

Policy and Procedures Manual

Conflict of Interest and Commitment

Policy Number: POL008.03
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1. Purpose

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 will be free from bias resulting from investigator or senior personnel financial conflicts of interest. Formulating policies and procedures to manage, reduce, or eliminate potential or real conflicts of interest (or conflicts of commitment) among NSABP management personnel, Senior Staff Members and other Significant Research Contributors (SRCs) as noted below in Scope, requires that the NSABP delineate the value structure to which the SRC must adhere.

2. Scope

This policy covers NSABP Significant Research Contributors (SRCs) which include:

- NSABP management (NSABP executives, directors, managers)
- Senior Staff Members (NSABP Operations physicians)
- NSABP Board of Directors
- NSABP Protocol Specific Steering Committees
- Key Personnel (investigators listed on cover page(s) of NSABP or NRG Pittsburgh protocols)
- NSABP Foundation Collaborating Scientific Investigators (CSI for NSABP Foundation Networks)
- Consultants involved in development and analysis of NSABP/NRG clinical trials and could potentially affect rights and welfare of research subjects.
- Key Employees as defined by IRS

3. Policy Statement

3.1. NSABP SRC's shall be familiar with this policy and shall follow these procedures. SRCs are expected to share a commitment to at least these values.

- a genuine commitment to research and to the institution
- academic freedom
- intellectual independence
- diversity
- open communication and dissemination of knowledge
- competence and integrity in research
- public service

3.2. The following examples illustrate potential or actual conflicts of interest:

- 3.2.1. Accepting gratuities or special favors related to research, or administrative duties.
- 3.2.2. Accepting payment that is above the accepted norm from companies or organizations whose economic or political interests are affected by an SRC's scholarly work.
- 3.2.3. Undertaking evaluative research when the SRC or the SRC's dependents have a financial, managerial or ownership interest in the sponsoring company or in the company producing the product being tested.
- 3.2.4. Entering into a paid consultants arrangement with an organization or individual having an economic interest in related research.
- 3.2.5. Using employees of the NSABP to perform services for a company in which a SRC has an ownership interest or from which he/she receives any type of remuneration.
- 3.2.6. Accepting support for research under terms and conditions that require results be held confidential, unpublished, or significantly delayed in publication.
- 3.2.7. Providing privileged access to information developed with NSABP resources or supported by independent sponsors, to an entity in which the SRC has a political or financial interest.
- 3.2.8. Purchasing equipment, instruments, or supplies for research from a firm in which the SRC has a financial or other interest.
- 3.2.9. Influencing the negotiation of contracts between the NSABP and outside organizations with which a SRC has a financial interest or other relationship.

4. **Definitions**

- 4.1. A **potential conflict of interest** exists whenever personal, professional, commercial, or financial interests or activities outside of NSABP have the possibility (either in actuality or in appearance) of (1) compromising a SRC's judgment; (2) biasing the nature or direction of scholarly research; (3) influencing a SRC's decision or behavior with respect to uses of NSABP resources; or (4) resulting in a personal or family member's gain or advancement at the expense of the NSABP. For purposes of this policy, family members include spouse, registered domestic partners, dependents and all members of household.

- 4.2. A **potential conflict of commitment** exists when a SRC's external relationships or activities have the possibility (either in actuality or in appearance) of interfering or competing with the NSABP's educational, research, or service mission, or with that individual's ability or willingness to perform the full range of responsibilities associated with his or her position.
- 4.3. **Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.
- 4.4. **Immediate Family** means an individual's spouse, dependents, and all members of the SRC's household, including registered domestic partners.
- 4.5. **Institutional Responsibilities** refer to an SRC's professional responsibilities on behalf of the NSABP, including activities such as research, institutional committee memberships, service on panels such as Institutional Review Boards, Data & Safety Monitoring Boards, and other administrative activities.
- 4.6. **NSABP Significant Research Contributor (SRC)** for the purpose of this policy means an individual involved in the development of a research proposal or the oversight of a clinical protocol; development or oversight of the statistical plan or interpretation of data resulting from a research project; the project director or principal Investigator of a research project; and any other person identified regardless of title or position as senior personnel by the NSABP in the clinical trial protocol, grant application, progress report, or any report submitted to the sponsor by the NSABP.
- 4.7. **Significant Financial Interest (SFI) means:**
- (1) a financial interest consisting of one or more of the following interests of the SRC (and those of the SRC'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 previous 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 (lesser amounts must still be reported to NSABP). This includes salary and any payment for services not otherwise identified as salary (such as consulting fees, honoraria, and paid authorship), as well as any kind of equity interest such as stock, a stock option, or other ownership interest.
 - Any remuneration received from a non-publicly traded entity in the previous 12 months, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to NSABP)
 - Any equity interest in a non-publicly traded entity, regardless of value.
 - Any income received from intellectual property rights and interests (patents, copyrights, and royalties from such rights) not held by the NSABP
 - (2) Certain reimbursed or sponsored travel paid to or on behalf of the SRC, except that paid for by a federal, state, or local government agency, a domestic non-profit institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education may constitute a Significant Financial Interest.

(3) The term SFI does not include:

- (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.

5. Procedures

5.1. **Notification of SRC** - NSABP shall notify affected SRCs of this policy, their responsibility to disclose Significant Financial Interests, and applicable federal regulatory requirements.

5.2. COI Training

5.2.1. The SRC will complete COI training prior to engaging in research related to any pre-clinical research study, clinical trial, research grant, cooperative agreement or contract according to NSABP requirements. SRCs may have training as required by SRC's institution. NSABP training is completed by reading and understanding the NSABP policy. Documentation of training (included in Part I) should be forwarded to NSABP upon request or at least every four years.

5.3. Disclosure & Review Process

5.3.1. On an annual basis, all SRCs must complete the Statement of Outside Interests and Activities (Part I of Disclosure Form, and Part II if applicable only if SRC answered "yes" to questions in Part I) and submit it to the Director of Quality Assurance or designee within one month of receiving the documents. During the 12 months following the submission of the annual Statement of Outside Interests and Activities Disclosure Form, if a new SFI arises, the Disclosure Form shall be updated promptly within 30 days. Should there be concerns related to the information, the individual filing the form will be contacted directly by a representative of the NSABP. Disclosures will be reviewed and evaluated by NSABP Quality Assurance Director with input from Chief Executive Officer of NSABP, in accordance with this policy. The CEO will notify the SRC of the appropriate course of action to manage, reduce, or eliminate the apparent, potential, or real conflict.

- 5.3.2. Examples of appropriate actions to resolve COIs include:
- a. public disclosure of SFIs in abstracts, publications, presentations, press releases, and applications or proposals for research funding;
 - b. monitoring of research by independent reviewers or an oversight committee;
 - c. disqualification from participation in all or a portion of the funded research;
 - d. divestiture of SFIs;
 - e. severance of relationships that create actual or potential conflicts;
 - f. refusal by the NSABP to enter into a research agreement if a COI cannot be managed effectively;
 - g. participation of one or more non-conflicted persons in the evaluation of future research data and/or preparation of manuscripts;
 - h. participation in a research ethics course, seminar, or workshop.
- 5.3.3. Within 60 days of disclosure, action to manage, reduce, or eliminate the apparent, potential, or real conflict will occur. If the SRC subject to this policy has not met with the Chief Executive Officer of NSABP and wishes to do so, an appointment for a meeting or phone conversation will be scheduled.
- 5.3.4. If the individual SRC fails to implement the resulting recommendation he/she will be subject to sanctions. An official of the NSABP, who is acting as reviewer, may require disclosure by the individual SRC of all outside income related to professional responsibilities, regardless of any threshold amount specified in the Statement of Outside Interests and Activities.
- 5.3.5. In the event of unresolved COI disclosures, an Ethics Advisory Panel composed of a minimum of three uninvolved parties will be convened. Within 60 days following the review by the CEO, the results of the Committee's deliberations will be provided to the CEO and the Chairman of the Board of Directors for NSABP Foundation. The parties will:
- a. keep confidential all COI disclosures submitted to them by SRCs, except to provide institutional or internal oversight as authorized by this COI policy, and to comply with requests from federal funding agencies as required under terms of a grant, contract, or cooperative agreement;
 - b. promptly review the COI disclosures for existing or potential conflicts of interest, and request and document additional details, including precise dollar figures or percentages for ownership interests or remuneration, if such details appear necessary to determine whether there is an impermissible conflict of interest;

5.3.6. If the individual is dissatisfied with the determination of the Ethics Advisory Panel, he/she may request that the Panel present the matter to the Vice Chairman of the Board of Directors for review, consideration, and recommendation for resolution.

5.4. **Reporting of Financial Conflicts of Interest** - NSABP shall send initial, annual, and revised FCOI reports to the NIH as required.

5.5. **Participating Sites** - NSABP carries out clinical trial research through participating sites and will take reasonable steps to ensure that participating site SRCs comply with this policy and applicable federal requirements by written agreements with participating sites. In writing, NSABP shall establish terms with each participating site to follow this policy including the participating site's SRCs.

5.6. **Public Accessibility** - This policy shall be publicly available on NSABP's website.

5.7. **Maintenance of Records** - NSABP will maintain all records relating to this policy.

5.8. **Ethics Advisory Panel** - The NSABP has demonstrated its commitment to proper internal monitoring and management of conflicts of interest by establishing an Ethics Advisory Panel. The Ethics Advisory Panel is responsible for the oversight and management of potential conflicts of interest or commitment on the part of the NSABP's employees and the institution itself related to this policy.

The Chair of the Ethics Advisory Panel shall be the Vice Chairman of the NSABP Board of Directors. Ethics Advisory Panel members shall consist of the following NSABP officials:

- Vice Chairman, NSABP Board of Directors
- Chief Executive Officer, NSABP
- Director, Quality Assurance, NSABP

The Chair of the Ethics Advisory Panel may add two (2) additional members to a specific meeting as needed. The Ethics Advisory Panel reports through its Chair to the NSABP Chairman.

5.9. **Annual Summary Reports** - At the first quarter of each calendar year, the Director, Quality Assurance will prepare an annual report which will include the following:

- The number of SRCs and others subject to this policy who completed a Statement of Outside Interests and Activities Form (Part I).
- The number of SRCs and others subject to this policy who submitted detailed Statements of Outside Interests and Activities (Part II) of Disclosure Form.
- The number of individuals whose outside interests and activities were found to be in conflict with their professional or NSABP commitments, and whose conflicts were managed, reduced, or eliminated;

- The number of individuals whose conflict of interest was not managed, reduced, or eliminated; and
- Details regarding remedial action recommended and taken. All data must be anonymous.

The CEO will receive the annual report to which he/she may add comments before informing the Chair of the NSABP of any issues associated with the report.

6. Applicable Legislation and Regulations

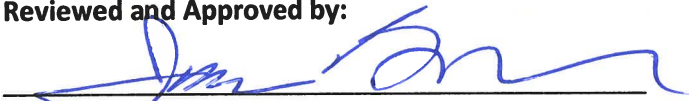
- 6.1. Department of Health and Human Services (HHS), 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors
- 6.2. HHS, 42 CFR Part 50, Subpart F, Promoting Objectivity in Research
- 6.3. NIH Grants Policy Statement 4.1.10 Financial Conflicts of Interest rev. April 2021
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm
- 6.4. IRS Form 990
- 6.5. Bylaws of the NSABP Foundation, Inc. Article 12 Conflicts of Interest

7. Related references, forms, policies

- 7.1. Part I, Declaration of Potential Conflict of Interest or Commitment Part I Statement of Outside Interests and Activities Form (and read and understand NSABP policy attestation)
- 7.2. Part II, Declaration of Conflict of Interest and Commitment Part II Statement of Outside Interests and Activities Form

Signature Page

Reviewed and Approved by:


 Jack Berkebile, Chief Executive Officer

13 Sept 2021
 Date

Effective Date 9/27/2021

Policy Version History:

Policy Version History			
Policy Version #	Author	Version Date	Policy Revisions
POL008.01	Joan Beyer Goldberg	7/1/2014	New Policy
POL008.02	Joan Beyer Goldberg	9/4/2018	New format; added scope, reorganized & clarified procedures; added references; add policy version history and effective date; added training step
POL008.02	Jack Berkebile	9/4/2018	Policy reviewed on 7/8/2020 and no changes needed.
POL008.03	Stephen Pickios	9/10/2021	Added to Scope, the Consultant COI Policy POL009 is to be retired and consultants COI disclosures will be collected under this policy POL008.