



Pacific Diabetes Technologies: Conflict of Interest Policy and Questionnaire

Effective Date: Sept 2, 2014

Revision Date: Sept 8, 2014

Responsible PDT Official (Institutional Officer, IO): Chief Science Officer (CSO)

Responsible PDT Committee (PDT COI Committee): This committee is composed of PDT's CEO, PDT's CSO, and one outside member. Currently (Sept-2014), these members include Robert Cargill, W.K. Ward and Sandra Shotwell, respectively.

I. Policy Statement

Pacific Diabetes Technologies (Portland, OR, PDT) is committed to overseeing research, product development and product sales (and potentially sponsored projects) in a manner that ensures the integrity of the process. This commitment requires PDT to establish standards that provide a reasonable expectation that results will not be biased by the external commitments and financial interests of persons who are responsible for the design, conduct, and reporting of PDT's work. Every PDT worker has an obligation to become familiar with, and abide by, the provisions of the policy.

The policy identifies and addresses the real or apparent financial conflicts of interest (FCOI) that may occur when a worker's private interests (such as outside professional or financial relationships) may compete with his or her obligations to PDT, and defines the requirements of all workers to ensure that those activities are conducted objectively and without consideration of personal financial gain. Procedures for implementing this policy are set forth in Section V.

Often, it may be difficult for a worker to determine if he/she has a FCOI. For this reason, workers are encouraged to report all *potential* COI's even if they are unsure whether or not it is, in fact, a true COI. The intent of the COI policy is for the COI Committee to make the final determination of whether a true COI exists.

PDT will comply with all applicable federal and state laws and regulations regarding Financial Conflicts of Interest (FCOI). In addition, PDT will comply with agency- or award-specific requirements where applicable. This policy includes the COI policy for conducting federal grant research such as for SBIR awards.

II. Reason for the Policy

The integrity of PDT's work is of the utmost importance. The principles and procedures of this policy



ensure that workers will report their external commitments and financial interests in a timely manner and that the FCOI (real and apparent) of investigators will be identified and responsibly managed. This policy promotes compliance with all applicable federal and state laws, regulations, and policies regarding financial conflicts of interest.

III. Applicability

This policy applies to all PDT staff, including PDT consultants/contractors. It also pertains to Public Health Service (PHS) funded awards.

IV. Principles

External Relationships

PDT recognizes the value of fostering synergistic relationships between its workers and the public and private sectors in research, instructional, and service activities. Conflicts of interest are an inevitable part of conducting these activities and do not necessarily suggest any impropriety on the part of the worker. Most conflicts of interest can be successfully resolved without impeding the project.

Academic Freedom and Responsibility

PDT is dedicated to upholding the principles of free and unbiased inquiry, the transfer of ideas and technologies for the benefit of the public, and stewardship of the resources entrusted to it as an integral part of its institutional mission. Real or apparent FCOI will be managed appropriately to allow workers the latitude needed to pursue both their commitments.

Human Subjects and Animal Research

Research involving human and animal subjects is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of participants in such research from harm or undue risks associated with FCOI is of the utmost importance and is a requirement of PDT workers.

Confidentiality and Sharing of Financial Information

PDT is committed to maintaining the confidentiality of reported information as far as is practicable and consistent with legal obligations. Individuals with access to confidential personal information are required to sign a confidentiality agreement. If PDT is requested to provide disclosure forms, conflict management plans (CMP), and related information to an outside entity, the Investigator will be informed of this disclosure.

V. Procedure for Disclosure of Financial Interests and Management of Conflicts of Interest



Annual Disclosure Process

PDT's *Conflict of Interest* (COI) policy requires all employees must annually disclose their and their family members' significant financial interests (SFI) that reasonably appear to be related to their institutional responsibilities. After disclosure, PDT can make an informed judgment about each case and require appropriate oversight, limitations, or prohibitions on the activity.

PDT workers must disclose (1) annually, (2) within thirty (30) days of discovering or acquiring a new SFI, (3) when required by the sponsor or by the specific terms of an award, (4) upon starting work at PDT, and (5) when otherwise required by PDT.

Review of Disclosures and Development of Conflict Management Plans (CMP)

The Institutional Official (IO), or his/her designee, will review the annual disclosure and any supplementary documents to determine whether any disclosed SFI is related to PDT work and, if so, whether a financial conflict of interest exists. If it is determined that no FCOI exists, it will be so noted and the disclosure will be stored in a manner to protect confidentiality; the project may proceed according to its plan. If it is determined that a FCOI exists, it will be managed in accordance with this policy.

Considerations in developing the conflict management plan (CMP) include the nature of the project, the magnitude of the interest and the degree to which the conflict is related to the project, the extent to which the interest could be directly and substantially affected by the work or project, and any conflict management strategies proposed or already in place.

Key elements of the management plan include the role and principal duties of the conflicted worker, conditions of the management plan, an explanation of how the management plan is designed to safeguard objectivity, confirmation of the worker's agreement to the management plan, a plan for monitoring the CMP, and any other information needed to manage the conflict effectively.

The conditions or restrictions that may be imposed to manage FCOIs include, but are not limited to:

- a. Public disclosure of the conflict to co-investigators, journal editors, research subjects, etc.; in publications and presentations; and, in the case of human research, the informed consent document
- b. Monitoring of the project by independent reviewers
- c. Designation of a substitute PI (peer or supervisor) who has no SFI in the project
- d. Changing personnel or personnel responsibilities, or disqualifying personnel from participation in all or in a portion of a project
- e. Modifying the project plan to manage, reduce, or eliminate the COI



- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- g. Severance of relationships that create financial conflicts

All disclosures of financial interest that require development of a management plan will be reported to the COI Committee for their review and recommendations.

The COI Committee will consider the proposed management plan at its next regularly scheduled meeting. No individual member of the committee who holds a SFI in a project may participate in the review of its management strategy. The committee may approve the plan as presented or require modifications that will be finalized in consultation with the IO.

The investigator and other parties to the CMP must agree within ten (10) days in writing to accept the management plan.

Annual Review and Oversight of the CMP

The IO (CSI) will monitor the CMP until the completion of the project, and report annually to the COI committee on the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and any changes to the management plan since the last review. To address complex situations, the IO may establish oversight committees to periodically review the ongoing activity, to monitor the conduct of the activity, to ensure open and timely dissemination of results, and to otherwise oversee compliance with the CMP. Projects that are determined by the COI committee to be compliant may continue in accordance with the requirements of the project.

Records

All disclosure forms, conflict management plans, and related documents in accordance with Oregon state law; or where no policy is specified, for a period of five years.

Public Disclosure of COI

If a COI was not disclosed or managed in compliance with this policy, federal law may require the investigator to disclose the COI in all public presentations or publications of the results.

Failure to Comply

Non-compliance with this policy or with restrictions imposed under this policy may result in disciplinary action and/or sanctions under PDT policies and procedures pertinent to such actions and circumstances.



VI. Definitions

Conflict of Interest (COI) may take many forms and exists whenever personal (including those of family members), professional, commercial, or financial interests or activities outside of PDT have the possibility of compromising an individual's judgment; biasing the nature or direction of work or scholarly research; influencing an individual's behavior with respect to teaching, service, student affairs, appointments and promotions, use of PDT resources, interactions with human subjects, or other matters of interest to PDT; resulting in personal gain or advancement.

Conflict Management refers to the actions that have been, or will be, taken to manage a Financial Conflict of Interests (FCOI).

Conflict Management Plans (CMP) are designed to afford a reasonable expectation that the design, conduct, and reporting of research, work, training or service activities will be free from bias or personal gain resulting from Investigator FCOI.

Disclosure is reporting financial interests related to the Investigator's Institutional responsibilities, including Significant Financial Interests (SFI).

Family means any member of the worker's immediate family, specifically, spouse/domestic partner and any dependent children.

Financial Conflict of Interest (FCOI) means a SFI that EITHER

- (1) Is related to work at PDT and that could directly and significantly affect the design, conduct, or reporting of the work, or
- (2) Could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest means anything of monetary value received or held by an Investigator or a member of the 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); 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 income related to such rights and interests. ONLY financial interests that arise to the level of significant (SFI, defined below) represent potential FCOI. Financial Interest does NOT include:

- Salary, royalties, or other remuneration received from or through PDT
- Intellectual property rights assigned to PDT and agreements to share in royalties related to such rights
- Income from the authorship of academic or scholarly works
- Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or U.S. research institutes that are affiliated with institutions of higher education, academic teaching hospitals, and medical centers
- Financial interests arising solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the employee does not exercise direct control



Institutional Official (IO) means the individual within the Institution, or his/her designee, that is responsible for the solicitation and review of disclosures of SFIs, including those of the Investigator's Family related to the Investigator's Institutional Responsibilities; development and oversight of Conflict Management Plans; and retention of disclosure forms, conflict management plans, and related documents. For PDT, the CSO is the IO.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, and service activities, administration, and institutional, internal and external professional committee service.

Investigator means any person, regardless of title, position, or employment status who is responsible for the design, conduct, or reporting of research, instruction, or service at, on behalf of, or in collaboration with PDT.

Worker is any employee of PDT.

Principal Investigator (PI) or Project Director (PD) is an individual formally designated by PDT who is responsible for the administrative and programmatic leadership of the project.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), the Indian Health Service (IHS), the Administration for Community Living (ACL), and the Agency for Healthcare Research and Quality (AHRQ).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, and development. All forms of scholarship and creative activities are included.

Significant Financial Interest (SFI) means a Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- If with a publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure, and the value of any equity interest during the twelve-month period preceding or as of the date of disclosure, exceeds \$5,000. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or 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.
- If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure exceeds \$5,000; or is an equity interest of *any value* during the twelve-month period preceding or as of the date of disclosure. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or 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.
- Is income related to intellectual property rights and interests (e.g., patents, copyrights, but NOT including income from the authorship of academic or scholarly works) not paid through the Institution.



Sponsored Project: Research, training, or service activity funded by an outside agency, either through a grant, contract, or other transaction.

VII. Reports to Funder:

The reports referred to in this Section apply to instances when the Funder is the US Public Health Service (PHS). Any Conflict of Interest reports to non-PHS Funders shall be made in accordance with such Funder's policy or instructions. In cases where the FCOI is eliminated prior to the expenditure of PHS-awarded funds, no FCOI Report will be submitted to the PHS awarding component.

i. FCOI Reports

(a) Required Information

All FCOI Reports must include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of PDT's Management Plan. The FCOI Report must include the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the Entity with which the Investigator has a FCOI;
- Nature of the SFI (e.g., equity, consulting fee, travel reimbursement, honorarium);
- The value of each SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts above that in increments of \$20,000, or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value);
- A description of how the SFI relates to the PHS-funded research and why PDT determined that the SFI conflicts with such research; and
- A description of the key elements of the Management Plan.

(b). Subrecipients

PDT must take reasonable steps to ensure that all Subrecipients that receive PHS funds from or through PDT comply with FCOI regulations promulgated by HHS. Subrecipients who rely on the Subrecipient's own FCOI policy must certify to PDT in writing that the Subrecipient's policy complies with 42 CFR Part 50 or Part 94, as applicable.

(c) Mitigation Reports

If bias is found in the course of a Retrospective Review conducted under Section III.b.iii, PDT shall notify the PHS awarding component promptly and submit a Mitigation Report to the PHS awarding component.



VIII. References

National Science Foundation Award Administration Guide (NSF 09-29) (April 2009).

Department of Health and Human Services (HHS), Public Health Service (PHS), 42 Code of Federal Regulations (CFR) Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" for grants and cooperative agreements; and 45 CFR Part 94, "Responsible Prospective Contractors" for contracts.

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Conflict of Interest Disclosure -

All members of the company are required to answer a set of short, general questions intended to identify individuals with a potential COI (*see questionnaire below*). Only those individuals who are identified as having a possible COI based on their responses to these questions will be contacted by the PDT COI review committee to answer additional, more detailed questions.

ROLES: If you have questions about PDT's COI policy, NIH regulations, or AAHRPP standards, please contact the IO (Chief Science Officer) of PDT.

Conflict of Interest Questionnaire:

THESE QUESTIONS MUST BE ANSWERED BY ALL EMPLOYEES OF PDT WITHIN 1 MONTH OF EMPLOYMENT (OR WITHIN ONE MONTH OF INITIATION OF THE COI POLICY), ANNUALLY, AND WITHIN 30 DAYS OF A CHANGE IN COI STATUS. FOR EXAMPLE, IF EMPLOYEE A ACQUIRES \$20,000 OF STOCK IN A VENDOR OR COMPETITOR OF PDT, HE/SHE MUST ANSWER THESE QUESTIONS WITHIN 30 DAYS. THE ANNUAL FORM WILL BE GIVEN TO ALL EMPLOYEES AT THE FIRST WORKING DAY OF JANUARY EVERY YEAR AND MUST BE TURNED IN BY THE LAST DAY OF JANUARY.

#1 *Do you, your spouse, domestic partner, or dependents have any outside interests or relationships to companies or entities related to your work at PDT (including research)?

Examples of outside interests include, but are not limited to, the following:

- receiving compensation whose value could be affected by the outcome of work performed at PDT
- IN THE AGGREGATE, having received compensation from the vendor, competitor (eg medical device company), or sponsor of the research of \$5,000 or greater in the last year
- having a proprietary interest in a vendor, competitor (eg medical device company), or the sponsor of the research or a product tested by this research including but not limited to, a patent, trademark, copyright, or licensing agreement, or the right to receive royalties from product commercialization
- individually or collectively, having an ownership interest (equity or stock options) in a vendor, competitor (eg medical device company) or the sponsor of the research or product being tested whose value cannot be readily determined through reference to public prices
- individually or collectively, having an ownership interest (equity or stock options) in a company or product whose value could be affected by work (e.g. R&D) at PDT
- IN THE AGGREGATE, having an ownership interest (equity or stock options) in a vendor, competitor (eg medical device company) or the sponsor of the research that exceeds \$10,000 or 1% when the sponsor is a publicly traded or private entity
- receiving significant payments of other sorts with an aggregate value of \$10,000 or made directly by a vendor, competitor (eg medical device company) or the sponsor of this research for unrestricted research or education, equipment, consultancy, or honorarium
- holding a position of management or leadership in company or entity related to work at PDT including, but not limited to, officer, director, or member of an advisory board. Includes work for a competitor (eg medical device company)
- when the sponsor is a publicly traded entity, having any ownership interest (equity or stock options) in the sponsor.

Yes No

If response to #1 is Yes, you must respond to the following questions:



#2 Please provide a detailed description of the outside interest in the box below.

#2.2 Has a management plan for this COI already been formalized by another organization?

Yes No

#2.2.1 If yes, attach the management plan here, as well as any other applicable conflict of interest documents.

#2.2.2 If no, describe the financial interest in sufficient detail to permit the PDT COI Committee to determine if such involvement represents a potential conflict-of-interest and/or should be disclosed to potential research subjects in the informed consent form.

