

Financial Conflict of Interest Policy

The purpose of the Financial Conflict of Interest Policy is to develop a standard for identifying financial conflicts of interest, reporting financial conflicts of interest, managing financial conflicts of interest, and informing investigators of these policies. Advanced Respiratory Technologies' policies will adhere to 42 CFR 50.601 – 42 CFR 50.607.

Definitions:

Disclosure of Significant Financial Interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI Report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service 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).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant Financial Interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial 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;

(ii) 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Notices and Public Access:

Advanced Respiratory Technologies will provide a copy of this Financial Conflicts of Interest Policy to all Investigators and inform Investigators of changes in said policy if and when changes or initial implementation occur. The Financial Conflicts of Interest Policy will serve to inform the Investigator of the policy, inform the Investigator of their disclosure responsibilities, and inform the Investigator of the applicable federal regulations.

Advanced Respiratory Technologies does not, at the time of the initial implementation of the policy, have a publicly accessible website. As such, Advanced Respiratory Technologies will provide a copy of its

Financial Conflicts of Interest Policy to any requestor within 5 business days of the request. In the event that Advanced Respiratory Technologies creates a publicly accessible website, it shall within thirty days post the Financial Conflict of Interest Policy on its website.

If Financial Conflicts of Interest have been identified for any investigators, these Financial Conflicts of Interest shall be made accessible to the public. Advanced Respiratory Technologies does not, at the time of the initial implementation of the policy, have a publicly accessible website. As such, Advanced Respiratory Technologies will provide a copy of any Financial Conflicts of Interest to any requestor within 5 business days of the request. In the event that Advanced Respiratory Technologies creates a publicly accessible website, it shall post the Financial Conflicts of Interest on its website. If posted on a company website, the Financial Conflicts of Interest postings will be updated within 60 days of identifying a new Financial Conflict of Interest and at least annually. The Financial Conflicts of Interest will be made available to the public for at least three years from the date the information was most recently updated. At a minimum, public postings of Financial Conflicts of Interest will include:

- The Investigator's name,
- The Investigator's title and role with respect to the research project,
- The name of the entity in which the Significant Financial Interest is held,
- 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; \$20,000-\$100,000 in 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.

Training:

All Investigators will be required to complete Financial Conflict of Interest training in the following instances:

- Prior to engaging in research relating to any PHS-funded grant,
- At least every 4 years, and
- Immediately, if:
 - Advanced Respiratory Technologies implements this initial Financial Conflicts of Interest Policy,
 - Advanced Respiratory Technologies revises its Financial Conflicts of Interest policy in a manner that affects the requirements of the Investigators

- An Investigator is new to Advanced Respiratory Technologies, or
- An Investigator is not in compliance with the policy or management plan.

Investigator Disclosures:

All financial disclosures will be sent to Advanced Respiratory Technologies' Primary Financial Conflicts Reviewer. In the event that the Primary Financial Conflicts Reviewer is also an Investigator, the Primary Financial Conflicts Reviewer will submit his or her financial disclosures to the Secondary Financial Conflicts Reviewer or Tertiary Financial Conflicts Reviewer if the Secondary Financial Conflicts Reviewer has a conflict on reviewing the disclosure. At the time of the implementation of this policy,

All Investigators will report Significant Financial Interest(s) of the Investigator, his or her spouse, and his or her dependent children to the applicable Financial Conflicts Reviewer in the form of a Significant Financial Interests Form:

- Upon implementation of this Financial Conflicts of Interest Policy,
- No later than at the time of application for PHS-funded research,
- At least annually during the period of the award of PHS-funded research, or
- Within 30 days of discovering or acquiring a new Significant Financial Interest.

Disclosure Review:

The Primary, Secondary, and/or Tertiary Financial Conflicts Reviewer(s) will, prior to Advanced Respiratory Technologies's expenditure of funds on a PHS-funded grant, award, or contract:

- Review all Investigator Significant Financial Interest disclosures,
- Determine if any Significant Financial Interests relate to PHS-funded research,
- Determine if a Financial Conflict of Interest exists as defined in the definitions section above and in federal regulations, and
- Develop and implement management plans, as needed, to manage Financial Conflicts of Interest.

When determining whether a Significant Financial Interest constitutes a Financial Conflict of Interest, the Primary, Secondary, and/or Tertiary Financial Conflicts Reviewer will consult the definitions of the federal regulations 42 CFR 50.601 – 42 CFR 50.607. If the federal regulations do not provide adequate guidance or there is doubt of their applicability, the Primary, Secondary, and/or Tertiary Financial Conflicts Reviewer will contact the applicable funding agency.

The above review process will also be conducted when:

- An Investigator discloses a new Significant Financial Interest,
- A new Investigator joins the research project,
- A PHS-funded research project is approaching an anniversary date, or
- within sixty days of Advanced Respiratory Technologies identifying a Significant Financial Interest that was either not reported by an Investigator in a timely manner or not previously reviewed by Advanced Respiratory Technologies.

Reporting:

Advanced Respiratory Technologies will send initial, annual, and revised Financial Conflicts of Interest Reports, including all reporting elements, to the awarding PHS agency (if Advanced Respiratory Technologies is the prime recipient Institution) or to the prime recipient institution (if Advanced Respiratory Technologies is the subrecipient Institution) for the Advanced Respiratory Technologies and its subrecipients:

- Prior to the expenditure of PHS-sponsored funds,
- within sixty days of identification of an Investigator who is newly participating in the project,
- within sixty days for new or newly identified Financial Conflicts of Interest for existing Investigators, and
- at least annually at the time when Advanced Respiratory Technologies is required to submit an annual progress report, multi-year progress report, or at the time of an extension to provide the status of the Financial Conflict of Interest and any changes to the management plan, if applicable, until the completion of the project.

If bias is found with the design, conduct, or reporting of PHS-funded research, Advanced Respiratory Technologies will notify the funding agency promptly and include a Mitigation Report and all other reports as required by 42 CFR 50.601 - 42 CFR 50.607.

If an Investigator fails to comply with Advanced Respiratory Technologies's Financial Conflict of Interest Policy or a Financial Conflict of Interest Management Plan appears to have biased the design, conduct or reporting of PHS research, Advanced Respiratory Technologies will promptly take corrective action for the noncompliance and will promptly notify the funding agency.

Records:

Advanced Respiratory Technologies will maintain Financial Conflict of Interest related records for at 3 years from the date of final expenditures and from other dates specified in 45 CFR 74.53(b) and 92.42(b), whichever is longer.

Enforcement:

In the event of non-compliance with the Financial Conflicts of Interest Policy or with a Financial Conflicts of Interest Management Plan, Advanced Respiratory Technologies will complete and document retrospective reviews within 120 days of Advanced Respiratory Technologies's determination of noncompliance for Significant Financial Interests not disclosed timely or previously reviewed or whenever a Financial Conflict of Interest is not identified or managed manner. Advanced Respiratory Technologies can sanction the Investigator in noncompliance by removal of the investigator from the project, by any enforcement actions deemed appropriate by the awarding agency, and/or by other sanctions not listed above.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of 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 a Financial Conflict of Interest that was not managed or reported by Advanced Respiratory Technologies as required by the federal regulations, Advanced Respiratory Technologies shall require the Investigator 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.

Subrecipients:

If there are Subrecipients on funding awarded to Advanced Respiratory Technologies, Advanced Respiratory Technologies will enter into a written agreements where the Subrecipient, at Advanced Respiratory Technologies discretion, will either follow the Financial Conflict of Interest Policy of Advanced Respiratory Technologies or the Subrecipient will follow its own Financial Conflicts of Interest Policy that meets or exceeds the federal regulations. If the Subrecipient follows its own Financial Conflicts of Interest Policy, then Advanced Respiratory Technologies will obtain a written certification that the Financial Conflicts of Interest Policy of the Subrecipient meets or exceeds federal regulations. In the written agreement, Advanced Respiratory Technologies will require the Subrecipient, at Advanced Respiratory Technologies discretion, to either report identified Financial Conflicts of Interest for its Investigators in a time frame that allows the awardee Institution to report identified Financial Conflicts of Interest to the funding agency, or to report Subrecipient Investigator disclosures that enable the awardee Institution to identify, manage, and report identified Financial Conflicts of Interest to the awarding agency.