

CONFLICT OF INTEREST
For HHS/PHS Funded Projects Only

INTRODUCTION

PerkinElmer, Inc., its affiliates and subsidiaries (collectively, “PerkinElmer”) is committed to conducting business with the highest ethical standards and in accordance with all applicable laws. The purpose of this policy is to implement the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94, and any additional regulations that may be in effect from time to time (collectively, the “Regulations”), governing certain responsibilities for promoting objectivity in HHS/PHS-funded Research (as defined herein). This policy supplements the existing PerkinElmer Standards of Business Conduct and does not replace it. Further, this policy only applies to PerkinElmer employees, contractors, consultants, and/or representatives who satisfy the definition of “Investigator” (as defined herein) in regard to any activity or project that is either directly or indirectly funded by, whether by subcontract, grant, or other collaboration, or which research funding is sought from, the Public Health Service (as defined herein).

The Company Official (as herein defined) is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Company Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action, up to and including termination of employment. This policy shall be construed in accordance with the Regulations and shall be deemed to include any requirements set forth in such Regulations that are not expressly set forth below as may be updated from time to time. If there are substantive differences between this policy and the requirements contained within the Regulations, then the requirements within the Regulations shall take precedence.

DEFINITIONS

“Company Official” means the individual within PerkinElmer that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s responsibilities at PerkinElmer. For the purposes of this policy, the Company Official is designated as the General Counsel or his/her designee.

“Company Responsibilities” means the Investigator’s professional responsibilities associated with his or her position.

“Family” means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

“Financial Interest” means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does **NOT** include:

- a) salary, royalties, or other remuneration from PerkinElmer;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Company Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It **excludes** travel reimbursed or sponsored by PerkinElmer, U.S. Federal, state or local governmental agencies, U.S. institutions of higher education as defined at 20 U.S.C. 1001(a), research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

“Significant Financial Interest” means a Financial Interest that reasonably appears to be related to the Investigator’s Company Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through PerkinElmer.

“Financial Conflict of Interest” means a Significant Financial Interest (or, where the Company Official requires disclosure of other Financial Interests, a Financial Interest) that PerkinElmer reasonably determines could directly and significantly affect the design, conduct or reporting of HHS/PHS sponsored research.

“Investigator” means any individual who is responsible for the design, conduct, or reporting of HHS/PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

“Public Health Service” or *“HHS/PHS”* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the HHS/PHS to which the authority of the HHS/PHS may be delegated. The components of the HHS/PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

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

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and PerkinElmer to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Company Official.

- 1) **Disclosure of Financial Interests.** All Investigators are required to disclose their *outside* Financial Interests (as defined above) to PerkinElmer on an annual and on an ad hoc basis, as described below. The Company Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.
 - a. *Annual Disclosures.* All Investigators must disclose their Significant Financial Interests that are related to the investigator's Company Responsibilities to PerkinElmer, through the Company Official, on an annual basis using the disclosure form. All forms must be submitted to the Company Official by April 1 for the previous calendar year or as determined by PerkinElmer.
 - b. *Ad hoc Disclosures.* In addition to the annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to PerkinElmer using the disclosure form within (30) days of their initial appointment or employment under a HHS/PHS funded project.

Prior to beginning any HHS/PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the accuracy of the annual disclosure or submit to the Company Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity.

In addition, all Investigators must submit to the Company Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

- 2) **Review and Decision of the Company Official.** If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Company Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Company Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Company Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of HHS/PHS-sponsored research. If the Company Official determines that there is a Financial Conflict of Interest that can be managed, he or she will work with PerkinElmer management to develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related HHS/PHS-sponsored research may proceed. The Company Official and/or PerkinElmer management will periodically review the ongoing activity, monitor the conduct of the activity, ensure open and timely dissemination of the research results, and otherwise oversee compliance with the management plan.

- 3) **Reporting to HHS/PHS.** The Company Official will report financial conflicts of interest or non-compliance to HHS/PHS in accordance with the Regulations. If the funding for the Research is made available from a prime HHS/PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the HHS/PHS.
- 4) **Investigator Non-Compliance.**
 - a. *Disciplinary Action.* In the event of an Investigator's failure to comply with this policy, the PerkinElmer may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Company Official is implemented. PerkinElmer's decision to impose disciplinary action on an Investigator because of failure to

comply with this policy, or failure to comply with the decision of the Company Official, will be documented in writing and will be provided to the Investigator, a copy of which will be recorded in the employee's personnel file. The Investigator shall be allowed to submit a rebuttal and such rebuttal will also be placed in the employee's personnel file. PerkinElmer will promptly notify the HHS/PHS of any action taken or to be taken, or if the funding for the Research is made available from a prime HHS/PHS awardee, such notification shall be made promptly to the prime awardee for reporting to HHS/PHS.

- b. **Retrospective Review.** In addition, if PerkinElmer determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Company Official will within 120 days of such determination complete a retrospective review of the Investigator's activities and the HHS/PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, principal investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review. PerkinElmer will update any previously submitted report to the HHS/PHS or the prime HHS/PHS-awardee relating to the research specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in the Regulations. If bias is found, the institution will promptly notify HHS/PHS or the HHS/PHS-awardee and submit a mitigation report in accordance with the Regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

- 5) **Mandatory Training.** All Investigators will be required to complete training on this policy and the Regulations. This training must be completed every four years and prior to engaging in research related to any HHS/PHS-funded project. Further training will also be required immediately if any of the following circumstances apply:
 - a. This policy or procedures contained within or the HHS/PHS financial disclosure form are revised in any manner that affects the requirements of Investigators;
 - b. An Investigator joins PerkinElmer; or
 - c. PerkinElmer is made aware of an Investigator who is not in compliance with this policy.

To fulfill the training requirement, all PerkinElmer personnel involved on any HHS/PHS-funded project will be required to read through this policy and sign an acknowledgment that they have read and understood all policies, rules, and regulations contained within this document. Further, all such personnel must complete the NIH Office of Extramural Research web-based "Financial Conflict of Interest Online Tutorial" at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. At the end of the tutorial, each person should fill out the Certificate of Completion and return a copy to the Company Official or his/her designee.

- 6) **Record Retention.** The Company Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the HHS/PHS or to the prime HHS/PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period. In such case, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

- 7) **Confidentiality**. To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, PerkinElmer may be required to make such information available to: (a) the HHS/PHS; (b) to a requestor of information concerning financial conflict of interest related to HHS/PHS funding; or (c) to the primary entity who made the funding available to PerkinElmer, if requested or required. Investigators understand and acknowledge that such information submitted may become publicly accessible.

- 8) **Public Accessibility**. Prior to the expenditure of funds, PerkinElmer will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:
 - a. The Significant Financial Interest was disclosed and is still held by the senior and/or key personnel, as defined in the Regulation;
 - b. A determination has been made that the Significant Financial Interest is related to the HHS/PHS-funded research; and
 - c. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the Regulations.