

NATIONAL BUREAU OF ECONOMIC RESEARCH

Research Financial Conflict of Interest Policy

Background

A conflict of interest occurs when an individual's private interests, and his or her professional obligations, diverge in ways that might lead an independent observer to reasonably question whether the individuals' professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not the character or actions of the individual. A primary category of concern is Financial Conflicts of Interest (FCOIs). There are multiple regulations and policies promulgated by government agencies and by other institutions that require the disclosure and management of potential FCOIs that may affect NBER investigators. To maintain confidence in the integrity and impartiality of NBER research, every effort is made to ensure that such potential conflicts are fully disclosed and that they are handled appropriately. This policy, which is closely based on federal regulations and is designed to comply with them, addresses such conflicts.

Coverage of this Policy

This policy applies to all investigators undertaking externally sponsored research at the NBER. "Investigator" for the purposes of this policy, means the Principal Investigator and anyone, regardless of title or position, identified by the Principal Investigator as responsible for the design, conduct, or reporting of research carried out under a sponsored project. These individuals would typically be listed as key personnel at the time of proposal submission. In addition, post-doctoral associates or fellows, graduate students, consultants, and subcontractors should be considered as covered by this policy to the extent they are responsible for the design, conduct, or reporting of the research associated with a sponsored project.

Training

The NBER has established processes to inform each investigator of the NBER's policy and disclosure requirements, as well as applicable federal regulations. During proposal preparation, NBER grant or program administrators will obtain the list of project investigators from the Principal Investigator. The grant or program administrators will disseminate this policy and inform the investigators of their disclosure responsibilities.

Investigators on Public Health Service (PHS) funded projects will additionally be required to complete the NIH Conflict of Interest Training Course, available at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. A disclosure certification and proof of completion of the training course, if required, will be collected at the time of proposal submission. The NBER does not accept completion of other training courses in lieu of completion of the NIH course.

The NBER maintains a database of investigators and tracks completion dates for their FCOI training. Each investigator must complete such training once every four years, and must repeat the training if he or she is not in compliance with the NBER's Research FCOI Policy or with a management plan. The NBER will require all investigators to complete additional training if it revises its FCOI policy in a way that alters the requirements placed on investigators.

Disclosure, Review and Monitoring Requirements

In accordance with federal regulations, the NBER requires that each investigator disclose to the NBER significant financial interests (SFIs) held by the investigator, the investigator's spouse, and the investigator's dependent children, when these interests reasonably appear to be related to the investigator's "institutional responsibilities" at NBER, no later than (i) at the time of application for a sponsored project; (ii) annually during the period of an award; and (iii) within thirty days of discovering or acquiring a new significant financial interest.

An investigator's institutional responsibilities are professional responsibilities on behalf of the NBER and may include research related to a sponsored project, an NBER conference, or pertaining to a data use agreement held by the NBER. They may also include participation in the work of NBER committees, service on panels such as the Institutional Review Board, or service as a Program or Working Group Director. An FCOI is a significant financial interest related to an investigator's institutional responsibilities that could directly and significantly affect the design, conduct or reporting of research.

"Significant Financial Interests" (SFIs) exist in the following situations:

- (i) For any publicly traded company, an SFI exists if the value of any remuneration received from the company in the twelve months preceding the disclosure and the value of any equity interest in the company as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interests, valued through reference to public prices or other reasonable measures of fair market value;
- (ii) For any non-publicly traded entity, an SFI exists if the total value of any remuneration received in the twelve months preceding the disclosure exceeds \$5,000, or when the investigator, the investigator's spouse, or the investigator's dependent children, hold any equity interest (e.g., stock, stock options, or another ownership interest);
- (iii) **For investigators whose research is funded by grants from the NIH or other agencies under the auspices of the Public Health Service, the calculation of total remuneration from both public and private entities must include the value of reimbursed or sponsored travel, i.e. travel that is paid for on behalf of the investigator and not reimbursed in a way that makes its exact monetary value readily available.** Reimbursed or sponsored travel from a federal, state, or local government agency, a college or university in the United States, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education in the United States is exempt from the regulation. When reporting travel, the investigator's disclosure must include, at a minimum, the purpose, destination, and duration of the trip, and the identity of the sponsor/organizer. The NBER follows NIH NOT-OD-12-004 in using a de minimus threshold of \$5,000 for the aggregated value per entity of remuneration, including sponsored or reimbursed travel.

- (iv) For intellectual property rights and interests (e.g., patents, copyrights), an SFI exists if these interests have generated income exceeding \$5,000 in the twelve month period preceding the date of disclosure;

Significant financial interests do not include any of the following:

- (i) Payments, salary, honoraria, reimbursements or sponsored travel, from the NBER. Such payments do not need to be reported to the NBER when filing financial disclosure forms with the NBER, but they are potentially reportable when filing such disclosure forms with other institutions, such as universities.
- (ii) Income from seminars, lectures, teaching engagements, services on advisory committees, or services on review panels sponsored by a federal, state, or local government agency, a domestic college or university, an academic teaching hospital, a medical center, or a research institute that is affiliated with a college or university.
- (iii) Income from diversified investment vehicles, such as mutual funds and other financial products managed by third parties, in which the investigator does not directly control the investment decisions.

Prior to August 2012, investigators were not required to report income from any nonprofit organizations as SFIs. **This is no longer the case.** After that date, any income from a non-profit organization other than a college or university in the United States, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. college or university is considered a significant financial interest and subject to disclosure.

The regulations for financial disclosure differ across federal funding agencies, and in particular researchers who are not funded by grants that are subject to the Public Health Service guidelines, in particular NSF grants, are only required to disclose SFIs that relate to their grant-sponsored research, while PHS-funded researchers must disclose all SFIs regardless of their connection to sponsored research. With prior approval from the Director of Research and Grants Management, investigators who are not carrying out research covered by the PHS rules may disclose only those SFIs that are reasonably related to their sponsored research.

Examples of circumstances in which a sponsored project could reasonably appear to be affected by an investigator's SFI might include the following:

1. The investigator (or the investigator's spouse or dependent child) receives compensation from or has equity in an entity and
 - a. The research is receiving either "in kind" or monetary support from that entity;
 - b. Proprietary access to data or rights to intellectual property coming out of the research is/are owned by that entity (e.g., pre-publication access to results of the research);
 - c. Research aims overlap with the aims of that entity;
 - d. Research uses or involves intellectual property owned by or licensed to that entity;
 - e. Research results could enhance the value of or increase the interest in intellectual property or other assets owned, made or provided by that entity; and/or

- f. New intellectual property could result from research under this grant and potentially be of interest to that entity.

Research uses or involves intellectual property owned or licensed to the investigator or for which the investigator receives royalties, or has the right to receive royalties.

The NBER will utilize a two-stage disclosure process. All investigators will be asked to disclose their SFIs by entity, to indicate the type(s) of relationships the investigator has with the entity (i.e., stock and equity, consulting, etc.) and whether the sum total of their SFIs in the entity is valued above or below \$5,000.

Review

Any disclosed significant financial interests under this policy will be reviewed by the Director of Research and Grants Management (DRGM) and the NBER President prior to the NBER's expenditure of funds. If upon initial review, the DRGM and the President determine a disclosure requires further examination, the investigator will be asked to provide additional details about the relationship(s) with the entity and to disclose the actual value of the SFI. At the President's discretion, he may call upon the Program Director of the investigator's program, or any other NBER Program Director, for assistance in determining whether the significant financial interest is related to the investigator's institutional responsibilities and, if so, whether a potential or actual financial conflict of interest exists. Should management of a potential or actual financial conflict of interest be required, the investigator, Principal Investigator, and Program Director along with the DRGM will develop and implement a management plan. Final management plans are approved by the President. Management plans may include some or all of the following elements:

- Public disclosure of the significant financial interest.
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
- Appointment of an independent reviewer, or team of reviewers, to closely monitor the specific research. The researcher could be required to file periodic reports with the President, which will be reviewed to ensure that potential conflicts are not affecting research. Publications that result from the research will also be carefully reviewed to guard against conflicts. If any arise during the course of the research, the President and Program Director will determine the appropriate course of action at that time. Courses of action could include increasing oversight of the research, requiring more frequent reports, or in extreme cases removing the investigator from work on the project.
- The President and Program Director may suggest modifications of the research plan. Necessary modifications will be acknowledged in writing by the investigator. Depending on the extent of the modifications, the President may require frequent reporting to ensure that conflicts are not occurring.
- Disqualification of the research project from the portion of sponsored research that would be affected by the significant financial interests. For new projects in the proposal stage, the funding agency would be alerted before an award was made. If research under an active NSF or PHS grant is disqualified, the Office of the General Counsel or other appropriate authority will be notified immediately.

- A recommendation that the researcher either divest the significant financial interests or sever the relationships that create conflicts.

The key elements of a management plan include:

- The role and principal duties of the conflicted investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance;
- The designation of a compliance monitor; and
- Other information as needed.

The monitor could be the Principal Investigator, Program Director, co-author, independent reviewer or the DRGM. Investigator compliance with the plan will be monitored until completion of the project.

If the NBER identifies a significant financial interest that was not previously reviewed by the NBER or that was not disclosed in a timely manner, any required management plan will be implemented within sixty days.

The NBER recognizes that its investigators participate in a broad range of professional activities that generate income and financial relationships. While the income or ownership value associated with certain activities must be reported to comply with the regulatory requirements, the NBER does not generally regard income from serving as an editor of a journal, royalties from a textbook, or travel reimbursements associated with travel to participate in annual meetings of professional societies, whether in the U.S. or abroad, as creating financial conflicts of interest.

Retrospective Reviews

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the investigator to disclose a significant financial interest that is determined by the NBER to constitute a FCOI;
- Failure by the NBER to review or manage such a FCOI; or
- Failure by the investigator to comply with a FCOI management plan;

the NBER shall, within 120 days of the NBER's determination of noncompliance, complete a "retrospective review" of the investigator's activities and the research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

The NBER shall document the retrospective review which must include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;

- Name of the investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings and conclusions of the review.

If bias is found, the NBER will notify the funding agency promptly. If the funding agency is subject to the PHS requirements, the NBER will submit a mitigation report. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the NBER's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the NBER will submit FCOI reports annually as prescribed by the regulation.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project or clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an investigator with an FCOI that was not managed or reported by the NBER as required by the regulation, the NBER shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Reporting Requirements

The DRGM will report on all financial conflicts of interest to the appropriate funding agencies according to their regulations.

For PHS-funded research, the DRGM will send initial, annual and revised FCOI reports including the required reporting elements, to the PHS component funding the sponsored project through the electronic Research Administration (eRA) Commons FCOI Module. The required reporting elements will include the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the investigator with the Financial Conflict of Interest;
- Name of the entity with which the investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (in dollar ranges: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, to a maximum category of "\$600,000 and above"), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and why the NBER determined that the financial interest conflicts with such research;
- A description of the key elements of the NBER's management plan, including:
 - Role and principal duties of the conflicted investigator in the research project;
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project;

- Confirmation of the investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Updated or annual FCOI reports will include the status of the management plan, including whether the financial conflict is still being managed or explaining why the financial conflict no longer exists, and a description of any changes to the management plan since the last FCOI report was submitted to the PHS component funding the research. FCOI reports will be submitted prior of the expenditure of funds for new awards, within sixty days of identification for an investigator who is newly participating in the project, or for new, or newly identified, FCOIs for existing investigators, and at least annually to provide the status of the FCOI and changes to the management plan, if applicable, until the completion of the project, and following a retrospective review to update a previously submitted report, if appropriate.

Maintenance of Records

All disclosure certifications and FCOI-related records will be kept on file for at least three years from the date the final expenditures report is submitted to the funding agency.

Enforcement Mechanisms

The NBER has established this Research Financial Conflict of Interest Policy to ensure compliance with regulations established by federal funding agencies. Non-compliance jeopardizes an Investigator's reputation, the ability of Investigators to participate in federally funded research and perhaps even the NBER's ability to participate in federally funded research. Investigators are required to promptly return any requested disclosure forms and to cooperate fully in any review proceedings or development of a management plan.

Investigators are expected to complete disclosure certification forms prior to the expenditure of award funds. The NBER may suspend all grant activity until the disclosure certification is complete.

Investigators are expected to complete disclosure certification forms once annually while they have active grants. Failure to return an annual disclosure certification could result in suspension of all grant activity and/or suspension of other NBER activity.

Intentional non-compliance with disclosure requirements or management plans will not be tolerated. Sanctions could include disclosing any identified FCOI in each public presentation of the results of the research and requesting an addendum to previously published presentations, removal of the Investigator from a sponsored project, disposition of a sponsored project, precluding the Investigator from involvement in future NBER sponsored projects, or termination of any relationship between the investigator and the NBER.

Subrecipient Requirements

The NBER may choose to allow subrecipient to follow their own FCOI policy if it is determined that the subrecipient's FCOI policy complies with the funding agencies regulations. This will be determined either by obtaining a certificate from the subrecipient that its FCOI policy complies with the regulation or by utilizing the Federal Demonstration Partnership Clearinghouse for NIH FCOI Compliant

Institutions. The NBER will establish as part of their subaward agreement whether the subrecipient will follow the FCOI policy of the NBER or its own compliant policy.

If the subrecipient will follow its own FCOI policy, the subaward agreement will include a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the NBER to report identified FCOIs as required by the regulations. The subrecipient report will include all the required reporting elements noted above. The subrecipient will be required to make identified FCOIs of senior/key personnel on PHS funded sponsored projects publicly accessible as required by the PHS regulations.

If the subrecipient will follow the NBER's policy, the subaward agreement will include a requirement to allow the NBER to solicit and review subrecipient Investigator disclosures that enable the NBER to identify, manage and report identified FCOIs to the funding agency.

Public Accessibility

This policy will be posted on the NBER's public web site at <http://www.nber.org/researchCOI.html>. The NBER will also make information concerning identified FCOIs of investigators on PHS-sponsored projects publicly accessible prior to the expenditure of funds. The information will be provided within five business days of the receipt of a written request. All requests must be submitted via email to fcoi-inquiry@nber.org and must contain the following information:

- First and last name of the requestor
- Postal mailing address of the requestor
- Investigator's first and last name and/or PHS award number

In addition, it would be very helpful if requests would indicate:

- Intended use of the information
- Affiliation of the requestor:
 - Member of the public
 - Media – organization name
 - Blogger/Social media commentator
 - Other

Each request should list either one investigator's name or one PHS award number. If an investigator's name is listed, information about all PHS-reported FCOI information for that investigator will be provided. If a PHS award number is listed, information about all PHS-reported FCOIs associated with that award will be provided. Multiple requests in one email and emails that do not include all of the required information will not be answered.

In response to written requests, the NBER will provide by postal mail the following information:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the significant financial interest is held;
- Nature of the significant financial interest; and

- Approximate dollar value of the significant financial interest (in dollar ranges: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, up to a maximum of "\$600,000 and above") or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The NBER will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates. Information on identified FCOIs of senior/key personnel will remain available for three years after the most recent update.

Questions regarding this policy should be directed to Alterra Milone, Director of Research and Grants Management at (617) 588-0306, or alterra@nber.org.

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