

**Translational Imaging Innovations, Inc.
Grant and Research Administration Procedure**

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1. Purpose

Translational Imaging Innovations (**TII**) strives to create and maintain a research climate that promotes objectivity in life science and medical research. In this context, we establish standards that ensure that the design, conduct and reporting of Public Health Service (**PHS**) funded research is free from bias resulting from financial conflict of interest ("**FCOI**"). This policy ("**Policy**") is intended to keep TII compliant with PHS (including NIH) requirements and prevent any financial conflict of interests.

2. Scope

- 2.1 This procedure applies to all TII (Translational Imaging Innovations, Inc.) who are planning to or are participating in research activity that is either partially or wholly supported by PHS funds.
- 2.2 The procedure applies to any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded, or proposed for such funding by the PHS, including collaborators or consultants ("**Investigator**").
- 2.3 The procedure applies to all contractors and consultants conducting research on behalf of TII in PHS funded research.

3. Responsibilities

- 3.1 At least one employee ("**FCOI Official**") shall receive training to administer this **Policy**, including any review or reporting requirements it may describe.
- 3.2 Any employee who will be the primary contact in coordinating with an **Investigator** who is external to **TII** ("**TII Liaison**"), regardless of whether that employee will be directly conducting research, is directed under this Policy to obtain disclosure from the external Investigator regarding any potential financial conflicts of interest.

4. References and Related Documents

Document Number	Document Title
GRAD-IntD-3	FCOI Disclosure Form

GRAD-IntD-3, FCOI Disclosure Form, has been designed to facilitate tracking, management, and reporting of any Significant Financial Interest or Financial Conflict of Interest

5. Definitions and Abbreviations

- 5.1 HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- 5.2 Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).
- 5.3 Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

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- 5.4 PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.
- 5.5 Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.
- 5.6 Financial Conflict of Interest (FCOI) means that an investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- 5.7 Significant Financial Interest (SFI) means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). **The term does not include:**
- 5.7.1 Salary, royalties, or other remuneration from the applicant institution; or
 - 5.7.2 Any ownership interests in the institution, if the institution is an applicant under the SBIR Program; or
 - 5.7.3 Income from seminars, lectures, or teaching engagement sponsored by public or nonprofit entities; or
 - 5.7.4 Income from service on advisory committees or review panels for public or nonprofit entities; or
 - 5.7.5 An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
 - does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - does not represent more than a five percent ownership interest in any single entity; or
 - 5.7.6 Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.
- 5.8 Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

6. Risk Management for This Process

- 6.1** When a SFI is uncovered, an internal report will be disclosed with the following time parameters in mind:

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- No later than at the time of application for PHS-funded research,
- At least annually during the period of the award, and
- Within 30 days of discovering or acquiring a new SF

7. Procedure

7.1 Preparation and Submittal of SFI Disclosures

- 7.1.1 FCOI Official will, upon the following occurrences, ensure that any covered Investigator provides or has provided a current FCOI Disclosure Form.
 - 7.1.1.1 Prior to application for a PHS funded grant; and
 - 7.1.1.2 Upon Notice of Intent to Award and prior to JIT submittals for a pending award; and
 - 7.1.1.3 Upon the introduction of a new investigator to any PHS funded research project.
- 7.1.2 FCOI Official will coordinate compliance with any funded subrecipient, per this policy.

7.2 Review of SFI Disclosures

- 7.2.1 All SFI disclosures will be reviewed by the FCOI Official.
- 7.2.2 In the event that reportable FCOI is disclosed, the FCOI Official will report to PHS appropriately as indicated in this policy.
- 7.2.3 In the event that a SFI is discovered to not have been disclosed in a timely manner, the FCOI Official will review this policy and implement a responsive management plan within sixty days.
- 7.2.4 The FCOI Official will determine whether the SFI relates to the PHS-funded research and constitutes an FCOI, based on guidance set by training undergone and 42 CFR Part 50 Subpart F.
- 7.2.5 Upon learning of any SFI, the FCOI Official will take actions to discuss and approve the implementation of a FCOI management plan for any SFI consistent with government regulation.

7.3 Minimum Content of Responsive Management Plan

- 7.3.1 The Management Plan shall at a minimum include:
 - 7.3.1.1 The role and principal duties of the conflicted PHS-funded Investigator in the research project; and
 - 7.3.1.2 How the management plan is designed to safeguard objectivity in the research project; and
 - 7.3.1.3 Confirmation of the PHS-funded Investigator's agreement to the management plan; and
 - 7.3.1.4 How the management plan will be monitored to ensure PHS-funded Investigator compliance; and
- 7.3.2 Conditions of the management plan shall include:

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- 7.3.2.1 Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s)); and
- 7.3.2.2 For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; and
- 7.3.2.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest; and
- 7.3.2.4 Modification of the research plan; and
- 7.3.2.5 Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research; and
- 7.3.2.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- 7.3.2.7 Severance of relationships that create financial conflicts.

7.4 Reporting to PHS

- 7.4.1 Based on the FCOI management plan, the designated FCOI Official will submit an initial FCOI report to the PHS-funding component, for example NIH.
- 7.4.2 The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.
- 7.4.3 The FCOI report for will be submitted prior to the expenditure of funds under the Notice of Award.
- 7.4.4 FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.
- 7.4.5 The FCOI Official will promptly notify the appropriate PHS-funding component and take proper corrective action if an Investigator fails to comply with this Policy, or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.
- 7.4.6 Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists.
- 7.4.7 These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

7.5 Training

- 7.5.1 The FCOI Official and any Investigator will undergo training including https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
- 7.5.2 Investigators will be required to take, or show proof of having taken this or an equivalent FCOI training in the following time periods:
 - 7.5.2.1 Prior to engaging in research related to any PHS-funded grant; and

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7.5.2.2 At least every 4 years; and

7.5.2.3 Immediately if

7.5.2.3.1 TII revises this Policy in a way that materially affects Investigator requirements; or

7.5.2.3.2 An Investigator is new to TII; or

7.5.2.3.3 An Investigator is not in compliance with this Policy.

7.6 Enforcement Mechanisms

7.6.1 Disclosure of SFI is essential to implementation of this Policy

7.6.2 If a PHS-funded Investigator fails to comply with this policy (with regard for instance to the SFI disclosure requirement or implementation of an FCOI management plan), and appears to have biased the PHS-funded research, the FCOI Official will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum.

7.6.3 This retrospective review will be completed and documented within 120 days of TII's determination of noncompliance.

7.6.4 In addition, the employee may be subject to employment discipline including, without limitation, suspension or termination of employment.

7.6.5 In any case, the PHS-funding agency will be promptly notified.

7.7 Retention of Records

7.7.1 Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report or any other date specified in 45 CFR 75.36.

7.8 Subrecipient Compliance

7.8.1 When working with a subrecipient, a written agreement will be put in place to clarify:

7.8.1.1 which organization's (prime awardee or subrecipient) FCOI policy will be followed, and,

7.8.1.2 in either case, clarify the timeline for disclosure and reporting.

7.8.2 Note that the prime awardee is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

7.9 Public Accessibility

7.9.1 As required by PHS regulation, this Policy is being made accessible on TII's website.

7.9.2 If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site the minimum elements required by the regulation, as follows: and

7.9.2.1 Within sixty (60) days of a newly identified FCOI; a

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7.9.2.2 Be updated annually; and

7.9.2.3 Remain available for three (3) years.

7.9.3 The website posting shall include contact information for a primary FCOI Official.

8. Attachments

8.1 Attachment 1 - NIH Financial Conflict of Interest (FCOI) External User Guide

9. Document History

Revision	Month/Yr	Originator	Revision Description
1	03/2021	E. Buckland	Original