

## INTERNATIONAL BROTHERHOOD OF TEAMSTERS

### Policy on Financial Conflicts of Interest for Principal Investigators

#### I. Definitions

- a. **Principal Investigator (PI)** - The person who is responsible for the development, administration, and reporting of training grants/research funded by the Public Health Service (PHS).
- b. **Compliance Officer** – Refers to the Director of the IBT Internal Audits Department
- c. **Federally-Funded Grants/Research** – Any training grant or research funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- d. **Financial Conflict of Interest (FCOI)** - A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial conflict could directly and significantly affect the design, conduct, or reporting of the PHS -funded research.
- e. **Manage** – Actions implemented to address, reduce, or eliminate a Financial Conflict of Interest to enable the IBT to ensure that Principal Investigators covered by this policy will be free from bias.
- f. **Financial Conflict of Interest Regulation** - 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (training grants).
- g. **Report** - refers to the IBT's report of identified Financial Conflicts of Interest to the applicable funding agency affected by the FCOI. For example, in the case of NIH funding, a report about the identified FCOI will be entered into the eRA Commons FCOI Module.
- h. **Senior/Key Personnel** – Refers to the Principal Investigator and any other person(s) identified as senior/key personnel by the IBT in the sponsored training grant application, progress report, or any other report submitted to the funding agency.
- i. **Significant Financial Interest** - means a financial interest of the Investigator and the Investigator's spouse or domestic partner and dependent children, alone or in combination, which reasonably appears to be related to the Investigator's institutional responsibilities for the IBT.

## **II. Purpose**

The International Brotherhood of Teamsters (IBT) Conflict of Interest Policy for Principal Investigators was developed to comply with applicable 2011 federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants). This policy is designed to establish a written, current administrative procedure to identify and manage Financial Conflict of Interest (FCOI) and is also consistent with and subject to the IBT Code of Conduct. The policy also provides a procedure to:

- Promote and enforce Principal Investigator compliance with applicable regulations
- Manage FCOI and provide initial and ongoing FCOI reports
- Provide FCOI and other relevant information available to the Department of Health and Human Services (HHS) promptly, upon request
- Ensure full compliance with applicable regulatory requirements.

## **III. Who Must Comply with the Principal Investigator FCOI Policy?**

This Policy applies to all IBT Principal Investigators, regardless of title or position, who are responsible for the development, administration, and reporting of training grants/research funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

## **IV. Training Requirements For Principal Investigators**

All Principal Investigators must complete IBT FCOI training that details relevant definitions, Investigator responsibilities regarding disclosure of significant financial interests, and applicable regulations. Newly hired PIs shall complete this training prior to participating in any Public Health Service (PHS)/National Institutes of Health (NIH)-funded grants or research projects. In addition, all PIs must receive training:

- Bi-annually
- If the IBT revises its FCOI policies or procedures in any manner that affects the requirements of Investigators
- If the IBT determines that an Investigator is not in compliance with the IBT's FCOI policy or management plan.

All IBT Principal Investigators are responsible for familiarizing themselves with all applicable regulations to ensure that they comply with the federal disclosure requirements therein and the associated Financial Conflict of Interest policies set forth by the IBT.

## V. Disclosure Requirements

By no later than January 31<sup>st</sup> of each year, the IBT Principal Investigators are required to complete and submit the Annual Disclosure Form to the IBT General Secretary-Treasurer and the IBT Compliance Officer any Significant Financial Interests<sup>1</sup> and Outside Activities to the extent to which they reasonably appear to be related to the Principal Investigator's Institutional Responsibilities. In addition, within 30 days, PI's must report any newly discovered or acquired Significant Financial Interests. Information that must be reported includes, but is not limited to:

- i. With regard to any publicly traded entity, domestic or foreign, the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest held in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000.
  - Remuneration includes salary and any payment for services not otherwise identified as salaries, such as consulting fees, honoraria, and paid authorship.
  - Equity interests include stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
- ii. A financial interest consisting of one or more of the following interests of the Principal Investigator (and those of the PI's spouse, domestic partner, and dependent children) that reasonably appears to be related to the PI's institutional responsibilities.

With regard to any publicly traded entity, *significant financial*

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<sup>1</sup> The term ***significant financial interest*** does not include the following types of financial interests: salary, royalties, or other remuneration paid by the IBT to the Principal Investigator if the PI is currently employed or otherwise appointed by the IBT., including intellectual property rights assigned to the IBT and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the PI does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

*interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, 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 option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- With regard to any non-publicly traded entity, *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Principal Investigator (or the Principal Investigator's spouse, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
  - Suppose there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity at the time of disclosure. In that case, the Principal Investigator (or the PI's spouse or dependent children) must fully describe the nature of the equity interest, including the number of shares owned, voting rights, etc.

iii. Principal Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Principal Investigator and not reimbursed to the PI so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- Pursuant to this Policy, Principal Investigators who travel as described above are required to disclose the following information:
  - a. Purpose of the trip:
  - b. Identity of the sponsor/organizer
  - c. Destination, and the duration, and
  - d. The monetary value of the trip.

- iv. Financial interests received in connection with patents, copyrights, know-how, or other intellectual property rights (e.g., royalties, license fees, equity or other consideration) that when aggregated over the prior 12 months exceeds \$5,000, including consideration received pursuant to an agreement to share royalties related to such intellectual property rights.
- v. Any advisory relationship, consulting, outside teaching, or scientific/academic appointment including adjunct, visiting or honorary, with any domestic entity, both paid and volunteer, as well as any unpaid appointment that provides the Principal Investigator with access to, or in-kind support for, supplies, equipment, staff participation or living expenses.

**Note:** Disclosure is not required for the following:

- a. Salary or other remuneration received from the IBT if the Principal Investigator is currently employed or appointed by the IBT.
  - b. Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
  - c. Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
- vi. All reimbursed expenses, gifts, gratuities, favors, lodging, or entertainment offers that, when aggregated over the prior 12 months, exceed \$1,000. As a reminder, Principal Investigators may not solicit or accept reimbursed expenses, gifts, gratuities, favors, lodging, or excessive entertainment for themselves, his/her spouse or domestic partner or dependent children, alone or in combination, or for any person or organization that does business or has the potential of doing business with the IBT.
  - vii. Sponsored/Reimbursed Travel that meets the following criteria:
    - a. Travel within the United States received from a U.S. entity that,

when aggregated, exceeds \$5,000.

**Note:** Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

b. Travel outside the United States received from the U.S. or foreign entity\* regardless of the dollar amount.

\*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

**Information needed for the disclosure of Sponsored/Reimbursed Travel:**

- c. Identity of the sponsor/organizer.
- d. Month and year of the travel.
- e. Financial value by the range of the travel.
- f. Value of any associated honorarium.
- g. Purpose of the travel.
- h. Destination of the travel.
- i. Time duration of the travel.

viii. **Review of the Annual Disclosure Form**

The IBT's Compliance Officer will review the Annual Disclosure Form and any new or revised Significant Financial Interests or Outside Activity or Interest related to PHS/NIH-funded grants or research.

The IBT's Compliance Officer will examine all disclosures to determine if Significant Financial Interest or Outside Activity or Interests are related to the PI's institutional responsibilities, i.e.:

- a. The entity has financial interests that could reasonably be considered to influence the development, implementation, or reporting of the PI's grant project or research.
- b. The entity has a reasonable possibility of being financially affected by PI's grant project or research.

An FCOI will be deemed to exist when the IBT, pursuant to the Compliance Officer utilizing the protocols described in this Principal Investigator Conflict of Interest Policy, reasonably determines that a Significant Financial Interest could directly and significantly affect the development, implementation, or reporting of the Principal Investigator's grant project or research.

ix. Managing and Reporting Financial Conflicts of Interest

Prior to the IBT expending any funds awarded under a PHS/HHS-funded grant program or research project, the IBT Compliance Officer will review all PI disclosures of significant financial interests; determine whether any SFIs relates to the PHS/HHS-funded grant programs or research projects. Suppose the IBT determines that a Financial Conflict of Interest (FCOI) exists. In that case, the Compliance Officer, in conjunction with the IBT General President's Office and the General Secretary-Treasurer's Office or their designees, will manage the FCOI by developing a management plan designed to eliminate or effectively manage the conflict.

This management plan may involve personnel from the IBT's Internal Audits, Legal, Human Resources, and Accounting & Budgeting Departments, as appropriate. In addition, the conflict of interest management plan may include provisions that require:

- Removal of the affected PI from participation in the grant program or research project
- Severing all relationships that created the conflict
- Public disclosure of the FCOI to affected training or research partners.

The IBT Compliance Officer will provide the PI with a document detailing the conflict management plan and its implementation. The PI will be asked to review and sign a letter acknowledging agreement with the conflict management plan. The PI will be allowed to appeal, in writing and within 30 days, to the Offices of the General President and the General Secretary-Treasurer for reconsideration. The General President has the final authority regarding the management of all FCOIs.

If a PI who is newly participating in a grant program or research project discloses a significant financial interest, or an existing PI discloses a new significant financial interest, the Compliance Officer will, within sixty days:

- Review the disclosure to determine if it is related to PHS/HHS-funded grant programs or research projects, and
- Determine if it creates a financial conflict of interest

If it is determined that a financial conflict of interest exists, the Compliance

Officer, in conjunction with the IBT General President's Office and the General Secretary-Treasurer's Office or their designees will develop and implement a management plan that shall specify the actions that have been and will be taken to manage the financial conflict of interest immediately.

x. Reporting a Financial Conflict of Interest to the Funding Agency

Prior to expending funds provided through PHS/HHS grant programs and research projects, the IBT will provide the appropriate agency within PHS/HHS an FCOI report regarding any significant financial interest that is an FCOI. The IBT will also submit a management plan and corrective actions to ensure that the FCOI has been adequately addressed.

- If an FCOI exists regarding new PHS/NIH-funded grant awards, the IBT will report such situations through the electronic Research Administration (eRA) Commons FCOI Module. The report will be submitted prior to spending any funds. The IBT will make every effort to eliminate the FCOI prior to spending any funds, thus eliminating the need to submit a report.
- If during an ongoing PHS/NIH-funded grant or research award, a new or existing PI discloses a new significant financial interest to the IBT, the Compliance Officer will review the disclosure within 60 days, determine whether the significant financial interest is related to PHS/NIH-funded grant programs or research projects; determine if an FCOI exists; and develop and implement a management program to eliminate or effectively manage the financial conflict.
- The IBT will submit an annual report in conjunction with the annual progress report that complies with the requirements set forth in 42 CFR 50.605.
- FCOI reports submitted by the IBT as per 42 CFR 50.605 (b)(1) or (b)(2) will include, but not be limited to that detailed in 42 CFR 50.605 (b)(3).
- As per 42 CFR Part 50.606, if a PI fails to comply with the IBT's FCOI Policy or an FCOI management plan appears to have biased the design, implementation, or reporting of the PHS/NIH-funded grant program or research project, the IBT will promptly notify NIH and take the appropriate corrective actions.

xi. Information Provided to PHS/NIH if a Financial Conflict of Interest is Identified:

- Project number/contract number



- Name of the Principal Investigator
- Name of the Principal Investigator with the FCOI.
- Name of the entity with which the Principal Investigator has the FCOI
- Statement about how the FCOI was managed
- The nature of the FCOI (e.g., equity interest, consulting fees, intellectual property rights and interests, travel reimbursement, and honoraria)
- The value of the financial interest; \$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; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value
- A description about how the FCOI relates to the grant program or research project and the basis for the IBT's determination that a Significant Financial Interest conflicts with such grant program or research project.

xii. Maintenance of Records

The IBT will maintain all FCOI-related records relating to all Principal Investigator disclosures of financial interests and the IBT's review of and response to such disclosures (whether or not a disclosure resulted in the IBT identifying an FCOI) and all actions pursuant to the IBT's policy or retrospective review for seven years from the date the final expenditures report is submitted to the PHS/NIH.

xiii. Non-Compliance and Enforcement

The IBT will establish adequate enforcement mechanisms, provide for employee sanctions, and take other administrative action, where appropriate if a Principal Investigator is non-compliant with the IBT Principal Investigator Conflict of Interest Policy or management plan. Violations of this Policy may be grounds for progressive disciplinary action up to and including termination.

A Principal Investigator is non-compliant and in violation of the Policy if he/she fails to:

- a. Submit an Annual Disclosure Form or provide an update to the Annual

Disclosure Form by the deadlines established for such submissions by IBT Compliance Officer.

- b. Provide the IBT Compliance Officer with a written acknowledgment of a management plan.
- c. Provide the IBT Compliance Officer with requested documentation regarding compliance with a management plan.

If a Principal Investigator fails to comply with IBT's Principal Investigatory Conflict of Interest Policy or management plan, within 120 days, the IBT will:

- a. Complete a retrospective review of the key elements (see below) of the Principal Investigator's activities and the PHS/NIH-funded grant program or research project to determine any bias in the development, implementation, or reporting regarding the grant program or research project.
- b. Document the retrospective review.
- c. Document the IBT's determination as to whether any PHS/NIH-funded grant program or research project, or portion thereof, conducted during the period of the Principal Investigator's non-compliance with the IBT Principal Investigator Conflict of Interest Policy or management plan, was biased in the development, implementation, or reporting regarding the grant program or research project.

If the IBT determines that bias is evident, the IBT will submit a mitigation report with the essential elements (see below) addressing the impact of the bias on the grant program or research project, including the extent of the harm done and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions the IBT has taken or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, the IBT may determine that additional interim measures are necessary regarding the Principal Investigator's participation in the grant program or research project between the date the FCOI is identified and the completion of IBT's retrospective review. Thereafter, the IBT will submit FCOI reports as prescribed by the regulation.

The following key elements apply to both the retrospective review and mitigation report:

- Project number
- Project title
- The PI or contact PI/PD if a multiple PI model is used
- Name of the Principal Investigator with the FCOI
- Name of the entity with which the Principal Investigator has an FCOI
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review,

including the methodology of the process, the composition of the review panel, documents reviewed, etc.

- Findings of the review
- Conclusions of the review

xiv. Public Accessibility Requirements

The IBT's Principal Investigator Conflict of Interest Policy is publicly available on its website ([www.teamstersafety.org](http://www.teamstersafety.org)).

The IBT maintains public accessibility to Significant Financial Interests of senior/key personnel identified as having Financial Conflicts of Interest and reported to the PHS/NIH. In compliance with applicable regulations, the IBT responds to all written requests for information within five business days and then releases the following information about such Significant Financial Interest.

- The name of the Principal Investigator
- The title and role of the PI with respect to the grant program or research project
- Name of the entity with which the Significant Financial Interest is held
- The nature of the Significant Financial Interest
- Approximate value of the Significant Financial Interest as determined by dollar range: \$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; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

The IBT will also:

- Update the website information on an annual basis
- Update, within sixty-day, any newly identified FCOIs
- Make available information for three years from the date the information was most recently updated.