

NSABP Foundation, Inc.
Financial Conflicts of Interest

Disclosure of Financial Interests	Page: 1 of 12
Effective Date: August 24, 2012	

POLICY

NSABP Foundation, Inc. (NSABP) is committed to maintaining objectivity in the research it conducts. NSABP promotes standards and maintains processes that are designed to create a reasonable expectation that the design, conduct, and reporting of research funded under NSABP's PHS grants, cooperative agreements, and contracts will be free from bias resulting from investigator or senior/key personnel financial conflicts of interest

NSABP employees whose responsibilities include reporting or managing financial conflicts of interest shall be familiar with this policy and shall follow these procedures.

PROCEDURE

- 1) Notification of Investigators and Senior/Key Personnel. NSABP shall notify affected Investigators and Senior/Key Personnel of this policy, their responsibility to disclose Significant Financial Interests, and applicable federal regulatory requirements.
- 2) Training of Investigators. Investigators and senior/key personnel subject to this policy will complete training within thirty (30) days of adoption of this policy.
 - a) Investigators. Investigators will complete training prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract. Investigators will have updated training at least every four (4) years, as well as immediately if:
 - NSABP revises its financial conflict of interest policies or procedures in a way that affects Investigators;
 - The Investigator is new to NSABP; or
 - NSABP determines that the Investigator is not in compliance with this policy or a financial conflict of interest management plan created under the NSABP Management of Financial Conflict of Interest Policy.
 - b) Senior/Key Personnel. Senior/Key Personnel will have training before providing services on research related to any PHS funded grant, cooperative agreement or contract, and will have updated training at least every four (4) years, as well as immediately if:

- NSABP revises its financial conflict of interest policies or procedures in a way that affects Senior/Key Personnel;
 - The person is new to NSABP; or
 - NSABP determines that the Senior/Key Person is not in compliance with this policy or a financial conflict of interest management plan created under the NSABP Policy on Management and Reporting of Financial Conflict of Interest.
- 3) Investigator Disclosure of Financial Interests. Each Investigator who is planning to participate in NSABP research funded by PHS must disclose to NSABP's Administrative Manager the Investigator's Significant Financial Interests, as well as the Significant Financial Interests of the Investigator's Immediate Family.
- a) *Completion of Disclosure Form*. To meet this disclosure obligation, the Investigator will complete the Declaration of Financial Interests form, included as **Attachment 1** to this policy.
- b) *Timing of Disclosure*.
- i) Disclosure must occur no later than the time of application for PHS funding.
 - ii) Each Investigator participating in the PHS-funded research must submit an updated disclosure at least annually. NSABP will circulate the Declaration of Financial Interests form, and will expect completed responses by within 30 days. Such disclosure shall include any information not disclosed to NSABP previously and shall include updated information regarding any previously disclosed Significant Financial Interest (such as the updated value of an equity interest).
 - iii) Each Investigator participating in the PHS-funded research shall submit an updated disclosure of Significant Financial Interests within thirty (30) days of discovering or acquiring (such as through purchase, marriage or inheritance) a new Significant Financial Interest.
- 4) Senior/Key Personnel Disclosure of Financial Interests. Senior/Key Personnel shall complete the Declaration of Financial Interests form, included as **Attachment 1** to this policy with the same timing as set forth for Investigators above.
- 5) Management of Financial Conflicts of Interest. NSABP's Administrative Manager will solicit and review the disclosures of each Investigator and Senior / Key Personnel who is planning to participate in, or is participating in, the PHS-funded research. Disclosures will be reviewed and evaluated, with input from the CEO of the Foundation, in accordance with the NSABP Policy on Management and Reporting of Financial Conflicts of Interest.

- 6) Reporting of Financial Conflicts of Interest. NSABP shall send initial, annual, and revised FCOI reports to the NIH as set forth in the NSABP Policy on Management and Reporting of Financial Conflicts of Interest.
- 7) Subrecipient Requirements. NSABP carries out PHS-funded research through subrecipients (i.e., subcontractors and consortium members) and will take reasonable steps to ensure that subrecipient Investigators comply with this policy and applicable federal requirements by:
 - a) *Written Agreements with Subrecipients*. In writing, NSABP shall establish terms with each subrecipient as to whether this policy or the financial conflict of interest policy of the subrecipient will apply to the subrecipient's Investigators.
 - i) If the subrecipient's financial conflict of interest policy will apply:
 - (1) the subrecipient shall certify in writing that its policy complies with Code of Federal Regulations Title 42, Part 50, Subpart F (Promoting Objectivity in Research). If this certification cannot be made, the subrecipient Investigators will be subject to this policy for disclosing Significant Financial Interests directly related to the subrecipient's work for NSABP; and
 - (2) the agreement between NSABP and the subrecipient will specify time period(s) for the subrecipient to report all identified FCOIs to NSABP sufficient to allow NSABP to provide timely FCOI reports as set forth in the NSABP Policy on Management and Reporting of Financial Conflicts of Interest.
 - ii) If this policy will apply, the agreement between NSABP and the subrecipient will specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures to NSABP, sufficient to enable NSABP to meet its review, management and reporting responsibilities set forth in this policy.
- 8) Enforcement and Noncompliance. NSABP has established adequate enforcement mechanisms to ensure Investigator and Senior/Key Personnel compliance. Such mechanisms are set forth in the NSABP Policy on Enforcement and Noncompliance Processes for FCOI Requirements.
- 9) Public Accessibility. This policy shall be publicly available on NSABP's website. Prior to expenditure of any funds under a PHS-funded research project, NSABP shall provide public accessibility of certain information concerning any Significant Financial Interest disclosed to the NSABP that: (1) was disclosed and is still held by the Senior/Key Personnel; (2) NSABP determines is related to the PHS-funded research at issue; and (3) NSABP determines is an FCOI. Additional information about this process is set forth in the NSABP Policy on Management and Reporting of Financial Conflicts of Interest.
- 10) Maintenance of Records. NSABP will maintain all records relating to this policy, including:

- Investigator and senior/key personnel Declaration of Financial Interest forms;
- NSABP's review of, and response to, such disclosures;
- All actions under this NSABP Policy, the NSABP Policy on Management and Reporting of Financial Conflicts of Interest, or the NSABP Policy on Enforcement and Noncompliance for FCOI Requirements;
- Any retrospective review, if applicable;

for three (3) years from the date the final expenditures report is submitted to the PHS, or, if applicable, from the dates specified in 45 C.F.R. § 74.53(b) and 92.42(b).

DEFINITIONS

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.

Immediate Family means an individual's spouse and dependent children.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators or consultants.

Senior/Key Person or Personnel means the project director or principal Investigator of a PHS-funded research project and any other person identified as senior/key personnel by the NSABP in the grant application, progress report, or any other report submitted to the PHS by the NSABP.

Significant Financial Interest means

(1) a financial interest consisting of one or more of the following interests of the individual (and those of the individual's Immediate Family) that reasonably appears to be related to the individual's NSABP responsibilities:

- With regard to any publicly traded entity, any remuneration received from the entity in the past 12 months, which when combined with the value of any equity interest in the entity as of the date of disclosure, exceeds \$5,000 in the aggregate. This includes salary and any payment for services not otherwise identified as salary (such as consulting fees, honoraria, paid authorship), as well as any kind of equity interest such as stock a stock option or other ownership interest.

- With regard to any non-publicly traded entity, (a) any remuneration received from the entity in the past 12 months that exceed \$5,000 in the aggregate, OR (b) any equity interest, regardless of value.
- Intellectual property rights and interests (patents, copyrights, etc.), if income has been received related to such rights and interests.

(2) any reimbursed or sponsored travel (including that paid on behalf of the individual directly) related to the individual’s NSABP responsibilities; provided however, that travel reimbursed or sponsored by a governmental entity, an institution of higher learning or its affiliated research institute, an academic teaching hospital, or a medical center is excepted.

(3) The following financial interests are not included in this definition: (a) salary, royalties or other remuneration paid by NSABP if the individual is employed by or otherwise appointed by NSABP (including intellectual property rights assigned to the NSABP and any agreement to share in royalties related to such right); (b) income from investment vehicles (including mutual funds and retirement accounts) if the individual does not directly control the investment decisions made in these vehicles; (c) income from seminars, lectures, or teaching engagements sponsored by a governmental entity, an institution of higher education or its affiliated research institute, an academic teaching hospital, or a medical center; (d) income from service on advisory committees or review panels for a governmental entity, an institution of higher education or its affiliated research institute, an academic teaching hospital, or a medical center.

REFERENCES/CITATIONS

Code of Federal Regulations Title 42, Part 50, Subpart F (Promoting Objectivity in Research)

Code of Federal Regulations, Title 45, Part 94 (Responsible Prospective Subcontractors)

Date Approved: _____	Date Revised/Reviewed: _____
Approved By: _____	_____
Title: _____	_____
Signature: _____	_____

Attachment 1

**NSABP FOUNDATION, INC.
Pittsburgh, PA**

DECLARATION OF FINANCIAL INTERESTS

PART I

Statement of Outside Interests and Activities

Only those outside financial interests related to Foundation activities need to be reported. Not all outside interests and financial relationships place the individual in conflict with the person's obligations to the Foundation or his profession. Not all conflicting interests are necessarily impermissible. Timely and complete disclosure of potential conflicts of interest protects you from suspicion and accusations of breach of integrity.

NAME _____ Date _____

(Please type or print clearly)

OFFICE ADDRESS _____

PHONE _____

E-MAIL _____

Employee of the Foundation? YES NO

Purpose

The purpose of this disclosure statement is to provide a process for senior/key personnel and investigators to ensure that no unresolved conflict exists between their Foundation commitments and their outside interests and activities. This statement conforms to current federal guidelines requiring disclosure for professional activities of senior/key personnel and investigators. This statement establishes specific guidelines to assist the Foundation in determining whether a potential conflict exists so that the potential conflict may be managed, reduced, or eliminated.

Procedure

All senior/key personnel (those defined as senior/key personnel by the Foundation in its federal grant applications or reports) and investigators must complete this form annually, as well as within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest and submit it to their supervisor. All forms must be submitted within 30 days of receipt of the document. In addition, investigators must submit a current copy of this form whenever the investigator is asked to serve as chair of a new protocol.

1. Ownership Interests

In the most recent 12 months, did you or any member of your immediate family,¹ own or have an equity interest that exceeds \$5,000 in value in any organization that reasonably appears related to your Foundation responsibilities?

YES NO

2. Remunerative Activities

Please answer the following questions with respect to all financial interests that reasonably appear to be related to your Foundation responsibilities:

- a. Have you and/or the members of your immediate family received any sort of remuneration (cash or in kind) from a publicly traded entity that, in the aggregate and coupled with any equity interest you and your immediate family hold in that entity (valued as of today), exceeds \$5,000?
- b. Have you and/or the members of your immediate family received any sort of remuneration (cash or in kind) from a non-publicly traded entity that, in the aggregate, exceeds \$5,000?
- c. Have you or a member of your immediate family received income related to any intellectual property rights or interest (e.g., patents, copyrights) that are reasonably related to your Foundation responsibilities?

¹ Immediate family is defined as your spouse and dependent children.

d. During the most recent 12 months, with respect to you or any member of your immediate family, are there other situations, not listed above, that you believe may create an actual or perceived conflict of interest?

- | | | |
|-----|------------------------------|-----------------------------|
| (a) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (b) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (c) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (d) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

3. Travel

In the past 12 months, did you have travel that was both (1) paid for or sponsored by an outside entity and (2) related to your Foundation responsibilities (excepting that paid for by a government agency, institution of higher education or its affiliated research institute, academic teaching hospital, or medical center)? *For example, reportable travel would include the following: a pharmaceutical company for which the Foundation is conducting a clinical study (whether or not in conjunction with an NCI grant to the Foundation) pays for the Senior/Key Person to attend an advisory board meeting in California.*

YES NO

The above is an accurate and current statement of my reportable outside interests and activities. I certify that I have read and understand the NSABP Disclosure of Financial Interest Policy.

Signature

Date

NOTE: IF YOU ANSWERED "YES" TO ANY OF THE QUESTIONS IN PART I, PLEASE COMPLETE PART II, CONFIDENTIAL DISCLOSURE (attached)

NSABP FOUNDATION, INC.

DECLARATION OF FINANCIAL INTERESTS

PLEASE COMPLETE ONLY IF YOU ANSWERED "YES" TO QUESTIONS IN PART I

PART II

Detailed Statement of Outside Interests and Activities (when applicable)

NAME _____ DATE _____
(Please type or print clearly)

OFFICE ADDRESS _____

PHONE _____

E-MAIL _____

1. Ownership Interests

If, during the most recent 12 months, you or any member of your immediate family¹ owned an equity interest in an entity that reasonably appears to be related to your Foundation responsibilities, give details below.

Organization	Address	Nature of Business	Relationship of Family Member (or "self")	Current Value of Equity Interest

¹ Immediate family is defined as spouse and immediate children.

2. Remunerative Activities

Please give details if, during the most recent 12 months and with respect to all financial interests that reasonably appear to be related to your Foundation responsibilities:

- a. you and/or members of your immediate family have received any sort of remuneration (cash or in kind) from a publicly traded entity that, in the aggregate and coupled with any equity interest you and your immediate family hold in that entity (valued as of today), exceeds \$5,000; or
- b. the aggregated sum of any sort of remuneration (cash or in kind) received by you or a member of your immediate family from a non-publicly traded entity exceeds \$5,000; or
- c. any receipt of income related to any intellectual property rights or interest (e.g., patents, copyrights) held by you or your immediate family members that are reasonably related to your Foundation responsibilities.

Organization	Address	Nature of Business	Relationship of Family Member (or "self")	Value of Income or Equity Interest

3. Other Transactions

During the most recent 12 months, did you or any member of your immediate family have an interest in any contract, sale or other transaction to which the Foundation was a party, or are there other situations, not listed above, that you believe may create an actual or perceived conflict of interest? If so, describe:

4. Travel

If, in the past 12 months, you have had travel paid for or sponsored by an outside entity that was related to your Foundation responsibilities (excepting that paid for by a government agency, institution of higher education or its affiliated research institute, academic teaching hospital, or medical center), please give details. *For example, reportable travel would include the following: a pharmaceutical company for which the Foundation is conducting a clinical study (whether or not in conjunction with an NCI grant to the Foundation) pays for the Senior/Key Person to attend an advisory board meeting in California.*

Date(s) of Travel	Purpose of Travel	Travel Destination	Identity of Travel Sponsor or Organizer	Value of Sponsored Travel

The above is an accurate and current statement of all my reportable outside interest and activities.

SIGNATURE

DATE

Reviewer's Findings

- I have reviewed these responses and find no reason for further action.
- I have reviewed these responses and find it necessary to proceed further.

SIGNATURE OF OFFICIAL

DATE