

# Virgin Instruments Corp.

## Financial Conflict of Interest Policy

Revised December 5, 2012

SUBJECT: Policy for Management of Financial Conflicts of Interest Related to Research and Technology Transfer Transactions.

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### **I. GENERAL POLICY**

No research, sponsored program, or technology transfer activities occurring at Virgin Instruments Corp. (the Company) shall be adversely affected by the financial interests of Virgin Instruments personnel carrying out those activities. Prior to participating in a research, sponsored program, or technology transfer activity, personnel having a potential conflict of interest shall disclose the details to the Company. An official designated by the Company shall be responsible for reviewing disclosures and instituting an adequate plan for the management of any potential financial conflicts of interest. The ultimate goal of this Policy is to protect the integrity and credibility of activities related to research and technology transfer and to maintain public trust and confidence in the Company and its employees.

All research and technology transfer transactions undertaken at the Company shall be conducted in full compliance with all Company policies and all applicable federal and state laws pertaining to conflicts of interest, including applicable rules and regulations of the United States government..

Persons failing to comply with this Policy shall be subject to sanctions as provided herein and by other applicable Company policies and rules.

### **II. BACKGROUND**

The competitiveness of the United States in the global marketplace depends on the efficient translation of research into new products, services and technologies. Enhancing national competitiveness, as well as national security, requires effective interaction among the federal

government, industry, and research universities. Federal policy clearly favors promotion of these governmental, university, and industry relationships in research and technology transfer.

The policies and incentives favoring collaboration also make stewardship of research and technology transfer transactions at the company complex and challenging, particularly when the safety and well-being of human subjects is involved. The benefits of research to the nation's health and economy must not be compromised by conflicts of interest that have the potential to produce bias in the design, conduct, or reporting of research or to distort technology transfer transactions. At the same time, it must be recognized that both significant human and economic costs will be incurred if the benefits of useful research are unreasonably delayed.

The policy and procedures set forth herein seek to maintain an appropriate balance among all of these competing interests by establishing effective mechanisms to identify and manage conflicts of interest that may adversely influence research or distort technology transfer transactions.

This Policy is intended to establish compliance with the rules adopted effective September 26, 2011 by the U.S. Public Health Service and October 1, 1995 by the U.S. National Science Foundation requiring that grantee institutions adopt, maintain and enforce written policies pertaining to researchers' financial conflicts of interest.

### III. DEFINITIONS

For purposes of this Policy, the following definitions shall apply:

1. “**Compensation**” means any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, honoraria, and paid authorship.
2. “**Conflict Management Plan**” means a written plan instituted by the Company for the management, reduction or elimination of a Financial Conflict of Interest.
3. “**Entity**” means any domestic or foreign, public or private, for profit or not-for-profit legal entity or organization other than the Company.
4. “**Equity**” means any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.
5. “**Financial Conflict of Interest**” or “**FCOI**” means a Significant Financial Interest of an Investigator or Innovator that could directly and significantly affect the design, conduct, or reporting of Research or adversely affect a Technology Transfer Transaction.
6. “**Financial Interest**” means anything of monetary value, including but not limited to Compensation, Equity, Gifts, and Intellectual Property, of an

Investigator or Innovator or the Immediate Family Member of an Investigator or Innovator, whether or not the value is readily ascertainable.

7. “**Financial Interest Disclosure System**” means a Company maintained and operated online system for reporting SFI Disclosures and Travel Disclosures.
8. “**Gift**” means anything of economic value for which no consideration is given.
9. “**Immediate Family Member**” means a person's spouse, domestic partner, parent, grandparent, grandchild, sibling, child, or anyone who qualifies as the person's dependent under the U.S. Internal Revenue Code.
10. “**Innovator**” means any Company personnel regardless of title or position who has created in whole or in part any Intellectual Property in which the Company has any right or interest.
12. “**Institutional Official**” means one or more persons designated by the Company as having responsibilities and authority under this Policy.
13. “**Institutional Responsibilities**” means any professional activity carried out by an Investigator or Innovator for which the Investigator or Innovator is compensated by the Company, including: (i) sponsored activities (such as Research, training, and similar activities sponsored by external sources including federal, state and local governments and private businesses, corporations, foundations and organizations), (ii) non-sponsored activities such as Company supported Research.
14. “**Intellectual Property**” means the rights comprising a patent, trademark, copyright, trade secret, know-how or other similar intangible property right, including but not limited to, inventorship or authorship.
15. “**Investigator**” means any company personnel regardless of title or position responsible for the design, conduct, or reporting of company Research. Investigator includes, but is not limited to, the Principal Investigator, project director, co-principal investigator, and may also include other Senior/Key Personnel, a post-doctoral fellow, graduate student, trainee, staff member, collaborator, or consultant, depending on the person's role in the Research. The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to the design, conduct and reporting of the Research and the degree of independence that individual may have in performing such Research-related tasks.
16. “**Non-PHS-Funded Investigator**” means an Investigator who is neither applying for nor participating in any PHS-Funded Research.

17. “**PHS**” means the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

18. “**PHS-Funded Investigator**” means an Investigator applying for or participating in any PHS-Funded Research. For the avoidance of doubt, PHS-Funded Investigator includes an Investigator applying for or participating in both PHS-Funded Research and non-PHS-Funded Research.

19. “**PHS-Funded Research**” means any Research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. Notwithstanding the foregoing, PHS-Funded Research does not include any Phase I SBIR Program application or award.

20. “**Policy**” means this Financial Conflict of Interest Policy.

21. “**Principal Investigator**” means any person designated by the Company with the title of “Principal Investigator” of a Research or other sponsored project or otherwise having primary responsibility for the management and conduct of a Research or other sponsored project, including a project director.

22. “**Reimbursed Travel**” means travel activity for which the Travel Expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such Travel Expenses. Notwithstanding the foregoing, Reimbursed Travel shall not include Travel Expenses that are reimbursed by the Company, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

23. “**Research**” means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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) and also includes any activity for which research funding is available through a grant or cooperative agreement, research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

24. “**Senior/Key Personnel**” means the Principal Investigator and any other person identified as senior or key personnel by the company in a grant application, award, or contract or in any progress report, or any other report submitted to the PHS or other funding source.

25. “**SFI Disclosure**” means a disclosure of a Significant Financial Interest as provided in this Policy.

26. “**Significant Financial Interest**” or “**SFI**” means any of the following Financial Interests related to the Institutional Responsibilities of an Investigator or Innovator:

a. With regard to any Entity whose Equity securities are publicly-traded, a Significant Financial Interest exists if the aggregate value of one or more of the following exceeds \$5,000: (i) any Compensation received during the twelve (12) months preceding the date of SFI Disclosure, (ii) any Compensation reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, (iii) the value of any Equity interest in the Entity as of the date of SFI Disclosure;

b. With regard to any Entity whose Equity securities are not publicly-traded, a Significant Financial Interest exists if (i) the value of any Compensation received from the Entity in the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, when aggregated, exceeds \$5,000, or (ii) the Investigator or Innovator holds any Equity interest (e.g., stock, stock option, or other ownership interest);

c. With regard to any Entity, a Significant Financial Interest exists if the Investigator or Innovator has received income related to any Intellectual Property during the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure which, when aggregated with other Financial Interests in the Entity, exceeds \$5,000;or

d. With regard to any Entity, a Significant Financial Interest exists if during the twelve (12) months preceding or following the date of SFI Disclosure, the Investigator or Innovator receives or reasonably anticipates receiving one or more Gifts (including but not limited to Reimbursed Travel or Sponsored Travel meeting the definition of Gift) having an aggregate value of \$50 or more from the Entity.

27. “**Small Business Innovation Research Program**” or “**SBIR Program**” means an extramural federal program providing financial sponsorship or support for small businesses through PHS awarding components and certain other federal agencies established under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this Policy, SBIR Program also

includes the Small Business Technology Transfer Program, established under Public Law 102-564.

28. “**Sponsored Travel**” means travel activity, the Travel Expenses for which are paid directly by an Entity on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available to the Investigator. Notwithstanding the foregoing, Sponsored Travel shall not include Travel Expenses that are paid by the University, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

29. “**Technology Transfer Transaction**” means a transaction through which the company conveys or transfers or negotiates to convey or transfer a company Intellectual Property right to a third-party.

30. “**Travel Disclosure**” means a disclosure of Sponsored Travel or Reimbursed Travel as provided in this Policy.

31. “**Travel Expenses**” means expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

## **IV. PROCEDURES**

### **A. Use of Financial Interest Disclosure System; Identification of Investigators**

Investigators and Innovators shall be personally responsible for ensuring that their SFI Disclosures and Travel Disclosures required to be disclosed under this Policy are submitted in a complete and timely manner through the Financial Interest Disclosure System and in accordance with procedures and guidelines established by the Company. For all Research projects, the Principal Investigator shall be responsible for identifying all Senior / Key Personnel who are also Investigators as they become known and reporting their identity within ten (10) days thereafter.

### **B. Authority of Institutional Official**

The Institutional Official is authorized to administer and enforce this Policy. Such authorization includes the authority to (i) obtain and review SFI Disclosures and Travel Disclosures under this Policy, (ii) develop and implement Conflict Management Plans, (iii) conduct any required late or retrospective FCOI reviews, including issuance of reports of findings and conclusions and development and implementation of conflict mitigation plans, (iv) communicate with federal and other sponsors on matters pertaining to this Policy; (v) make recommendations to the company with respect to matters covered by this Policy; (vi) develop and implement reasonable and appropriate summary procedures for the disposition of

matters involving compliance with this Policy; and (vii) suspend, for good cause, an ongoing Research project or pending Technology Transfer Transaction to prevent any probable or continued violations of this Policy.

### **C. SFI Disclosures by Investigators**

All SFI Disclosures required to be disclosed by Investigators under this Policy shall be submitted through the Financial Interest Disclosure System in accordance with the following:

1. PHS-Funded Investigators are required to disclose all SFI's within thirty (30) days of acquiring the SFI, but in no event later than submission of an application for PHS-Funded Research.
2. Non-PHS-Funded Investigators are required to disclose only those SFIs that are related to their Research no later than submission of an application for the related Research.
3. Once a Research project has been funded, Investigators shall disclose, prior to participating in the project, all SFI's that have arisen since the time of application and all changes to SFI's previously disclosed.
4. With regard to ongoing Research projects -
  - a. all Investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI, and
  - b. when a new Investigator joins an ongoing Research project, the new Investigator shall submit SFI Disclosures within thirty (30) days of joining the project.
5. All Investigators shall submit an updated SFI Disclosure annually.

### **D. Travel Disclosures**

All Travel Disclosures required by this Policy shall be submitted by Investigators through the Financial Interest Disclosure System in accordance with the following.

1. PHS-Funded Investigators are required to disclose all Sponsored Travel and Reimbursed Travel in accordance with the following:

a. The timing of Travel Disclosures shall be as follows:

i. At the time of application for PHS Funded Research, all Sponsored Travel and Reimbursed Travel occurring in the preceding twelve (12) months shall be disclosed,

ii. Prior to participating in the PHS Funded Research project, all Sponsored Travel and Reimbursed Travel that occurred since the time of application; and

iii. Thereafter, during the course of the Investigator's participation in PHS Funded Research -

(a) no more than thirty (30) days after the occurrence of any Sponsored Travel or Reimbursed Travel, and

(b) an updated disclosure of all Sponsored and Reimbursed Travel annually.

b. If a PHS Investigator is able to reasonably anticipate the occurrence of Sponsored Travel or Reimbursed Travel, the Investigator may elect to submit Travel Disclosures up to twelve (12) months in advance of the anticipated travel. Unless an advance Travel Disclosure becomes materially inaccurate, no further disclosure of such travel shall be required.

c. All Travel Disclosures by PHS-Funded Investigators shall include information regarding:

i. the purpose,



- ii. the identity of the sponsor/organizer,
- iii. the destination,
- iv. the duration,
- v. the inclusion of any Immediate Family Member, and
- vi. an estimate of the approximate value of the travel.

2. Non PHS-Funded Investigators shall submit Travel Disclosures in accordance with the following:

a. Non-PHS-Funded Investigators shall disclose Sponsored Travel and Reimbursed Travel from an Entity if -

- i. Either solely, or when aggregated, relative to the same Entity, with the value of Compensation, Equity or Intellectual Property, the total value constitutes an SFI, **and**
- ii. The SFI is related to their specific current or proposed Research project.

b. All Travel Disclosures required by this Policy for Non-PHS-Funded Investigators must include an estimate of the approximate value of the travel.

### **E. Disclosures by Innovators**

When an Innovator has an SFI related to a Technology Transfer Transaction, the Innovator shall disclose the SFI prior to the conclusion of the Technology Transfer Transaction. All SFI Disclosures related to Technology Transfer Transactions shall be submitted by Innovators through the Financial Interest Disclosure System. The University's Center for Commercialization will be responsible for identifying Innovators and ensuring that Innovators who have an SFI related to the proposed Technology Transfer Transaction submit SFI Disclosures.

### **F. Review of Disclosures; Aggregation and Entity Rules**

1. All SFI Disclosures and Travel Disclosures will be automatically forwarded through the Financial Interest Disclosure System to the Institutional Official for review.
2. All Investigators and Innovators making SFI Disclosures or Travel Disclosures shall specify those Research projects and Technology Transfer Transactions that are related to the SFI Disclosures or Travel Disclosures. With respect to PHS-Funded Research, the Institutional Official will have the responsibility and authority to determine whether a SFI Disclosure or Travel Disclosure is related to the PHS-Funded Research and constitutes an FCOI.
3. In general and except as otherwise provided in this Policy, the determination of the existence of an SFI and the requirement to disclose Financial Interests constituting an SFI will be based on the aggregation of all Financial Interests by Entity.
4. If an SFI Disclosure or Travel Disclosure is related to a Research or Technology Transfer Transaction, the Institutional Official shall review the SFI Disclosure or Travel Disclosure to determine whether the Financial Interest constitutes an FCOI. Reviews will generally not be conducted until after a Research proposal has been funded or until after a Technology Transfer Transaction has been agreed upon in principle. Most reviews are completed within thirty (30) days following submission of all information required for the conduct of the review as determined by the Institutional Official.
5. No Investigator having an FCOI may participate in Research without prior written approval from the Institutional Official. All FCOI reviews, including any required Conflict Management Plan, must be completed before any Research activity begins or Research expenses are incurred under an award and before any Technology Transfer Transaction can be completed. In the event the Institutional Official concludes that a FCOI cannot be reduced, eliminated or managed, the Research project or Technology Transfer Transaction will not be allowed to proceed.

## **G. Management of Financial Conflict of Interests**

1. If the Institutional Official determines that an SFI Disclosure or Travel Disclosure constitutes an FCOI relating to either Research or a Technology Transfer Transaction, a Conflict Management Plan shall be developed and implemented by the Institutional Official. The FCOI review and Conflict Management Plan shall be

completed prior to a conflicted Investigator participating in the Research or prior to the completion of the Technology Transfer Transaction, as the case may be. As part of an FCOI review and development of a Conflict Management Plan, the Institutional Official shall confirm with the Investigator or Innovator that SFI Disclosures and Travel Disclosures in the Financial Interest Disclosure System are current as of the date of the review.

2. Conflict Management Plans shall consist of measures that in the reasonable judgment of the Institutional Official will reduce, eliminate, or manage the effects of the FCOI. In developing a Conflict Management Plan, the Institutional Official may conduct factual inquiries and consult with and receive recommendations from such persons as the Institutional Official deems necessary and appropriate. The terms of a Conflict Management Plan shall be consistent with all legal and regulatory requirements, the requirements of this Policy, and may include one or more of the following:

- a. Disclosure of FCOIs, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
- b. Monitoring or oversight of Research by independent co-researchers, reviewers, disinterested individuals, or committees;
- c. Maintaining copies of Research data with a neutral party;
- d. Restricting participation in activity affecting or affected by a Research project or Technology Transfer Transaction;
- e. Requiring that the SFI creating the FCOI be divested, restructured, or placed in a blind trust;
- f. Modification or severance of relationships that create or are likely to create FCOI's;
- g. Modifying the terms of written agreements relating to the Research or Technology Transfer Transaction;
- h. Reduction in Company appointment;

i. Requiring compliance with other relevant Company policies, including those referenced in Section VI below;

j. Requiring that participation in the recruitment or consent of subjects in human subjects Research by a conflicted Investigator be prohibited or restricted;

k. Requiring additional disclosures or actions with respect to matters before a human subjects review committee; and

l. Requiring that the Investigator or Innovator not participate in any business transactions between the Company and parties to agreements involving sponsored Research or Technology Transfer Transactions.

3. Submission of an SFI Disclosure by an Investigator or Innovator shall not constitute approval for purposes of this policy nor be deemed to constitute compliance with any applicable provisions of the Ethics Act. Compliance with the safe harbor provisions of the 2005 Ethics Act Amendment occurs if (a) the University has developed and issued a Conflict Management Plan in accordance with this policy, (b) the Conflict Management Plan covers the SFI that is the subject of the SFI Disclosure, and (c) the Investigator or Innovator has substantially complied with the terms of the Conflict Management Plan.

#### **H. Access to SFI Disclosures and Travel Disclosures**

1. The following company individuals and groups shall have access to all SFI Disclosures and Travel Disclosures submitted under this Policy:

a. The Chairman of the Board;

b. The Chief Executive Officer;

c. The Chief Scientific Officer;

d. The Institutional Official and designees.

2. Public Access for PHS Funded Research

a. If Senior/Key Personnel who are also Investigators are determined to have an FCOI related to PHS-Funded Research, the FCOI shall be posted on a publicly accessible company website and contain no less than the following information:

i. The name of Senior/Key Personnel Investigator(s);

ii. The title and role of the Senior/Key Personnel's Investigator(s) in the Research project;

iii. The name of the Entity giving rise to the SFI and FCOI;

iv. The nature of the FCOI; and

v. The approximate dollar value of the FCOI set forth in range amounts (\$0-\$4,999, \$5,000-\$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 in increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

b. The publicly-accessible website will be maintained under the direction of the Chief Scientific Officer of the company. The information on the website shall be updated at least annually, and in any event within sixty (60) days of the company's identification of a new FCOI of Senior/Key Personnel.

c. The FCOI information of each Senior/Key Personnel shall remain available on the company's publically accessible website for at least three (3) years from the date the information was most recently updated.

## **I. Annual Update Reporting**

All Investigators and Innovators who are subject to a Conflict Management Plan shall provide annual update reports using the Financial Interest Disclosure System in a form and in a manner specified by the company. In general, annual update reports shall require Investigators and Innovators to confirm there has been no material increase in the nature or amount of the Investigator's SFI and that the Investigator is complying with the terms of the Conflict Management Plan. Investigators will be restricted from submitting funding applications, expending funds, and conducting Research on projects whose annual update reports are not current.

## **J. Disclosure and Review of Increased SFI's and New Investigators**

1. Any Investigator participating in an existing Research project who acquires a new or increased SFI that would otherwise be required to be disclosed under this Policy shall submit a new SFI Disclosure within thirty (30) days of the acquisition of the new or increased SFI through the Financial Interest Disclosure System. The Company shall complete its review of the new or increased SFI within sixty (60) days of the submission of the SFI Disclosure.
2. Any Company personnel joining an existing Research project who has an SFI that would otherwise be required to be disclosed under this Policy shall submit an SFI Disclosure prior to participating as an Investigator in the Research project and shall not participate as an Investigator in the Research project until an FCOI review has been completed.

## **K. Retrospective Reviews of PHS-Funded Research; Mitigation Plans**

1. For PHS-Funded Research, if an FCOI is not identified or managed in a timely manner due to noncompliance by the Investigator or the company (including failure of an Investigator to submit SFI Disclosures or Travel Disclosures in a timely manner, a failure by the Company to review an SFI or manage an FCOI in a timely manner, or a failure by an Investigator to materially comply with a Conflict Management Plan), the Company shall, within one-hundred twenty (120) days from the date the non-compliance was identified, complete a retrospective review of the Investigator's activities and the Research project and make a reasonable determination whether there was any bias in the design, conduct or reporting of the Research resulting from the FCOI.
2. The Institutional Official shall document all retrospective reviews, including PHS project number, project title, Principal

Investigator, name of the Investigator with the FCOI, name of the Entity in which the Investigator has an FCOI, the reasons for the retrospective review, a detailed description of the methodology used for the retrospective review, and the findings and conclusions of the review.

3. If an FCOI is identified in the course of a retrospective review, the Institutional Official shall develop and submit a mitigation plan to the PHS funding agency. The mitigation plan shall include, at a minimum, the key elements documented in the retrospective review, a description of any impact of the bias on the Research, and the company's plan to mitigate the effect of the bias.

4. With respect to PHS-Funded Research in which a mitigation plan has been developed, the company shall submit annual FCOI reports addressing the status of the identified FCOI and any changes to the Conflict Management Plan for the duration of the PHS-Funded Research.

#### **L. Training for Investigators Participating in PHS Funded Research**

Prior to engaging in PHS-Funded Research, and no less often than every four (4) years, all PHS-Funded Investigators must complete training with respect to this Policy and the then-current PHS FCOI rules and regulations. Additionally, PHS Investigators shall complete such training whenever -

1. The Company revises this Policy or related procedures in any manner that materially affects the obligations and responsibilities of PHS-Investigators;
2. A PHS-Investigator first becomes associated with the Company; and
3. The Company determines that a PHS-Investigator is not in compliance with this Policy or any applicable Conflict Management Plan.

#### **M. Sanctions and Remedies for Violation of Policy**

Whenever the Institutional Official determines that a person has violated this Policy, including any failure to make a required SFI Disclosure or Travel Disclosure or comply with a requirement of a Conflict Management Plan, the Institutional Official shall recommend appropriate sanctions consistent with Company policies and procedures relating to faculty, employee, or other discipline. The Institutional Official is authorized to suspend, for good cause, an

ongoing Research project or pending Technology Transfer Transaction to prevent any probable or continued violations of this Policy.

## **N. Record Retention**

Unless some other applicable record retention law, requirement, or policy requires a longer period of retention, records created and maintained under this Policy, including SFI Disclosures, Travel Disclosures and Conflict Management Plans, shall be retained by the Company for a period of no less than five (5) years after the termination or completion of the Research or Technology Transfer Transaction to which they relate.

## **O. Subrecipient Compliance**

**1. Non-PHS-Funded Research.** With respect to awards to the Company for non-PHS-Funded Research, Company subrecipients shall provide appropriate assurances that policies and procedures no less stringent than this Policy exist and are enforced in connection with the execution of subcontracts or other subaward agreements. Company officials shall confirm that all researchers employed by subrecipients, including sub-grantees, contractors, subcontractors and collaborators participating in Company Research are subject to conflict of interest rules and procedures that are no less stringent than this Policy.

**2. PHS-Funded Research.** With respect to awards to the Company for PHS-Funded Research, each Company subrecipient shall:

a. Provide written certification to the Company that subrecipient's FCOI policy complies with all applicable PHS and federal FCOI rules and requirements, or alternatively and only if permitted by the Company, that subrecipient researchers are subject to the University's policy with respect to disclosing SFI's that are directly related to the subrecipient's work for the University;

b. If subrecipient's FCOI policy applies, specification of the time periods for the subrecipient to report all identified subrecipient research FCOI's to the University, which shall be sufficient to enable the Company to provide timely reports to PHS under this Policy; and



c. If the Company allows subrecipient researchers to comply with the Company's FCOI policy, specification of the time periods for the subrecipient to submit subrecipient researcher SFI Disclosures to the Company, which shall be adequate to enable the Company to perform the review, management and reporting required by this Policy.

## **P. Federal Reporting**

The Office of Sponsored Programs is responsible for reporting matters involving FCOI disclosures in accordance with applicable federal requirements.

1. Prior to the expenditure of any funds under a PHS-Funded Research project, the Company shall provide to the PHS awarding component an FCOI report regarding any Investigator's SFI or Travel Disclosure determined by the Company to constitute an FCOI and ensure that the Company has implemented an appropriate Conflict Management Plan.
2. In the event the Company identifies a previously unreported FCOI related to an ongoing PHS-Funded Research project, the Company shall provide the PHS awarding component an FCOI report regarding any Investigator's SFI found by the Company to be an FCOI and ensure that the Company has implemented an appropriate Conflict Management Plan within sixty (60) days of identifying this interest.
3. All FCOI reports to PHS awarding components shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the Company's Conflict Management Plan. Elements of the FCOI report shall include no less than the following and may include such additional information that the Institutional Official or the PHS awarding component may request:
  - a. Project Number;
  - b. Principal Investigator;
  - c. Name of the Investigator with the FCOI;
  - d. Name of the Entity with which the Investigator has an FCOI;

e. Nature of the Financial Interest (e.g., Compensation, Equity, Intellectual Property, consulting fees, Sponsored Travel, Reimbursed Travel);

f. Value of the Financial Interest (dollar ranges are acceptable);

g. Description of how the FCOI relates to the PHS-Funded Research and the basis for the Company's determination that it is an FCOI; and

h. Description of the key elements of the Company's Conflict Management Plan, including -

i. Role and principal duties of the conflicted Investigator;

ii. Conditions of the Conflict Management Plan;

iii. How the Conflict Management Plan is designed to safeguard objectivity in the Research project;

iv. How the Conflict Management Plan will be monitored to ensure Investigator/Innovator compliance; and

v. Other information as needed, including information regarding the FCOIs of all subrecipient Investigators consistent with the requirements of the 2011 PHS rule.

#### **Q. Auditing and Oversight Monitoring.**

Office of Research shall take such actions that it deems reasonable to audit and/or monitor compliance with Conflict Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with Conflict Management Plans.

#### **V. GUIDELINES**

The following guidelines are adopted for use in the administration and application of this Policy, subject to such exceptions as the Institutional Official deems appropriate.

**A. Participation in Business Negotiations.** No company employee having an FCOI related to a commercial or non-profit organization outside the company may participate in negotiating the terms and conditions of any agreement between the company and that organization.

**B. Participation in Administration of Agreements.** No company employee having an FCOI related to or a management position in an Entity may have primary responsibility for administering an agreement between the company and that Entity.

**C. Availability of Research Data.** All data and results arising from Research in which an Investigator has an FCOI subject to a Conflict Management Plan under this Policy shall be available for disinterested scientific review.

**D. Clinical Trial Investigators.** No one may participate as an Investigator in a clinical trial sponsored by a start-up commercial or non-profit organization in which the Investigator has a related Equity or Intellectual Property interest, holds a management position in the organization, or serves on the organization's Board of Directors unless the Institutional Official has determined there are compelling circumstances and has made a finding of an overriding public interest justifying participation by the Investigator in the clinical trial.

**E. Outside Work.** Investigators receiving Compensation from an Entity must ensure that no services performed as part of outside work duplicate any work performed on behalf of the company while participating in Research and that prior approval for such outside work is obtained.

**F. Performance of University Obligations.** Any Investigator or Innovator receiving Compensation from an Entity must ensure that no outside work activity is inconsistent with the obligations of the Investigator or Innovator to the University.

**G. Informed Consent.** Except in compelling circumstances as determined by the Institutional Official, no Investigator having an FCOI may participate in the informed consent process in Research involving human subjects.

**H. Disclosure of Interests.** All Investigators having an FCOI must disclose the nature of the Financial Interest in connection with scholarly publication or presentation of the results of the Research.

**I. Financial Interests in Competitors and Competitive Products.** For purposes of this Policy, a Financial Interest in a business that produces a competing product that could reasonably appear to affect or be affected by a particular Research

project or Technology Transfer Transaction shall be deemed to be related to the Research project or Technology Transfer Transaction.

**J. Data Production and Analysis.** Investigators having an FCOI shall not perform primary data analysis or production of data involving subjective scoring or similar methods of obtain data unless there is a clear and convincing indication that the design of the Research and its analysis would provide no opportunity for bias.

**K. Oversight Arrangements.** In general, oversight committees or other oversight arrangements will be established in cases involving Intellectual Property interests, Equity interests in start-up companies, student researchers, and the potential for inappropriate use of state resources.

**Institutional Official**

**Dr. Marvin L. Vestal PhD**

**Chairman of the Board**

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