

Title: Corporate Policy – Federal Awards Conflict Of Interest
Effective 05/22/1996

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Effective Date:
03/21/2019
Revision: 4

Policy Number: 200-010

A. PURPOSE

This policy is designed to minimize the probability that the objectivity of activities at ATCC sponsored by the NSF and PHS will be adversely affected by personal financial interests of individuals involved in the design, conduct or reporting of sponsored projects.

B. SCOPE

This policy applies to each person at ATCC who is responsible for the design, conduct or reporting of research or educational projects that are proposed for, or awarded, funding by the NSF and PHS.

C. DEFINITIONS

1. Significant Financial Interest - means anything of monetary value, including but not limited to:

- a. salary or other payment for services (e.g. consulting fees or honoraria) which exceeds \$5,000 per year;
- b. equity interests in any non-publicly traded entity in the 12 months preceding the disclosure;
- c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights) which exceeds \$5,000 in annual income.
- d. For Public Health Service funded investigators, the term significant financial interest also includes any reimbursed or sponsored travel related to institutional responsibilities, including travel paid on behalf of the investigator and not reimbursed to the investigator (so that the exact monetary value may not be readily available); except for travel reimbursed or 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 affiliated with an institution of higher education. The disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Sr. VP, Finance and Administration/CFO or designee will determine if further information is needed, including monetary value, in order to determine whether the travel constitutes a financial conflict of interest with Public Health Service funded research.

2. Specific exclusions from the definition include:

- a. salary, royalties, or other remuneration from ATCC;
- b. income from seminars, lectures or teaching engagement sponsored by public or nonprofit entities;
- c. income from service or advisory committees or review panels for public or nonprofit entities;
- d. intellectual property rights assigned to ATCC and agreements to share in royalties related to such rights;
- e. Income from investment vehicles, such as mutual funds and retirement accounts as

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long as the investigator does not control the investment decisions made in these vehicles.

3. Relevant Significant Interest - means a Significant Financial Interest consisting of one or more of the following interests of the investigator and those of the investigator's immediate family, (spouse, dependent children), that would reasonably appear to be related to:
 - a. the investigator's institutional responsibilities if the research will be Public Health Service funded, or
 - b. the study sponsor or an entity that would have an interest in the work and/or outcome for the research project if the research is not Public Health Service funded.
4. Significant Financial Interest - 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 combined with the value of any equity interest held in the entity as of the date of disclosure, when aggregated exceeds \$5000. 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, 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 or his/her immediate family member holds an equity interest (e.g. stock, stock option, or other ownership interest).
5. Conflict of Interests - means where ATCC has found that a relevant significant interest could directly and significantly affect the design, conduct or reporting of program activities.
6. Investigator - means the Principal Investigator, Co-principal Investigator(s), and any other person at ATCC who is responsible for the design, conduct or reporting of research or educational activities funded, or proposed for such funding, by the NSF and PHS. In the context of Relevant Significant Financial Interests which are reported, "investigator" includes the investigator's spouse and dependent children.

D. POLICY

1. In order to protect the integrity/objectivity of NSF & PHS sponsored programs, all ATCC investigators who have relevant significant financial interests that in some manner might influence or appear to influence the conduct of those projects must: - a) inform ATCC of this fact at the time of proposal submission, and b) prior to acceptance of the awards, develop acceptable strategies to manage those conflicts.

E. PROCEDURE

1. Disclosure Process

- a. For a sponsored program proposal prepared for submission by ATCC to the NSF or PHS, each "Investigator" shall complete the form "Statement of Relevant Significant Financial Interest" (Form) and submit it to the Grant or Contract Point of Contact prior to submission of the proposal.

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- b. Each proposal “Investigator” should review Form as a guide for determining if a “Significant Financial Interest” that might compromise the objectivity of the project (a “Relevant Significant Interest”) is present.
- c. Investigators participating in Public Health Service funded research must submit an updated disclosure of significant financial interests annually, in accordance with ATCC’s annual request for such disclosure. Such disclosure shall include any information that was not disclosed previously disclosed significant financial interest.
- d. An investigator who is participating in any sponsored research, whether or not Public Health Service funded, must submit an updated disclosure to the Sr. VP, Finance and Administration/CFO within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest.

2. Managing a Relevant Significant Financial Interest

- a. If a potential for conflict which requires management exists, a strategy for managing, reducing, or eliminating the actual or potential conflicts must be adopted prior to acceptance of the award by ATCC. The “Investigator” making the disclosure shall submit a proposed strategy in a timely manner to the Sr. VP, Finance and Administration//CFO. The Sr. VP, Finance and Administration/CFO has the authority to approve or not approve a management strategy to ensure objectivity in the project.
- b. The Sr. VP, Finance and Administration/CFO together with the Principal Investigator and any other investigator with a relevant significant financial interest shall agree in writing on the management strategy. Such written documentation will be delivered to the Grant or Contract Point of Contact, prior to acceptance by ATCC of the affected award. Documentation of the management strategy will become part of the sponsored program record maintained by ATCC.
- c. Strategies for management of an actual or potential conflict of financial interest might include: (a) public disclosure and notification of affected entities of a Significant Financial Interest; (b) monitoring of research by independent reviewers (c)modification of the research plan; (d) disqualification of an investigator or investigators from participation in all or a portion of the research funded by the federal agency; (e) divestiture of Significant Financial Interests; (f) severance of relationships that creates actual or potential conflicts; or (g) informing the awarding agency that the proposal has been withdrawn by ATCC.
- d. If a management strategy satisfactory to the Principal Investigator and all other involved investigators is not approved by the Sr. VP, Finance and Administration/CFO, the Principal Investigator or other involved investigator may appeal the matter to the President or CEO.

3. Records Retention

- a. The Grant or Contract Point of Contact will maintain the disclosures and records pertaining to each funded award for at least three years beyond the termination or completion of the award, or until resolution of any action by a federal agency involving the records, whichever is longer. Documents pertaining to disclosure of a Significant Financial Interest shall be treated as privileged communications so long

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as they are under ATCC control. Disclosure documents may be subject to Freedom of Information statutes; each such request will have to be decided on a case-by-case basis.

4. Enforcement:

- a. Compliance with this policy shall be considered an accepted practice in proposing, carrying out or reporting results from research and scholarly activity. Failure of investigators to comply with this policy shall be subject to appropriate disciplinary actions up to and including suspension or termination of employment as provided in applicable policies. The Sr. VP, Finance and Administration/CFO will conduct a retrospective review to determine if the non-compliance has resulted in any bias in the research and if so, shall implement a mitigation plan and do any required reporting.

5. Communications with Funding Agencies:

- a. ATCC official(s) authorized to execute proposals shall make such certifications to federal agencies as are required by regulation in regard to this policy and its implementation.
- b. If a conflict of interest cannot be resolved, the awarding agency (either NSF or PHS) must be so notified. Further, PHS regulations require that the Institute report to the PHS awarding component the “existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated.” The Sr. VP Finance and Administration/CFO is responsible for providing appropriate written notice to the funding agency and, where appropriate, will request that the conflict be permitted to continue.

6. Public Health Service Investigator Training

- a. Each investigator is required, per federal regulations, to complete training regarding disclosure of financial interests prior to engaging in research related to any Public Health Service funded grant and at least every four years, and immediately when any of the following apply:
 - 1) ATCC revises its Financial Conflict of Interest policies or procedures in any manner that affects the requirements of investigators;
 - 2) Any investigator new to ATCC;
 - 3) ATCC finds that an investigator is not in compliance with ATCC’s Conflict of Interest policy or management plan.

7. Research Carried Out Through Subcontracts

- a. If Public Health Service funded research will be carried out through a sub-recipient (e.g. a subcontractor or consortium member):

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- 1) the sub-recipient will certify in a written agreement that its research conflict of interests policy complies with HHR Regulations on Promoting Objectivity in Research, and that it will report any financial conflicts of interests of its investigators to ATCC by dates sufficient for timely reporting by ATCC to Public Health Service; or
 - 2) if it is unable to certify compliance, the sub-recipient shall enter into a written agreement requiring its investigators to report significant financial interests to ATCC pursuant to the policy and associated procedures.
8. Responding to Public Requests for Information about Public Health Service Funded Research:
- a. ATCC will respond in writing within five business days to requests from the public for information about financial conflicts of interest of senior/key personnel (the principal investigator or project director and any other person identified as key/senior in the Public Health Service funding application or other reports to Public Health Service) if such conflicts are related to Public Health Service funded research. The response will be made in writing, post marked within five business days, and include the investigators name, a description of the interest, and its dollar value range as required by the HHS regulations on Promotion Objectivity in Research. This information will remain available for 3 years from the date the information was most recently updated.

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