



Virtuoso Surgical, Inc.  
5701 Old Harding Pike Suite 200  
Nashville, Tennessee 37205  
www.virtuososurgical.net  
(615) 352 9519

## **Financial Conflicts of Interest Policy**

### **Policy Statement**

As a medical device research and development corporation, Virtuoso Surgical, Inc. (“the Company”) is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. The Company has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to the Company’s other research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining the Company’s high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

### **Reason for Policy**

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the following federal regulations:

- 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies

These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

### **Definitions**

- **Conflict Management Plan:** the document specifying the actions to be taken to manage a Financial Conflict of Interest.
- **Designated Official:** the individual designated by the Company to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.
- **Equity Interest:** this includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

- **Financial Conflict of Interest:** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by the Company through the Designated Official.
- **Financial Interest:** anything of monetary value, whether or not the value is readily ascertainable.
- **Immediate Family Member:** a spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling.
- **Investigator:** the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.
- **PHS:** the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involves may be delegated, including the National Institutes of Health.
- **PHS Awarding Component:** the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.
- **PHS-funded research:** research funded under PHS grants, cooperative agreements, or contracts.
- **Public Health Service Act, or PHS Act:** the statute codified at 42 U.S.C. 201 et seq.
- **Remuneration:** salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships)
- **Research:** a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.
- **Significant Financial Interest:** a foreign or domestic financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's the Company project responsibilities, including:
  1. With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
  2. With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant financial interests also include any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's the Company project responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

Significant financial interest does not include the following:

- a) Salary, royalties, or other remuneration paid by the Company (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including that paid for intellectual property rights assigned or licensed to The Company and agreements to share in royalties related to such rights;
- b) Any ownership interest in the Company (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- c) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- d) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or
- e) Income from service on advisory committees or review panels for a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

- **the Company:** refers to Virtuoso Surgical, Inc.

## **The Procedures**

### **Responsibilities of the Company's Designated Official**

The Designated Official or his/her designee shall be responsible for the following:

- Informing the Company Investigators of their disclosure responsibilities of all foreign and domestic significant financial interests (SFI) under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with the Company's Administrator to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, the Company's review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide the Company with sufficient assurances to enable the Company's compliance with all applicable laws or regulations. To this end, the written agreement between the Company and the subrecipient will specify whether the Company's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
  - Obtain certification from the subrecipient that its policy complies with the Company's policy and the applicable regulations (absent such certification, the Company's policy will apply to the subrecipient's Investigators, and
  - Establish time periods for subrecipient reporting of financial conflicts of interest to the Company that enable the Company to report such conflicts in a timely manner, as required under its policy and the applicable regulations.



If the Company's policy will apply to the subrecipient Investigators, the Company will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

### **Internal Reporting Requirements**

For PHS-funded research, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to the Company's Administrator. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with the annual training and will otherwise be made available. The Company's Administrator will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant foreign and domestic financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

The Company's Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to the Company's Administrator.

Investigators are expected to submit an updated SFID Form no later than at the time of application for PHS/NIH-funded research, during the period of the award as necessary (at least annually for PHS-funded research), and/or within thirty (30) days of discovering or acquiring a new SFI. The annual update will typically be done in conjunction with completion of the annual training.

### **Determination and Management of Financial Conflicts of Interest**

Upon receipt of a completed SFID Form, and prior to the Company's expenditure of funds, the Designated Official shall review and determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If the Company determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

The Company's Designated Official shall review, determine, and implement, at least on an interim basis, a management plan within sixty (60) days of the following scenarios if an FCOI exists:

- A new Investigator participates in the research project
- an existing Investigator discloses a new SFI
- an SFI that was not disclosed timely by an Investigator, or
- an SFI, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project.

In addition to the conditions or restrictions described above, the Company may require the management of conflicting financial interests in other ways as it deems appropriate until completion of the project.

#### **External Reporting Requirements**

The Company will disclose financial conflicts of interest as required by applicable laws or regulations.

The Company shall send initial, annual, and revised FCOI reports, including all required information as defined in the regulation:

- Prior to the expenditure of funds;
- Within sixty (60) days of identification for an Investigator who is newly participating in the project;
- Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators;
- At least annually; this report shall provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

If bias is found with the design, conduct, or reporting of PHS/NIH-funded research, the Company will promptly notify the PHS Awarding Component and submit a Mitigation Report to explain what actions have or will be taken to mitigate the effects in accordance with the regulation.

Upon request, the Company will provide HHS with information relating to any Investigator disclosure of significant financial interests; the Company's review of, and response to, such disclosure; and whether the disclosure resulted in the Company's determination of a financial conflict of interest.

The Company will also promptly notify NIH and take corrective action if an Investigator fails to comply with the FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the research.

Before expending any funds under a PHS award, the Company will ensure public accessibility by posting their FCOI policy on the Company's Web site. Any available information concerning identified FCOIs held by senior or key personnel as defined by the regulation shall be made available within five (5) business days of a written request. This information shall be updated annually, updated within sixty (60) days of a newly identified FCOI, and remain available for three (3) years from the date the information was most recently updated.

#### **Confidentiality**

The Company will, to the extent possible, protect the confidentiality of disclosures. In every instance, the Company will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to the Company staff only on a need-to-know basis and will not be disclosed outside of the Company unless necessary to comply with contractual, legal, or regulatory requirements.

#### **Investigator Noncompliance**

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), the Company may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research.

In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in a retrospective review within 120 days of the Company's determination of a noncompliance. This review shall include:

- Failure by the Investigator to disclose a significant financial interested that is determined by the Company to be a FCOI;
- Failure by the Company to review or manage such FCOI;
- Failure by the Investigator to comply with the FCOI management plan;



If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, the Company shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

The Company will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts. If HHS determines that a clinical PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was neither disclosed nor managed, the Company shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

### **Training and Education**

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Web site](#).

The Company requires Investigators to complete such training at least every four years. Training must be completed prior to engaging in research related to any PHS/NIH-funded grant. However, training must be completed immediately if and when any of the following occurs:

- The Company revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's requirements;
- An Investigator is new to the Company; or
- The Company finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

### **Retention of Records**

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with the Company's Record Retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by the Company with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

### **Point of Contact**

If you have a conflict of interest or if you have a question, please call Virtuoso Surgical (615.352.9519), and you will be put in contact with the Company Administrator of FCOI.