

Document #:	00040	Revision:	A
Description:	Financial Conflicts of Interest (FCOI)	PROCEDURE	

1.0 SCOPE

This Procedure applies to the conduct of Research Projects receiving funding directly or indirectly as a sub-recipient (sub-award), from any agency of the US Public Health Service (PHS), including the National Institutes of Health (NIH). It is intended to comply with the 2011 Revised Financial Conflict of Interest Regulation, 42 CFR Part 50, Subpart F, for PHS grants and cooperative agreements as implemented from August 24 2012.

The regulation is intended to promote research objectivity by providing a reasonable expectation that the design, conduct and reporting of NIH funded research will free from bias resulting from investigator financial conflicts of interest.

A copy of the Federal Regulation is at

<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Details of the final rule are at:

[“Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”](#)

The requirements apply to SBIR/STTR Phase II awards, SBIR/STTR Phase I Awards are exempt.

2.0 FCOI PROCESS

2.1 Disclosure

Significant Financial Interest (SFI) as defined in Appendix A shall be disclosed by any investigator prior to the receipt of funding from PHS sources, or if a conflicting SFI arises during the project.

2.2 Responsibilities.

The Principal Investigator (PI) is responsible for ensuring that SFI's of all key personnel are identified and disclosed. The items listed in Appendix B may be used as a guide to the required information.

Disclosures are reviewed by the Company President for approval. If a significant FCOI is determined, a management plan is defined and implemented to mitigate the FCOI effect on the project.

2.3 Reporting requirements to NIH

Routine FCOI Reports are provided to NIH:

- a) Prior to expenditure of funds on an approved project (this may be done as a Just In Time (JIT) submission for project approval)
- b) Within 60 days of FCOI identification for a new participant or change in FCOI situation for existing investigators.
- c) Annually, with the required annual progress report.
- d) As needed for changes in previous reports

Findings of

- a) Bias in conduct or reporting of funded research
 - b) Failure of an investigator to comply with this company procedure
 - c) Failure to comply with a FCOI management plan
- are to be reported promptly with a mitigation report detailing actions taken.

Reports will normally be submitted via the eRA Commons FCOI Module. Demonstration and Instructions are provided at:

http://grants.nih.gov/grants/policy/coi/fcoi_webinar_2012/FCOI%208-14-2012_WEBINAR.pptx

and further information at <http://grants.nih.gov/grants/policy/coi/index.htm>

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2.4 Records

Records of FCOI documentation shall be maintained by the Company Administrative Manager and retained for at least 3 years after submission of the project final expenditure report.

2.5 Enforcement

- a) Retrospective reviews of non-compliance for SFI's not disclosed or managed in a timely manner shall be conducted, documented and reported within 120 days.
- b) If the US Department of Health and Human Services (DHHS) determines that any PHS funded study to evaluate the safety and effectiveness of a device has been conducted or reported by and investigator with an unreported or unmanaged FCOI then:
 - The FCOI must be disclosed in any public presentation
 - An addendum be requested to previous publications.

2.6 Subrecipients (Sub-awardees)

Subrecipients of Healionics project funding shall, as applicable:

- provide certification of a FCOI policy in compliance with the regulation.
- provide notice of indentified FCOI's in a timely manner permitting the Healionics to report to NIH or: provide for internal compliance and reporting to NIH.

These requirements apply reciprocally if the company is a subrecipient from another institution.

2.7 Training

a) All investigators on a PHS funded project shall receive training to include:

- Awareness of the Federal Regulation
- Review of this procedure
- Disclosure responsibilities

Training may be achieved by use of the NIH provided web based tutorial at

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

On completion, the FCOI certificate may be saved and printed as a record of the training.

b) Training shall be completed:

- prior to participating in PHS funded research
- at least every 4 years
- at any time when
 - this procedure is revised
 - a new employee is engaged on a PHS funded project
 - an investigator is not in compliance with this procedure or a FCOI management plan.

c) Training records are maintained in accordance with company Procedure 00034.

Further training materials are available at:

http://grants.nih.gov/grants/policy/coi/fcoi_webinar_20111130.htm

http://grants.nih.gov/grants/policy/coi/FCOI_NIH_Regional_Seminar-June_22_2012.ppt
[New and Updated Frequently Asked Questions](#)

2.8 Public Access.

This procedure will be placed on a publically accessible website.

Identified FCOI's will be made available within 5 calendar days of a legitimate request.

See Appendix B for required information.

3.0 APPENDICES

APPENDIX A: Definition of Significant Financial Interest

APPENDIX B: FCOI public disclosure requirements.

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APPENDIX A: Definition of Significant Financial Interest. (SFI)

A Significant Financial Interest consists of one or more of the following interests of the Investigator (and those of the Investigator's spouse/partner and dependent children) that reasonably appear to be related to the Investigator's responsibilities on the PHS funded project.

- (i) **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 for the investigator, investigator's spouse and dependent children, 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;
- (ii) **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
- (iii) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (iv) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 and reasonably appears related to the Investigators project responsibilities must be disclosed. **Excludes** travel paid for by Healionics or affiliated companies and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, or an U.S. Institution of higher education.

A Significant financial Interest does not include

- (i) Salary, royalties, or other remuneration paid by Healionics or affiliates to the Investigator while employed or otherwise appointed by Healionics. This includes any assigned intellectual property rights and agreements to share in royalties related to such rights.
- (ii) Any ownership interest in Healionics held by the investigator.
- (iii) Income from investment vehicles, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions.
- (iv) Income from seminars, lectures, or teaching engagements sponsored by an U.S. federal, state, or local government agency, an Institution of higher education or similar.
- (v) Income from service on advisory committees or review panels for an U.S. federal, state, or local government agency or an Institution of higher education.

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APPENDIX B. FCOI public disclosure requirements

Healionics will provide within 5 days a response to a written request for information on any SFI that meets the following conditions.

- (i) The Significant Financial Interest was disclosed and is still held by the PD/PI or any other person identified as senior/ key personnel by Healionics in the award (or subaward) application for PHS funding or listed in a progress report. AND
- (ii) Healionics has determined that the Significant Financial Interest is related to conduct of the research funded.

Information made available will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$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 by increments of \$50,000), OR:
- (vi) 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.

(This list may also be used for internal disclosures per Section 2.2)