

Policy and Procedure for the Financial Conflict of Interest in Research

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1 Overview

An actual or potential conflict of interest occurs when a Significant Financial Interest could directly affect the design, conduct, or reporting of research. When researchers have an involvement with industry, such a conflict of interest can occur.

2 Purpose

The purpose of this document is to establish the 21st Century Oncology policy regarding financial conflict of interest when conducting research funded by the Public Health Service (PHS), in accordance with 42 CFR 50 subpart F.

3 Scope

This policy applies to 21st Century Oncology, related party companies, all 21st Century Oncology subsidiary companies, third-party companies and independent contractors, hereinafter referred to collectively as the Company. This policy applies to investigators, research staff, and their spouses and dependent children (investigators).

4 Keywords/Definitions

Term	Meaning
Financial Conflict of Interest (FCOI)	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Investigator	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.
PD/PI	Project Director or Principal Investigator of a PHS-funded research project.
PHS	Public Health Service, an operating division of the US Department of Health and Human Services and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
Research	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.
Financial Conflict of Interest Report	<p>A report by the Company to the PHS Awarding Component regarding an Investigator's significant financial interest found by the institution to be conflicting. Elements of the report shall include, but are not necessarily limited to the following:</p> <ol style="list-style-type: none"> (1) Project number; (2) PD/PI or contact PD/PI is a multiple PD/PI model is used; (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 (dollar ranges are permissible), 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; (7) 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; (8) A description of the key elements of the Institution's management plan in accordance with 42 CFR 50 subpart F.
Significant Financial Interest	<p>(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:</p> <p style="padding-left: 40px;">(i) With regard to any publicly traded entity, a <i>significant financial interest</i> 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;</p> <p style="padding-left: 40px;">(ii) With regard to any non-publicly traded entity, a <i>significant financial interest</i> 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</p> <p style="padding-left: 40px;">(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</p>

	<p>(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (<i>i.e.</i>, 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.</p> <p>(3) The term <i>significant financial interest</i> 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.</p>
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5 Policy

- 5.1 It is expected that all investigators conducting research within 21st Century Oncology will adhere to the highest ethical standards. Research will be performed objectively, and the design, conduct, and reporting of research must not be biased by any conflicting financial interest of the Investigator.

6 Roles and Responsibilities

- 6.1 All investigators have the responsibility to disclose any Significant Financial Interests when applying for PHS funding.
- 6.2 The Executive Director of Research and Education is responsible for reviewing disclosures for potential and actual conflicts of interest, reporting to 21st Century

Oncology officers and the PHS when such conflicts exist, and maintaining records of all financial disclosures and actions taken with respect to each conflicting interest.

7 Procedures

7.1 Review of Disclosures

7.1.1 Any conflict of interest indicated on the Financial Disclosure Form will be reviewed by the Executive Director of Research and Education to determine whether an actual or potential conflict of interest exists. If a conflict of interest exists, the Executive Director of Research and Education will confer with relevant Company officials to determine what actions may be necessary to manage, reduce, or eliminate such conflict of interest. The Company shall monitor Investigator compliance with this management plan on an ongoing basis until the completion of the PHS-funded research project. Possible such actions may include, but are not limited to:

- 7.1.1.1 Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- 7.1.1.2 For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 7.1.1.3 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;
- 7.1.1.4 Modification of the research plan;
- 7.1.1.5 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- 7.1.1.6 Reduction or elimination of the financial interest;
- 7.1.1.7 Severance of relationships that create financial conflicts.

7.2 Reporting to the PHS

7.2.1 Prior to the expenditure of any funds under the award, the Company will provide to the PHS awarding component a financial conflict of interest report regarding any Investigator's significant financial interest found by the Company to be conflicting and ensure that the company has implemented a management plan in accordance with 42 CFR 50 subpart F.

7.2.2 If the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company shall not submit a financial conflict of interest report to the PHS.

7.2.3 If any significant financial interest that the Company determines is conflicting subsequent to the initial financial conflict of interest report, the Company shall review the disclosure and provide to the PHS a financial conflict of interest report within 60 days and if determined to be related to the PHS-funded research will implement a management plan on at least an interim basis.

7.2.4 If a financial conflict of interest report involves a significant financial interest that was not disclosed in a timely manner by an Investigator or was not previously reviewed or managed by the Company, the Company shall review within 60 days the significant financial interest, determine whether it is related to PHS-funded research and if a financial conflict of interest exists. If a conflict does exist, the Company must implement at least an interim management plan to manage such conflict of interest,

and the Company must complete a retrospective review within 120 days to determine whether the financial conflict of interest biased the design, conduct, or reporting of the involved research, and if bias is found, the Company is required to notify the PHS promptly and submit a mitigation report as defined in 42 CFR 50 subpart F to the PHS.

7.2.5 The Company must also ensure public accessibility, via written response to any requestor within five business days of a request or information concerning any significant financial interest disclosed to the Company that meets the following criteria:

7.2.6 The significant financial interest is still held by the senior/key personnel;

7.2.7 The Company determines that the significant financial interest is related to the PHS-funded research; and

7.2.8 The company determines that the significant financial interest is a financial conflict of interest.

7.2.9 The public information shall include at least: the Investigator's name, title and role on the research project, the name of the entity in which the significant financial interest is held, the nature of the significant financial interest, the approximate value of the interest, or a statement that the value of the interest cannot be readily determined. The company 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 within 60 days of the Company's identification of a new financial conflict of interest which should be requested subsequently by the requestor. Information concerning the significant financial interest of an individual shall remain available for responses to written requests for at least three years after the date that the information was most recently updated.

7.3 Enforcement and Remedies

7.3.1 If the Investigator with the financial conflict of interest declines to follow the actions necessary to manage, reduce, or eliminate such conflict of interest, Corporate management may take additional disciplinary actions up to and including termination of employment. If the failure of the Investigator to comply with the Company's financial conflicts of interest policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Company shall notify the PHS with the understanding that the PHS may take additional appropriate action. The Company understands that the PHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Company's review thereof, and will submit relevant records or permit on-site review of such records and the Company will cooperate with any such investigation and any corrective actions.

7.4 Record Keeping

7.4.1 The Company will maintain records of all financial disclosures and all actions taken with respect to each conflicting interest for at least three years from the date of submission of the final expenditure report or other date as applicable.

8 Responsibilities

8.1 All investigators have the responsibility to disclose any Significant Financial Interests when applying for PHS funding.

- 8.2 The Executive Director of Research and Education is responsible for reviewing disclosures for potential and actual conflicts of interest, reporting to 21st Century Oncology officers and the PHS when such conflicts exist, and maintaining records of all financial disclosures and actions taken with respect to each conflicting interest.
- 8.3 21st Century Oncology will maintain an up-to-date, written, enforced policy on financial conflicts of interest and make such policy available on its publicly accessible web site.
- 8.4 21st Century Oncology shall inform each Investigator of 21st Century Oncology's policy, the Investigator's responsibilities regarding disclosure of significant financial interests and of 42 CFR 50 subpart F and require each Investigator to complete training regarding this policy 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:
- 8.4.1 The Company revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- 8.4.2 An Investigator is new to the Company; or
- 8.4.3 An Institution finds that an Investigator is not in compliance with the Company's financial conflict of interest policy or management plan.
- 8.4.4 If the Company carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Company (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart.
- 8.4.5 All investigators who are planning to participate in PHS-funded research are required to report to the Executive Director of Research and Education or designee all Significant Financial Interests (and those of the Investigator's spouse and dependent children) as follows:
- 8.4.6 Each Investigator who is planning to participate in the PHS-funded research must disclose to the Executive Director of Research and Education the Investigator's significant financial interests no later than the time of application for PHS-funded research.
- 8.4.7 Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially and must include updated information regarding any previously disclosed significant financial interest.
- 8.4.8 Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring a new significant financial interest.

9 Compliance

- 9.1 All investigators must comply with this policy.

10 Sources Referenced

- 10.1 eCFR – Code of Federal Regulations, 42 CFR 50 subpart F, accessed April 13, 2017 at <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rqn=div5&view=text&n ode=42:1.0.1.4.23&idno=42#sp42.1.50.f>



Disclosure of Significant Financial Interests Related to PHS-Funded Research

Instructions

Who must complete this form? The Principal Investigator(s), Co-Investigator(s), and any other person who is independently responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS) or any of its awarding components (ie. NRG).

When must this form be completed? This form must be completed when the Company's Policy for the Financial Conflict of Interest in Research is revised, at the time of grant submission, when a grant is awarded, within 30 days of acquiring a new Significant Financial Interest is identified, or annually.

Name of person reporting: _____

Disclosures

<p>Publicly Traded Entity Have you, a member of your family (including spouse and dependent children), received in the past twelve (12) months remuneration and/or the value of any equity interest in the entity, from any publically traded entity exceeding \$5,000 in aggregate?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Non-Publicly Traded Entity Have you, a member of your family (including spouse and dependent children), received in the past twelve (12) months any payments exceeding \$5,000 in aggregate from any non-publicly traded entity?</p> <p>Do you, a member of your family (including spouse and dependent children), hold any equity interest in any non-publicly traded entity (such as stock, stock options, or other ownership interest)?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Intellectual Property Have you, a member of your family (including spouse and dependent children), received any payments in the past twelve (12) months, for any intellectual property rights and interests (ie. patents, copyrights) exceeding \$5,000?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Travel Have you received any travel reimbursement or been sponsored for travel (ie. travel expenses paid on your behalf and not reimbursed to you) in the past twelve (12) months by any entity, exceeding \$5,000?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

If you answered "Yes" to any questions, please complete page 2 of this form.

I certify that the information above is complete and true to the best of my knowledge.

Signature

Date

Please submit the following page if you answered “yes” to any of the questions on page 1 of this form. **Please provide the following information regarding the entity or entities (ie. pharmaceutical company) in which you have a Significant Financial Interest (use an additional page if necessary):**

Name of Entity	Type of Compensation Received
	<input type="checkbox"/> Salary <input type="checkbox"/> Consulting fees <input type="checkbox"/> Honoraria <input type="checkbox"/> Paid authorship <input type="checkbox"/> Loan <input type="checkbox"/> Stock <input type="checkbox"/> Stock options <input type="checkbox"/> Reimbursed travel <input type="checkbox"/> Other: _____
	<input type="checkbox"/> Salary <input type="checkbox"/> Consulting fees <input type="checkbox"/> Honoraria <input type="checkbox"/> Paid authorship <input type="checkbox"/> Loan <input type="checkbox"/> Stock <input type="checkbox"/> Stock options <input type="checkbox"/> Reimbursed travel <input type="checkbox"/> Other: _____
	<input type="checkbox"/> Salary <input type="checkbox"/> Consulting fees <input type="checkbox"/> Honoraria <input type="checkbox"/> Paid authorship <input type="checkbox"/> Loan <input type="checkbox"/> Stock <input type="checkbox"/> Stock options <input type="checkbox"/> Reimbursed travel <input type="checkbox"/> Other: _____
	<input type="checkbox"/> Salary <input type="checkbox"/> Consulting fees <input type="checkbox"/> Honoraria <input type="checkbox"/> Paid authorship <input type="checkbox"/> Loan <input type="checkbox"/> Stock <input type="checkbox"/> Stock options <input type="checkbox"/> Reimbursed travel <input type="checkbox"/> Other: _____
Travel	
For travel that was purchased on your behalf, rather than for which you were reimbursed, please explain:	Purpose of the trip: _____ Identity of the entity organizing the trip: _____ Destination: _____ Duration of the trip: _____ Estimate of value (if known): _____

I certify that the information above is complete and true to the best of my knowledge.

Signature

Date