

Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Public Health Services Sponsored Awards for Research

I. PURPOSE & SCOPE

This Policy implements the Public Health Service (PHS) regulations on Promoting Objectivity in Research, and is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, or proposal for supplemental funding. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a PHS Research Activity.

The Policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research. This Policy is to be reviewed in conjunction with O.N. Diagnostics' "Investigators' Statement of Financial Interest" form.

II. DEFINITIONS

For the purposes of this policy, the following terms shall apply:

Designated Official: O.N. Diagnostics staff designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator to determine whether an Investigator's Significant Financial Interest is related to the Investigator's PHS Research Activity and if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest. Furthermore, the Designated Official is also charged with determining if Significant Financial Interests that are related to the proposed research constitute Financial Conflicts of Interest and developing plans to eliminate, reduce or manage Financial Conflicts of Interest. The Designated Official will be appointed by the Chief Executive Officer and/or Chief Science Officer.

Financial Conflict(s) of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS Research Activity.

Institutional Responsibilities: All job functions including research and staff management on behalf of O.N. Diagnostics which are in the course and scope of the Investigator's employment at O.N. Diagnostics.

Investigator: The Principal Investigator or project director, and any other person regardless of title or position, who is responsible for the design, conduct or reporting of research proposed for funding or funded by PHS.

Key Personnel: The Principal Investigator or project director and any other personnel considered essential to work performance and identified as Key Personnel in the contract or grant proposal.

PHS Research Activity(ies): Any award for which research funding is available from PHS, including research contracts and grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

PHS Awarding Component: The Health and Human Services agency issuing the funds for the PHS research activity (e.g. the National Institutes of Health).

Principal Investigator (PI): An Investigator who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.

Significant Financial Interest (SFI): Anything of monetary value that:

- meets the PHS thresholds (see Section III.C below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse or registered domestic partner and dependent children for the following categories; and
- reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

Examples of SFIs include:

- Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside of O.N. Diagnostics. Any such activities must first be cleared through O.N. Diagnostics' Chief Science or Chief Executive Officer.
- Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's research and/or administrative responsibilities.
- Receipt of income from any organization other than O.N. Diagnostics for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers and universities.
- The occurrence of travel by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, *excluding* a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

III. STATEMENT

The PHS regulations on Objectivity in Research (revised in August 2011) are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest.

Each institution applying for or receiving research support from PHS must comply with the regulations by putting in place a policy to ensure that:

A. Investigators complete a training/education program:

1. Before engaging in PHS Research Activities and at least every four years thereafter while receiving PHS research funding, and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

B. Investigators disclose SFIs at the following times:

1. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
2. Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:
 - Within 30 days of acquiring or discovering any new SFI; and
 - At least annually
3. New Investigators must complete an initial disclosure of SFIs before joining an ongoing PHS Research Activity.

C. Investigators disclose to O.N. Diagnostic, SFIs that meet the following thresholds:

1. For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months *and* the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement

funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a *non-publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds \$5,000, or equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.

[Investigators are not required to disclose (a) payments made by O.N. Diagnostics, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from O.N. Diagnostics; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

3. *Intellectual property rights and interests*: Income received during the previous 12 months that exceeds \$5,000 for such rights and interests.
4. *Travel*: The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:
 - a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
 - b. Within 30 days of the occurrence if the trip wasn't reported prospectively.

IV. DISCLOSURES BY COLLABORATORS

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from O.N. Diagnostics are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by O.N. Diagnostics will indicate that the subrecipient organization is responsible for reviewing and managing SFI disclosures and for sending O.N. Diagnostics notification of identified conflicts that cannot be managed 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 O.N. Diagnostics should be identified as Investigators by the O.N. Diagnostics PI and must complete the O.N. Diagnostics disclosure forms. If, upon review, O.N. Diagnostics determines that an SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to manage the identified conflicts of interest.

V. REVIEWS AND REPORTING

A. Disclosed SFIs will be reviewed prior to acceptance of new and renewal awards, and before submission of progress reports, proposals for supplemental funding, or requests for no-cost time extensions. Investigators may be asked to provide additional information about the SFIs that they previously disclosed. This information will be used by O.N. Diagnostics to conduct a preliminary review in order to reasonably determine whether any of an Investigator's SFIs:

- Could be affected by the PHS Research Activity; or
- Are in an entity whose financial interest could be affected by the research.

If after review it is determined that an SFI is related to the proposed PHS Research Activity, a second review will be conducted by the Designated Official to determine whether the SFI(s) reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS Research Activity and thereby constitute an FCOI that may need to be managed.

In accordance with the PHS regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the PHS Research Activity. Each management plan will specify the way in which that will be accomplished.

B. Initial reports of FCOI must be made to the PHS awarding component prior to O.N. Diagnostics' expenditure of any funds provided under a PHS Research Activity. O.N. Diagnostics is not required to submit a report to the PHS awarding component if conflicts of interest are eliminated before research funds are expended.

Additional FCOI reports must be submitted to PHS under the following circumstances:

1. Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (either through extension notification or an NIH prior approval request). When during the course of an ongoing PHS Research Activity an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
2. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS Research Activity.
3. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing PHS Research Activity.

C. When during the course of an ongoing PHS Research Activity, O.N. Diagnostics identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within 60 days to determine whether it is related to PHS Research Activities and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be an FCOI, or O.N. Diagnostics did not review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, O.N. Diagnostics must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS Research Activities. The purpose of this retrospective review is to determine if the ongoing PHS Research Activity was biased in its design, conduct or reporting.

- Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that O.N. Diagnostics will take to manage the identified FCOI.
- If bias was found during the retrospective review, O.N. Diagnostics will promptly notify PHS 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 O.N. Diagnostics' plans to eliminate or mitigate the effect of the bias.

VI. RECORDS ACCESS AND RETENTION

A. PHS regulations require that O.N. Diagnostics respond within 5 business days to any request for information about SFIs held by Key Personnel when O.N. Diagnostics has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs.

B. The information provided in the disclosure forms may be released or transmitted to PHS upon request. Completed disclosure forms also may be released in response to a public records request, pursuant to the terms of the California Public Records Act.

C. Records of financial disclosures, Designated Official's determinations, and actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

VII. PUBLIC ACCESSIBILITY

A. Prior to the expenditure of funds, O.N. Diagnostics will publish on the company's public website.

B. Prior to the expenditure of funds, O.N. Diagnostics will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the senior and key personnel;
 - A determination has been made that the SFI is related to the PHS-funded research; and
 - A determination has been made that the SFI is a FCOI.
- The information to be made available shall be consistent with the requirements of the PHS regulation.

C. FCOI-related postings will be reviewed and updated at least annually. Information related to newly identified FCOI will be posted within 60 days of discovery. Information in response to written requests will also be updated.

D. Information concerning identified FCOI will remain available for three years from the date the information was most recently updated.

VIII. SANCTIONS

Failure by an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline and/or dismissal. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, an agreement with a subrecipient organization may be terminated for cause if that organization fails to comply with its obligations under the PHS regulations. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and company policy.