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<b>CONFLICT OF INTEREST POLICY FOR PHS-SPONSORED INVESTIGATORS</b>			

## **INTRODUCTION**

This policy governing financial conflict of interest applies to all Public Health Service, or PHS, sponsored Investigators of Vivani Medical, Inc. ("Vivani"). The Compliance Officer is responsible for ensuring implementation of this policy and may suspend all relevant activities until any financial conflict of interest is resolved or other action deemed appropriate by Compliance Officer is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Vivani policy.

## **DEFINITIONS**

*Clinical Trial* means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

*Conflict of Interest Committee (COIC)* means the Vivani committee that advises the Compliance Officer on conflict of interest matters. The committee consists of the Compliance Officer and members appointed by the Compliance Officer.

*Family* means any member of the Investigator's immediate family, specifically, a spouse or domestic partner, children, parents, and/or siblings.

*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, benefits, bonuses, stock options, or other remuneration from Vivani;
- 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



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- 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.

*Significant Financial Interest* means a Financial Interest, other than remuneration from Vivani, that reasonably appears to be related to the Investigator's 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 Vivani.

*Financial Conflict of Interest* means a Significant Financial Interest (or, where the Compliance Officer requires disclosure of other Financial Interests, a Financial Interest) that Vivani reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

*Compliance Officer* means the individual within Vivani 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 Vivani responsibilities.

*Vivani responsibilities* means the Investigator's professional responsibilities associated with his or her Vivani position, such as research, clinical activities, and administration.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of 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. The definition may also include collaborators or consultants as appropriate.

*Public Health Service* means the Public Health Service of the U.S. Department of Health and Human Services, 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 Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality,



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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 Vivani 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 Compliance Officer.

## **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests as defined above to Vivani on an annual, and on an ad hoc basis, as described below. The Compliance Officer is responsible for the distribution, receipt, processing, and review of disclosure forms. Disclosure forms will be retained in the Employee's personnel file kept by the Manager of Human Resources.

### **a) Annual Disclosures**

All Investigators must disclose their Significant Financial Interests that are related to the Investigator's responsibilities to Vivani, through the Compliance Officer, on an annual basis on the form attached to this policy as Exhibit A. All forms should be submitted to the Compliance Officer or designee by March 1 for the previous calendar year.

### **b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to Vivani, through the Compliance Officer, within 30 days of their initial appointment or employment.



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Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Compliance Officer an ad hoc updated disclosure of his or her Significant Financial Interests with an outside entity. Vivani will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Compliance Officer 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 COMPLIANCE OFFICER**

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Compliance Officer or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Compliance Officer, in consultation with the COIC, 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 Compliance Officer or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Compliance Officer determines that there is a Financial Conflict of Interest that can be managed, he or she must 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 PHS-sponsored research goes forward.

The Compliance Officer will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

## **3) CLINICAL TRIALS**

### **Review of Significant Financial Interests Related to Clinical Trials**

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.



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- a) In conducting clinical trials, the safety of the subject is always paramount. Vivani only conducts clinical trials under IRB (“Institutional Review Board”) approval with review by an independent safety monitor.
- b) In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations. Investigators shall also disclose affiliation with Vivani in any public presentation of results of PHS-sponsored research.

#### **4) REPORTING TO PHS**

The Compliance Officer will report Financial Conflicts of Interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime 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 PHS.

#### **5) INVESTIGATOR NON-COMPLIANCE**

##### **a) Disciplinary Action**

In the event of an Investigator’s failure to comply with this Policy, the Compliance Officer may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Compliance Officer is implemented.

A Compliance Officer’s decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Compliance Officer, will be described in a written explanation of the decision to the Investigator, COIC, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. Vivani will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

##### **b) Retrospective Review**



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In addition, if the Compliance Officer 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 COIC will complete a retrospective review of the Investigator's activities and the 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.

The Compliance Officer will update any previously submitted report to the PHS or the prime 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 PHS regulations. If bias is found, Vivani will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS 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.

## **6) TRAINING**

Each Investigator must complete training on this Policy, the Investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Compliance Officer in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to Vivani, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## **7) RECORD RETENTION**

The Manager of Human Resources 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 PHS or to the prime PHS awardee, unless any litigation, claim,



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financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

## **8) CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Vivani may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to Vivani, if requested or required. If Vivani is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **9) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, Vivani will publish on a publicly-accessible website or 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 key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the 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 PHS regulation.

## **10) REGULATORY AUTHORITY**

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.





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## Exhibit A

### Financial Interests Report

(Submitted pursuant to the requirements of the Vivani Conflict of Interest policy)

Name: \_\_\_\_\_

I am reporting on activities: ☐ for the year \_\_\_\_\_ ☐ as an addendum to my most recent report

<input type="checkbox"/> Yes	<input type="checkbox"/> No	1. Compensation (including travel expenses). Have you or a member of your family received compensation from a for-profit entity other than Vivani Medical, Inc. (Vivani) for activities such as consulting, expert witness, advisory board membership, and the like, that reasonably appears to be related to your Investigator's responsibilities? If yes, furnish information on an additional page.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity other than Vivani, that reasonably appears to be related to your Investigator's responsibilities? If yes, furnish information on an additional page.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of Vivani, that reasonably appears to be related to your Investigator's responsibilities? If yes, furnish information on an additional page.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity, that reasonably appears to be related to the your Investigator's responsibilities? Do <b>NOT</b> include intellectual property owned or managed by Vivani. If yes, furnish information on an additional page.



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**Certification:**

I have read and understand the Vivani Conflict of Interest Policy in PHS Funded Projects and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by Vivani to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

\_\_\_\_\_  
(Date) (Signature)

☐ Additional page(s) attached

Addition to Financial Interests Report of: \_\_\_\_\_

Reporting for ☐ Self ☐ Family Member:

Name: \_\_\_\_\_

Relationship: \_\_\_\_\_

Name of External Entity: \_\_\_\_\_

Address of External Entity: \_\_\_\_\_

Type of external relationship: (check all that apply)

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: \$ \_\_\_\_\_

If travel paid by entity:

Destination: \_\_\_\_\_

Amount: \$ \_\_\_\_\_

Comments or explanatory information