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Policy Number: 200-010

**A. PURPOSE**

1. This Policy implements FCOI disclosure requirements found in the regulation 42 CFR Part 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94 (subcontracts), which apply to research funded by the U.S. Department of Health & Human Services (HHS). This regulation and ATCC Policy promotes objectivity in research and establishes standards that provide a reasonable expectation to ensure that ATCC's employees and other individuals involved in the administration of federal awards are able to perform their duties objectively and impartially, free from bias and any real or perceived conflicts of interest in the design, conduct, or reporting of HHS funded research (grants and cooperative agreements). ATCC supports federally funded research, and this Policy establishes standards and procedures to meet our obligation to disclose a financial conflicts of interest, if they exist. ATCC will maintain this appropriate written Policy on financial conflict of interest disclosure as a condition for receiving HHS funding. Furthermore, if ATCC carries out the HHS-funded research through a sub-recipient (e.g., subcontractors or consortium members), ATCC will take reasonable steps to ensure that any sub-recipient Investigator complies with FCOI requirements.

This Policy establishes a process of identifying, disclosing, and managing independent reviews of COIs related to federal awards, in accordance with all applicable federal laws and regulations when an Investigator has a Significant Financial Interest (SFI). If declared monies are such an interest that might reasonably affect the Research directly and significantly, ATCC will develop a mitigation plan to manage or eliminate the conflict.

2. This Policy is available at the following publicly accessible website as required: Federal Solutions for Government Contracts | ATCC under the "ATCC Corporate Policy – Federal Awards Financial Conflict of Interest" heading.
3. By committing to preserving the public's trust, ATCC is protecting its reputation and integrity, and avoiding risk of fraud, waste, or abuse of federal funds, ensuring that the research HHS supports is conducted without bias and with the highest scientific and ethical standards.

**B. SCOPE**

1. This policy applies to all individuals at ATCC and their immediate family members, regardless of title or position, who are responsible for the decision making, design, conduct, or reporting of research or educational projects proposed for or awarded funding by HHS. Each Investigator must follow the process in this Policy. These requirements are applicable to all Research projects for which ATCC submits a proposal to or receives Research funding from HHS. Each Investigator who is planning to participate in, or is participating in such Research, is required to disclose to ATCC his/her SFIs, his/her spouse's SFIs, and his/her dependent children's SFIs no later than the time of application for HHS funded Research. Additionally, each Investigator, including staff responsible for the design, conduct, or reporting of Research funded by the HHS, is required to disclose FCOI. ATCC Senior Executives shall ensure applicable staff comply with these obligations.
2. Subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements or comply with this Policy.

**C. DEFINITIONS**

1. HHS – U.S. Department of Human & Health Services (HHS)
2. Significant Financial Interest (SFI) - Any interest of the Investigator, his/her spouse, and

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dependent children that reasonably appears to be related to the Investigator's responsibilities including one or more of the following means or 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 publicly traded entity in the 12 months preceding the disclosure. With regard to any publicly traded entity, a SFI 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) and 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.
- c. equity interests in any non-publicly traded entity in the 12 months preceding the disclosure. With regard to any non-publicly traded entity, an SFI 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);
- d. Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights) upon receipt of income related to such rights and interests.
- e. For HHS-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 ATCC Institutional Official 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.
- f. Specific exclusions from the definition include:
  - 1) salary, royalties, or other remuneration from ATCC made to the Investigator if the Investigator is currently employed or otherwise appointed by ATCC.
  - 2) income from seminars, lectures, or teaching engagement 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.
  - 3) income from service or advisory committees or review panels for public or nonprofit entities.

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- 4) intellectual property rights assigned to ATCC and agreements to share in royalties related to such rights.
  - 5) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not control the investment decisions made in these vehicles.
3. Relevant Significant Financial 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 HHS 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 HHS funded.
  4. Significant Financial Interest (SFI) - 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. Financial Conflict of Interests (FCOI) - means where ATCC has found that a relevant significant interest could directly and significantly affect the decision making, design, conduct, or reporting of HHS-funded Research.
  6. Investigator - means the Principal Investigator, Co-principal Investigator(s), consultants, subcontractors, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of research or educational activities funded, or proposed for such funding by HHS. In the context of Relevant Significant Financial Interests, which are reported, "investigator" includes the investigator's spouse and dependent children.
  7. Institutional Official (IO) - An official designated by ATCC to solicit and review disclosures (Statement of Relevant Significant Financial Interest Form) from each Investigator who is planning to participate in, or who is participating in, HHS funded Research and to determine whether any reported SFI is an FCOI. References to the IO in this document include his/her delegate.
  8. Research - Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research as well as product development (e.g., a diagnostic test or drug) and research being carried out by subcontractors through ATCC.

#### D. POLICY

1. ATCC has a corporate responsibility to establish and maintain policies that promote objectivity in the design, conduct, and reporting of research activities in accordance with best practices, sponsor requirements, and federal and state law. In accordance with regulation 42 CFR Part 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94

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(subcontracts), this policy and administrative procedures described herein, shall apply to ATCC staff, contractors and third parties.

2. In order to protect the integrity/objectivity of HHS-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.
3. FCOI disclosures shall be submitted in accordance with this policy and described procedures, to the ATCC IO and will be reviewed by the ATCC IO or their delegate(s). FCOI that cannot be sufficiently reduced, mitigated, or eliminated may not be permitted and, as such, the proposed ATCC activity may need to be redesigned to reduce, mitigate, or eliminate the FCOI or shall not proceed, as determined by the IO, in collaboration with other persons/offices affected, as required to ensure ATCC and individual compliance with applicable state and federal requirements.

#### E. PROCEDURE

1. ATCC FCOI Policy and Training
  - a. ATCC is required to establish a written FCOI policy that outlines procedures for identifying, managing, and reporting FCOIs as HHS funding is received.
  - b. ATCC provides training to all Investigators who receive HHS funding on the FCOI policy and their obligations to disclose and manage FCOIs prior to engaging in research related to any HHS-funded grant and annually.
2. Department of Human & Health Services 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 HHS funded research 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.
3. Disclosure Process
  - a. For a sponsored program proposal prepared for submission by ATCC to HHS, each "Investigator" shall complete the form "Statement of Relevant Significant Financial Interest" (Form) and submit it to the ATCC Federal Solutions Director of Contracts. The Director of Contracts will review all required Forms and notify the ATCC Institutional Official of any SFIs reported on the Forms.
  - b. Each proposal "Investigator" should review the Form as a guide for determining if a "Significant Financial Interest" that might compromise the objectivity of the project (a

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“Relevant Significant Interest”) is present.

- c. Prior to ATCC's expenditure of any funds under an HHS-funded Research project, the ATCC Institutional Official will review all Forms with SFIs to determine whether the SFIs relate to the HHS-funded Research and whether an FCOI exists. ATCC will provide to the HHS Awarding Agency an FCOI report regarding any Investigator's SFI found by ATCC to be an FCOI. Additionally, ATCC will ensure that it has implemented a management plan in accordance with Section E.# (Managing a Relevant Significant Financial Interest) of this Policy. In situations where ATCC identifies an FCOI and eliminates it prior to the expenditure of HHS-awarded funds, ATCC is not required to submit an FCOI report to the HHS Awarding Agency.
  - d. Investigators participating in HHS-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.
  - e. An investigator participating in any sponsored research, whether or not HHS funded, must submit an updated disclosure to the ATCC Institutional Official within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. For any SFI that ATCC identifies as an FCOI after ATCC's initial report during an ongoing HHS-funded Research project, ATCC will provide to the HHS Awarding Agency an FCOI report regarding the FCOI within 60 days of identification of the FCOI. Additionally, ATCC will ensure that it has implemented a management plan in accordance with Section E.3 of this Policy and, if required, complete a retrospective review and a mitigation report according to this Policy.
  - f. For any FCOI previously reported by ATCC regarding an ongoing HHS funded Research project, ATCC will provide to the HHS Awarding Agency an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the HHS-funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. ATCC will provide annual FCOI reports to the HHS Awarding Agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the HHS Awarding Agency.
4. Contents of an FCOI Report 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.
- a. Any FCOI report will include sufficient information to enable the HHS Awarding Agency to understand the nature and extent of the FCOI and to assess the appropriateness of ATCC's management plan. The FCOI report will include the following minimum information:
    - 1) Project number;
    - 2) PI or Contact PI if a multiple PI model is used;
    - 3) Name of the Investigator with the FCOI;
    - 4) Name of the entity with which the Investigator has an FCOI;
    - 5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

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- 6) 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 readily be determined through reference to public prices or other reasonable measures of fair market value;
  - 7) A description of how the financial interest relates to the HHS funded Research and the basis for ATCC's determination that the financial interest conflicts with such Research; and
  - 8) A description of the key elements of ATCC's management plan, including the following minimum information:
    - a) Role and principal duties of the conflicted Investigator in the Research project;
    - b) Conditions of the management plan;
    - c) Explanation of how the management plan is designed to safeguard objectivity in the Research project;
    - d) Confirmation of the Investigator's agreement to the management plan; and
    - e) Explanation of how the management plan will be monitored to ensure Investigator compliance.
- b. 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.
5. 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 ATCC Institutional Official. The ATCC Institutional Official has the authority to approve or not approve a management strategy to ensure objectivity in the project.
  - b. The ATCC Institutional Official, 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:
    - 1) public disclosure and notification of affected entities of a Significant Financial Interest;
    - 2) monitoring of research by independent reviewers

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- 3) modification of the research plan;
  - 4) disqualification of an investigator or investigators from participation in all or a portion of the research funded by the federal agency;
  - 5) divestiture of Significant Financial Interests;
  - 6) severance of relationships that create actual or potential conflicts; or
  - 7) informing the awarding agency that ATCC has withdrawn the proposal.
- d. If a management strategy satisfactory to the Principal Investigator and all other involved investigators is not approved by ATCC Institutional Officials, the Principal Investigator or other involved investigator may appeal the matter to the President or CEO.
6. Monitoring
- a. Whenever ATCC implements a management plan, ATCC will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the HHS-funded Research project.
7. Reporting and Record Retention
- a. ATCC will maintain records of all FCOI disclosures, management plans, and any corrective actions taken.
  - b. ATCC will report all FCOIs to HHS agencies as required by law or regulation. ATCC will notify HHS promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the HHS-funded research.
  - c. 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, where applicable, from other dates specified in 45 CFR 74.53(b) and 45 CFR 92.42(b), or until resolution of any action by a federal agency involving the records, whichever is longer. Documents pertaining to a Significant Financial Interest disclosure shall be treated as privileged communications while they are under ATCC control. Disclosure documents may be subject to Freedom of Information statutes; each such request must be decided on a case-by-case basis.
8. Oversight and 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 ATCC Institutional Official 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 (further described in Section E.7.b).
  - b. Whenever an FCOI is not identified, disclosed, or managed in a timely manner or an Investigator fails to comply with an FCOI management plan, ATCC has additional review and reporting obligations. If, in these situations, ATCC determines that an SFI constitutes an FCOI, ATCC's Institutional Official will, within 120 days of ATCC's

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determination of noncompliance, complete a retrospective review of the Investigator's activities and the HHS funded Research project to determine whether any HHS funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. ATCC is required to document the retrospective review. Documentation shall include all of the following key elements:

- 1) Project number;
  - 2) Project title;
  - 3) PI or contact PI if a multiple PI model is used;
  - 4) Name of the Investigator with the FCOI;
  - 5) Name of the entity with which the Investigator has an FCOI;
  - 6) Reason(s) for the retrospective review;
  - 7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - 8) Findings of the review; and
  - 9) Conclusions of the review.
- c. As necessary, based on the results of the retrospective review, ATCC will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, ATCC will notify the HHS Awarding Agency promptly and submit a mitigation report to the HHS Awarding Agency. Minimally, the mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the Research project, and ATCC's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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, ATCC will submit FCOI reports annually. Depending on the nature of the FCOI, ATCC may determine that additional interim measures are necessary with regard to the Investigator's participation in the HHS funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of ATCC's retrospective review.
- d. If the failure of an Investigator to comply with this Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the HHS funded Research, ATCC is required to promptly notify the HHS Awarding Agency of the corrective action taken or to be taken by ATCC. The HHS Awarding Agency will consider the situation and, as necessary, take appropriate action, or refer the matter to ATCC for further action, which may include directions to ATCC on how to maintain appropriate objectivity in the HHS funded Research project. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of SFI related to federally sponsored projects.

## 9. Communications with Funding Agencies:



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- 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 must be so notified. Further, HHS regulations require that the Institute report to the HHS 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 ATCC Institutional Official is responsible for providing appropriate written notice to the funding agency and, where appropriate, will request that the conflict be permitted to continue.

#### 10. Department of Human & Health Services 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 HHS funded research 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.

#### 11. Research Carried Out Through Sub-Recipients

- a. If HHS-funded research will be carried out through a sub-recipient (e.g., a subcontractor, consultant, or consortium member): Each Sub-recipient will certify in a written agreement that its research conflict of interest policy and that it will report any financial conflicts of interest of the Investigators to ATCC by dates sufficient for timely reporting by ATCC to HHS or
- b. If it is unable to certify compliance, the sub-recipient shall enter into a written agreement requiring its investigators to report significant financial interest to ATCC pursuant to the policy and associated procedure.
- c. the sub-recipient performs services within the definition of an Investigator must maintain a policy that complies with the aforementioned regulatory requirements. The sub-recipient will certify in a written agreement that its research conflict of interests policy complies with ATCC’s Federal Conflicts of Interest policy and that it will report any financial conflicts of interests of its investigators to ATCC by dates sufficient for timely reporting by ATCC to HHS; or
- d. 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.
- e. All applicable sub-recipient agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy. Examples of this clause are provided below:
  - 1) Financial Conflicts of interest – Compliance with Subcontractor’s Policy

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- a) Subcontractor agrees to comply with any and all requirements relating to Department of Human & Health Services (HHS) funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor certifies that it maintains a policy that requires compliance with these requirements. Subcontractor shall report all identified financial conflicts of interests to ATCC immediately and submit a mitigation plan for ATCC's review and approval. ATCC is under no obligation to approve a mitigation plan. ATCC reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.
- 2) Financial Conflicts of interest – Compliance with ATCC's Policy
- a) Subcontractor agrees to comply with any and all requirements relating to Department of Human & Health Services (HHS) funded projects. Without limiting the generality of the foregoing, Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor agrees to comply with ATCC's Policy on Financial Conflicts of Interest in Department of Human & Health Services (HHS). Subcontractor shall report all identified financial conflicts of interests to ATCC immediately and submit a mitigation plan for ATCC's review and approval. ATCC is under no obligation to approve a mitigation plan. ATCC reserves the right to terminate this Agreement or request removal of Subcontractor's employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor's financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.
12. Responding to Public Requests for Information about Department of Human & Health Services 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 Department of Human & Health Services 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.