

DANYA INTERNATIONAL, INC.

FINANCIAL CONFLICT OF INTEREST POLICY

December 21, 2012

A. Danya Financial Conflict of Interest Policy

Danya International, Inc. (Danya), is adopting this Financial Conflict of Interest (FCOI) Policy to promote objectivity in research by establishing and adhering to clear standards to provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants, cooperative agreements, and contracts will be free from bias resulting from Investigator FCOI. In accordance with federal regulations, set forth at 42 CFR Part 50 Subpart F, and 42 CFR Part 94, as they may be amended from time to time (the “PHS regulations”), Danya will manage any FCOIs that may be presented by a significant financial interest (SFI) of an Investigator, including maintenance of records, enforcement mechanisms, and reporting to PHS and other authorities.

Thus, for applicable research projects, Danya’s project director, principal investigator, and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding (which may include, for example, collaborators and consultants), are required by this FCOI Policy to disclose to Danya’s designated official (as identified below) all of his/her significant financial interests (including those of his/her spouse and dependent children) that could reasonably appear to be related to his/her Institutional responsibilities to Danya.

Danya’s designated officials will then determine, pursuant to this FCOI Policy, whether the significant financial interest is related to the PHS-funded research, and, if related, whether it could directly and significantly affect the design, conduct, or reporting of that PHS funded research. When the significant financial interest meets these criteria, it will constitute an FCOI, and Danya will then take whatever actions are necessary to manage that FCOI, including development and implementation of a management plan, and, if necessary, a retrospective review and mitigation report.

It is the purpose of this FCOI Policy to (1) set forth the principles for identifying the potential for such FCOIs and the procedures for reviewing and addressing the FCOIs that occur to ensure that they do not improperly affect or in any way bias Danya research and other activities; and (2) comply with applicable federal regulations of the PHS and National Science Foundation (NSF).

B. Applicability

This FCOI Policy implements federal requirements pertaining to “Objectivity in Research” promulgated by the PHS, which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 Subpart F and 45 CFR Part 94. This Policy also implements federal requirements contained in the NSF’s “Investigator Financial Disclosure Policy.” Both agencies

require Danya to maintain an appropriate written policy on conflict of interest disclosure as a condition for receiving federal grants, cooperative agreements, or contracts. These federal requirements, as implemented in this FCOI Policy, are applicable to all proposals for extramural awards submitted to these two federal agencies. However, this FCOI Policy does not apply to PHS Small Business Innovation Research (SBIR) Program Phase I applications. Application of this Policy will be expanded, if necessary, to comply with official requirements imposed by other federal agencies or other extramural sponsors.

Additionally, Investigators may have questions, on occasion, about whether certain financial arrangements or relationships whose disclosure is not required under the terms of this FCOI Policy may nevertheless appear to constitute an actual or potential conflict of interest with respect to a sponsored project. In such cases, Investigators may exercise an option voluntarily to apply the disclosure requirements of this FCOI Policy to the sponsored project in question. Should Danya subsequently determine that the voluntarily disclosed interest might reasonably appear to be directly and significantly affected by the sponsored project, Danya may take steps either to manage or to eliminate the conflict.

C. Definitions

This Policy uses certain terms that are defined in the PHS Regulations, at 42 CFR 50.603, including the following:

- **“Financial conflict of interest,”** or **“FCOI,”** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **“Financial interest”** means anything of monetary value, whether or not the value is readily ascertainable.
- **“Institutional responsibilities”** means an Investigator’s professional responsibilities on behalf of Danya, including, without limitation, activities such as research, research consultation, teaching, professional practice, and service on panels such as Institutional Review Boards.
- **“Investigator”** means Danya’s project director, the principal investigator, and any other person who is responsible for the design, conduct, or reporting of Danya research funded by the PHS or other external sponsor, or proposed for such funding (which may include, for example, collaborators, consultants, and other independent contractors). In this context, the term “Investigator” includes the Investigator’s spouse and dependent children.
- **“Research”** means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development, and any such activity for which research funding is available from the PHS.

- **“Significant Financial Interest”** means
 - (1) a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouses and dependent children) that reasonably appears to be related to the Investigator’s Institutional responsibilities to Danya:
 - (i) remuneration received from a publicly traded entity in the 12 months preceding the disclosure and the value of any equity interest in the entity on the date of disclosure, when aggregated, exceeds \$5,000; or
 - (ii) remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000; or
 - (iii) intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
 - (2) any reimbursed or sponsored travel (paid for and not reimbursed) related to the Investigator’s Institutional responsibilities to Danya, but not including travel reimbursed by a federal, state, or local government, an Institution of higher education, affiliated research institute, academic teaching hospital, or medical center;
 - (3) not including salary, royalties, or other remuneration paid by Danya to the Investigator if he or she is employed or appointed by Danya, including intellectual property rights assigned to Danya and agreements to share in royalties related to such rights, and ownership in Danya held by the Investigator; and not including other exclusions specified in 42 CFR 94.3.

D. Danya Responsibilities regarding Financial Conflicts of Interest

Danya’s responsibilities under this FCOI Policy are as follows:

- (1) Danya will maintain this FCOI Policy and ensure that it complies with PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94. For such purpose, Danya will post this FCOI Policy on a publically accessible website, www.danya.com/portfolio.asp
- (2) Danya will inform each Investigator of this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94, and of the Investigator’s responsibilities to disclose to Danya any and all of his/her significant financial interests as defined under this FCOI Policy or by the regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94.
- (3) Danya will require each Investigator to complete training regarding this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94 prior to engaging in any research related to any PHS-funded grant, cooperative agreement, or contract, and thereafter at least every 4 years, and immediately in the event (i) Danya revises its FCOI Policy in a manner that affect the requirements of the Investigator, (ii) the Investigator is new to Danya, or (iii) Danya finds that the Investigator is not in compliance with this FCOI Policy. The training can be found at: www.citiprogram.org/default.asp?language=english. The training must be taken on an

annual basis, no later than 31 January of each year and provide the required certification that the training has been done on the FCOI Form, attached hereto.

- (4) Danya will take reasonable steps to ensure that any of Danya's subrecipients (subcontractors or consortium members) carrying out Danya research funded by PHS comply with Section D of this FCOI Policy and with 42 CFR 50.604 (c), pertaining to subrecipient Investigators.
- (5) Danya will designate two Danya officials to solicit and review disclosures of significant financial interest from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

The current designated officials of Danya are Robert Braun, Senior Director of Contracts, at RBraun@danya.com or telephone 301-960-2964, and Dr. Jennifer Scherer, Vice President of Global Evaluation and Training at JScherer@danya.com or telephone 240-645-1131.

- (6) Danya will require that each Investigator who is planning to participate in PHS-funded research disclose to Danya's designated officials the Investigator's significant financial interests (including those of his/her spouse and dependent children) no later than the time for application for the research for each project that they are working on. The individuals shall complete the FCOI Form, and if an FCOI does exist, provide such details as may be requested and complete the Conflict of Interest Addendum (attached). All completed FCOI Forms shall be forwarded to Danya's Director of Contracts at RBraun@danya.com for electronic filing under "Procedures, Financial Conflict of Interest Forms/Completed in the contracts directory. If the FCOI Addendum Form is completed it will be forwarded to Danya's designated officials for review and determination of what steps are to be followed to mitigate any FCOI.
- (7) Danya will require each Investigator who is participating in the research to submit an updated disclosure of significant financial interests, at least annually, on each assigned project, in accordance with the specific time period designated by Danya, during the period of the award, and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- (8) Danya will provide guidelines consistent with this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94 for its designated official to determine whether an Investigator's significant financial interest is related to PHS-funded research, and, if so, whether the significant financial interest is an FCOI.
- (9) Danya's policy is that a significant financial interest is related to PHS-funded research when Danya, through its designated official, reasonably determines that the significant financial interest could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research.
- (10) Danya's policy is that an FCOI exists when Danya, through its designated official, reasonably determined that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

- (11) Danya will (a) take such actions as necessary to manage FCOIs, including any FCOI of a subrecipient Investigator; (b) provide initial and ongoing FCOI reports to the PHS as required; (c) maintain records relating to all Investigator disclosures of financial interest and Danya's review of and response to such disclosures and other actions under this FCOI Policy, for at least 3 years from the date the final expenditure report on the applicable research is submitted to PHS; (d) establish enforcement mechanisms, including employee sanctions or other actions to ensure Investigator compliance; and (e) comply with all other provisions of the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94 that are applicable to Danya.

E. Investigator Responsibilities Regarding Disclosures of Financial Interests

An Investigator's responsibilities under this FCOI Policy are as follows:

- (1) The Investigator will disclose to Danya's designated officials any and all of the Investigator's significant financial interests (including those of his/her spouse and dependent children), as defined under this FCOI Policy or by the regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94.

Danya's designated officials are Robert Braun at Rbraun@danya.com or telephone 301-960-2964, and Dr. Jennifer Scherer at JScherer@danya.com or 240-645-1131.

- (2) An Investigator who is planning to participate in PHS-funded research shall disclose to Danya's designated officials the Investigator's significant financial interests (including those of his/her spouse and dependent children) no later than the time for application for the research.
- (3) An Investigator who is participating in PHS-funded research shall submit an updated disclosure of significant financial interests (including those of his/her spouse and dependent children) to Danya's designated officials at least annually, for each assigned project, in accordance with the specific time period designated by Danya, during the period of the award, and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- (4) An Investigator shall complete training regarding this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94 prior to engaging in any research related to any PHS-funded grant, cooperative agreement or contract, and thereafter at least every 4 years, and immediately in the event (i) Danya revises its FCOI Policy in a manner that affects the requirements of the Investigator, (ii) the Investigator is new to Danya, or (iii) Danya finds that the Investigator is not in compliance with this FCOI Policy.
- (5) The requirement that an Investigator must report a significant financial interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential conflict of interest. The existence of an FCOI is determined subsequently by Danya, as described in Section D(11) of this FCOI Policy. If a financial conflict of interest is identified, Danya will require additional steps to manage or eliminate the conflict as described in Section D(11) of this FCOI Policy.

- (6) Regardless of the above minimum requirements, a staff member, in his/her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.
- (7) All significant financial interests or other potential conflicts of interest must be disclosed by an Investigator prior to the time a proposal is submitted to the PHS or other sponsor. When an Investigator does not have a significant financial interest under this FCOI policy, a written negative statement in documented form should be submitted to Danya's designated official.
- (8) To disclose any and all significant financial interests or other potential conflicts of interest, the Investigator shall complete an **INVESTIGATOR SIGNIFICANT FINANCIAL INTEREST AND OTHER CONFLICTS OF INTEREST DISCLOSURE FORM** and attach all required supporting documentation. The completed Form shall be submitted to Danya's designated official. Supporting documentation that identifies the research, the business enterprise or entity involved, and the nature and amount of the financial interest can be submitted in a sealed envelope marked confidential and accompany the disclosure form.
- (9) All disclosures by Investigators to authorized Danya officials under this FCOI Policy shall be kept private and confidential to the extent possible.

F. Danya Management of Financial Conflicts of Interest

Danya will manage any financial conflicts of interest as follows:

- (1) Prior to Danya's expenditure of any funds under a PHS-funded research project, Danya's designated officials shall review all Investigator disclosures of significant financial interests, determine whether any significant financial interests relate to PHS-funded research; determine whether an FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI, in accordance with this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94.
- (2) Whenever in the course of an ongoing PHS-funded research project an Investigator new to the project discloses a significant financial interest, or an existing Investigator discloses a new significant financial interest, Danya's designated official shall, within 60 days, review the disclosure of significant financial interest, determine whether it is related to PHS-funded research; determine whether an FCOI exists; and, if so, implement on at least an interim basis a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI, in accordance with this FCOI Policy and the PHS regulations at 42 CFR Part 50 Subpart F and 42 CFR Part 94.
- (3) Whenever Danya identifies a significant financial interest that was not disclosed timely by an Investigator, or was not previously reviewed by Danya, the designated officials shall, within 60 days, review the significant financial interest, determine whether it is related to PHS-funded research; determine whether an FCOI exists; and, if

so, implement on at least an interim basis a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI going forward.

- (4) The designated officials, in making this determination, shall proceed as follows:
- (a) If the designated official determines that there is no apparent or potential conflict of interest, the Investigator may submit the application for an NSF or PHS grant, cooperative agreement, or contract, or may continue an existing NSF- or PHS-funded project. The designated official will indicate by their signatures on the **INVESTIGATOR SIGNIFICANT FINANCIAL INTEREST AND OTHER CONFLICTS OF INTEREST DISCLOSURE FORM** that they have completed their review of the disclosure.
 - (b) If the initial determination is made that there may be a potential for conflict of interest covered by this policy, then the designated official shall refer the disclosure packet to the President of Danya.
 - (c) Upon receiving a referred disclosure packet, the President of Danya may consult with any or all of the following persons: Danya's designated officials, the Chief Executive Officer (CEO), the Senior Vice President for Operations, the Senior Vice President for Finance and Administration, and the Director of Contracts. The President may also consult with Danya's outside legal counsel or other advisors as may be determined necessary. The President and his advisors, including the designated official, shall determine the final management plan, in accordance with this FCOI policy and the PHS regulations, and including what additional conditions or restrictions, if any, should be imposed by Danya to manage actual or potential conflicts of interest arising from disclosed significant financial interests or other conflicts of interest.
 - (d) Examples of conditions or restrictions that might be imposed by Danya to manage conflicts of interest include, but are not limited to:
 - Public disclosure of significant financial interests;
 - Review of the research protocol by independent reviewers;
 - Monitoring of the research by independent reviewers;
 - Modifications of the research plan;
 - Disqualification from participation in all or a portion of the research funded by PHS or NSF;
 - Divestiture of significant financial interests; or
 - Severance of relationships that create actual or potential conflicts of interest.
 - (e) A Memorandum of Understanding shall be prepared that details the conditions or restrictions imposed on the Investigator in the conduct of the project or in the relationship with the business enterprise or entity. The Memorandum of Understanding shall be signed by the Investigator and Danya's designated official and President (or designees). Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated prior to expending any funds from the award.

- (5) In addition, in any case where Danya identifies a significant financial interest that was not disclosed timely by an Investigator or was not previously reviewed by Danya, or if Danya fails to manage an FCOI, or an Investigator fails to comply with a management plan, then Danya shall, within 120 days of its determination of such failure, 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 period of noncompliance was biased in the design, conduct, or reporting of that research. Danya will document any such retrospective review and, if appropriate, update the previously submitted FCOI report, and notify and submit a mitigation report to the PHS awarding component, in accordance with the PHS regulations, 42 CFR 50.605.

G. Danya's Website and Reporting of Financial Conflicts of Interest

- (1) Whenever Danya institutes a management plan under this FCOI Policy, Danya shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
- (2) Prior to Danya's expenditure of any funds under a PHS-funded research project, Danya shall ensure public accessibility, via a publicly accessible website located at www.danya.com/portfolio.asp, or by a written response to any requestor within 5 business days of a request, of information concerning any significant financial interest disclosed to Danya that meets the following three criteria:
 - (a) The significant financial interest was disclosed and is still held by Danya's project director, principal investigator, or any other person identified as senior/key in Danya's grant application, progress report, contract proposal or contract, or any other report submitted to the PHS by Danya under the PHS regulations.
 - (b) Danya determines that the significant financial interest is related to the PHS-funded research; and
 - (c) Danya determines that the significant financial interest is an FCOI.
- (3) The information that Danya makes available on its publicly accessible website or written response to any requestor shall include, at a minimum, the information listed in the PHS regulations at 42 CFR 50.605(a)(5)(ii), including:
 - a. the Investigator's name, title and role with respect to the project;
 - b. the name of the entity in which the significant financial interest is held; and
 - c. the nature and approximate dollar value of the significant financial interest (ranges are permissible per the PHS regulations).
- (4) The information that Danya posts on its publicly accessible website shall be updated at least annually, and within 60 days of identification of any new FCOI, or more frequently as required by the PHS regulations. The website shall note that the information is current as of the date listed. The information shall remain available for at least 3 years from the date that the information was most recently updated.

- (5) Records of Investigator financial disclosures, and of actions taken to manage actual or potential conflicts of interest, shall be retained by Danya until three years after the final expenditure report is made or as required in 45 CFR 74.53(6), or the resolution of any government action involving those records.
- (6) Prior to Danya's expenditure of any funds under a PHS funded research project, Danya shall provide to the PHS awarding component a FCOI report regarding any Investigator's significant financial interest found by Danya to be conflicting and ensure that Danya has implemented a management plan in accordance with this FCOI policy and the PHS regulations. However, if Danya identifies a financial conflict of interest and eliminates it prior to the expenditure of funds, Danya shall not submit a FCOI report. The report shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict and assess the appropriateness of the management plan, including all the information listed in the PHS regulations at 42 CFR 605(b)(3).
- (7) According to NSF regulation, Danya shall inform NSF's Office of the General Counsel only if it is unable to manage satisfactorily a conflict prior to expending funds on the affected PHS award.

H. Danya Enforcement of FCOI Policy

- (1) Failure of an Investigator to comply with this FCOI policy or with any of the conditions or restrictions imposed on the conduct of the research, project, or contract under this policy, will be grounds for disciplinary action up to and including termination, pursuant to applicable Danya employee policies as applicable. In addition, federal regulations may require reports to the federal sponsor of any information that may show a violation of Danya policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.
- (2) If the failure of an Investigator to comply with Danya's FCOI policy or any management plan under this policy appears to have biased the design, conduct, or reporting of the PHS-funded research, Danya shall promptly notify the PHS awarding component of the corrective action taken or to be taken. Such corrective action may include suspension termination by Danya of the Investigator involved from the applicable research project, and direction by Danya that the Investigator involved disclosed the FCOI in each public presentation of the results of the research, including an addendum of any previously published presentations.

I. Danya Reservation of Authority

- (1) Danya reserves the right and is authorized to revise, amend, or otherwise change this FCOI policy from time to time, in accordance with PHS regulations and other applicable rules and regulations. Danya will post any such revisions or other changes on the publicly accessible website.

FCOI FORM

Disclosure of Investigator's Financial Conflict of Interest

PI Last Name		Phone #	
PI First Name		Fax #	
Title		Email	

Type of Proposal / Disclosure:

Agency Information:

<input type="checkbox"/> New	<input type="checkbox"/> Renewal*	<input type="checkbox"/> National Institutes of Health - NIH	<input type="checkbox"/> Other DHHS Agencies
<input type="checkbox"/> Continuation*	<input type="checkbox"/> Resubmission*	<input type="checkbox"/> National Science Foundation - NSF	
<input type="checkbox"/> Add Researcher to the Project*	<input type="checkbox"/> Competitive Supplement*	<input type="checkbox"/> American Cancer Society - ACS or American Heart Association - AHA	
<input type="checkbox"/> Change of Principal Investigator*		<input type="checkbox"/> Subaward - List Subaward agency and "Prime" funding names below:	
<input type="checkbox"/> Change in Financial Interest of Principal Investigator or Researcher*			

* If not a "New" proposal, list: _____

Previous Danya # _____

Subaward Agency Name: _____

Award # _____

Subaward "Prime" Funding Agency Name: _____

Proposal Title: _____

Budget Period From _____ Through _____ Project Begin Date _____ Project End Date _____

Principal Investigator Disclosure and Certification

Please disclose any financial interests that reasonably appear to be related to your institutional responsibilities¹ and that meet the minimum criteria to be considered significant².

Danya's Committee for determining FCOI may decide that additional information is required; if so, the attached Addendum must be completed. In such a case the Addendum should be submitted to the Committee for each entity requested.

I acknowledge and certify:

- (1) My responsibility to disclose any new reportable financial interests obtained during the term of the project; and
- (2) All Co-Principal Investigators, Other Investigators, and Key Personnel who will have the responsibility for the design, conduct, or reporting of research will submit the **Form**; this is a complete disclosure of my financial interests related to the proposed project.

I certify that I have taken the FCOI training.

No
 Yes

 Signature, Principal Investigator

 Date

Co-Principal Investigator, Other Investigators, or Key Personnel Disclosure and Certification

Please disclose any financial interests that reasonably appear to be related to your institutional responsibilities¹ and that meet the minimum criteria to be considered significant².

Danya's Committee for determining FCOI may decide that additional information is required; if so, the attached Addendum must be completed. In such a case the Addendum should be submitted to the Committee for each entity requested.

I acknowledge and certify:

- (1) My responsibility to disclose any new reportable financial interests obtained during the term of the project; and
- (2) All Co-Principal Investigators, Other Investigators, and Key Personnel who will have the responsibility for the design, conduct, or reporting of research will submit the **Form**; this is a complete disclosure of my financial interests related to the proposed project.

I certify that I have taken the FCOI training.

- No
 Yes

Signature, Co-Principal Investigator, Other Investigator, or Key Personnel

Date

Co-Principal Investigator, Other Investigators, or Key Personnel Disclosure and Certification

Please disclose any financial interests that reasonably appear to be related to your institutional responsibilities¹ and that meet the minimum criteria to be considered significant².

Danya's Committee for determining FCOI may decide that additional information is required; if so, the attached Addendum must be completed. In such a case the Addendum should be submitted to the Committee for each entity requested.

I acknowledge and certify:

- (1) My responsibility to disclose any new reportable financial interests obtained during the term of the project; and
- (2) All Co-Principal Investigators, Other Investigators, and Key Personnel who will have the responsibility for the design, conduct, or reporting of research will submit the Form; this is a complete disclosure of my financial interests related to the proposed project.

I certify that I have taken the FCOI training.

- No
 Yes

Signature, Co-Principal Investigator, Other Investigator, or Key Personnel

Date

¹ "Institutional Responsibilities." We proposed this definition in the NPRM to mean an Investigator's professional responsibilities on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

² "Significant Financial Interest" was defined under the 1995 regulations as anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include: (1) Salary, royalties, or other remuneration from the applicant Institution; (2) any ownership interests in the Institution, if the Institution is an income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) income from service on advisory committees or review panels for public or nonprofit entities; (5) an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or (6) salary, royalties, or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected (or, in the case of PHS contracts, are not reasonably expected) to exceed \$10,000. 42 CFR 50.603; 45 CFR 94.3.

ADDENDUM FORM

Addendum to Investigator's Statement of Financial Conflict of Interest

Principal Investigator / Co-Principal Investigator / Key Personnel

Last Name		Mail Code	
First Name		Phone #	
Title		Fax #	
Department		Email	

Proposal Title			
Disclosure Type	<input type="checkbox"/> Nongovernmental (Contract, Grant, Gift, MTA, Clinical Trial)	<input type="checkbox"/> Federal (NSF)	

Related entity in which you have a financial interest

Entity Name		Business Type	
Street Address		City, State, Zip	

I. Description of Financial Interests: If more space is required for explanations, please attach separate page(s).

A. Management	<p>1. Do you, your spouse, registered domestic partner, or a dependent child(ren) hold a position of management or employment with this entity?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," please indicate the position(s).</p> <p><input type="checkbox"/> Director <input type="checkbox"/> Partner <input type="checkbox"/> Member, Board of Directors <input type="checkbox"/> Employee</p> <p><input type="checkbox"/> Trustor <input type="checkbox"/> Officer <input type="checkbox"/> Member, Scientific Advisory Board <input type="checkbox"/> Other: _____</p> <p>2. Describe the responsibilities of your position(s) with the entity and how they relate to the project funded by the entity.</p>																									
B. Income	<p>1. Excluding contracts, or grants administered by Danya, have you, your spouse, registered domestic partner, or dependent child(ren) received income from the entity in the past 12 months? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, indicate Income Range and Nature of Income:</p> <table style="width: 100%;"> <tr> <td style="width: 30%;"></td> <td style="width: 20%;">Income Range:</td> <td style="width: 50%;">Nature of the Income:</td> </tr> <tr> <td></td> <td><input type="checkbox"/> \$500-\$9,999</td> <td><input type="checkbox"/> Consulting</td> </tr> <tr> <td></td> <td><input type="checkbox"/> \$10,000-\$19,999</td> <td><input type="checkbox"/> Honoraria</td> </tr> <tr> <td></td> <td><input type="checkbox"/> \$20,000-\$49,999</td> <td><input type="checkbox"/> Payment in Kind</td> </tr> <tr> <td></td> <td><input type="checkbox"/> \$50,000 and above</td> <td><input type="checkbox"/> Per Diem</td> </tr> <tr> <td></td> <td></td> <td><input type="checkbox"/> Salary</td> </tr> <tr> <td></td> <td></td> <td><input type="checkbox"/> Other: _____</td> </tr> </table> <p>2. Do you have a loan arrangement with the entity? <input type="checkbox"/> No <input type="checkbox"/> Yes Provide the loan amount: \$_____</p> <p style="margin-left: 150px;">Explain the arrangements:</p>						Income Range:	Nature of the Income:		<input type="checkbox"/> \$500-\$9,999	<input type="checkbox"/> Consulting		<input type="checkbox"/> \$10,000-\$19,999	<input type="checkbox"/> Honoraria		<input type="checkbox"/> \$20,000-\$49,999	<input type="checkbox"/> Payment in Kind		<input type="checkbox"/> \$50,000 and above	<input type="checkbox"/> Per Diem			<input type="checkbox"/> Salary			<input type="checkbox"/> Other: _____
	Income Range:	Nature of the Income:																								
	<input type="checkbox"/> \$500-\$9,999	<input type="checkbox"/> Consulting																								
	<input type="checkbox"/> \$10,000-\$19,999	<input type="checkbox"/> Honoraria																								
	<input type="checkbox"/> \$20,000-\$49,999	<input type="checkbox"/> Payment in Kind																								
	<input type="checkbox"/> \$50,000 and above	<input type="checkbox"/> Per Diem																								
		<input type="checkbox"/> Salary																								
		<input type="checkbox"/> Other: _____																								
C. Equity	<p>1. Do you, your spouse, registered domestic partner, or dependent child(ren) hold an equity interest in this entity?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," answer questions 2, 3, and 4.</p> <p>2. Indicate the percentage of equity: _____%</p> <p>3. What is the nature of this equity interest? <input type="checkbox"/> Bonds <input type="checkbox"/> Stocks/Stock Options <input type="checkbox"/> Convertible Security <input type="checkbox"/> Other: _____</p> <p>4. What is the value of this equity interest? <input type="checkbox"/> Up to \$1,999 <input type="checkbox"/> \$10,000-\$99,999 <input type="checkbox"/> \$1,000,000 and above</p> <p style="margin-left: 100px;"><input type="checkbox"/> \$2,000-\$9,999 <input type="checkbox"/> \$100,000-\$999,999</p> <p>Note: If the stock is not publicly traded, provide an internal estimate of value \$_____</p>																									
D. Consulting	<p>1. Are you a consultant with this entity? <input type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," answer questions 2, 3, and 4.</p> <p>2. Do you have a written consulting agreement? <input type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," provide a copy, which will be returned.</p> <p>3. Describe in detail the frequency and nature of your consulting activities and how the consulting is separate from your research.</p> <p>_____</p> <p>4. Will the terms of your consulting in any way restrict the release of information or other dissemination of research results by Danya?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes; explain: _____</p>																									

II. Relationship with Entity

A. Direct and Significant Impact on Financial Interests

1. Is the entity a subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the project?
 No Yes If "Yes," explain: _____

2. Are you the inventor of any device, vaccine, procedure, drug, or any other product associated with this research? No Yes
3. Does the entity manufacture or commercialize any device, vaccine, procedure, drug, or any other product associated with this research?
 No Yes If "Yes," explain: _____

4. Will the project purchase/lease any device/material from the entity?
 No Yes If "Yes," provide the name and approximate cost. Name: _____ Cost: \$ _____
5. Is it reasonable to anticipate that the entity will or could be directly and significantly affected by the design, conduct, or reporting of the research activity? No Yes If "Yes," explain: _____

6. Is the entity a nonprofit foundation?
 No Yes If "Yes," answer questions A and B and explain: _____
 - A. Do you have a financial interest in the company (ies) that is (are) providing funds to this nonprofit foundation? No Yes
 - B. If the sponsoring foundation is primarily a vehicle for one or two companies or a closely cooperating group of businesses, identify these firms.

B. Separation of Danya and Outside Interests

1. Explain how you are keeping your interests and obligations to the entity separate from your Danya activity. _____

2. Were you part of a formal committee/body that made the decision that led to the award?
 No If "No," and you were present when the decision was made, provide either a written statement or a copy of the meeting minutes.
 Yes If "Yes," explain: _____

3. Please attach a brief description (statement of work or abstract) of the research. If the project involves testing of any drugs or devices, or the development of a product, please describe in detail: _____

4. Is the entity providing any proprietary data, materials, or equipment?
 No Yes If "Yes," explain what control on access to the research will be necessary: _____

5. Is the entity providing any proprietary data, materials, or equipment?
 No Yes If "Yes," explain what role the entity will play: _____

II. Relationship with Entity (continued)

C. Use of Danya Resources and Facilities

1. For nongovernmental sponsored projects, is the entity supporting full direct and indirect costs of this project? If a gift or MTA, indicate "Not Applicable." No Yes Not Applicable
2. List any other entity funding this research and their amount of support. Also, identify any Danya funds that will be supplementing the project.

_____	\$ _____	\$ _____
Entity Name	Entity Support	Danya Supplement
3. Will the research be conducted in the entity's facilities?
 No Yes If "Yes," how many hours per week will be spent in the entity's facilities? _____
4. Will any of the entity's personnel work on the research?
 No Yes If "Yes," explain in what capacity: _____

D. Licensing

1. For nongovernmental sponsored projects:
Will the contract, grant, or gift that will fund this research require the granting of an exclusive license or option to the entity?
 No Yes If "Yes," explain how it is documented in a research agreement or clinical trial agreement: _____
2. Does the entity hold rights to a pending application or issued patent to an invention(s), license rights, or software copyright for you, your spouse, registered domestic partner, or dependent child (ren)?
 No Yes, the entity holds a license(s) from Danya.
 Yes, however, Danya assigned the invention(s) to me.
 Yes, and the application, patent, license, or copyright is not assigned from Danya.

E. Protection of Human and Animal Subjects

1. Does this project involve:
Human Subjects No Yes If "Yes," indicate protocol #: _____
Animal Subjects No Yes If "Yes," indicate protocol #: _____
2. Are you involved in recruiting and/or obtaining consent of human subjects to participate in this study?
 No Yes
3. Will the entity provide a drug, device, vaccine, or procedure for use in this protocol?
 No Yes
4. Are you the inventor of any drug, device, vaccine, or procedure?
 No Yes If "Yes," indicate the name of the drug, device, vaccine, or procedure: _____

III. Verification

I certify under penalty of perjury that this is a complete disclosure of all financial interests related to the specified project. I have used all reasonable diligence in preparing this Addendum to Investigator's Statement of Economic Interests and, to the best of my knowledge, it is true and complete.

Signature

Date (mm/dd/yy)

Please Note:

The principal purpose for requesting this information is to accomplish the independent and substantive review of positive financial disclosures as required by the US Government Regulations related to the Financial Conflict of Interest Policy related to Grants. Failure to submit this information could result in your removal from the project. **Please send the information to the assigned Danya Designated Officials.**