

BI/COI FORM 1

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

BACKGROUND INFORMATION
AND
CONFIDENTIAL CONFLICT OF INTEREST DISCLOSURE
For Studies Related to Government Regulation

NAME: _____

TELEPHONE: _____

ADDRESS: _____

EMAIL ADDRESS: _____

CURRENT EMPLOYER: _____

COMMITTEE: _____

There are two parts to this form, Part I Background Information, and Part II Confidential Conflict of Interest Disclosure. Complete both parts, **sign** and **date** this form on the last page, and return the form to the responsible staff officer for the project and committee activity to which this form applies. **Retain a copy for your records.**

PART I BACKGROUND INFORMATION

INSTRUCTIONS

Please provide the information requested below regarding **relevant** organizational affiliations, government service, public statements and positions, research support, and additional information (if any). Information is "relevant" if it is related to -- and might reasonably be of interest to others concerning -- your knowledge, experience, and personal perspectives regarding the subject matter and issues to be addressed by the committee activity for which this form is being prepared. If some or all of the requested information is contained in your curriculum vitae, you may if you prefer simply attach your CV to this form, supplemented by additional responses or comments below as necessary.

I. ORGANIZATIONAL AFFILIATIONS. Report your relevant business relationships (as an employee, owner, officer, director, consultant, etc.) and your relevant remunerated or volunteer non-business relationships (e.g., professional organizations, trade associations, public interest or civic groups, etc.).

II. GOVERNMENT SERVICE. Report your relevant service (full-time or part-time) with federal, state, or local government in the United States (including elected or appointed positions, employment, advisory board memberships, military service, etc.).

III. RESEARCH SUPPORT. Report relevant information regarding both public and private sources of research support (other than your present employer), including sources of funding, equipment, facilities, etc.

IV. PUBLIC STATEMENTS AND POSITIONS. List your relevant articles, testimony, speeches, etc., by date, title, and publication (if any) in which they appeared, or provide relevant representative examples if numerous. Provide a brief description of relevant positions of any organizations or groups with which you are closely identified or associated.

V. ADDITIONAL INFORMATION. If there are relevant aspects of your background or present circumstances not addressed above that might reasonably be construed by others as affecting your judgment in matters within the assigned task of the committee or panel on which you have been invited to serve, and therefore might constitute an actual or potential source of bias, please describe them briefly.

PART II CONFIDENTIAL CONFLICT OF INTEREST DISCLOSURE

INSTRUCTIONS

It is essential that the work of committees of the institution used in the development of reports not be compromised by any significant conflict of interest. For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.** Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed.

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the committee.

Conflict of interest requirements are *objective* and *prophylactic*. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of conflicting interests.

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is not a current interest.

The term "conflict of interest" applies not only to the personal interests of the individual but also to the *interests of others* with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a

fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

This disclosure form is used for any committee that will be used by the institution in the development of one or more reports to be provided by the institution to a sponsoring agency for use in a government regulatory process. For such projects, *the focus of the conflict of interest inquiry is on the identification and assessment of any interests that may be directly affected by the use of such reports in the regulatory process.*

For example, if this institution were conducting a study of proposed modifications in the government regulation of a particular application of biotechnology, the focus of the conflict of interest inquiry would be on the identification and assessment of any interests that would be directly affected by that regulatory process if the institution's report were to provide the basis for regulatory action or inaction. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has specific interests that could be directly affected by the regulatory process, the individual's objectivity could be impaired.

Such interests could include an individual's stock holdings in excess of \$10,000 in a potentially affected biotechnology company or being an officer, director, or employee of the company. Serving as a consultant to the company could constitute such an interest if the consulting relationship with the company could be directly affected or is directly related to the subject matter of the regulatory process.

An individual's other possible interests might include, for example, relevant patents and other forms of intellectual property, serving as an expert witness in litigation directly related to the subject matter of the regulatory process, or receiving research funding from a party that would be directly affected by the regulatory process if the research funding could be directly affected or is directly related to the subject matter of the regulatory process and the right to independently conduct and publish the results of this research is limited by the sponsor. Consideration would also need to be given to the interests of others with whom the individual has substantial common financial interests -- particularly spouses, employers, clients, and business or research partners.

The following questions are designed to elicit information from you concerning possible conflicts of interest that are relevant to the functions to be performed by the particular committee on which you have been invited to serve.

1. EMPLOYMENT. (a) If the reports resulting from this committee activity were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(i) If you are employed or self-employed, could your current employment or self-employment (or your spouse's current employment or self-employment) be directly affected?

(ii) To the best of your knowledge, could any financial interests of your (or your spouse's) employer or, if self-employed, your (or your spouse's) clients and/or business partners be directly affected?

(iii) If you are an officer, director or trustee of any corporation or other legal entity, could the financial interests of that corporation or legal entity be directly affected?

(iv) If you are a consultant (whether full-time or part-time), could there be a direct effect on any of your current consulting relationships?

(v) Regardless of the potential effect on the consulting relationship, do you have any current or continuing consulting relationships (including, for example, commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, serving as an expert witness in litigation, or providing services in exchange for honorariums and travel expense reimbursements) that are directly related to the subject matter of the possible government regulatory action or inaction?

(b) If you are or have ever been a U.S. Government employee (either civilian or military), to the best of your knowledge are there any federal conflict of interest restrictions that may be applicable to your service in connection with this committee activity?

(c) If you are a U.S. Government employee, are you currently employed by a federal agency that is sponsoring this project? If you are not a U.S. Government employee, are you an employee of any other sponsor (e.g., a private foundation) of this project?

If the answer to all of the above questions under EMPLOYMENT is either "no" or "not applicable," check here _____ (NO).

If the answer to any of the above questions under EMPLOYMENT is "yes," check here ____ (YES), and briefly describe the circumstances on the last page of this form.

2. INVESTMENT INTERESTS. Taking into account stocks, bonds, and other financial instruments and investments including partnerships (but excluding broadly diversified mutual funds and any investment or financial interest valued at less than \$10,000), if the reports resulting from this committee activity were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(a) Do you or your spouse or minor children own directly or indirectly (e.g., through a trust or an individual account in a pension or profit-sharing plan) any stocks, bonds or other financial instruments or investments that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

(b) Do you have any other significant financial investments or interests such as commercial business interests (e.g., sole proprietorships), investment interests (e.g., stock options), or personal investment relationships (e.g., involving parents or grandchildren) that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

If the answer to all of the above questions under INVESTMENT INTERESTS is either "no" or "not applicable," check here ____ (NO).

If the answer to any of the above questions under INVESTMENT INTERESTS is "yes," check here ____ (YES), and briefly describe the circumstances on the last page of this form.

3. PROPERTY INTERESTS. Taking into account real estate and other tangible property interests, as well as intellectual property (patents, copyrights, etc.) interests, if the reports resulting from this committee activity were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(a) Do you or your spouse or minor children own directly or indirectly any such property interests that could be directly affected?

(b) To the best of your knowledge, do any others with whom you have substantial common financial interests (e.g., employer, business partners, etc.) own directly or indirectly any such property interests that could be directly affected?

If the answer to all of the above questions under PROPERTY INTERESTS is either "no" or "not applicable," check here ____ (NO).

If the answer to any of the above questions under PROPERTY INTERESTS is "yes," check here ____ (YES), and briefly describe the circumstances on the last page of this form.

4. RESEARCH FUNDING AND OTHER INTERESTS. (a) Taking into account your research funding and other research support (e.g., equipment, facilities, industry partnerships, research assistants and other research personnel, etc.), if the reports resulting from this committee activity were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(i) Could the research funding and support for you or your close research colleagues and collaborators be directly affected, or

(ii) If you have any research agreements for current or continuing research funding or support from any party whose financial interests could be directly affected, and such funding or support is directly related to the subject matter of the regulatory process, do such agreements significantly limit your ability to independently conduct and publish the results of your research (other than for reasonable delays in publication in order to file patent applications)?

(b) Is the central purpose of the project for which this disclosure form is being prepared a critical review and evaluation of your own work or that of your employer?

(c) Do you have any existing professional obligations (e.g., as an officer of a scientific or engineering society) that effectively require you to publicly defend a previously established position on an issue that is relevant to the functions to be performed in this committee activity?

(d) To the best of your knowledge, will your participation in this committee activity enable you to obtain access to a competitor's or potential competitor's confidential proprietary information?

(e) Could your service on the committee on which you have been invited to serve create a specific financial or commercial competitive advantage for you or others with whom you have substantial common financial interests?

(f) If the committee activity for which this form is being prepared involves reviews of specific applications and proposals for contract, grant, fellowship, etc. awards to be made by sponsors, do you or others with whom you have substantial common financial interests, or a familial or substantial professional relationship, have an interest in receiving or being considered for awards that are currently the subject of the review being conducted by this committee?

(g) If the committee activity for which this form is being prepared involves developing requests for proposals, work statements, and/or specifications, etc., are you interested in seeking an award under the program for which the committee on which you have been invited to serve is developing the request for proposals, work statement, and/or specifications -- or, are you employed in any capacity by, or do you have a financial interest in or other economic relationship with, any person or organization that to the best of your knowledge is interested in seeking an award under this program?

If the answer to all of the above questions under **RESEARCH FUNDING OR OTHER INTERESTS** is either "no" or "not applicable," check here ____ (NO).

If the answer to any of the above questions under **RESEARCH FUNDING OR OTHER INTERESTS** is "yes," check here ____ (YES), and briefly describe the circumstances below.

EXPLANATION OF "YES" RESPONSES:

During your period of service in connection with the activity for which this form is being completed, any changes in the information reported, or any new information, which needs to be reported, should be reported promptly by written or electronic communication to the responsible staff officer.

YOUR SIGNATURE

DATE

Reviewed by: _____
Executive Director

Date