Conflicts of Interest and Commitment Policy

PURPOSE

Education Development Center, Inc. (“EDC”) assumes that its Employees will act with the highest level of personal responsibility, integrity, and commitment to EDC. Complex situations can arise involving potential conflicts—or the appearance of conflict—that require attention and specialized knowledge. This policy assumes that most potential conflicts of interest or commitment can be managed properly if the facts are disclosed fully as soon as they are known. This policy applies to all EDC Employees, including full-time, part-time and/or casual (includes temporary Employees not hired through an agency).

Appropriate management of conflicts (1) protects the credibility and integrity of EDC as a recipient of funding by federal agencies, state and local governments and agencies, and private organizations, and (2) promotes objectivity and establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research and other work will be free from bias resulting from financial conflicts of interest, and (3) establishes the integrity of EDC’s decision-making process.

This policy is applicable to all Employees and covers all business transactions in which EDC is involved. This policy is designed to:

(1) explain in appropriate detail what constitutes a potential conflict of interest or commitment;

(2) describe what an Employee should do when s/he believes a conflict exists;

(3) describe Employee disclosure obligations;

(4) describe the process EDC will use to review disclosed conflicts (Appendix A); and

(5) describe agency-specific requirements that are applicable to NSF, PHS and certain other funders (Appendix B).

Please note that many of the topics addressed in this policy are also included in EDC’s Code of Business Conduct. For issues related to procurement integrity, please refer to EDC’s Procurement Policy.
II. Conflict of Interest Procedure/Process

A. What to Disclose:

(i.) Significant Financial Interest. Activities involving Significant Financial Interests are presumed to present a conflict of interest. Employees must disclose Significant Financial Interests of themselves, their spouse, domestic partner, and dependent child(ren) only when that financial interest is:

(1) reasonably related to or affected by the Employee’s research or other EDC institutional responsibilities for EDC, or

(2) in an organization that would reasonably appear to be affected by or benefit from the research or work performed by the Employee.

A “Significant Financial Interest” means anything of monetary value, including, but not limited to:

1. Salary or other payments for services (e.g., consulting fees or honoraria);

2. Financial interests (e.g., stocks, stock options, or other ownership interests, loans, leases) or honoraria) that in the twelve months preceding and on the disclosure date have an aggregated value that exceeds $5,000;

3. Income received from intellectual property rights(e.g., patents, copyrights, and royalties);

4. Equity interest in a non-publicly traded entity; or

5. For PHS-funded research only: Travel costs paid for or reimbursed by an entity other than EDC; 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

“Significant Financial Interests” do NOT include:

1. Salary, royalties, or other remuneration from EDC;

2. Income from investments, such as mutual funds and retirement accounts, unless directly controlled by a person or entity who has a relationship with EDC or its work;

3. Income from seminars, lectures, or teaching engagements, service on advisory or review panels, and/or travel reimbursed or sponsored by 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;
Note such engagements could constitute a conflict of commitment, particularly if they involve discussing your EDC work with a potential competitor or take a substantial amount of time away from your EDC work and responsibilities. Discuss this with your supervisors and engage Human Resources and the Office of Legal Affairs as needed.

4. Financial interests in a publicly traded entity that in the twelve months preceding and on the date of disclosure, when aggregated, do not exceed $5,000; or

5. Non-equity financial interests in a non-publicly traded entity that in the twelve months preceding, when aggregated, do not exceed $5,000.

(ii) Other Conflict of Interest

1. Business Transactions. An Employee may be involved in an EDC business transaction, whether solely or as a member of a group, with an entity that the employee, or the employee’s family member has an involvement in. This could result in inappropriate outcomes or the appearance of impropriety for EDC and/or the Employee. Some examples of tasks that an employee could be responsible for and the employee or the employee’s family members are involved may include the following:

   - initiating, making the recommendation for or approving a purchase, contract or award;
   - recommending or selecting a vendor or contractor;
   - drafting or negotiating the terms of such transaction;
   - using EDC’s confidential or proprietary information; or
   - authorizing or making payments from EDC accounts.

These types of Conflicts of Interest may include not only transactions for EDC’s procurement of goods and services, but also the disposition of EDC property and the provision of services or space by EDC.

2. Personal Interest/Duality of Interests. An Employee may have divided loyalties when the Employee has a personal interest or is in a position of influence in another organization that might conflict with the interest of EDC so that when the Employee takes part in a decision it appears that s/he may be unable to remain impartial in choosing between the interest of EDC and her/his personal interest. The result may be the appearance of a lack of integrity in EDC’s decision-making process.

For example, an Employee has a personal interest or is in a position of influence (i.e., director, officer or board member) in an organization that collaborates, conducts business or competes with EDC. A Conflict of Interest may arise if the Employee is involved in the decision-making process in both organizations.
If there is any doubt about whether a Significant Financial Interest or Other Conflict of Interest exists, Employees should err on the side of disclosing the interest. It is important to note that a disclosure will not have a negative effect on your employment so long as it is properly managed.

If you have any questions about your own conflicts, a potential conflict of others, perceptions of conflicts, or the disclosure process, please contact Christine Filosa, Senior Attorney and Director of the Office of Legal Affairs, your Human Resources representative or your Divisional Liaison (refer to Definition, page 5) to resolve questions about possible conflicts.

B. When to Disclose:

1. At Hire – New Employees must submit a Conflict of Interest Disclosure Statement.

2. Annually – Employees must submit a Conflict of Interest Disclosure Statement in January of each year, even if no changes from the prior year.

3. When a New Significant Financial Interest or Other Conflict of Interest arises – Employees must update their last submitted Conflict of Interest Disclosure Statement before or as soon as possible after the Significant Financial Interest or Other Conflict of Interest arises, but in no case later than thirty (30) days after the interest arises. Note that such an interest may arise as a result of new interests acquired by the Employee (the acquisition of new assets or income sources, through purchase, marriage, or inheritance, for example) or as a result of new responsibilities at EDC (e.g. participation in a research activity funded by an entity in which the Employee has a Significant Financial Interest). If possible, a new Significant Financial Interest or Other Conflict of Interest should be disclosed before the interest arises to minimize disruption of the activities of the Employee and EDC.

4. Prior to Submitting a Proposal to a PHS Agency, NSF, or any other sponsor that has adopted the PHS financial disclosure requirements* –

Employees meeting the definition of “Investigator” must update their Conflict of Interest Disclosure Statement before submitting a proposal to a PHS Agency, NSF, or any other sponsor that has adopted the PHS financial disclosure requirements, whether EDC is the prime applicant or a subrecipient to an organization that is a prime applicant.

Certificates of completed Employee disclosures must be received by OSP prior to proposal submission. Proposals may not be submitted without proof of completion of all Employee Investigator disclosures.

*Agencies include but are not limited to (please check proposal/award terms):
5. As required by the specific terms and conditions of a contract award, e.g. FAR 52.203-16, OSP will notify program staff when an unusual contract term (other than the conditions listed in II.B.1-4) applies.

C. How To Disclose:

Employees must complete the Conflict of Interest Disclosure Statement on the EDC Intranet at the times described in section B above. Employees must complete a training on the EDC Conflicts of Interest and Commitment Policy each year prior to completing their annual disclosure statement.

D. Process for Disclosure Once Submitted:

The Conflicts Review Committee (the “CRC”) shall review all disclosures to determine appropriate next steps. If the CRC determines that a conflict does exist, it shall present the Employee with its determination for managing the conflict. For further details related to the CRC process, please see Appendix A.

No expenditure of newly awarded funds may be made until the CRC either (1) determines that no conflict exists or (2) approves a management plan. Further details related to disclosures for awards funded by PHS, NSF, or any other sponsor that has adopted the PHS financial disclosure requirements are found in Appendix B. For ongoing project work, if a new conflict emerges, the CRC will notify the Employee if a management plan is required, which may include stopping work or other requirement, depending on the nature of the conflict.

All information disclosed by Employees pursuant to this policy shall be shared only with those individuals or agencies necessary to fulfill the conflict of interest review and resolution policies of EDC or to comply with sponsor requirements. Confidential information may be disclosed to individuals affiliated with EDC who must consider conflicts of interest in the performance of their duties.

Confidential information may also be shared with Federal or State government officials as required under the regulations of PHS, NSF, or other sponsoring agency, and as otherwise
required by law or court order. Significant Financial Interests related to PHS funding may be publicly posted or presented. Please refer to Appendix B for PHS requirements.

III. Disciplinary Action for Conflict of Interest Violations

Potential, apparent, and actual conflicts of interest may arise as a natural part of an Employee’s engagement with the world outside EDC. The existence or development of a potential, apparent, or actual conflict of interest or commitment is not necessarily itself a violation of this policy. Failure to disclose such conflicts, however, is a violation of this policy.

An Employee may be subject to disciplinary action, up to and including termination, for the failure to disclose a conflict; for the furnishing of false, misleading, or incomplete information; or for the failure to comply with the determination of the CRC.

IV. Identifying and Disclosing Potential Conflicts of Commitment

Potential, perceived or actual conflicts of commitment do not need to be disclosed via the Conflicts of Interest Disclosure Statement, but must be disclosed to your supervisor and if in his or her judgment it is necessary, discussed with Human Resources and the Office of Legal Affairs.

Conflicts of Commitment may arise when an Employee has personal or other professional commitments that may interfere with the Employee’s Institutional Responsibilities to EDC. Conflicts of Commitment may include, but are not limited to the following examples:

- Self Employment (e.g., as a consultant or independent contractor), or working for another entity while employed by EDC;
- Using office supplies or information technology systems to perform private consulting work or work for another employer;
- Using materials owned by EDC, including intellectual property, for personal gain or to benefit a third party; or
- Participating in personal activities or volunteer opportunities that interfere with an Employee’s scheduled work hours.

V. Definitions

CRC – Conflicts Review Committee – Committee which reviews disclosures made via Conflict of Interest Disclosure Statement.

Divisional Liaison – A designated liaison from the following divisions.
Employee – All EDC Employees, including full-time, part-time and/or casual (includes temporary Employees not hired through an agency).

Institutional Responsibilities – An Employee’s professional responsibilities on behalf of EDC.

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 EDC’s program activities.

Non-publicly Traded Company – A non-publicly traded entity does not offer or trade its company stock or shares to the general public on a stock exchange.

NSF – National Science Foundation.

Other Conflict of Interest – See Section II(A)(ii).

PHS – Public Health Service.

Significant Financial Interest – See Section II(A)(i).

Sponsor – A sponsor is any entity that provides support for any of EDC’s program activities.

Subaward/Subawardee/Subrecipient – A subaward is a formal written agreement made between EDC and another organization to perform a portion of a sponsored project. A subaward may be referred to as a subcontract, subgrant, and/or subagreement. EDC receives subawards from prime grantees and contractors, and also issues subawards to other organizations. An organization that receives a subaward is called a subawardee or subrecipient.
Appendix A
Guidelines for Conflicts Review Committee

I. Purpose

These Conflict Review Committee (CRC) Guidelines are intended to provide a basis for the consistent and efficient consideration and resolution of issues arising from Conflict of Interest Disclosure Statements submitted to the CRC.

These Guidelines do not provide rigid rules for resolution of issues. The CRC shall consider all cases on their individual merits and shall interpret and apply these Guidelines in a manner that is in the interest of an appropriate resolution.

II. General

A. Composition

The CRC shall be composed of the Director of Human Resources, the Director of the Office of Legal Affairs, and the Corporate Compliance Manager. Other project staff will be consulted as needed. A CRC member shall recuse him/herself when the CRC is considering such member’s completed disclosure statement.

B. Record Keeping

The Office of Legal Affairs shall retain records of all disclosures received and all actions taken by the CRC for a period of six (6) years from the date of the disclosure to the CRC, the date of the application to which it relates, or the date of termination or completion of the award or grant activity to which it relates, or submission of final expenditure report to the relevant agency, whichever is later. The CRC shall submit a fiscal year summary report to the President, Senior Vice President of Finance and Administration, and the Chief Compliance Officer.

III. Procedure for Review

A. Within thirty (30) business days of submission, the CRC shall review all disclosure forms submitted that indicate a potential conflict and, applying the guidelines set forth in this policy, determine whether there is a conflict of interest and if so to (a) approve work on the project; (b) approve with conditions; (c) request more information or (d) determine that the conflict cannot be sufficiently managed. If the CRC conditionally approves a conflict, a notice detailing such action shall be sent to the Employee.

B. In all cases, the CRC shall provide a written response to the Employee, indicating its determination.

C. Appeal of CRC Determination
1. Circumstances for Appeal – If an Employee has not received a response within the time frame provided in Paragraph III.A or if the Employee is not satisfied with the decision of the CRC, s/he may request that the matter be referred to the Chief Compliance Officer of EDC within thirty (30) business days of the time when the CRC decision was provided.

2. Determination by the Chief Compliance Officer – The Chief Compliance Officer or his/her designee, which shall be a person other than a member of the CRC, shall review the CRC decision, and shall render a decision within fifteen (15) days. In reaching a decision, and as s/he determines to be appropriate, the Chief Compliance Officer or his/her designee may consult with the CRC, the person who brings the appeal, and any other person. The Chief Compliance Officer’s (or his/her designee’s) decision will be final.

IV. Identifying and Resolving or Managing Conflicts

A. Identifying a Conflict of Interest

Not all financial interests with a connection to the institutional responsibilities of an Employee necessarily result in a Significant Financial Interest or a conflict of interest. And not all business transactions or personal interests/duality of interest will be deemed a conflict of interest.

In reviewing disclosures, the CRC must determine whether an Employee’s Significant Financial Interest is related to his or her research or other institutional responsibilities and, if so, whether the Significant Financial Interest constitutes a financial conflict of interest. The CRC may also decide whether an Employee’s Other Conflict of Interest results in inappropriate outcomes, the appearance of impropriety for EDC and/or the Employee, or the appearance of a lack of integrity in EDC’s decision-making process.

For Significant Financial Interests:

Step 1: The CRC shall determine whether a Significant Financial Interest is related to an Employee’s research or other institutional responsibilities based upon whether such Significant Financial Interest (a) could be related to the research or Institutional Responsibilities, or (b) is in an entity whose financial interest could be related to the research or institutional responsibilities.

Step 2: If the CRC determines the Significant Financial Interest is so related, the CRC must then determine that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of an Employee’s research or institutional responsibilities and therefore is a conflict of interest. The CRC shall consider the following factors and may consider others:
The nature of the Significant Financial Interest.

The CRC shall consider the nature of the financial interest. The CRC should consider, for example, the value of the financial interest, whether the financial interest is fixed (e.g. fixed payment for services) or variable (e.g. equity interests), the nature of the equity in which the financial interest exists (e.g. large, public, diversified company, versus small, private, single-product company), etc.

The research and/or institutional responsibilities of the Employee.

The CRC shall consider the extent to which the Employee is responsible for the design, conduct, or reporting of research, conduct of educational activities, or other institutional functions that involve or are relevant to the entity in which the Employee holds the financial interest, including the degree of responsibility over such activities and the ability to affect the integrity of the activities. The CRC shall also consider the nature of the EDC research or educational activity (e.g. whether it involves human research subjects).

The possible impact of the Significant Financial Interest on the Employee’s research and/or institutional responsibilities.

The CRC shall consider, in light of the nature of the financial interest of the Employee and his or her EDC responsibilities, the degree to which the financial interest would reasonably be expected to influence his or her research, educational, or institutional activities. The CRC shall consider, for example, how direct the relationship is between the financial interest and the research or educational activities, how significant the effect is or likely to be, and the degree to which the research, educational, or institutional activities of the Employee can affect his or her financial interest in the entities in which he or she has a financial interest.

For Other Conflicts of Interest:

In reviewing Other Conflicts of Interest, the CRC will determine whether an Employee’s Other Conflict of Interest results in inappropriate outcomes, the appearance of impropriety for EDC and/or the Employee, or the appearance of a lack of integrity in EDC’s decision-making process. In its review, the CRC shall consider the technical impact to the program and project deliverables.

B. Resolution or Management of Conflicts

1. Methods of Resolving a Conflict
The CRC may consider, but is not limited to, the following means of addressing conflicts through the development of a management plan and/or providing further direction. Among the ways to be considered are:

- Disclosure - which could include public disclosure (e.g. in all written publications and oral presentation), disclosure to other Employees involved in the research or educational activity and to sponsors, and/or disclosure to human subjects;

- Monitoring of the research or educational activity by independent reviewers (e.g. internal/external reviewers who would review abstracts and manuscripts, protocols, research results or conclusions, and other matters as appropriate);

- Modification of the research plan or educational activity to minimize potential bias (e.g. using multiple sites or blinding for minimization of bias in research);

- Disqualification or limitation on his or her involvement in the research or educational activity (e.g. restriction from being principal investigator, from analyzing data, from determining whether potential subjects are eligible for enrollment, from soliciting consent, and/or from determining whether an adverse event report is required);

- Modification of the external activity (e.g. restriction on service as director or officer);

- Abstention by the Employee from the external activity or severance of the relationship causing the conflict;

- Reduction of, or insulation from the financial interest (e.g. placement of stock in escrow until a specified date or requirement that options, warrants, etc. not be exercised without CRC consent);

- Divestment of the financial interest.

- Recusal of the Employee from the business transaction.

- Recusal of the Employee from the decision-making process.

- Removal of the organization in which the Employee has a personal interest from a bid or proposal as a potential vendor, partner or subawardee.

In all cases, the Employee will be required to submit confirmation of his or her agreement to the plan and annual reports to the CRC regarding compliance with the prescribed management plan. The CRC shall monitor
Employee compliance with the plan on an ongoing basis until the completion of the relevant project.

2. Determination of How to Avoid or Manage a Conflict

The determination of how to resolve a specific conflict should be the result of consideration of the interests of research and integrity, the institutional interests of EDC, and the individual interests of the Employee. In particular, the CRC shall consider and balance the following factors:

- The severity of the conflict.

Resolution of a conflict in a manner that maintains research and integrity is of principal importance. Where necessary, the CRC shall consider requiring or accepting higher costs of conflict management, modification of the financial interest, modification of the work plan, or modification of the involvement of the Employee in matters related to the research, the decision making process or certain business transactions. For less severe conflicts, the CRC shall consider measures that do not require such changes, such formal recusal from decision making or monitoring of the research to guarantee that the process is not affected.

- The difficulty of implementing effective mitigation measures.

The CRC shall consider limiting the involvement of the Employee in the decision making process or certain business transactions or requesting the Employee to modify his or her financial interest, where alternative mitigation measures of the research or educational work plan are not feasible.

- The personal hardship to the Employee.

The CRC shall attempt to avoid recommending that the Employee divest a financial interest where divestiture of such financial interest would result in significant personal hardship to such individual, particularly where the financial interests pre-exist the conflicting EDC professional responsibilities. When consistent with the person’s professional obligations, in cases where the CRC determines divestiture to be an appropriate conflict mitigation measure, they shall also consider offering the Employee the option to limit the scope of his or her involvement in the research or educational activity, the decision making process or certain business transactions as an alternative.

- The importance of the involvement of the Employee in the EDC research, educational, or institutional activity, decision making or business transaction.
The CRC may recommend that EDC adopt higher administrative costs for management of a conflict where the Employee’s involvement in the EDC research or educational activity, decision making or business transaction is critical (e.g. unique expertise). In such circumstances, the CRC may also consider modification of the research or educational activity as part of the measures to mitigate the conflict. Where involvement of the Employee is critical, the CRC may also look to the Employee to go to extra lengths to accommodate the institutional needs, such as minimizing or insulating the financial interest. Finally, the CRC may consider the removal of the organization in which the Employee has a personal interest from the bid/proposal process and not allow such organization to collaborate or conduct business with EDC.

Whenever possible, and to the extent reasonable, the CRC shall consult with the Employee and other relevant persons prior to recommending that the Employee modify his or her financial interest, that the research or educational work plan be modified, that the involvement of the Employee in the research or educational activity, the decision making or the business transaction be limited, or that the organization in which the Employee has a personal interest be removed from the bid/proposal process.
Appendix B

Agency-Specific Requirements

I. Public Health Service (42 C.F.R. § 50.600 et seq. and 45 C.F.R. § 94 et seq.)

A. Definitions

See Section VI of the Conflict of Interest and Commitment Policy.

B. Reporting Requirements of the Public Health Service

1. Certification by EDC – The Office of Sponsored Programs shall certify in each application for funding to a PHS agency that (a) there is in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS agency, (b) EDC shall promote and enforce Investigator compliance with the PHS requirements including those pertaining to disclosure of Significant Financial Interests; (c) EDC shall manage financial conflicts of interest and provide initial and ongoing Financial Conflict of Interest Reports to the PHS funding agency consistent with the reporting requirements listed below; (d) EDC agrees to make information available, promptly upon request, to the Department of Health and Human Services relating to any Investigator disclosure of financial conflicts of interest and EDC’s review of and response to such disclosure, whether or not the disclosure resulted in EDC’s determination of a financial conflict of interest; and (e) EDC will otherwise comply with the PHS Financial Conflict of Interest regulations.

2. Financial Conflict of Interest Reports – Prior to EDC’s expenditure of any funds under a PHS-funded research project, EDC will provide to the PHS funding agency a Financial Conflict of Interest Report regarding any Investigator’s Significant Financial Interest found by EDC to be conflicting and ensure that EDC has implemented a management plan in accordance with the PHS Financial Conflict of Interest regulations. If EDC eliminates a financial conflict of interest prior to expenditure of PHS-awarded funds, it need not submit a Financial Conflict of Interest Report to the PHS funding agency.

3. Report of Conflicts that Arise After Award

a. If an Employee discloses the existence of a new Significant Financial Interest after the award of funding by a PHS agency, within sixty (60) days the CRC shall review and determine whether
the interest is related to PHS-funded research and whether a financial conflict of interest exists and, if so, the CRC shall take action to manage or resolve the conflict and EDC shall then submit a Financial Conflict of Interest Report to the PHS funding agency.

b. If an Employee discloses the existence of a Significant Financial Interest after the time period required by this policy or if the disclosed Significant Financial Interest was not previously reviewed during an ongoing PHS-funded research project (e.g. was not timely reviewed or reported by a subrecipient), within sixty (60) days the CRC shall review and determine whether the interest is related to PHS-funded research and whether a Financial Conflict of Interest exists. If so, the CRC shall take action to manage or resolve the conflict. EDC shall also file a Financial Conflict of Interest Report with the PHS funding agency.

4. Financial Conflict of Interest Reports – Any Financial Conflict of Interest Report required under paragraphs 2 and 3 above shall include sufficient information to enable the PHS funding agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of EDC’s management plan. Elements of the report shall include, but are not necessarily limited to, the following:

- Funding agency
- EDC project number
- Project Title
- Federal award number or, if for a subaward, the identifier assigned to the subaward by the prime awardee;
- Project director/principal investigator (as defined by PHS regulations);
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has the financial conflict of interest;
- Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges 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 EDC’s determination that the financial interest conflicts with such research; and

- A description of the key elements of EDC’s management plan, including:
  
  - Role and principal duties of the conflicted Investigator in the research project;
  
  - Conditions of the management plan;
  
  - How the management plan is designed to safeguard objectivity in the research project;
  
  - Confirmation of the Investigator’s agreement to the management plan;
  
  - How the management plan will be monitored to ensure Investigator compliance; and
  
  - Other information as needed.

For any financial conflict of interest previously reported by EDC with an ongoing PHS-funded research project, EDC shall, for the duration of the project, provide an annual financial conflict of interest report that addresses the status of the financial conflict of interest and any changes to the management plan, and specifying whether the financial conflict of interest is still being managed or explain why it no longer exists.

5. Retrospective Review

a. Whenever a financial conflict of interest is not identified or managed in a timely manner, including the failure of an Employee to comply with the requirement to disclose a Significant Financial Interest determined by the CRC to be a financial conflict of interest, the failure of the CRC to review or manage a financial conflict of interest, or the failure of an Investigator to comply with a financial conflict of interest management plan, EDC shall, within 120 days of the CRC’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.
b. EDC shall document the retrospective review, including, but not necessarily limited to, the following key elements:

- Funding agency
- EDC project number
- Federal award number or, if for a subaward, the identifier assigned to the subaward by the prime awardee;
- Project title;
- Project director/principal investigator or contact project director/ principal investigator;
- Name of the Investigator with the financial conflict of interest;
- 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.

c. Based on the results of the retrospective review, if appropriate, EDC shall update the previously submitted Financial Conflict of Interest Report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

d. If bias is found, EDC is required to notify the PHS funding agency promptly and submit a mitigation report, including, at a minimum, key elements documented in the retrospective review above and a description of the impact of the bias on the research project and EDC’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).

6. To the extent EDC maintains a policy on financial conflicts of interest that includes standards that are more stringent than those required by PHS financial conflicts of interest regulations for grants, cooperative
agreements and contracts (42 C.F.R. § 50.600 et seq.; 45 C.F.R. § 94 et seq.), EDC shall adhere to its more stringent policy and shall provide reports regarding identified financial conflicts of interest to the PHS funding agency in accordance with EDC’s own standards and within the timeframes prescribed above.

C. Investigator Training

1. PHS-funded research Investigators are required to complete training regarding EDC’s policy on financial conflicts of interest, the Investigator’s responsibilities regarding disclosure to EDC of Significant Financial Interests, and the PHS financial conflict of interest regulations for grants, cooperative agreements and contracts found at 42 C.F.R. § 50.600 et seq.; 45 C.F.R. § 94 et seq. prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract. This training must be repeated every four years.

2. Investigators must receive training immediately when any of the following circumstances apply:

   - EDC revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
   - An Investigator is new to EDC; or
   - EDC finds that an Investigator is not in compliance with EDC’s financial conflict of interest policy or management plan.

D. Information Publicly Available

EDC shall make the following information publicly accessible:

1. Conflict of Interest Policy – PHS-funding recipients must make available an up-to-date, written, enforced policy on financial conflicts of interest that complies with the PHS financial conflicts of interest regulations for grants, cooperative agreements and contracts (42 C.F.R. § 50.600 et seq.; 45 C.F.R. § 94.4 et seq.) via a publicly accessible website. In the event EDC is without such a publicly accessible website, EDC shall make its written policy available to any requestor within five (5) business days of a request.

2. Information on Identified Financial Conflicts of Interest – Significant Financial Interests determined to be financial conflicts of interest held by Senior/Key Personnel must be made available to any requestor via written response within five days of request.

   a. Information made available shall include, at a minimum, the following: the Investigator’s name, the Investigator’s title and role
with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value or range of the Significant Financial Interest, 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.

b. EDC will note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of EDC’s identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

c. Information under this section shall remain available for at three years from the date the information was most recently updated.

E. Subrecipient Investigator Requirements

If EDC carries out PHS-funded research through a subrecipient (e.g., subgrantees, subcontractors, consortium members, collaborators, or consultants responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding), EDC must take reasonable steps to ensure that any subrecipient Investigator complies with the PHS financial conflicts of interest regulations for grants, cooperative agreements and contracts (42 C.F.R. § 50.600 et seq.; 45 C.F.R. § 94 et seq.) by:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the EDC financial conflicts of interest policy or that of the subrecipient will apply to the subrecipient’s investigators.

a. If the subrecipient’s Investigators must comply with the subrecipient’s financial conflicts of interest policy, the subrecipient shall certify as part of its written agreement with EDC that its policy complies with 42 C.F.R. § 50.600 et seq. and 45 C.F.R. § 94 et seq. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to EDC’s financial conflict of interest policy for disclosing Significant Financial Interests that are directly related to the subrecipient’s work for EDC.

b. In either case, the written agreement between EDC and the subrecipient shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to EDC. Such time period(s) shall be sufficient to enable EDC to comply timely with its review, management, and reporting obligations.
2. Providing Financial Conflict of Interest Reports to the PHS funding agency regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified financial conflict of interest.

II. National Science Foundation (NSF AAG, IV.A)

A. Reports to NSF – EDC shall keep NSF’s Office of the General Counsel appropriately informed if EDC finds it is unable to satisfactorily manage a conflict of interest.

B. Subawardees, Collaborators, Contractors – If EDC carries out NSF-funded research through subawardees, collaborators or contractors, EDC must take reasonable steps to ensure that:

- The entity has its own policies in place that meet the NSF conflict of interest policy requirements, including Investigator disclosure of significant financial interests of the Investigator, his/her spouse and dependent children (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities; or

- Investigators working for such entities follow the EDC conflict of interest policies.
Appendix C

Forms

This Part includes the forms required to be completed by various individuals under the Conflicts of Interest and Commitment Policy:

- Conflict of Interest Disclosure Statement
- Subrecipient Research Conflict of Interest Certification Form
Conflict of Interest Disclosure Statement

All EDC Employees are required to disclose Significant Financial Interests of themselves, their spouse, domestic partner, and dependent child(ren) where that financial or other interest may be (1) reasonably related to or affected by the Employee’s research or other institutional responsibilities for EDC, or (2) in any organization that would reasonably appear to be affected by or benefit from the research or work performed by the Employee. Employees must also disclose all Other Conflicts of Interest. If you are uncertain whether you have a conflict of interest please report it and let EDC make the appropriate determination.

Employees are NOT required to disclose Significant Financial Interests NOT reasonably related to or affected by their EDC work or other responsibilities.

Disclosure is required:

- at the time of hire and annually thereafter;

- at the time a new proposal is submitted to a PHS Agency, NSF, or any other sponsor that has adopted the PHS financial disclosure requirements. Employees meeting the definition of “Investigator” must update their Conflict of Interest Disclosure Statement before submitting a proposal to these sponsors, whether EDC is the prime applicant or a subrecipient to an organization that is a prime applicant.

- whenever there is a change in the Employee’s Significant Financial Interests or any Other Conflict of Interest arises.

Failure to do so may result in disciplinary action, including, but not limited to, termination from employment.

“Significant Financial Interest” 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); intellectual property rights (e.g., patents, copyrights, and royalties from such rights); and reimbursed or sponsored travel (by an entity other than EDC). Note that any equity interest in a non-publicly traded entity that is reasonably related to or affected by your EDC work must be disclosed.

“Significant Financial Interests” do NOT include:

1. Salary, royalties, or other remuneration from EDC;

2. Income from investments, such as mutual funds and retirement accounts, unless directly controlled by a person or entity who has a relationship with EDC or its work;

3. Income from seminars, lectures, or teaching engagements, service on advisory or review panels, and/or travel 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.

Note such engagements could constitute a conflict of commitment, particularly if they involve discussing your EDC work with a potential competitor or take a substantial amount of time away from your EDC work and responsibilities. Discuss this with your supervisors and engage Human Resources and the Office of Legal Affairs as needed.

4. Financial interests in a publicly traded entity that in the twelve months preceding and on the date of this disclosure, when aggregated, do not exceed $5,000; or
5. Non-equity financial interests in a non-publicly traded entity that in the twelve months preceding, when aggregated, do not exceed $5,000.

**Employees are not required to disclose Significant Financial Interests not reasonably related to or affected by their EDC work or other responsibilities.**

See the Conflicts of Interest and Commitment Policy located on EDC’s Intranet for additional guidance as to what interests and activities must be reported on this disclosure form. THIS SUBMITTAL is for a:

- [ ] New Hire Disclosure
- [ ] Annual Disclosure
- [ ] New Other Conflict of Interest or Significant Financial Interest Disclosure
- [ ] Proposal Compliance Disclosure: for proposals being submitted to a PHS Agency, NSF, or any other sponsor that has adopted the PHS financial disclosure requirements (see Section II.B.4 of the policy for a partial list). Employees meeting the definition of “Investigator” must update their Conflict of Interest Disclosure Statement before submitting a proposal to these sponsors, whether EDC is the prime applicant or a subrecipient to an organization that is a prime applicant.

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
</tr>
</tbody>
</table>

Proposal/Project Title and Application Date (if relevant):

Sponsor Name (both direct and prime sponsor), Award Number (if relevant), and Period of Performance:

---

**Significant Financial Interests**

1. During the preceding twelve (12) months, did you, your spouse, domestic partner and/or your dependent child(ren) receive salary or other payments for services (e.g., consulting fees or honoraria), or equity interests (e.g., stocks, stock options, or other ownership interests) from a publicly traded entity, that, when aggregated, exceeds $5,000, and is reasonably related to or affected by your EDC work or responsibilities?

- [ ] No
- [ ] Yes

If yes, please explain the interest and its value.

2. During the preceding twelve (12) months, did you, your spouse, domestic partner and/or your dependent child(ren) receive salary or other payments for services (e.g., consulting fees or honoraria) from a non-publicly traded entity, that, when aggregated, exceeds $5,000, and is reasonably related to or affected by your EDC work or responsibilities?
3. During the preceding twelve (12) months, did you, your spouse, domestic partner and/or your dependent child(ren) receive any equity interest (e.g., stocks, stock options, or other ownership interests of any amount) in a non-publicly traded entity that is reasonably related to or affected by your EDC work or responsibilities?

☐ No

☐ Yes

If yes, please explain the interest and its value.

4. During the preceding twelve (12) months did you, your spouse, domestic partner and/or your dependent child(ren) receive income related to rights and interests in intellectual property (e.g., patents, copyrights) and is reasonably related to or affected by your EDC work or responsibilities?

☐ No

☐ Yes

If yes, please describe the rights or interests and the value of the income.

5. During the preceding twelve (12) months, if you participated in PHS-funded research, did you receive any reimbursement or have any sponsored travel paid on your behalf related to your Institutional Responsibilities? You do not need to include travel reimbursed or sponsored by EDC, federal, state, or local government agencies, or any institution of higher education.

☐ No

☐ Yes

If yes, describe the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. Provide the monetary value of the travel that was reimbursed or sponsored, if known.

☐ Not Applicable

Other Conflicts of Interests

6. During the preceding twelve (12) months did you have any Other Conflict of Interest?
□  No

□  Yes

If yes, please describe the Conflict of Interest.

7. Is there anything else that has not been for in this disclosure form that you believe EDC should know, e.g., previous employment by a competitor or major vendor or supplier of EDC, previous membership on the Board of a competitor or major vendor or supplier of EDC, etc.

□  No

□  Yes

If yes, please describe the Conflict of Interest.

Certification (To be completed by all EDC Employees)

In submitting this form, I certify that the above information is true and complete, and that I have read EDC’s Conflicts of Interest and Commitment Policy.

I acknowledge that I am supplying this information for review by authorized EDC personnel.

Signed: ___________________________ Date: ___________________________
Subrecipient Certification Form

EDC must ensure that subrecipients disclose to EDC any significant financial interests that would reasonably appear to be related to or affected by their research work for EDC.

“Significant Financial Interest” 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); intellectual property rights (e.g., patents, copyrights, and royalties from such rights); and reimbursed or sponsored travel (by an entity other than EDC). Note that any equity interest in a non-publicly traded entity is reasonably related to or affected by your EDC work must be disclosed.

“Significant Financial Interests” do NOT include:

1. Salary, royalties, or other remuneration from Subrecipient;
2. Income from investments, such as mutual funds and retirement accounts, unless directly controlled by a person or entity who has a relationship with Subrecipient, or its work;
3. Income from seminars, lectures, or teaching engagements, service on advisory or review panels, and/or travel 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.
4. Financial interests in a publicly traded entity that in the twelve months preceding and on the date of this disclosure, when aggregated, do not exceed $5,000; or
5. Non-equity financial interests in a non-publicly traded entity that in the twelve months preceding, when aggregated, do not exceed $5,000.

Subrecipient, ____________________________________, hereby certifies that (check one):

☐ Subrecipient Investigators have NO Significant Financial Interests (a) that would reasonably appear to be reasonably related to or affected by the research in connection with which
Subrecipient is, or is proposed to be, an EDC subrecipient, or (b) in any entity whose financial interests would reasonably appear to be reasonably related to or affected by such research.

☐ Subrecipient Investigators have Significant Financial Interests (a) that would reasonably appear to be reasonably related to or affected by the research in connection with which
Subrecipient is, or is proposed to be, an EDC subrecipient, or (b) in the following entity whose financial interests would reasonably appear to be reasonably related to or affected by such research.

If Subrecipient discloses a Significant Financial Interest, Subrecipient must include sufficient information to enable EDC to understand the nature and extent of the financial conflict, and to assess the appropriateness of Subrecipient’s management plan. Subrecipient must attach the following information to this Form:

- Funding agency
- EDC project number
- Project Title
- Federal award number or, if for a subaward, the identifier assigned to the subaward by the prime awardee;
- Project director/principal investigator name
• Name of the Investigator with the financial conflict of interest;
• Name of the entity with which the Investigator has the 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 research and the basis for Subrecipient’s determination that the financial interest conflicts with such research; and
• A description of the key elements of the Subrecipient’s management plan, including:
  o Role and principal duties of the conflicted Investigator in the research project;
  o Conditions of the management plan;
  o How the management plan is designed to safeguard objectivity in the research project;
  o Confirmation of the Investigator’s agreement to the management plan;
  o How the management plan will be monitored to ensure Investigator compliance; and
  o Other information as needed.

Subrecipient may not expend any funds until the EDC Agreement Officer has notified Subrecipient in writing that its plan to mitigate the conflict is acceptable.

Note: Your statements are considered continuing representations. You must promptly notify EDC if any of your representations cease to be fully accurate.

EDC will rely upon your representations when making certifications to the U.S. Government. False or misleading statements may be grounds for immediate termination of your subgrant, contract or other agreements with EDC.

Signed: ___________________________________________ Date: ____________________________
Title: ________________________________________________