

# Public Health Service (PHS) Requirements for Financial Disclosures and Conflict of Interest Policy

## I. Overview

Employees of TheraNova, L.L.C. (referred to as the “Company”) are responsible for advancing the mission and purpose of TheraNova, L.L.C. to provide innovative medical device solutions to improve the quality of life of patients. Accordingly, employees have an obligation to conduct the affairs of the Company in a manner consistent with that purpose and to make decisions on a basis that promotes the best interests of the Company. The Company maintains and enforces a general Conflict of Interest (COI) Policy. This policy requires employees, collaborators, and consultants, who are responsible for the design, conduct, or reporting of research funded by the U.S. Public Health Service (PHS), to disclose potential or apparent conflicts of interest or commitment so that the Company can effectively manage, reduce or eliminate such conflicts.

With respect to sponsored projects and research carried out by TheraNova Investigators, the Company complies with additional PHS requirements, and other federal agency disclosure and financial COI regulations, as applicable, in order to maintain institutional compliance and eligibility for the application of and receipt of federal funding, including grants, subawards and cooperative agreements.

## II. Purpose

This policy is intended to meet federal PHS requirements for promoting objectivity in research and ensuring that the design, conduct and reporting of PHS-funded research is free from bias that may arise from an Investigator’s perceived or real financial conflict of interest (FCOI). This policy is compliant with current federal FCOI regulations entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" ([42 CFR Part 50, Subpart F](#)).

This policy applies to all Investigators of the Company who apply for, or receive, PHS funding by means of a grant, cooperative agreement, subaward or other funding agreement administered by the Company. Investigators carrying out sponsored projects and research supported by the National Institutes of Health, and other PHS agencies, are covered by this policy.

## III. Investigator Requirements

Any person that meets the federal definition of an Investigator (see Definitions section below) is required to comply with the policy and procedures outlined below. An Investigator is defined as the Project Director (PD), Principal Investigator (PI) or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposal for such funding. Investigators also include collaborators and consultants.

In summary, Investigators are required to:

1. Disclose any significant financial interests (SFIs) at the time of application for federal PHS funding by completing and signing a disclosure form, and submitting this to the Grants department;
2. Disclose SFIs using the disclosure form at least on an annual basis during the course of an award;
3. Disclose within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new SFI; and

4. Take part in FCOI training at least once every four years.

#### **IV. Investigator FCOI Training Requirements**

The Company's Grants department is responsible for ensuring that each Investigator is informed about this FCOI policy and procedures for disclosure, and ensuring that each Investigator has completed FCOI training prior to engaging in PHS-funded research and at least once every four years. Training will also be required immediately when any of the following occurs:

1. this FCOI Policy, the SFI Disclosure Form, or the Company's procedures are revised in any manner that affects the requirements of Investigators;
2. a PHS-supported Investigator is newly appointed to the Company; or
3. the Company determines that an Investigator is not in compliance with this policy or an FCOI management plan.

"Immediately" means that training will be provided or made available and that Investigators will participate in the training expeditiously after one of the aforementioned qualifying events. The Grants department will be responsible for retaining records of FCOI training.

The Company uses the Financial Conflict of Interest online tutorial provided by the National Institutes of Health for satisfying training requirements. Investigators must provide assurance they have completed the NIH tutorial by sending a copy of the Certificate of Completion to the Grants department. The NIH tutorial is available at:

[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

TheraNova investigators who are supported from non-PHS sources are not required to complete the NIH tutorial, however they are encouraged to do so to learn about FCOI-related topics.

#### **V. Procedure for Submitting a Disclosure**

The Grants department is responsible for collecting SFI Disclosure Forms via email prior to proposal submission to external PHS funding agencies. The SFI Disclosure Form conforms to the requirements of PHS FCOI Regulations ([42 CFR Part 50.604](#)). The following procedures will be followed:

1. All investigators involved in the project/proposal are required to complete, sign and submit the SFI Disclosure Form prior to the Company submitting a proposal to a PHS agency.
2. The Investigator must list all of their SFIs (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities in teaching, scholarship or service.
3. The form requires the Investigator to include, at minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined. If needed, the Grants department may request supporting documentation to determine whether an FCOI exists (e.g., a copy of any applicable consulting agreement or stock purchase agreement).
4. For SFI disclosures related to sponsored or reimbursed travel, the disclosure must include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value.

5. The Investigator is required to submit an updated SFI Disclosure Form during the period of the award at least annually, and within 30 days of discovering or acquiring a new SFI. The SFI Disclosure Form notifies the Investigator of this requirement to provide updated disclosures.

## **VI. Review of SFI Disclosures**

The Company has designated the Grants Manager as the institutional official who initially reviews disclosures and determines whether a disclosed SFI is related to the PHS-funded research, and if so, whether it constitutes an FCOI.

An Investigator's SFI is related to PHS-funded research when the Institution, through its designated official, reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. An FCOI exists when the institution reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The Company may request additional information from the Investigator to determine whether an SFI is related to the PHS-funded research. In making these determinations, the Company may take into account financial interests in a previously disclosed entity related to PHS- or other federally-funded research. The Grants department may consult with appropriate institutional and agency officials during the review process.

If it is determined that an FCOI exists, the conflict will either be approved with conditions or restrictions in place (subject to a management plan), or prohibited. Management plans shall be implemented by an oversight committee comprised of the Chief Executive Officer, Vice President of Research, Development and Regulatory Affairs, and Grants Manager. The management plan shall be completed prior to the expenditure of any funds under a PHS grant, cooperative agreement, subaward, or contract. The Company, via the management plan committee, will monitor compliance with management plans on an ongoing basis until the completion of the PHS-funded research project.

For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of SFIs; (2) for research projects involving human subjects, disclosure of FCOIs directly to participants; (3) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; (4) modification of the research plan; (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all, or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts.

When an Investigator who is new to a PHS-funded research project discloses an SFI or an existing Investigator discloses a new SFI, the Company will within 60 days: review the disclosure; assess whether the SFI constitutes an FCOI with PHS-funded research; and if so, implement, at least, on an interim basis, the actions that have been, and will be, taken to manage such FCOI.

## **VII. Reporting Financial Conflicts of Interest to PHS**

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company will provide to the PHS Awarding Component (e.g., NIH) an FCOI report regarding any

Investigator's significant financial interest found by the Company to be conflicting and ensure that the Company has implemented a management plan. In cases in which the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company is not required to submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that the Company identifies as conflicting subsequent to the Company's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Company will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that the Company has implemented a management plan.

Any FCOI report required by PHS will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Company's management plan. Elements of the FCOI report will include, but are not necessarily limited to the following:

Project number; PD/PI or Contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); value of the financial interest (dollar ranges are permissible: \$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 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; a description of how the financial interest relates to the PHS-funded research and the basis for the Company's determination that the financial interest conflicts with such research; and a description of the key elements of the Company's management plan, including:

- (a) Role and principal duties of the conflicted Investigator in the research project;
- (b) Conditions of the management plan;
- (c) How the management plan is designed to safeguard objectivity in the research project;
- (d) Confirmation of the Investigator's agreement to the management plan;
- (e) How the management plan will be monitored to ensure Investigator compliance; and
- (f) Other information as needed.

For any financial conflict of interest previously reported by the Company with regard to an ongoing PHS-funded research project, the Company will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Company will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

### **VIII. Mitigation Reporting Due to Noncompliance**

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Company to constitute a financial conflict of interest; failure by the Company to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Company will, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-

funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Company is required to document the retrospective review; such documentation will include, but not necessarily be limited to, all of the following key elements:

Project number; project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the FCOI; name of the entity with which the Investigator has a financial conflict of interest; reason(s) for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); findings of the review; and conclusions of the review.

Based on the results of the retrospective review, the Company will update any previously submitted FCOI report, as applicable, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Company will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Company's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Company will submit FCOI reports annually, as specified elsewhere in [42 CFR Part 50, Subpart F](#). The initial and annual FCOI reports must be submitted to the NIH through the eRA Commons FCOI Module. Depending on the nature of the financial conflict of interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Company's retrospective review.

Whenever the Company implements a management plan pursuant to this policy, the Company will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

All FCOI reports, including revised FCOI reports and mitigation reports, must be submitted through the electronic Research Administration (eRA) Commons FCOI Module.

## **IX. Subrecipient Requirements**

If a portion of PHS-funded research is carried out by a subrecipient, the Company, via the Grants department, will incorporate as part of a written agreement with the subrecipient terms that establish whether the PHS FCOI policy of the Company (the awardee Institution) or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient requires its Investigators to comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the subrecipient agreement that its policy complies with [42 CFR Part 50, Subpart F](#). If the subrecipient cannot provide such certification, the agreement will state that subrecipient Investigators are subject to the PHS FCOI policy of the Company for disclosing SFIs that are directly related to the subrecipient's work for the Company. The subrecipient agreement will further include, if applicable, terms that allow the Company to solicit and review subrecipient Investigator disclosures that enable the Company to identify, manage and report identified FCOIs to the PHS Awarding Component.

TheraNova will comply with all provisions of [42 CFR Part 50.604](#) regarding subrecipients including, providing FCOI reports to the appropriate PHS awarding agency regarding all FCOIs

of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

## **X. Remedies, Enforcement and Sanctions**

If an Investigator fails to comply with this policy or a management plan and the noncompliance appears to have biased the design, conduct or reporting of the PHS-funded research, the Company will promptly notify the agency of the corrective action taken or to be taken. The Company will ensure compliance with the requirements for retrospective review and prepare a mitigation report, as applicable, for submission to the funding agency as required under PHS FCOI regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the Company to take further action to maintain the objectivity of the research.

All TheraNova Investigators proposing or conducting PHS-funded research are subject to this policy (except those applying to or funded by the Phase I Small Business Innovative Research or the Small Business Technology Transfer program). Investigators are expected to comply with it fully. Whenever an Investigator has violated this policy, the Company will take appropriate action in accordance with disciplinary sanctions incorporated in the Company's *Employee Handbook*.

*Note on Clinical Research:* In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 Company as required by the regulation, the Company will require the Investigator involved to: 1) disclose the FCOI in each public presentation of the results of the research, and 2) request an addendum to previously published presentations.

## **XI. Records and Public Access**

The Company, via the Grants department, will maintain all SFI Disclosure Forms, training certifications, management plans, reports and all related records of actions taken by the Company with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS as governed by 42 CFR Part 50 Subpart F, and from other dates specified in 45 CFR 75.361, where applicable.

The Company has posted this policy on the TheraNova website, a public website, in accordance with the PHS regulations.

In addition, this policy allows for certain information concerning identified FCOIs held by Investigators to be made available and publicly accessible. The information will:

- Include the minimum elements as provided in the regulation
- Be made available within 5 calendar days of a written request
- Be updated, at least annually (website only but any response to a written request should include the updated information)
- Be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information)
- Remain available for three years from the date the information was most recently updated.

## Definitions

*Disclosure of significant financial interests:* an Investigator's disclosure of significant financial interests to the Company.

*Financial conflict of interest (FCOI):* a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

*FCOI report:* the Company's report of a financial conflict of interest to a PHS Awarding Component.

*Financial interest:* anything of monetary value, whether or not the value is readily ascertainable.

*HHS:* the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

*Institution:* any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. TheraNova represents the institution for the purposes of this policy.

*Institutional responsibilities:* an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company in its policy on financial conflicts of interest, which include responsibilities of teaching, scholarship and service.

*Investigator:* the Project Director or 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.

*Manage:* taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

*PD/PI:* a Project Director or Principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.

*PHS:* 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).

*PHS Awarding Component:* the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F.

*Public Health Service Act or PHS Act:* the statute codified at 42 U.S.C. 201 *et seq.* *the regulation:* 42 CFR Part 50, Subpart F: "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"

*Research* (according to federal regulations governing this policy): 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. 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). 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

*Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS by the Company.

*Significant financial interest* 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:

(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, 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 12 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) 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.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; 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.

*Small Business Innovation Research* (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Additional Information and Resources: Financial Conflicts of Interest, the National Institutes of Health, Office of Extramural Research: <http://grants.nih.gov/grants/policy/coi/>