

## **1.0 PURPOSE**

This policy describes Transonic Systems, Inc.'s Financial Conflict of Interest Policy. The Financial Conflict of Interest Policy is to promote objectivity in research funded by the Public Health Service (PHS).

## **2.0 SCOPE**

This policy is applicable to Transonic subcontractors, employees, agents, consultants and/or researchers participating or planning to participate in PHS funded research, not including SBIR Phase I applications/grants, hereafter referred to as investigator(s).

## **3.0 INTERNAL and EXTERNAL REFERENCES**

- A. 42 CFR Part 50 Subpart F

## **4.0 DEFINITIONS**

- A. Disclosure of significant financial interests means an investigator's disclosure of significant financial interests to Transonic
- B. Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- C. Investigator means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- D. PI means a principal Investigator of a PHS-funded research project
- E. PHS 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 involved may be delegated, including the National Institutes of Health (NIH).
- F. PHS Awarding Component means the organizational unit of the PHS that funds the research
- G. Senior/Key Personnel means the PI and any other person identified as senior/key personnel by Transonic in the grant application, progress report, or any other report submitted to the PHS by Transonic.
- H. Significant financial interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - a) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, 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;
  - b) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of 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 their institutional 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. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Transonic to the Investigator if the Investigator is currently employed or otherwise appointed by Transonic, including intellectual property rights assigned to Transonic and agreements to share in royalties related to such rights; any ownership interest in Transonic held by the Investigator; 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; 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 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.

- I. Signing Official means the person who has authority to bind Transonic in grant administration matters by providing signature approval on grant application submissions for PHS funded research projects.
- J. Small Business Innovation Research (SBIR) Program means the research program for small businesses.

## **5.0 TOOLS, EQUIPMENT and/or MATERIALS**

- A. NIH Office of Extramural Research online FCOI tutorial:  
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

## **6.0 PROCEDURE**

### **A. Training**

1. At the time of application, the Principal Investigator of each new PHS funded research, not including SBIR Phase I, will be responsible for creating a list of investigators who plan to be engaged in the research and this list will be sent to Human Resources.
2. Human Resources will inform each investigator on the list of this policy, their disclosure responsibilities, and the federal regulation regarding this policy.
3. Human Resources will be responsible for ensuring each investigator is trained on this policy before engaging in the research and at least every 4 years. Immediate training must be conducted when Transonic revises this policy, an investigator is new to Transonic, or Transonic finds that an investigator is not in compliance with this policy.
4. Training will consist of reviewing this policy and going through the NIH Office of Extramural Research online FCOI tutorial.

### **B. Disclosure to Transonic**

1. Each investigator must disclosure significant financial interests (and those of the investigator's spouse and dependent children) that meet or exceed the definition of significant financial interest by using form at the end of this policy.
2. This must be done no later than at the time of application for PHS funded research, at least annually during the period of award, and within 30 days of discovering or acquiring a new SFI.

### **C. Transonic Review of Disclosures and Relatedness Determination**

1. Review of SFI
  - a) Finance is responsible for reviewing disclosures of significant financial interests from each investigator. The Principal Investigator is responsible for identifying sources to contact for the disclosures; this can be completed with the assistance of Finance.
2. Relatedness Determination
  - a) After reviewing SFI disclosures, Finance is responsible for determining whether the disclosed significant financial interests are related to the PHS funded research. A SFI is related to PHS funded research when it is reasonably determined that the SFI: could be affected by the PHS funded research; or is an entity whose financial interest could be affected by the research. The investigator may be asked to help in the determination.
3. Timing of Review
  - a) SFI disclosures received by Transonic at the time of grant application or time of funding will be reviewed prior to the expenditure of funds.
  - b) SFI disclosures received by Transonic during the course of a project whether by a new investigator or an existing investigator with a new SFI, will be reviewed within 60 days to determine: (i) if the SFI is related to the PHS funded research; (ii) if it relates, determine if it qualifies as a FCOI; (iii) if it is a FCOI, implement a management plan.

### **D. Transonic Determination of FCOI**

1. If a SFI is found to be related to the PHS funded research, Finance will make a reasonable determination whether a FCOI exists.

2. A FCOI exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of PHS funded research.
3. If a FCOI is discovered, it must be reported in accordance with Section 6.0 G of this policy.

#### **E. Management of FCOI**

1. For any identified FCOI, Transonic will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research. Research in which an investigator is found to have an FCOI will not be permitted to proceed until the investigator has agreed to implement an acceptable management plan. The appropriate techniques identified by Transonic to manage an identified FCOI will be outlined in a written management plan. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:
  - a) Public disclosure of the FCOI (e.g., when presenting or publishing the research).
  - b) For research involving human subjects, disclosure of the FCOI directly to participants.
  - c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
  - d) Modification of the research plan.
  - e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
  - f) Reduction or elimination of the financial interest (e.g., sale of an equity interest).
  - g) Severance of relationships that create FCOI.
2. In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research 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 an FCOI that was not managed or reported by the Transonic, the investigator will be required to disclose the FCOI in each public

presentation of the results of the research and to request an addendum to previously published presentations.

3. Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be subject to disciplinary action.

#### **F. Retrospective Reviews and Mitigation Reports**

1. If Transonic identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by Transonic during an on-going research project (e.g., was not timely reviewed or reported by a subrecipient), Transonic will within sixty (60) days of identifying such an interest: (i) determine if the financial interest relates to the research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan to manage the FCOI going forward.
2. There may be times when an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose a significant financial interest that is determined by Transonic to constitute an FCOI; failure by Transonic to review or manage such an FCOI; or failure by the investigator to comply with an FCOI management plan. In the event such noncompliance is identified, Transonic will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the research to determine whether there was any bias in the design, conduct or reporting of the research or any portion thereof during the time period of the noncompliance. Transonic will maintain written procedures regarding the conduct and documentation of the retrospective review, as well as notification of the relevant awarding agency.
3. For PHS-funded research, Transonic will document at least the following information regarding any retrospective review:
  - a) Project number.
  - b) Project title.
  - c) Principal investigator (PI)
  - d) Name of the investigator with the FCOI.
  - e) Name of the entity with which the investigator has the FCOI.

- f) Reason(s) for the retrospective review.
  - g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
  - h) Findings of the review.
  - i) Conclusions of the review.
4. If bias is found in the design, conduct or reporting of PHS-funded research during the period of noncompliance, Transonic will promptly notify the relevant PHS awarding agency and will submit a mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the research project and Transonic's plan of action taken to eliminate or mitigate the effect of the bias.

#### **G. Reporting Requirements to PHS Awarding Agencies**

1. For all identified FCOIs, Transonic will provide required FCOI reports to the PHS awarding agency at the following times:
  - a) Initial FCOI Report: prior to the expenditure of funds
  - b) Updated FCOI Reports: within 60 days of identification of a new FCOI (whether due to a new investigator or a new FCOI disclosed by an existing investigator) or identification of an FCOI that was not timely disclosed (following a retrospective review).
  - c) Annual FCOI Reports: at least annually. For NIH-funded research, the Annual FCOI Report is due at the same time as Transonic is required to submit the annual progress report for a grant or at the time of extension.
2. Any FCOI Report shall provide sufficient information to enable the PHS awarding agency to understand the nature and extent of the FCOI and to assess the appropriateness of Transonic's management plan. Any FCOI Report will include at least the following information:
  - a) Project number
  - b) PI
  - c) Name of the investigator with the FCOI
  - d) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
  - e) Value of the financial interest, provided in dollar ranges, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

- f) A description of how the financial interest relates to the PHS-funded research and the basis for Transonic's determination that the financial interest conflicts with such research.
- g) A description of the key elements of Transonic's management plan, including:
  - (1) The role and principal duties of the conflicted Investigator in the research.
  - (2) The conditions of the management plan.
  - (3) How the management plan is designed to safeguard objectivity in the research.
  - (4) Confirmation of the Investigator's agreement to the management plan.
  - (5) How the management plan will be monitored to ensure Investigator compliance.
3. The Signing Official, PI, or other appointed person will be responsible for sending the required reports and notifications to the PHS awarding agencies when necessary.
4. In addition to the required FCOI reports, Transonic will promptly notify the relevant PHS awarding agency in the event that it finds that an Investigator's failure to comply with this Policy or an imposed management plan has biased the design, conduct, or reporting of PHS-funded research (such notification will include the corrective action taken or to be taken in response to the identified Investigator non-compliance).

## **H. Subrecipient Requirements**

1. If a subrecipient is included in a PHS funded research, the FCOI policy should be included as part of the subaward agreement between Transonic and the subrecipient.
  - a) If the subrecipient will follow the FCOI policy of the awardee (Transonic), the subaward agreement should state this and the time period(s) for the subrecipient to report all identified FCOIs to Transonic should be established. The subaward agreement should include the requirement for Transonic to solicit and review subrecipient investigator disclosures that enable Transonic to identify, manage, and report FCOIs to the PHS.
  - b) If the subrecipient will follow their own FCOI policy, the subaward agreement should state this and certify that the policy complies with applicable PHS regulations.

## **I. Public Accessibility Requirements**

1. This FCOI policy will be made publicly available on Transonic's website. When a revision to this policy is released, the document will be updated on the Transonic website.
2. Transonic will provide a written response to any requestor within five business days of a request of information concerning identified FCOIs held by senior/key personnel.

The information made available will include at a minimum:

- a) the Investigator's name
- b) the Investigator's title and role with respect to the research project
- c) the name of the entity in which the significant financial interest is held
- d) the nature of the significant financial interest;
- e) the approximate dollar value of the significant financial interest provided in dollar ranges, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

**J. Maintenance of Records**

1. Transonic will maintain all FCOI related records for at least 3 years from the date the final expenditure report is submitted to the PHS.

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**Financial Disclosure Form – Transonic Systems Inc.**

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

Project/Grant Title: \_\_\_\_\_ Project PI: \_\_\_\_\_

Project Role: \_\_\_\_\_ Project Period (if known): \_\_\_\_\_

Sponsor: \_\_\_\_\_ Sponsor Grant # (if known): \_\_\_\_\_

I, \_\_\_\_\_, have reviewed the NIH Office of Extramural Research online FCOI tutorial, located on the NIH website: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

I am disclosing the following significant financial interests as defined in Section 4.0 H of the Transonic Financial Conflict of Interest Policy (42 CFR Part 50, Subpart F). I am attaching supporting documentation, if necessary, that identifies the business enterprise or entity involved and the nature and amount of the interest:

\_\_\_\_\_ Salary or other payment for services (e.g., consulting fees, Honoraria, paid authorship)

\_\_\_\_\_ Equity interests (e.g. stocks, stock options, or other ownership interests)

\_\_\_\_\_ Intellectual property rights (e.g., patents, copyrights, and royalties from such rights, not including intellectual property assigned to Transonic)

\_\_\_\_\_ Travel that is sponsored or reimbursed by an outside entity (not including travel related to PHS funded research)

\_\_\_\_\_ Other significant financial interests that possibly could affect or be perceived to affect the results of the research proposed for funding

\_\_\_\_\_ I have no significant financial interests associated with this project

I agree:

- To update this disclosure during the period of the award, either on an annual basis or as new reportable significant financial interests are obtained. In the case of travel, the disclosure will occur no more than 30 days after the date of travel.
- To cooperate in the development of a plan to resolve any conflicts of interest.
- To comply with any conditions or restrictions imposed by Transonic to manage, reduce, or eliminate actual or potential conflicts of interests.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

 <p><b>transonic</b> THE MEASURE OF BETTER RESULTS.</p>	<p><i>Financial Conflict of Interest Policy</i></p>	<p><i>Rev: A</i></p>
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**7.0 REVISION HISTORY**

<b>Rev Date</b>	<b>Rev</b>	<b>Chg#</b>	<b>Description</b>	<b>Written By</b>
Nov 20 2020	A	ECO-	Initial release of document in Innovator	D. Cooper-Schifitto

**-END-**