

Financial Conflict of Interest in Research

Applies To:	All Employees
Managed By:	General Research Policies
Effective Date:	8/24/2012
Last Review Date:	10/26/2020

PURPOSE:

Boys Town National Research Hospital/Father Flanagan's Boy's Home and any affiliates (known collectively as Boys Town, BT or "Institution") are committed to promoting objectivity in research for which Public Health Service Funding is sought.

This policy applies to all persons at BT who meet the definition of INVESTIGATOR/SUPPORT PERSONNEL (including Key Staff and Post-Doctorate Fellows), and applies to all Institutional activities meeting the definition of research where the activity is funded by the Public Health Service (including the National Institutes of Health, the Food and Drug Administration and Health Resources and Services Administration), other federal agencies, or non-governmental agencies or foundations.

Research not funded by the Public Health Service (PHS) may be subject to agency-specific regulations relating to financial conflicts of interest in research. Affected Investigators must comply with those regulations in addition to PHS regulations and are advised to review such regulations prior to submission of a research proposal or application.

POLICY:

All Investigators/Support Personnel shall disclose all known Significant Financial Interests of the Investigator/Support Personnel and his/her family members.

New investigators must complete online form Statement of Significant Financial Interest, available on the BTNRH Access website Forms/Other Forms tab.

The online form must be updated annually, or any time reportable information is changed or added.

In all cases, Financial Conflicts of Interest will be satisfactorily managed, reduced, or eliminated in accordance with this Policy.

The BT Research Compliance Officer will oversee compliance with this policy for applicable research conducted at BT.

Definitions:

Disclosure: An Investigator/Support Personnel's statement to BT of any Significant Financial Interests.

Equity interest: Any stock, stock option, or other ownership interest.

Family member: Investigator's/Support Personnel's spouse or dependent children.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Institution of higher education: An educational institution in any state that:

- admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate; or
- persons who have completed a secondary school education in a home school setting that is treated as a home school or private school under state law;
- Is legally authorized within such state to provide a program of education beyond secondary education;
- Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary of Health and Human Services;
- Is a public or other nonprofit institution; and
- Is accredited by a nationally recognized accrediting agency or association. If not so accredited, the institution must have been granted pre-accreditation status by an agency or association recognized by the Secretary of Health and Human Services for the granting of pre-accreditation status, and the Secretary has determined that the institution will meet the accreditation standards of the agency or association within a reasonable time.

Institutional (professional) responsibilities: An Investigator's/Support Personnel's responsibilities on behalf of BT, including:

- Research,
- Research consultation,
- Training of students,
- Consulting or other services to third parties related to Investigator's/Support Personnel's academic field and/or academic subject matter expertise
- Institutional committee memberships or
- Service on panels, such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator/Support Personnel: The Principal Investigator, Sub-Investigator, Co-Investigator, and any other person, regardless of title or position, involved in the design, conduct, or reporting of a research project.

PHS awarding component(s): The organizational unit(s) of the Public Health Service of the United States Department of Health and Human Services that funds the research project.

Reimbursed travel: Travel and related expenses (transportation, lodging, meals, incidentals) that are reimbursed to the PHS-funded Investigator/Support Personnel and are related to the Investigator's/Support Personnel's institutional (professional) responsibilities. This does NOT include travel that is

reimbursed by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;
- A medical center; or
- A research institution that is affiliated with an institution of higher education.

Related to the research: When the Research Compliance Office (RCO) determines that the Significant Financial Interest could be affected by the research or is in an entity whose financial interest could be affected by the research.

Remuneration: Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including, but not limited to, that relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes, but is not limited to, any such activity for which research funding is available from a PHS awarding component through a contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest (SFI): Anything of monetary value (whether or not that value is readily ascertainable) that reasonably appears to be related to the Investigator's/Support Personnel's institutional (professional) responsibilities and is received, obtained, or held directly or indirectly by the Investigator/Support Personnel and/or a family member, including one or more of the following interests:

With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 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, as determined through reference to public prices or other reasonable measures of fair market value. (Note: \$5,000 threshold for both remuneration and equity interests.)

With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator/Support Personnel and/or family member holds any equity interest. (Note: Remuneration has a \$5,000 threshold; equity interests have a \$0 threshold.)

Reimbursed or sponsored travel in any amount (Note: \$0 threshold), only if received by a PHS-funded Investigator/Support Personnel.

The term Significant Financial Interest does NOT include the following types of financial interests:

- Salary, royalties, or other remuneration paid by BT to the Investigator/Support Personnel;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the

Investigator/Support Personnel 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, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsored travel: Travel and related expenses (transportation, lodging, meals, incidentals, etc.) that are paid on behalf of the PHS-funded Investigator/Support Personnel and are not reimbursed to the Investigator/Support Personnel and are related to the Investigator's/Support Personnel's institutional (professional) responsibilities. This term does NOT include travel that is sponsored by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital; A medical center; or
- A research institution that is affiliated with an institution of higher education.

Subrecipient: Subgrantees, contractors, collaborators, or subcontractors.

Procedure:

1. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

The online form will be completed in accordance with the following:

- **Initial Disclosure** of Significant Financial Interests to the Research Compliance Office via the online form available on the BTNRH Access Forms website.
- **Annual Disclosure:** Investigators/Support Personnel shall submit an updated disclosure form annually.
- **New Research Projects.** If an annual disclosure form has not been submitted, all Investigators/Support Personnel shall complete and submit a disclosure form before any research project may be submitted to an external sponsor or for internal funding, as well as before all Institutional Review Board/Institutional Animal Care and Use Committee/Institutional Biosafety Committee applications are submitted.
- **Investigator/Support Personnel Added to an Existing Project.** If an annual disclosure form has not been submitted, all Investigators/Support Personnel added to an existing research project shall complete and submit a disclosure form. No one shall be added to the project until the disclosure form has been reviewed pursuant to this Policy.
- **New or Additional Financial Interests.** Any Investigator/Support Personnel or his/her family member who discovers or acquires (e.g., through purchase, marriage, or inheritance) a new or additional Significant Financial Interest during the period of a research project must submit an updated disclosure form to the Research Compliance Office within 30 days of discovering or acquiring the new or additional Significant Financial Interest.

Reimbursed Travel or Sponsored Travel. If not disclosed on the annual disclosure form, PHS-funded Investigators/Support Personnel shall disclose reimbursed or sponsored travel. When a disclosure includes a report of reimbursed travel or sponsored travel received by a PHS-funded Investigator/Support Personnel, the disclosure shall include:

- The purpose of the trip,
- The identity of the sponsor/organizer,
- The destination of the travel,
- The duration of the travel, and
- The monetary value of the travel.

Sponsored travel does **NOT** include travel that is sponsored by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;
- A medical center; or
- A research institution that is affiliated with an institution of higher education.

Additional Information. Investigators/Support Personnel shall provide such additional information about disclosures as may be requested at any time by the Executive Vice President of Healthcare or his/her designee or the RCO.

2. REVIEW PROCESS

Review by the Research Compliance Office. The Research Compliance Officer (RCO), or his/her designee, will review each disclosure form to ensure that it has been properly completed and signed by the Investigator/Support Personnel to determine the existence of any Significant Financial Interest.

- a. If NO Significant Financial Interest is disclosed, the disclosure form is filed, the Chairs of the IRB and IACUC are informed and no further action is required.
- b. If a Significant Financial Interest is disclosed, the Research Compliance Office shall determine whether it is related to any grants or contracts, or to any current research activities. The nature of the study is reviewed relative to the Significant Financial Interest.
- c. The RCO shall determine whether any Financial Conflict of Interest exists and, if so, how to manage, reduce, or eliminate the Financial Conflict of Interest before expenditure of project funds. No project funds shall be released until a final determination has been made.

Conflict of Interest Review Process: The RCO shall review (and, where necessary, investigate) all information contained in the disclosure to determine whether an Investigator/Support Personnel's Significant Financial Interest is related to the research and, if so, whether it constitutes a Financial Conflict of Interest.

The following are possible determinations the RCO may make regarding Financial Conflicts of Interest:

- a. If it is determined that there is no Significant Financial Interest, the RCO shall notify the Investigator/Support Personnel in writing, and this correspondence shall be included in the

project file.

- b. If it is determined that there is a Significant Financial Interest, the RCO shall determine whether any Financial Conflict of Interest exists and, if so, how to manage, reduce, or eliminate the Financial Conflict of Interest before expenditure of project funds, including developing and implementing a management plan and, if necessary a retrospective review and mitigation report.

Examples of conditions or restrictions that might be imposed in a management plan include, but are not limited to:

- Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research).
- For research projects involving human subjects, disclosure of Financial Conflicts of Interest directly to participants.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest.
- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest).
- Severance of relationships that create financial conflicts.

Review of Projects Involving Human and Animal Subjects:

Participation of an Investigator/Support Personnel with a Significant Financial Interest. Any Significant Financial Interest(s) of Investigators/Support Personnel who are involved in human or animal subjects' research may present real or perceived risks to the welfare of human or animal subjects and may require additional review. In most cases, an Investigator/Support Personnel may not participate in human or animal subjects' research while he/she has a Significant Financial Interest in the project or with the sponsor. The RCO may grant an exception on a case-by-case basis if the Investigator/Support Personnel provides compelling reasons to maintain the Significant Financial Interest and participate in the research. These compelling circumstances or facts shall be consistent with the rights and welfare of human subjects and the welfare of animal subjects.

Role of BT's Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC). The IRB/IACUC may accept or decline the RCO's determination and resolution. The IRB and IACUC are ultimately responsible for protecting the rights and welfare of human subjects and the welfare of animal subjects, respectively. If the appropriate Committee is not satisfied that the RCO's final determination will protect the rights and welfare of human subjects or the welfare of animal subjects, it shall independently review the Significant Financial Interest and may withhold approval of the study until the Committee's recommendations to the RCO to manage, reduce, or eliminate the Financial Conflict of Interest are met. The IRB/IACUC has the final authority to determine whether any interest and its management allow the research to be approved.

Intellectual Property Rights. An Investigator/Support Personnel is NOT required to disclose as a Significant Financial Interest income (including royalties, license fees, or other forms of revenue) paid by BT to the Investigator/Support Personnel due to intellectual property rights assigned to the institution by the Investigator/Support Personnel and agreements to share in revenue related to such rights. However, BT's Director Research shall provide a report to the RCO of any such intellectual property rights and agreements. The RCO shall determine whether a Financial Conflict of Interest exists and whether a management plan is required. The involved Investigator/Support Personnel shall be

required to comply with any such management plan, and the Financial Conflict of Interest identified shall be disclosed as required.

New or Undisclosed Significant Financial Interests. Whenever:

- An Investigator/Support Personnel new to a research project discloses a Significant Financial Interest,
- An existing Investigator/Support Personnel discloses a new Significant Financial Interest, or
- BT identifies a Significant Financial Interest that was not previously disclosed by an Investigator/Support Personnel or, for whatever reason, was not previously reviewed by BT during an ongoing research project (e.g., was not reviewed or reported by a subrecipient),

The RCO shall, within 60 days:

- Review the Significant Financial Interest,
- Determine whether it is related to the research,
- Determine whether a Financial Conflict of Interest exists.

If it is determined that a financial conflict of interest exists the RCO will implement, on at least an interim basis, a management plan specifying the actions that have been and will be taken to manage such Financial Conflict of Interest going forward.

Depending on the nature of the Financial Conflict of Interest, BT may determine that additional interim measures are necessary regarding the Investigator's/Support Personnel's participation in the research project between the date that the Financial Conflict of Interest or the Investigator's/Support Personnel's noncompliance is determined and the completion of BT's retrospective review.

3. APPEAL RIGHTS:

If the Investigator/Support Personnel disagrees with a management plan developed by the RCO, he/she may appeal the determination by submitting a written request and any supporting materials to the RCO for reconsideration within 14 days after receiving notification of the management plan. The RCO shall review the request and supporting materials and issue its final determination, which shall not be subject to further appeal. The Investigator/Support Personnel shall sign any management plan required by the RCO before any funds may be expended.

4. ONGOING MONITORING:

Whenever BT implements a management plan, BT, through the Research Compliance Office, shall monitor Investigator/Support Personnel compliance with the management plan on an ongoing basis until the research is completed.

5. RECORDS RETENTION:

The Research Compliance Office shall retain records of all disclosures and BT's review of and response to each disclosure as follows:

- **PHS-Funded Projects:** Three years after the date of submission of the final expenditures report or, where applicable, from other dates specific in 45 CFR 74.53 (b) for different situations.
- **NSF-Funded Projects:** Three years beyond the termination or completion of the project, or until the resolution of any NSF action involving those records, whichever is longer.

- **All Other Externally or Internally Funded Projects:** Three years after the termination or completion of the project.

6. ENFORCEMENT, SANCTIONS, AND NONCOMPLIANCE

General

Investigators/Support Personnel shall fully comply with this Policy. Examples of breaches of this Policy include, but are not limited to:

- Failure to submit the disclosure form,
- Intentionally filing an incomplete, erroneous, or misleading disclosure form, or
- Failing to provide any additional information requested by the Research Compliance Office.

Failure to comply with this Policy may result in disciplinary action, ranging from a public letter of reprimand to dismissal and termination of employment or affiliation with BT. Disciplinary action shall be consistent with and subject to BT's progressive disciplinary policy or applicable sections of the Employee Handbook.

PHS-Funded Projects

Retrospective Review: When a Financial Conflict of Interest is not identified or managed in a timely manner, BT shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's/Support Personnel's activities and the PHS-funded research project.

This review shall determine whether there was any bias in the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the time period of the noncompliance. BT shall document the retrospective review, including, but not limited to, all of the following key elements:

- Project number,
- Project title,
- Project Director/Principal Investigator (or contact Project Director/Principal Investigator, if a multiple Project Director/Principal Investigator model is used),
- Name of the Investigator/Support Personnel who has the Financial Conflict of Interest,
- Name of the entity with which the Investigator/Support Personnel 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),
- Findings of the review and
- Conclusions of the review

If an Investigator's/Support Personnel's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, BT shall promptly notify the PHS awarding component of the corrective action taken or to be taken.

PHS Notification:

Prior to BT's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS awarding component a Financial Conflict of Interest report regarding any Investigator's/Support Personnel's Financial Conflict of Interest and ensure that the Institution has

implemented a management plan.

In cases in which the Institution identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit a Financial Conflict of Interest report to the PHS awarding component.

For any Financial Conflict of Interest that the Institution identifies after its initial report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator/Support Personnel who is new to the research project), the Institution shall provide to the PHS awarding component, within 60 days, an updated Financial Conflict of Interest report regarding the conflict and ensure that the Institution has implemented a management plan.

Mitigation Report: If, after conducting a retrospective review, the Institution finds that it is warranted, it shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If bias is found, the Institution shall notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component.

The mitigation report must include, at a minimum, the key elements documented in the retrospective review, as well as a description of the impact of the bias on the research project (e.g., 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) and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, the Institution shall submit Financial Conflict of Interest reports annually.

Any Financial Conflict of Interest report required under paragraphs (1) (2), or (3) above shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the Institution's management plan.

Elements of the Financial Conflict of Interest report shall include, but are not limited to, the following:

- Project number,
- Name of the Investigator/Support Personnel who has the Financial Conflict of Interest,
- Name of the entity with which the Investigator/Support Personnel has a Financial Conflict of Interest,
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium),
- Value of the financial interest (dollar ranges are permissible: \$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 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 the basis for the Institution's determination that the financial interest conflicts with the research,
- A description of the key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator/Support Personnel 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/Support Personnel's agreement to the management plan,
- How the management plan will be monitored to ensure Investigator/Support Personnel compliance, and
- Other information as needed.

For any Financial Conflict of Interest associated with an ongoing PHS-funded research project that was previously reported by the Institution, the Institution shall provide to the PHS awarding component an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan. These annual reports will be required for the duration of the PHS-funded research project, including extensions with or without funds. The annual Financial Conflict of Interest report shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.

In some cases, the U.S. Department of Health and Human Services (HHS) may determine that a PHS-funded clinical research project 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/Support Personnel with a Financial Conflict of Interest that was not managed or reported by the Institution as required. In these cases, the Institution shall require the Investigator/Support Personnel involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research, and to request an addendum to previously published presentations.

Other Sponsors: The Research Compliance Office shall notify any other sponsor of Financial Conflicts of Interest and management plans imposed, as required by sponsor policy or contractual obligation.

7. OTHER REQUIREMENTS

PHS Certification. The appropriate Institutional official shall certify on each PHS-funded proposal that the Institution:

- Has in effect an up-to-date, written, and enforced administrative process to identify and manage Financial Conflicts of Interest,
- Shall promote and enforce Investigator/Support Personnel compliance with the requirements of 42 CFR Part 50 and 45 CFR Part 94, including those pertaining to disclosure of Significant Financial Interests,
- Shall manage Financial Conflicts of Interest and provide initial and ongoing Financial Conflict of Interest reports to the PHS awarding component, consistent with 42 CFR Part 50 and 45 CFR Part 94,
- Agrees to make information available to HHS, promptly upon request, relating to any Investigator /Support Personnel disclosure and the Institution's review of and response to such disclosure, whether or not the disclosure results in the Institution's determination of a Financial Conflict of Interest, and
- Shall fully comply with the requirements of 42 CFR Part 50 and 45 CFR Part 94.

8. PUBLIC ACCESSIBILITY

Policy Availability. The Research Compliance Office shall post and maintain this Policy on a publicly-accessible BT web site. BT shall make its written policy available to any requestor within five business days of a request.

Financial Conflict of Interest Public Accessibility Notice: Within a reasonable time after determining an Investigator/Support Personnel has a Financial Conflict of Interest and, for PHS-funded research, prior to the Institution's expenditure of any funds for that research, the Research Compliance Office shall ensure the public accessibility of information concerning any Financial Conflicts of Interest held by Investigators/Support Personnel participating in PHS-funded research. Response to all written requests for information shall be provided within five business days of receipt of the request. Written requests may be sent to the Research Compliance Office, 555 N 30th St, Omaha, NE 68131.

The information included in a response to a request for information shall include, at a minimum,

- The following: The Investigator's/Support Personnel's name,
- The Investigator's/Support Personnel's title and role with respect to the research,
- The name of the entity in which the Significant Financial Interest is held,
- The name/title of the research project,
- The nature of the Significant Financial Interest, and
- The approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The Research Compliance Office shall update the information annually. In addition, the Research Compliance Office shall update the information within 60 days of the Institution's receipt or identification of information concerning any additional Financial Conflict of Interest of the Investigator/Support Personnel that was not previously disclosed, or upon the determination of Financial Conflict of Interest of Investigators/Support Personnel new to the research project. Information concerning the Financial Conflict of Interest of an individual shall remain available via written request for three years from the date that the information was most recently updated.

9. INVESTIGATOR EDUCATION AND TRAINING REQUIREMENTS

Initial Training: All current Investigators/Support Personnel shall be informed of and trained on this Policy, including the Investigator's/Support Personnel's responsibilities regarding disclosure of Significant Financial Interests, and the PHS Federal regulations on Financial Conflict of Interest. All Investigators/Support Personnel must complete initial Financial Conflict of Interest training before beginning work on any research project.

Training Updates: Investigators/Support Personnel shall complete re-training on Financial Conflict of Interest every four years after initial training, or more often when any of the following circumstances apply:

- The Institution revises its Financial Conflict of Interest policies or procedures in any manner that affects the requirements of Investigators/Support Personnel;

- The Institution finds that an Investigator/Support Personnel is not in compliance with this Policy or a management plan.

Research Compliance Office Services. The Research Compliance Office shall provide and/or arrange for and track required training. Training can be via CITI Compliance Training or any successive educational service.

10. FEDERALLY FUNDED SUBCONTRACTS

If the Institution carries out Federally funded research through a subrecipient, the Institution shall take reasonable steps to ensure that any subrecipient Investigator/Support Personnel complies with Federal requirements for Financial Conflicts of Interest by completing [Form A-Outgoing Subaward FCOI Questionnaire](#)

Incorporating as part of the written agreement with the subrecipient terms that require the subrecipient to:

- Apply its Financial Conflict of Interest policy to its Investigators/Support Personnel;
- Certify that its policy complies with applicable Federal regulations; and
- Agree to report all identified Financial Conflicts of Interest to the Institution within a certain time period. Such time period(s) shall be sufficient to enable the Institution to provide timely Financial Conflict of Interest reports, as necessary, to the Federal agency.

Providing Financial Conflict of Interest reports to the Federal agency regarding all Financial Conflicts of Interest of all subrecipient Investigators/Support Personnel (i.e., prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest.

If the subrecipient does not have a Financial Conflict of Interest policy or refuses to apply the policy or certify compliance of the policy with Federal regulations, the agreement with the subrecipient shall:

- Require the subrecipient's Investigators/Support Personnel to comply with this Policy, and
- Specify time period(s) for the subrecipient to submit all Investigator/Support Personnel disclosures of Significant Financial Interests to the Institution. Such time period(s) shall be sufficient to enable the Institution to comply with its review, management, and reporting obligations.

Disclosures submitted by subrecipients shall be reviewed by the RCO, and any Financial Conflicts of Interest shall be managed and monitored as set forth in this Policy.

ADMINISTRATION AND INTERPRETATION:

Questions regarding this Policy may be directed to the Research Compliance Office or the Office of General Counsel at the Institution.

AMENDMENTS OR TERMINATION OF THIS POLICY

BT reserves the right to modify, amend, or terminate this Policy at any time. Nothing in this Policy should be construed as a contract between the Institution and its employees.