



**Cancer Targeted Technology LLC**  
**Financial Conflict of Interest (FCOI) Policy**  
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## Purpose

All research, development and technology transfer activities occurring at Cancer Targeted Technology (the Company) shall be carried out in an ethical manner and shall not be adversely affected or influenced by the financial interests of personnel carrying out those activities. Prior to participating in research or development for the Company, personnel having a potential conflict of interest shall disclose the details to the Company. An official designated by the Company shall be responsible for reviewing disclosures and instituting an adequate plan for the management of any potential financial conflict of interest. The ultimate goal of this Policy is to protect the integrity and credibility of activities related to the research and products developed by the Company and to maintain public trust and confidence in the Company and its employees.

All research and development undertaken at the Company shall be conducted in full compliance with all Company policies and all applicable federal and state laws pertaining to conflicts of interest, including applicable rules and regulations of the United States government.

Cancer Targeted Technology respects the rights and choices of our personnel and contractors and consultants. However, as part of contractual employment with CTT, personnel have an obligation of allegiance to CTT and should avoid conflicts of interest with their work and research at CTT whenever possible.

Persons failing to comply with this Policy shall be subject to sanctions as provided herein and by other applicable Company policies and rules.

This policy is intended to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for promoting Objectivity in Research for which Public Health Services Funding is Sought" requiring that grantee institutions adopt, maintain and enforce written policies pertaining to researchers' financial conflicts of interest (FCOI).

## Definitions

For purposes of this Policy, the following definitions shall apply:

**"Company"** shall mean or be used interchangeably with Cancer Targeted Technology.

**"Compensation"** means any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, honoraria, and paid authorship. Other common types of financial conflicts of interest include but are not limited to: external engagements including outside employment, personal financial interests, family and personal relationships, gifts, meal, travel, entertainment and other favors.

Compensation shall not include any of the following:

1. Salary, royalties, or other remuneration paid by the Company to an Investigator or Innovator if the Investigator or Innovator is currently employed by the Company;
2. Income from investment vehicles, such as mutual funds and retirement accounts, providing the Investigator or Innovator does not directly control the investment decisions made by such vehicles;
3. Income from service on advisory committees or review panels for the Company, a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.
4. If the Investigator is supported by an NIH grant through a for-profit company (i.e., the for-profit company is the grantee), the Investigator would not need to disclose the equity interest to the for-profit company that is applying for, or that receives, NIH research funding because any ownership interest held by an Investigator in a commercial or for-profit organization is excluded from disclosure.

**“Conflict Management Plan”** means a written plan instituted by the Company for the management, re-education or elimination of a Financial Conflict of Interest.

**“Entity”** means any domestic or foreign, public or private, for profit or not-for-profit legal entity or organization other than the Company, any agency of the State of Washington, or the federal government.

**“Equity”** means any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.

**“Financial Conflict of Interest”** or **“FCOI”** means a *Significant Financial Interest* of an Investigator or Innovator that could directly and significantly affect the design, conduct, or reporting of Research or adversely affect a Technology Transfer Transaction.

**“Financial Interest”** means anything of monetary value, including but not limited to Compensation, Equity, Gifts, and Intellectual Property, of an Investigator or Innovator or the Immediate Family Member of an Investigator or Innovator, whether or not the value is readily ascertainable.

**“Gift”** means anything of economic value for which no consideration is given but shall not include those items excluded from the definition of gift as set forth in RCW 42.52.010(9).

**“Immediate Family Member”** means a person’s spouse and dependent children.

**“Innovator”** means any Company personnel regardless of title or position, including a Company Research Employee or company-paid contractor, who has created in whole or in part any Intellectual Property in which the Company has any right or interest.

**“Institutional Official”** means one or more persons designated by the Company as having responsibilities and authority under this Policy.

**“Institutional Responsibilities”** means any professional activity carried out by a company-employee, consultant or contractor for which the employee, consultant or contractor is compensated by the Company.

**“Intellectual Property”** means the rights comprising a patent, trademark, copyright, trade secret, know-how or other similar intangible property right, including but not limited to, inventorship or authorship.

**“Investigator”** means any Company personnel regardless of title or position, including company-paid consultants and contractors, responsible for the design, conduct, or reporting of Company Research. Investigator includes, but is not limited to an employee, manager, director, part time employee, or intern. Investigator on PHS-funded programs includes but is not limited to the Principal Investigator, project director, co-principal investigator, and may also include other Senior/Key Personnel, a post-doctoral fellow, graduate student, trainee, collaborator, or consultant, depending on the person’s role in the Research. The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to the design, conduct and reporting of the Research and the degree of independence that an individual may have in performing such Research-related tasks.

**“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

**“PHS-Funded Investigator”** means an Investigator applying for or participating in any PHS-Funded Research.

**“PHS-Funded Research”** means any Research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement. Notwithstanding the foregoing, PHS-Funded Research does not include any Phase I SBIR Program application or award.

**“Policy”** means this Financial Conflict of Interest Policy.

**“Principal Investigator”** means any person designated by the Company with the title of “Principal Investigator” of a Research or other sponsored project or otherwise having primary responsibility for the management and conduct of a Research or other sponsored project, including a program manager or a project director.

**“Reimbursed Travel”** means travel activity for which the Travel Expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such Travel Expenses. Notwithstanding the foregoing, Reimbursed Travel shall not include Travel Expenses that are reimbursed by the Company.

**“Research”** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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) and also includes any activity for which research funding is available through a grant, contract or cooperative agreement.

**“Senior/Key Personnel”** means the Principal Investigator and any other person identified as senior or key personnel by the Company in a grant application, award, or contract or in any progress report, or any other report submitted to the PHS or other funding source.

**“SFI Disclosure”** means a disclosure of a Significant Financial Interest as provided in this Policy.

**“Significant Financial Interest”** or **“SFI”** means any of the following Financial Interests related to the Institutional Responsibilities of an Investigator or Innovator (and those of the Investigator’s spouse and dependent children):

1. With regard to any Entity whose Equity securities are publicly-traded, a Significant Financial Interest exists if the aggregate value of one or more of the following exceeds \$5,000: (i) any Compensation received during the twelve (12) months preceding the date

- of SFI Disclosure, (ii) any Compensation reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, (iii) the value of any Equity interest in the Entity as of the date of SFI Disclosure;
2. With regard to any Entity whose Equity securities are not publicly-traded, a Significant Financial Interest exists if (i) the value of any Compensation received from the Entity in the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure, when aggregated, exceeds \$5,000, or (ii) the Investigator or Innovator holds any Equity interest (e.g., stock, stock option, or other ownership interest);
  3. With regard to any Entity, a Significant Financial Interest exists if the Investigator or Innovator has received income related to any Intellectual Property during the twelve (12) months preceding the date of SFI Disclosure and/or reasonably anticipated to be received in the twelve (12) months following the date of SFI Disclosure which, when aggregated with other Financial Interests in the Entity, exceeds \$5,000; or
  4. With regard to any Entity, a Significant Financial Interest exists if during the twelve (12) months preceding or following the date of SFI Disclosure, the Investigator or Innovator receives or reasonably anticipates receiving one or more Gifts (including but not limited to Reimbursed Travel or Sponsored Travel meeting the definition of Gift) having an aggregate value of \$50 or more from the Entity.

**“Small Business Innovation Research Program” or “SBIR Program”** means an extramural federal program providing financial sponsorship or support for small businesses through PHS awarding components and certain other federal agencies established under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this Policy, SBIR Program also includes the Small Business Technology Transfer Program, established under Public Law 102-564.

**“Sponsored Travel”** means travel activity, the Travel Expenses for which are paid directly by an Entity on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available to the Investigator. Notwithstanding the foregoing, Sponsored Travel shall not include Travel Expenses that are paid by the Company, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

**“Travel Disclosure”** means a disclosure of Sponsored Travel or Reimbursed Travel as provided in this Policy.

**“Travel Expenses”** means expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

## Procedures

### **A. Identification of Investigators**

Investigators and Innovators shall be personally responsible for ensuring that their Significant Financial Interests Disclosures and Travel Disclosures required to be disclosed under this Policy are submitted in a complete and timely manner and in accordance with the Policy. For all Research projects, the Principal Investigator shall be responsible for identifying all Senior / Key Personnel

who are also Investigators as they become known and reporting their identity within ten (10) days thereafter.

## **B. Authority of Institutional Official**

The Institutional Official is authorized to administer and enforce this Policy. Such authorization includes the authority to (i) obtain and review SFI Disclosures and Travel Disclosures under this Policy, (ii) develop and implement Conflict Management Plans, (iii) conduct any required late or retrospective FCOI reviews, including issuance of reports of findings and conclusions and development and implementation of conflict mitigation plans, (iv) communicate with federal and other sponsors on matters pertaining to this Policy; (v) make recommendations to the Company CEO with respect to matters covered by this Policy; and (vi) develop and implement reasonable and appropriate summary procedures for the disposition of matters involving compliance with this Policy.

Current CTT Institutional Official for SFI and FCOI: Janet Bien, CTT controller

## **C. Potential COIs and SFI Disclosures by Investigators**

Potential types of engagements and payments for services or external engagements which may create, or appear to create, a conflict of interest.

1. Receipt of fees for consulting, honoraria and other payments for services. Personnel should not have any kind of paid or unpaid engagements with a CTT supplier, customer or competitor, unless it clearly does not influence and cannot be perceived as influencing their business judgment.
2. The use of working time or company resources to support a CTT supplier or customer or competitor.
3. Require the use or disclosure of Company confidential information to support a CTT supplier or customer or competitor.
4. Acts as an official/advisor/consultant to a government agency, particularly in a role involving regulatory or supervisory power over (or other ability to affect) CTT.
5. Serving on another entity's board of directors
6. Personnel must inform their Institutional Official and obtain prior approval prior to accepting any such position, or giving paid speeches and other presentations.

In addition:

Personnel, substantial consultants or contractors must not own (directly or indirectly) any publicly traded stock or other financial interest equal to or greater than 1% (or greater than \$5000) in any company which competes with or does (or seeks to do) business with CTT .

All SFI Disclosures required to be disclosed by Investigators under this Policy shall be submitted to the Institutional Official in accordance with the following:

7. PHS-Funded Investigators are required to disclose all SFI's (and those of their spouse and dependent children) within thirty (30) days of acquiring the SFI, but in no event later than submission of an application for PHS-Funded Research.

8. Non-PHS-Funded Investigators are required to disclose only those SFIs that are related to their Research no later than submission of an application for the related Research.
9. Once a Research project has been funded, Investigators shall disclose, prior to participating in the project, all SFI's that have arisen since the time of application and all changes to SFI's previously disclosed.
10. With regard to ongoing Research projects –
  - a. all Investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI, and
  - b. when a new Investigator joins an ongoing Research project, the new Investigator shall submit SFI Disclosures within thirty (30) days of joining the project.
11. All Investigators shall submit an updated SFI Disclosure annually.

## **D. Travel Disclosures**

All Travel Disclosures required by this Policy shall be submitted by Investigators to the Institutional Official in accordance with the following.

- a) The timing of Travel Disclosures shall be as follows:
  - i. i. At the time of application for PHS Funded Research, all Sponsored Travel and Reimbursed Travel occurring in the preceding twelve (12) months shall be disclosed,
  - ii. Prior to participating in the PHS Funded Research project, all Sponsored Travel and Reimbursed Travel that occurred since the time of application; and
  - iii. Thereafter, during the course of the Investigator's participation in PHS Funded Research –
- b) no more than thirty (30) days after the occurrence of any Sponsored Travel or Reimbursed Travel, and
- c) an updated disclosure of all Sponsored and Reimbursed Travel annually.
- d) If a PHS Investigator is able to reasonably anticipate the occurrence of Sponsored Travel or Reimbursed Travel, the Investigator may elect to submit Travel Disclosures up to twelve (12) months in advance of the anticipated travel. Unless an advance Travel Disclosure becomes materially inaccurate, no further disclosure of such travel shall be required.
- e) All Travel Disclosures by PHS-Funded Investigators shall include information regarding:
  - i. the purpose,
  - ii. the identity of the sponsor/organizer,
  - iii. the destination,
  - iv. the duration,
  - v. the inclusion of any Immediate Family Member, and
  - vi. an estimate of the approximate value of the travel.

## **E. Disclosures by Innovators**

When an Innovator has an SFI related to a non-Company patent or provisional filing or a Technology Transfer Transaction, the Innovator shall disclose the SFI prior to the conclusion of intellectual property disclosures or the Technology Transfer Transaction.

## **F. Review of Disclosures; and Entity Rules**

1. All SFI Disclosures and Travel Disclosures will be submitted to the Institutional Officer for review via email within the time frames described above (Procedures section C)
2. All Investigators and Innovators making SFI Disclosures or Travel Disclosures shall specify those Research projects, grants and Technology Transfer Transactions that are related to the SFI Disclosures or Travel Disclosures. The Institutional Official shall review the SFI Disclosure or Travel Disclosure to determine whether the Financial Interest constitutes an FCOI. Most reviews are completed within thirty (30) days following submission of all information required for the conduct of the review as determined by the Institutional Official.
3. When the Company identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Institutional Officer shall, within sixty (60) days, review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward.
4. No Investigator having an FCOI may participate in Research without prior written approval from the Institutional Official. All FCOI reviews, including any required Conflict Management Plan, must be completed before any Research activity begins or Research expenses are incurred under an award and before any Technology Transfer Transaction can be completed. In the event the Institutional Official concludes that an FCOI cannot be reduced, eliminated or managed, the Research project or Technology Transfer will not be allowed to proceed.

## **G. Management of Financial Conflict of Interests**

1. If the Institutional Official determines that an SFI Disclosure or Travel Disclosure constitutes an FCOI relating to either Research or a Technology Transfer Transaction, a Conflict Management Plan shall be developed and implemented by the Institutional Official. The FCOI review and Conflict Management Plan shall be completed prior to a conflicted Investigator participating in the Research .
2. Conflict Management Plans shall consist of measures that in the reasonable judgment of the Institutional Official will reduce, eliminate, or manage the effects of the FCOI. In developing a Conflict Management Plan, the Institutional Official may conduct factual inquiries and consult with and receive recommendations from such persons as the Institutional Official deems necessary and appropriate. The terms of a Conflict Management Plan shall be consistent with all legal and regulatory requirements, the requirements of this Policy, and may include one or more of the following:
  - a) Disclosure of FCOIs, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
  - b) Monitoring or oversight of Research by independent co-researchers, reviewers, disinterested individuals, or committees;



- c) Restricting participation in activity affecting or affected by a research project or Technology Transfer Transaction;
- d) Requiring that the SFI creating the FCOI be divested, restructured, or placed in a blind trust;
- e) Modification or severance of relationships that create or are likely to create FCOI's;
- f) Modifying the terms of written agreements relating to the Research or Technology Transfer Transaction;
- g) Requiring compliance with other relevant Company policies
- h) Requiring that participation in the recruitment or consent of subjects in human subjects Research by a conflicted Investigator be prohibited or restricted;
- i) Requiring additional disclosures or actions with respect to matters before a human subjects review committee;
- j) Requiring that the Investigator or Innovator not participate in any business transactions between the Company and parties to agreements involving licensed research.

## H. Access to SFI Disclosures and Travel Disclosures

1. The following Company individuals and groups shall have access to all SFI Disclosures and Travel Disclosures submitted under this Policy:
  - a) Chief Executive Officer
  - b) b. The Institutional Official and designees.
2. Public Access for PHS Funded Research: The Company's FCOI policy will be publicly accessible on its website.
  - a) If Senior/Key Personnel who are also Investigators **are determined to have an FCOI related to PHS-Funded Research.** the FCOI shall be posted on a publicly accessible Company website and contain no less than the following information:
    - i. i. The name of Senior/Key Personnel Investigator(s);
    - ii. The title and role of the Senior/Key Personnel's Investigator(s) in the Research project;
    - iii. The name of the Entity giving rise to the SFI and FCOI;
    - iv. The nature of the FCOI; and
    - v. The approximate dollar value of the FCOI set forth in range amounts (\$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 in increments of \$50,000), or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.
  - b) The publicly accessible website will be maintained by the Company and will be monitored by the Institutional Officer. The information on the website shall be

updated at least annually, and in any event within sixty (60) days of the Company's identification of a new FCOI of Senior/Key Personnel.

- c) The FCOI information of each Senior/Key Personnel shall remain available on the Company's publicly accessible website for at least three (3) years from the date the information was most recently updated.

## **I. Annual Update Reporting**

All CTT personnel, employees, investigators and innovators, and consultants and contractors providing significant input into company research and development, shall provide annual update reports (see Appendix A) In general, annual update reports shall require employees, significant contractors and consultants, whether they are Investigators and Innovators or not, to confirm there has been no material increase in the nature or amount of the Investigator's SFI and if applicable, that the Investigator is complying with the terms of the Conflict Management Plan. Employees will be restricted from submitting funding applications, expending funds, and conducting Research on projects whose annual update reports are not current.

## **J. Disclosure and Review of Increased SFI's and New Investigators**

1. Any Investigator participating in an existing Research project who acquires a new or increased SFI that would otherwise be required to be disclosed under this Policy shall submit a new SFI Disclosure within thirty (30) days of the acquisition of the new or increased SFI. The Company shall complete its review of the new or increased SFI within sixty (60) days of the submission of the SFI Disclosure.
2. Any Company personnel joining an existing Research project who has an SFI that would otherwise be required to be disclosed under this Policy shall submit an SFI Disclosure prior to participating as an Investigator in the Research project and shall not participate as an Investigator in the Research project until an FCOI review has been completed.

## **K. Retrospective Reviews of PHS-Funded Research; Mitigation Plans**

1. For PHS-Funded Research, if an FCOI is not identified or managed in a timely manner due to noncompliance by the Investigator or the Company (including failure of an Investigator to submit SFI Disclosures or Travel Disclosures in a timely manner, a failure by the Company to review an SFI or manage an FCOI in a timely manner, or a failure by an Investigator to materially comply with a Conflict Management Plan), the Company shall, within one-hundred twenty (120) days from the date the non-compliance was identified, complete a retrospective review of the Investigator's activities and the Research project and make a reasonable determination whether there was any bias in the design, conduct or reporting of the Research resulting from the FCOI.
2. The Institutional Official shall document all retrospective reviews, including PHS project number, project title, Principal Investigator, name of the Investigator with the FCOI, name of the Entity in which the Investigator has an FCOI, the reasons for the retrospective review, a detailed description of the methodology used for the retrospective review, and the findings and conclusions of the review.

3. If an FCOI is identified in the course of a retrospective review, the Institutional Official shall develop and submit a mitigation plan to the PHS funding agency. The mitigation plan shall include, at a minimum, the key elements documented in the retrospective review, a description of any impact of the bias on the Research, and the Company's plan to mitigate the effect of the bias.
4. With respect to PHS-Funded Research in which a mitigation plan has been developed, the Company shall submit annual FCOI reports addressing the status of the identified FCOI and any changes to the Conflict Management Plan for the duration of the PHS-Funded Research.

## **L. Training for Investigators Participating in PHS Funded Research**

Prior to engaging in PHS-Funded Research, and no less often than every four (4) years, all Company Investigators (and company consultants, contractors, collaborators, and subcontractors as applicable) must complete training with respect to this Policy and the then-current PHS FCOI rules and regulations. Training shall consist of familiarization with this policy manual, discussing current policy practices with the Institutional Officer and completing the current NIH tutorial ([https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)). Managers should additionally be trained on their specific responsibility to evaluate and address conflicts of interest.

Additionally, PHS Investigators shall complete such training whenever –

1. The Company revises this Policy or related procedures in any manner that materially affects the obligations and responsibilities of PHS-Investigators;
2. A PHS-Investigator first becomes associated with the Company; and
3. The Company determines that a PHS-Investigator is not in compliance with this Policy or any applicable Conflict Management Plan.

## **M. Sanctions and Remedies for Violation of Policy**

Whenever the Institutional Official determines that a person has violated this Policy, including any failure to make a required SFI Disclosure or Travel Disclosure or comply with a requirement of a Conflict Management Plan, the Institutional Official shall recommend to Company CEO, appropriate sanctions consistent with those specified in section G-2.

## **N. Record Retention**

Unless some other applicable record retention law, requirement, or policy requires a longer period of retention, records created and maintained under this Policy, including SFI Disclosures, Travel Disclosures and Conflict Management Plans, shall be retained by the Company for a period of no less than three (3) years after the termination or completion of the Research or Technology Transfer Transaction to which they relate.

## O. Subrecipient Compliance

With respect to awards to the Company for PHS-Funded Research, each Company subrecipient shall:

1. Provide written certification to the Company that subrecipient's FCOI policy complies with all applicable PHS and federal FCOI rules and requirements, or alternatively and only if permitted by the Company, that subrecipient researchers are subject to the Company's policy with respect to disclosing SFI's that are directly related to the subrecipient's work for the Company;
2. If subrecipient's FCOI policy applies, specification of the time periods for the subrecipient to report all identified subrecipient research FCOI's to the Company, which shall be sufficient to enable the Company to provide timely reports to PHS under this Policy; and
3. If the Company allows subrecipient researchers to comply with the Company's FCOI policy, specification of the time periods for the subrecipient to submit subrecipient researcher SFI Disclosures to the Company, which shall be adequate to enable the Company to perform the review, management and reporting required by this Policy.

## P. Federal Reporting

The Institutional Officer is responsible for reporting matters to the CTT Signing Official involving FCOI disclosures in accordance with applicable federal requirements.

1. Prior to the expenditure of any funds under a PHS-Funded Research project, the Company shall provide to the PHS awarding component an FCOI report regarding any Investigator's SFI or Travel Disclosure determined by the Company to constitute an FCOI and ensure that the Company has implemented an appropriate Conflict Management Plan.
2. In the event the Company identifies a previously unreported FCOI related to an ongoing PHS-Funded Research project, the Company shall provide the PHS awarding component an FCOI report regarding any Investigator's SFI found by the Company to be an FCOI and ensure that the Company has implemented an appropriate Conflict Management Plan within sixty (60) days of identifying this interest.
3. All FCOI reports to PHS awarding components shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the Company's Conflict Management Plan. Elements of the FCOI report shall include no less than the following and may include such additional information that the Institutional Official or the PHS awarding component may request:
  - a) Project Number;
  - b) Principal Investigator;
  - c) Name of the Investigator with the FCOI;
  - d) Name of the Entity with which the Investigator has an FCOI;
  - e) Nature of the Financial Interest (e.g., Compensation, Equity, Intellectual Property, consulting fees, Sponsored Travel, Reimbursed Travel);
  - f) Value of the Financial Interest (dollar ranges are acceptable);

- g) Description of how the FCOI relates to the PHS-Funded Research and the basis for the Company's determination that it is an FCOI; and
- h) Description of the key elements of the Company's Conflict Management Plan, including:
  - i. Role and principal duties of the conflicted Investigator;
  - ii. Conditions of the Conflict Management Plan;
  - iii. How the Conflict Management Plan is designed to safeguard objectivity in the research project;
  - iv. How the Conflict Management Plan will be monitored to ensure Investigator/Innovator compliance; and
  - v. Other information as needed, including information regarding the FCOIs of all subrecipient Investigators consistent with the requirements of the 2011 PHS rule.

## Guidelines

The following guidelines are adopted for use in the administration and application of this Policy.

**Availability of Research Data.** All data and results arising from PHS-funded Research in which an Investigator has an FCOI subject to a Conflict Management Plan under this Policy shall be available for disinterested scientific review.

**Clinical Trial Investigators.** No one may participate as an Investigator in a clinical trial sponsored by a start-up commercial or non-profit organization or conducted as a result of licensed technology by the Company, in which the Investigator has a related Equity or Intellectual Property interest, holds a management position in the organization, or serves on the organization's Board of Directors unless the Institutional Official has determined there are compelling circumstances and has made a finding of an overriding public interest justifying participation by the Investigator in the clinical trial.

**Outside Work.** Investigators receiving Compensation from an Entity must ensure that no services performed as part of outside work duplicate any work performed on behalf of the Company while participating in Research and that prior approval for such outside work is obtained.

**Performance of Company Obligations.** Any Investigator or Innovator receiving Compensation from an Entity must ensure that no outside work activity is inconsistent with the obligations of the Investigator or Innovator to the Company.

**Informed Consent.** Except in compelling circumstances as determined by the Institutional Official, no Investigator having an FCOI may participate in the informed consent process in Research involving human subjects.

**Disclosure of Interests.** All Investigators having an FCOI must disclose the nature of the Financial Interest in connection with scholarly publication or presentation of the results of the Research.

**Data Production and Analysis.** Investigators having an FCOI shall not perform primary data analysis or production of data involving subjective scoring or similar methods of obtaining data unless there is a clear and convincing indication that the design of the Research and its analysis would provide no opportunity for bias.

APPENDIX A

**Significant Financial Interests (SFI) Disclosure Form**

Investigator: \_\_\_\_\_ Title \_\_\_\_\_

Applicable NIH Grant or Contract Number: \_\_\_\_\_

Type of disclosure:      Annual report            Change in SFI report     

Policy Statement (date read): \_\_\_\_\_

Training required at employment with CTT and/or award from PHS and required every 4 years or as deemed necessary by Institutional Official): [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

Training (date completed): \_\_\_\_\_

**Significant Financial Interest (SFI):** anything of monetary value received or held by an investigator or family member (spouse or children), whether or not the value is readily ascertainable, that reasonably appears to be related to the investigator's institutional responsibilities. SFI includes:

- Salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received from a publicly traded entity during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- Salary or other payments for services, when the aggregated value received from a non-publicly traded entity during the 12 month period preceding the disclosure exceeds \$5,000; or
- Equity interests (e.g., stocks, stock options, or other ownership interests) in a non-publicly traded company of any value during the 12 month period preceding or as of the date of disclosure; or
- Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through CTT, and
- Reimbursed or sponsored travel that is related to investigator's institutional responsibilities. This includes travel that is paid on behalf of the investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

**SFI does NOT include:** 1) Salary, royalties, or other remuneration from CTT; 2) income from the authorship of academic or scholarly works; 3) income from seminars, lectures, or peer review engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, or medical centers; or 4) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles.

- Investigator certification: *(mark one as applicable)*  
I certify **no SFI** related to my Cancer TargetedTechnology responsibilities; or
- I **disclose SFI** (as indicated above) which may be related to my CTT responsibilities. These interest(s) are described below, or provided as an attachment.  
*Describe the external entity, the type of business, the role/nature of financial interest that you or your family has in the entity, as well as any other relevant details:*

*By signing below, I certify that I have read and understand the [CTT: FINANCIALCONFLICT OF INTEREST POLICY](#). I understand that disclosure is required annually, and upon any changes requiring disclosure of a SFI.*

Investigator Signature \_\_\_\_\_ Date \_\_\_\_\_

Printed Name: \_\_\_\_\_

Return completed form to: Janet Bien, via email: [janetbien@outlook.com](mailto:janetbien@outlook.com)      Maintain electronic copy in personnel folder

----- REVIEW SECTION -----

*This section completed by the CTT Institutional Officer (CTT financial Controller)*

**Financial Conflict of Interest (FCOI):** a Significant Financial Interest (SFI) that CTT determines could directly and significantly affect the design, conduct or reporting of grant- or contract-related PHS research.

Institutional Review Officer :

- No SFI.** I have reviewed this disclosure form, and agree and acknowledge that the investigator has no significant financial interests related to their CTT institutional responsibilities.
- Review pending.** I acknowledge receipt of this disclosure form, and will review upon notice of funding award, or if required under [Policy 151.1, EXTERNAL ACTIVITIES AND CONFLICTS OF INTEREST](#).
- Review of SFI disclosure.** I have reviewed the significant financial interest(s) described here, and in consultation with the investigator have determined:
  - No potential FCOI exists.
  - Actual or apparent FCOI exists that may directly and significantly affect the design, conduct or reporting of CTT research. Referred to CTT CEO for final review and management.

*By signing below, I certify that I have read and understand CTT's Financial Conflict Of Interest (FCOI) Policy.*

CTT Controller  
(Institutional Official)

\_\_\_\_\_  
*Signature* *Date*

\_\_\_\_\_  
*Printed Name*

CTT CEO:

\_\_\_\_\_  
*Signature* *Date*

\_\_\_\_\_  
*Printed Name*

Comments:

*Return completed form to: Janet Bien, via email: [janetbien@outlook.com](mailto:janetbien@outlook.com) Maintain electronic copy in employee's/consultant's/contractor's personnel folder*