIONS

Failure of an individual to file a complete and truthful financial disclosure related to this Policy for pending PHS Research proposals, or when a new Significant Financial Interest related to the Key Personnel's Company Responsibilities is obtained during PHS-funded Research, or failure to comply with any conditions or restrictions directed or imposed under this Policy or by a DHHS funding agency, will be grounds for discipline pursuant to the applicable employee disciplinary policies of the Company. Agreements with consultants who either fail to file a complete disclosure under this Policy or fail to comply with any conditions or restrictions imposed by this Policy may be terminated for cause. In addition, federal regulations may require reports to the DHHS funding agency of any violations of federal regulations and Company policy.

J. RESOURCES

https://grants.nih.gov/grants/policy/coi/nih_review.htm

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