



## **Children's Cancer Therapy Development Institute Conflict of Interest Policy**

Children's Cancer Therapy Development Institute (hereinafter "cc-TDI") is an Internal Revenue Service (hereinafter "IRS") recognized, tax exempt 501(c)(3) non-profit organization. As a result, cc-TDI must comply with IRS laws, state laws and any and all regulatory policies, whether known to its members or unknown. Board members, officers, employees, interns and any and all individuals conducting any activities for cc-TDI must conform to all such laws and regulations and owe a fiduciary duty of loyalty and care to cc-TDI. By assuming their position, role or affiliation with cc-TDI, each person is expected to exercise good faith in their management and dealings, and to not utilize their position, role or affiliation with cc-TDI for personal gain or adversely to the interests of cc-TDI. cc-TDI is committed to promoting objectivity in research and compliance with Public Health Services regulations, including the National Institutes of Health (hereinafter "NIH") regarding the disclosure of Significant Financial Interests (hereinafter "SFI") and the management of Financial Conflicts of Interest (hereinafter "FCI") affecting research activities.

### **I. Purpose**

The purpose of this Conflict of Interest policy (hereinafter "COI") is to ensure that the goals of cc-TDI are met by providing guidelines and policies to directors, employees, affiliates and interns with a stated COI policy. This COI policy provides policies and procedures for cc-TDI to be followed when cc-TDI is contemplating entering into any transaction or relationships or arrangements that might benefit the private interest of any person acting as a director, officer, employee, affiliate or intern of cc-TDI. This COI policy is intended to supplement but not replace any federal or state laws or

regulations with respect to conflicts of interest whether real or perceived. cc-TDI strictly adheres to the Financial Conflict of Interest Guidelines as codified by 42 C.F.R. 50, and adhered to by the National Institutes of Health and in maintaining our certification of compliance with Federal Demonstration Partnership (FDP).<sup>1</sup> This COI policy incorporates the policies and procedures as enumerated in cc-TDI's Articles of Incorporation and Bylaws.

## II. Definitions

This COI policy is directed not only to the directors and officers of cc-TDI, but also to all employees, committee members, volunteers, affiliates and interns who may be in a position to exercise substantial influence over the actions and affairs of cc-TDI including anyone who has proprietary information concerning cc-TDI. In this COI policy, all the preceding individuals are referred to as “**Responsible Persons.**”

**A. “Interested Person”** shall mean a Responsible Person, as well as the Family Members and Controlled Entities of that Responsible Person, if any of them has a direct or indirect interest in a transaction or arrangement involving cc-TDI.

**B. “Family Member”** shall mean the spouse, ancestors, children, grandchildren, great grandchildren, and brothers and sisters (whether of the whole or half blood) of a Responsible Person, and the spouse of each such child, grandchild, great grandchild, and brother or sister.

**C. “Controlled Entity”** shall mean any corporation or organization of which a Responsible Person is a board member, an officer, a partner, participates in the management of or is employed by, or is, directly or indirectly, a debt holder or the beneficial owner of any class of equity securities; and any trust or other estate in which a

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<sup>1</sup> <http://grants.nih.gov/grants/policy/coi/> specifically incorporated herein, including all subparts and amendments thereto.

Responsible Person has a substantial beneficial interest or as to which a Responsible Person serves as a trustee or in a similar capacity.

**D. “Investigator”** is the project director or principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the research funded by NSF or PHS, or proposed for such funding, which may include faculty, staff, postdoctoral scholars, students, external collaborators and co- investigators from other institutions or organizations.

**E. “Institutional Responsibilities”** includes an Investigator’s professional responsibilities on behalf of cc-TDI, including activities such as teaching, research, committee or board membership and services and other administrative duties.

**F. “COI Management Committee”** has oversight for reporting of conflicts of interest and approval of management plans. The COI Management Committee shall include at a minimum the President of the Board of Directors, The Executive Director and the General Counsel or Compliance Officer.

**G. “Significant Financial Interest”** The term Significant Financial Interest (SFI) is defined differently for PHS and NSF. Please review the following carefully to understand the differences and to ensure accurate reporting.

**1. SFI For purposes of PHS (NIH) Funding:** SFI means 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 relate to the Investigator’s Institutional Responsibilities:

**a.** With regard to any publicly traded entity, an SFI 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and other

payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria); equity interests includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

**b.** With regard to any non-publicly traded entity, an SFI exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, 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);

**c.** Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of any income by the Investigator related to such rights and interests.

**2.** Included in the definition of SFI is the occurrence of any reimbursed or sponsored travel (i.e. "sponsored travel" is travel which is paid on behalf of the Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities.

**3.** The term SFI does not include the following:

**a.** For cc-TDI employees, salary, royalties, or other remuneration from cc-TDI, including intellectual property rights assigned to cc-TDI and agreements to share in royalties related to such rights;

**b.** 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;

c. Income from a Federal, state or local government agency, an institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute, when such income is payment for sponsored seminars, lectures, teaching engagements, or service on advisory committees or review panels, or travel reimbursement.

2. **SFI For purposes of NSF funding:** 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).

3. The term does not include:

a. salary, royalties or other remuneration from the applicant institution

b. any ownership interests in the business, if the business is an applicant under a Phase I Small Business Innovation Research Program or Small Business Technology Transfer Program;

c. income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by public or non-profit entities;

d. 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 5% ownership interest in any single entity; or

e. salary, royalties, or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children are not expected to exceed \$10,000 during the twelve month period.

4. Disclosure is the submission of the cc-TDI Conflict of Interest Disclosure form (COID) by each cc-TDI individual who meets the definition of Investigator. The Disclosure should include the details of the nature of any SFI for the applicable Federal agency (as defined by the agency), and which is held by the Investigator, his/her spouse and/or dependent children. For NSF and PHS proposals or awards involving an external collaborator who meets the definition of Investigator and who has an SFI, Disclosure can take one of two forms:

a. If the collaboration is with an Investigator whose institution complies with NSF or PHS policies, an annual certification from the institution asserting that it complies with NSF and PHS policy will suffice.

### **III. Nature of Potential Conflicts of Interest**

The purpose of this COI policy is not to identify all potential conflicts of interest. Each potential instance or circumstance that may constitute a conflict of interest will be identified and reviewed individually. The facts of each situation will determine whether the interest in question is such as to give rise to a potential conflict, either real or perceived, including the amount of money involved, the extent to which a person affected could influence cc-TDI's decisions, and whether the interest is of such a nature that it might affect the objectivity or the business judgment of the person involved. The following information is intended to provide general guidelines with respect to the analysis of all potential conflicts of interest.

**A. Personal Gain From Position.** A potential for a conflict of interest arises whenever cc-TDI proposes to engage in any transaction or arrangement with an Interested Person, and such Interested Person stands in any way to gain from that

transaction or arrangement. Examples of potential conflict of interest transactions include the following:

1. An Interested Person supplies facilities, goods, or services to, or acquires facilities, goods, or services from, cc-TDI.

2. An Interested Person may receive any compensation or other consideration from a third party in connection with a gift, purchase or sale of real estate, securities, or other property involving that third party.

3. An Interested Person is employed by or holds a position of authority or responsibility with another organization that may compete with cc-TDI with respect to programs, services, or donors.

4. An Interested Person uses cc-TDI's personnel, equipment, supplies, or good will for other than cc-TDI approved activities, programs, and purposes.

5. An Interested Person receives a substantial gift, loan, or other similar benefit from a third party that would not have been made but for a Responsible Person's duties towards or relationship with cc-TDI.

**B. Use of Confidential Information.** A Responsible Person may have a conflict of interest when he or she uses for personal advantage or for the advantage of any other group, organization or business any confidential information or material acquired in course of carrying out the Responsible Person's responsibilities with cc-TDI. (cc-TDI's Confidentiality policy is hereby incorporated herein by reference and it is understood that all directors, officers, employees, affiliate or intern is required to execute and strictly adhere to the terms of this Agreement).

**C. Prohibition Against Loans.** State law prohibits the making of any loans by nonprofit organizations to its directors and officers. Any director or officer who

participates in the making of any such loan shall be liable to nonprofit organization for the amount of such loan until it is repaid and may face further discipline, including discharge or removal.

**D. Conflicts Arising From Affiliated or Connected Entities.** Where any director, officer, employee, affiliate or intern has any business relationship with an unrelated entity or any entity or organization that has shared control, management or ownership, and such director, officer, employee, affiliate or intern may gain financially or otherwise through the relationship and management decisions of cc-TDI or their ability to exert control over any such relationship, the specific transaction or agreement shall be specifically reviewed and the person or persons subject to such potential conflict shall recuse themselves from any potential decision or review of the potential underlying conflict of interest. In no case shall any person maintaining any such relationship make unilateral decisions or be in any fashion involved in any such decisions as to the engagement in any potential business relationship between cc-TDI and the mutually controlled entity.

**E. Transactions Generally Excluded.** Certain types of transactions, either because of their incidental nature, because they are a necessary consequence of cc-TDI's ordinary and routine operations, or otherwise, generally do not arise to the level of presenting a conflict of interest. Certain transactions may include:

1. An Interested Person's participation in cc-TDI's normal employee benefits programs.
2. An Interested Person's gift or receipt of common courtesies, such as flowers or other inexpensive gifts on special occasions, occasional meals, or reasonable entertainment appropriate to a business relationship and associated with business discussions, if such may be regarded as being consistent with sound business practice.

3. Because of the compatibility of their mission, programs, and services, transactions and arrangements between cc-TDI and any potentially affiliated entities are not subject to the conflicts of interest policy set forth in this statement. However, transactions or arrangements between cc-TDI and individuals who may occupy positions of influence with any affiliated entities may fall within the scope of this conflict of interest policy and, under appropriate circumstances, such individuals should be considered Responsible Persons with respect to cc-TDI.

#### **IV. Procedures for Disclosure, Review, and Action on Conflicts of Interest.**

The mere fact that an Interested Person may have a financial interest in a transaction or arrangement involving cc-TDI does not necessarily mean that a conflict of interest exists, or that, if one does exist, that it is material enough to be of practical importance, or if material, that upon full disclosure of all relevant facts and circumstances, it is necessarily adverse to the interests of cc-TDI. It is the policy of cc-TDI that only its board of directors, general counsel and those to whom it has properly delegated such authority are authorized to determine whether a conflict of interest exists with respect to any particular transaction.

In order that the board of directors may exercise that authority responsibly, it is important that each Responsible Person scrutinize his or her transactions and outside business interests and relationships for potential conflicts and make appropriate disclosures to the full board of directors and general counsel before cc-TDI enters into a transaction that raises a potential conflict of interest. Therefore, in each case in which a Responsible Person believes or reasonably should believe that a proposed transaction creates a potential for a conflict of interest, the following steps shall be taken:

**A. Duty to Disclose.** In connection with, and prior to cc-TDI's entering into any transaction or arrangement that might present an actual or possible conflict of interest, the Responsible Person involved shall disclose, in writing and transmitted to the COI Management Committee, the existence and nature of his or her interest in the

transaction, as well as all material facts relating to the transaction. In the case of cc-TDI staff, this disclosure should be made to the Executive Director, and the General Counsel (or if the Executive Director is the one with the conflict, then to the Board President). It shall be the responsibility of the Executive Director to bring the matter to the attention of the full board. In the case of directors, this disclosure should be made to the board President and General Counsel, (or if the board President is the one with the conflict, then to the board Vice President), who shall bring the matter to the attention of the board as a whole.

**B. Time for Disclosure.** After a Responsible Person's discovery or knowledge of the existence of an actual or potential conflict of interest, the Responsible Person has five (5) business days within which to make such disclosure as enumerated in IV A.

**C. Determining Whether a Conflict of Interest Exists.** After a Responsible Person's full disclosure in writing of any interest in a proposed transaction or arrangement and of all material details concerning the transaction, the board, or any committee of the board properly delegated such power, and in consultation with the General Counsel if necessary, may discuss the matter with the applicable Responsible Person to clarify or obtain additional relevant information. The applicable Responsible Person shall then leave the meeting, and the board, such committee as is delegated responsibility, and if necessary in consultation with the General Counsel, shall determine whether a conflict of interest exists and whether the conflict can be eliminated or avoided. In connection with such determination, the board, or such committee as is delegated responsibility, and if necessary in consultation with the General Counsel shall consider whether cc-TDI can obtain a more advantageous transaction or arrangement with reasonable efforts from a person or entity that would not give rise to a conflict of interest, and the chair of the board, or such committee as is delegated responsibility, and if necessary the General Counsel, may, if appropriate, appoint a disinterested person or committee to assist in such an investigation.

**D. Procedures for Addressing a Conflict of Interest.** If the board, or any committee of the board properly delegated such power, and in consultation with the General Counsel if necessary, determines that a conflict of interest exists and cannot be eliminated or avoided and, if appropriate, that a more advantageous transaction or arrangement is not reasonably attainable under circumstances that would not give rise to a conflict of interest, the board, or committee, in consultation with the General Counsel if necessary, shall determine by a majority vote of disinterested directors whether the transaction or arrangement is in cc-TDI's best interest and whether the transaction or arrangement is fair and reasonable to cc-TDI despite the existence of the conflict, based on whether the proposed transaction or arrangement is at least as favorable to cc-TDI as an arm's-length transaction with disinterested individuals or organizations. The decision of the board, or committee, in consultation with the General Counsel if necessary, shall rest in its sole discretion, but shall be made in good faith and in a manner such board or committee reasonably believes to be in cc-TDI's best interest.

**E. Abstention of Responsible Person.** The Responsible Person involved shall not be present during any discussions or vote by the board, or such committee, and in consultation with the General Counsel if necessary, on the proposed transaction or arrangement and shall not participate in any final deliberations or vote on such matter.

**F. Violations of Duty to Disclose.** If the board, or any proper committee, in consultation with the General Counsel if necessary, has reasonable cause to believe that a Responsible Person has failed to disclose any actual or potential conflict of interest, it shall inform the Responsible Person of the basis for its belief and afford the Responsible Person an opportunity to explain the alleged failure to disclose within ten days (10) from the date that the Responsible Party is notified of such reasonable cause. If, after hearing the Responsible Person's response and after making such further investigation as may be warranted under the circumstances, the board, or committee, in consultation with the General Counsel if necessary, determines that the Responsible Person has in fact failed to disclose an actual or potential conflict of interest in violation

of this policy statement, appropriate disciplinary or corrective action may be instituted, up to discharge from cc-TDI.

#### **V. Physician Payments Sunshine Act.**

In maintaining all notions of transparency and compliance is a commitment for cc-TDI and all Responsible Persons. It is acknowledged and understood that cc-TDI adheres to the policies and procedures as proscribed by the Physicians Payments Sunshine Act. cc-TDI makes no legal assessment or opinion as to whether or not the Physician Payments Sunshine Act legally applies to cc-TDI personnel. cc-TDI does however utilize the Physician Payments Sunshine Act for guidance to ensure that there is financial transparency in any and all relationships with covered entities or other entities and individuals that may be specifically covered by the terms of the Physician Payments Sunshine Act. Responsible Persons are required to track and monitor any and all transfers of value provided by any of the covered entities by the Physician Payments Sunshine Act. The application of this provision may be altered, changed or amended depending upon any formal legal opinion as to its applicability, amendment as to the application of the provisions of the Act or any other coverage of its applicability.

#### **VI. Record of Proceedings.**

The minutes of the board and all committees with board-delegated powers shall contain:

**A.** The names of the persons who, at such meeting, disclosed or otherwise were found to have an actual or potential conflict of interest in connection with a proposed transaction or arrangement, the nature of the interest, any action taken to determine whether a conflict of interest existed, and the decision as to whether a conflict of interest in fact existed.

**B.** The names of the persons who were present for the discussions and votes relating to the transaction or arrangement, a summary of the content of the discussion, including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection with the proceedings.

## **VII. Compensation.**

**A.** A member of the board who receives compensation, directly or indirectly, from cc-TDI for services shall not vote on matters pertaining to his or her compensation.

**B.** A member of any committee, if applicable, whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from cc-TDI for services shall not vote on matters pertaining to his or her compensation.

**C.** Members of the board or any committee whose jurisdiction includes compensation matters and who receive compensation, directly or indirectly, from cc-TDI, either individually or collectively, are not precluded from providing information to the board or any committee regarding compensation matters.

## **VIII. Annual Statements.**

Each director, executive team member, officer and member of a committee with board-delegated powers shall, at the time of appointment to such position and annually thereafter, sign a Disclosure Statement in a form substantially similar to that attached that affirms that such person:

**A.** Has received a copy of this conflicts of interest policy,

**B.** Has read and understands this policy,

**C.** Has agreed to comply with this policy,

**D.** Discloses any transactions or arrangement between cc-TDI and such person during the preceding year that might have given rise to a conflict of interest.

In addition, each director, executive team member, officer and member of a committee with board-delegated powers shall annually sign a Gift Policy Disclosure Form in a form substantially similar to that attached acknowledging that such person understands cc-TDI's policy concerning the receipt of gifts, entertainment, or other favors and agrees to comply with that policy.

#### **IX. Periodic Reviews.**

To ensure cc-TDI operates in a manner consistent with its status pursuant to IRS code section 501(c)(3) and all other applicable federal and state laws and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

**A.** Whether compensation arrangements and benefits are reasonable, based on competent survey information, and the result of arm's-length bargaining.

**B.** Whether partnerships, joint ventures, and arrangements with management organizations and third-party vendors conform to cc-TDI's written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further charitable purposes and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

#### **X. Use of Outside Experts.**

When conducting the periodic reviews as provided for in Section 9, cc-TDI may, but need not, use outside advisors. If outside advisors are used, their use shall not relieve the board of its responsibility for ensuring periodic reviews are conducted. In addition,

any outside advisors must not have any conflicts of interest directly or indirectly with cc-TDI.

## **XI. Restrictions on Lobbying Activities.**

As a tax-exempt, 501(c)(3) nonprofit organization, significant restrictions exist with respect to the amount of political activities that any Responsible Person or cc-TDI may conduct. As a best practice, no Responsible Person may take any political position on behalf of cc-TDI or express any political opinions on behalf of cc-TDI in an attempt to influence the political process or the outcome of any election or legislation. Responsible Persons are not to make any financial contributions in the name of or on behalf of cc-TDI in an attempt to influence legislation or the political process. Although nonprofit organizations may devote an “insubstantial” portion of its activities to lobbying, it is the practice of cc-TDI to refrain from traditional lobbying activities as defined by the Internal Revenue Service. Any Responsible Person who does conduct any lobbying activities must document such activities by providing a statement of the following: purpose of lobbying activity, individual(s) met with, date, and time expended in such activities regardless of whether such activities were on behalf of cc-TDI or another entity or organization. It is not the intention of cc-TDI to become registered as an organization to conduct lobbying activities. The statements in this provision are subject to change based upon current state and federal laws. Nothing in this provision limits a Responsible Person from participating in the political process on an individual basis without reference to cc-TDI, or as a representative of cc-TDI. Any Responsible Person who is a registered lobbyist with the United States Senate must make such information known through a disclosure statement prepared and submitted on an annual basis or at any time the Responsible Person’s registration status changes.

**XI. Enforcement.**

Failure to comply with the policies and mandates of this COI policy may result in disciplinary action up to and including termination. In addition, willful or intentional violation of this COI policy that results in civil, criminal or administration action against cc-TDI may result in liability against the person responsible for such willful or intentional violation. This COI policy will be provided to all directors, officers, employees, affiliates, volunteers and interns.

By signing this, I agree that I have read, understood and agree to be bound by the terms of the Agreement. Please retain a copy for your records.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Full Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_